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**HL7 Implementation Guide for CDA, Release 2**

**Clinical Oncology Treatment Plan and Summary**

MAY 2013

**HL7 Draft Standard for Trial Use (DSTU) Ballot**

**Sponsored by:  
Structured Documents Work Group**

**American Society for Clinical Oncology HIT Work Group**

*DRAFT FOR STAKEHOLDER REVIEW AND DESIGN DISCUSSIONS*

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# Introduction

Purpose

This document describes constraints on the Clinical Document Architecture Release 2 (CDA R2) header and body elements for the Clinical Oncology Treatment Plan and Summary document which is derived from the American Society of Clinical Oncology (ASCO) Breast Cancer Adjuvant Treatment Plan and Summary. Standardization of information used in this form will promote interoperability; create information suitable for reuse in quality measurement, public health, research, and for reimbursement.

This guide contains a library of CDA templates, and is compliant with the Consolidated CDA R2 cited in [Final Rules for Stage 2 Meaningful Use](http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-21050.pdf) and [45 CFR Part 170 – Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule](http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf).

Audience

The audience for this document includes software developers and implementers with reporting capabilities within their electronic health record (EHR) systems; developers and analysts in receiving institutions; and local, regional, and national health information exchange networks who wish to create and/or process Clinical Oncology Treatment Plan and Summary document according to this specification.

Business analysts and policy managers can also benefit from a basic understanding of the use of Clinical Document Architecture (CDA) templates across multiple implementation use cases.

Approach

Overall, the approach taken here is consistent with balloted implementation guides for CDA. These publications view the ultimate implementation specification as a series of layered constraints. CDA itself is a set of constraints on the HL7 Reference Information Model (RIM) defined in the CDA Release 2 (CDA R2) Refined Message Information Model (RMIM). Implementation guides such as this add constraints to CDA through conformance statements that further define and restrict the sequence and cardinality of CDA objects and the vocabulary sets for coded elements.

This implementation guide is a conformance profile, as described in the “Refinement and Localization”[[1]](#footnote-1) section of the *HL7 Version 3 Interoperability Standards*. The base standard for this implementation guide is the *HL7 Clinical Document Architecture, Release 2.0*[[2]](#footnote-2). As defined in that document, this implementation guide is both an annotation profile and a localization profile. It does not describe every aspect of CDA.

The development of this guide includes a review and analysis of previously successfully balloted clinical exchange standards and published IGs for cancer treatment templates such as the [Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries](http://www.cdc.gov/phin/library/guides/Implementation_Guide_for_Ambulatory_Healthcare_Provider_Reporting_to_Central_Cancer_Registries_August_2012.pdf), [Consolidated CDA R2](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7)[, HL7 Implementation Guide for CDA® R2: Quality Reporting Document Architecture, DSTU Release 2 (QRDA)](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35).[[3]](#footnote-3),[[4]](#footnote-4) If similar templates exist they will be updated and/or re-used create a design that is standard with Consolidated CDA R2. Establishment of reusable templates through standards development organizations will promote the use of the templates for future inclusion meaningful use.

CDA R2

CDA R2 is “… a document markup standard that specifies the structure and semantics of ‘clinical documents’ for the purpose of exchange” [CDA R2, Section 1.1; see [References](#_References)]. Clinical documents, according to CDA, have the following characteristics:

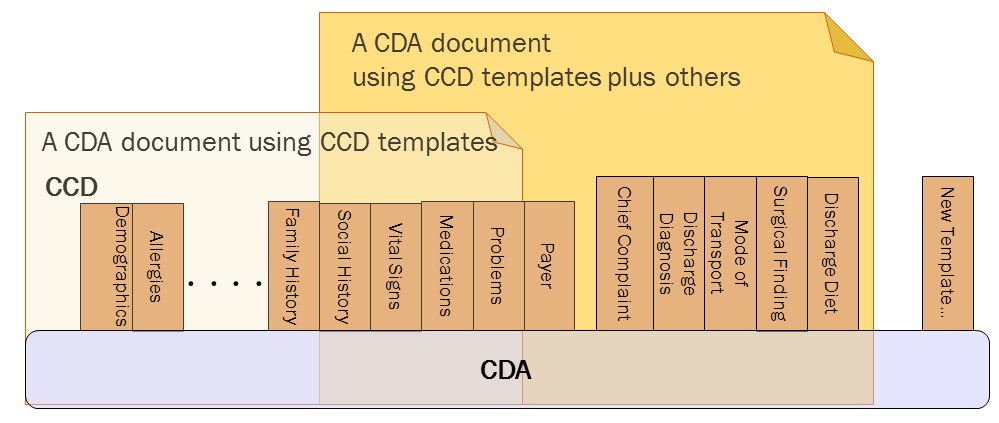
* Persistence
* Stewardship
* Potential for authentication
* Context
* Wholeness
* Human readability

CDA defines a header that for classification and management and a document body that carries the clinical record. While the header metadata are prescriptive and designed for consistency across all instances, the body is highly generic, leaving the designation of semantic requirements to implementation.

Templated CDA

CDA R2 can be constrained by mechanisms defined in the “Refinement and Localization”[[5]](#footnote-5) section of the *HL7 Version 3 Interoperability Standards*. The mechanism most commonly used to constrain CDA is referred to as “templated CDA”. In this approach, a library of modular CDA templates are constructed such that they can be reused across any number of CDA document types, as shown in the following figure.

Figure 1: Templated CDA

* **Document-level templates**: These templates constrain fields in the CDA header, and define containment relationships to CDA sections. For example, a History-and-Physical document-level template might require that the patient’s name be present, and that the document contain a Physical Exam section.
* **Section-level templates**: These templates constrain fields in the CDA section, and define containment relationships to CDA entries. For example, a Physical-exam section-level template might require that the section/code be fixed to a particular LOINC code, and that the section contain a Systolic Blood Pressure observation.
* **Entry-level templates**: These templates constrain the CDA clinical statement model in accordance with real world observations and acts. For example, a Systolic-blood-pressure entry-level template defines how the CDA Observation class is constrained (how to populate observation/code, how to populate observation/value, etc) to represent the notion of a systolic blood pressure.

There are many different kinds of templates that might be created. Among them, the most common are:

* **Document-level templates**: These templates constrain fields in the CDA header, and define containment relationships to CDA sections. For example, a History-and-Physical document-level template might require that the patient’s name be present, and that the document contain a Physical Exam section.
* **Section-level templates**: These templates constrain fields in the CDA section, and define containment relationships to CDA entries. For example, a Physical-exam section-level template might require that the section/code be fixed to a particular LOINC code, and that the section contain a Systolic Blood Pressure observation.
* **Entry-level templates**: These templates constrain the CDA clinical statement model in accordance with real world observations and acts. For example, a Systolic-blood-pressure entry-level template defines how the CDA Observation class is constrained (how to populate observation/code, how to populate observation/value, etc) to represent the notion of a systolic blood pressure.

A CDA implementation guide (such as this one) includes reference to those templates that are applicable. On the implementation side, a CDA instance populates the templateId field where it wants to assert conformance to a given template. On the receiving side, the recipient can then not only test the instance for conformance against the CDA XML schema, but can also test the instance for conformance against asserted templates.

## Background

Electronic health records (EHRs) often contain data that is not shared between providers or not captured for research, quality or public health reporting. Disease-specific templates are required for the continuity of care for cancer patients and current templates lack the specificity needed for this population. ASCO’s strategy is to promote interoperability and information exchange among cancer care providers and patients.

The 2012 strategy for the American Society of Clinical Oncology (ASCO) is to promote and improve delivery of care to cancer patients through improved exchange and interoperability of the clinical information most critical for that care. Though multiple types of breast cancer treatment forms are utilized to record treatment and plans, the scope of the data elements were derived from the ASCO Breast Adjuvant Treatment Plan and Summary form which is a paper form that records demographic, general medical, family, treatment and plan history for a patient with moderately advanced stage breast cancer. This particular subgroup of cancer patients represents an ideal use case as most of the diagnostic and treatment approaches used in cancer are represented here.

## Current Project

The intent of the project is to develop an initial, high-priority set of clinical oncology templates for CDA for HL7 ballot. This project will extend the initial, small set of data elements required for general meaningful use to cover elements crucial for cancer care patients. This document describes constraints on the Clinical Document Architecture Release 2 (CDA R2) header and body elements for the Clinical Oncology Treatment Plan and Summary document in the US Realm.

The intent of the document is to communicate a basic set of patient oncology-related health status information and treatment plan between health care providers for an episode of care. This document type is not intended to be used when a patient is discharged or transferred from one facility to another or contain detailed specialty specific information (e.g. exact radiation treatment dosages). Instead, the Clinical Oncology Treatment Plan and Summary document will provide a limited summary of a patient’s care during and/or after treatment and continue to serve as a form of on-going communication to augment the coordination of care between health care providers while a patient is receiving care. Providers involved in the care of the patient may include the patient’s primary care provider, medical oncologist, surgical oncologist and radiation oncologist. The document may also serve as a treatment plan or summary of care for patients

The project will reuse information already available in some electronic form through development of cancer-specific data standards. The library of templates created in this implementation guide will range from detailed data elements, such as tumor stage, to sections such as Treatment Plan which may contain full notes from a report from a medical oncologist to a primary care physician.

The CDA architecture and the use of a template library support and encourage greater capture and exchange of structured data. Standardization information in this form will promote interoperability; create information suitable for reuse in quality measurement, public health, research, and for reimbursement

## Organization of This Guide

This guide includes a set of CDA Templates and prescribes their use within a Questionnaire Assessment CDA document. The main chapters are:

Chapter 2: [General Header Templates](#_General_Header_Templates) defines the document header constraints that apply to Questionnaire Assessment Documents.

Chapter 3: [Document Level Templates](#_Document_level_templates) defines the document constraints that apply to Questionnaire Assessment Documents.

Chapter 4: [Section-Level Templates](#_Section-Level_Templates) defines the section templates in Questionnaire Assessment Documents.

Chapter 5: [Entry-Level Templates](#_Entry-Level_Templates_1) Entry-Level Templates defines the entry template in Questionnaire Assessment Documents.

## Conformance Conventions Used in This Guide

Templates Not Open for Comment

Most of the templates in this implementation guide were balloted and published in the July 2012 guide and are, therefore, closed for comment in this ballot. These templates are indicated throughout this guide with the notation [Closed for comments; published December 2011] after the template name. If errors are found or enhancements are desired in these templates, please document them on [Consolidated CDA Templates Errata](http://wiki.hl7.org/index.php?title=Consolidated_CDA_Templates_Errata)[[6]](#footnote-6) or [Consolidated CDA Templates Suggested Enhancements](http://wiki.hl7.org/index.php?title=Consolidated_CDA_Templates_Suggested_Enhancements)[[7]](#footnote-7) HL7 structured Document WIKI pages.

Templates and Conformance Statements

Conformance statements within this implementation guide are presented as constraints from a Trifolia Workbench [[8]](#footnote-8)An algorithm converts constraints recorded in Trifolia to a printable presentation. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:7345). These identifiers are persistent but not sequential.

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the templateId, and whether the template is [open or closed](#_Open_and_Closed).

Each section and entry template in the guide includes a context table. The "Used By" column indicates which documents or sections use this template, and the "Contains Entries" column indicates any templates that the template uses. Value set tables, where applicable, and brief XML example figures are included with most explanations.

A typical template, as presented in this guide, is shown in the [Constraints format example figure](#F_Constraints_format_example). The next sections describe specific aspects of conformance statements—open vs. closed statements, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors.

Figure 2: Constraints format example

**Severity Observation**

[observation: templateId 2.16.840.1.113883.10.20.22.4.8(open)]

Table xxx: Severity Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| Reaction Observation  Allergy Observation |  |

This clinical statement represents the severity of the reaction to an agent. A person may manifest many symptoms …

Table yyy: Severity Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.8'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | 7345 | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
| … |  |  |  |  |  |  |

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:7345).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 ActMood) **STATIC** (CONF:7346).
3. SHALL contain exactly one [1..1] templateId (CONF:7347) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.8" (CONF:10525).
4. **SHALL** contain exactly one [1..1] **code**="SEV" Severity Observation (CodeSystem: 2.16.840.1.113883.5.4 ActCode) **STATIC** (CONF:7349).
5. **SHOULD** contain zero or one [0..1] **text** (CONF:7350).
   1. This text, if present, **SHOULD** contain zero or one [0..1] **reference/@value** (CONF:7351).
      1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:7378).
6. **SHALL** contain …

Figure 3: Constraints format example

**Severity Observation**

[observation: templateId 2.16.840.1.113883.10.20.22.4.8(open)]

Table xxx: Severity Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Reaction Observation](#E_Reaction_Observation)  [Allergy Observation](#E_Allergy_Observation) |  |

This clinical statement represents the severity of the reaction to an agent. A person may manifest many symptoms …

Table yyy: Severity Observation Contexts

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.8'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7345](#C_7345) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
| … |  |  |  |  |  |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:7345).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:7346).
3. SHALL contain exactly one [1..1] templateId (CONF:7347) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.8" (CONF:10525).
4. SHALL contain exactly one [1..1] code="SEV" Severity Observation (CodeSystem: ActCode 2.16.840.1.113883.5.4) (CONF:7349).
5. SHOULD contain zero or one [0..1] text (CONF:7350).
   1. The text, if present, SHOULD contain zero or one [0..1] reference/@value (CONF:7351).
      1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:7378).
6. SHALL contain exactly one [1..1] statusCode="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:7352).
7. …

Open and Closed Templates

In open templates, all of the features of the CDA R2 base specification are allowed except as constrained by the templates. By contrast, a closed template specifies everything that is allowed and nothing further may be included. Templates included in BCTS are open.

Keywords

The keywords shall, should, may, need not, should not, and shall not in this document are to be interpreted as described in the *HL7 Version 3 Publishing Facilitator's Guide*[[9]](#footnote-9):

* shall: an absolute requirement
* shall not: an absolute prohibition against inclusion
* should/should not: best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course
* may/need not: truly optional; can be included or omitted as the author decides with no implications

Cardinality

The cardinality indicator (0..1, 1..1, 1..\*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators are interpreted with the following format “m…n” where m represents the least and n the most:

* 0..1 zero or one
* 1..1 exactly one
* 1..\* at least one
* 0..\* zero or more
* 1..n at least one and not more than n

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In the next figure, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

Figure 4: Constraints format – only one allowed

1. SHALL contain exactly one [1..1] **participant** (CONF:2777).

a. This participantSHALL contain exactly one [1..1] **@typeCode**="LOC"   
 (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType)   
 (CONF:2230).

In the next figure, the constraint says only one participant “like this” is to be present. Other participant elements are not precluded by this constraint.

Figure 5: Constraints format – only one like this allowed

1. SHALL contain exactly one [1..1] **participant** (CONF:2777) such that it

a. SHALL contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem:

2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).

Vocabulary Conformance

The templates in this document use terms from several code systems. These vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC® and SNOMED CT® vocabularies.

Note that value-set identifiers (e.g., ValueSet 2.16.840.1.113883.1.11.78 Observation Interpretation (HL7) **DYNAMIC)** do not appear in CDA submissions; they tie the conformance requirements of an implementation guide to the appropriate code system for validation.

Value-set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (shall, should, may, etc.) and an indication of dynamic vs. static binding. Value-set constraints can be static, meaning that they are bound to a specified version of a value set, or dynamic, meaning that they are bound to the most current version of the value set. A simplified constraint, used when the binding is to a single code, includes the meaning of the code, as follows.

Figure 6: Binding to a single code

1. … code/@code="11450-4" Problem List (CodeSystem: 2.16.840.1.113883.6.1 LOINC).

The notation conveys the actual code (11450-4), the code’s displayName (Problem List), the OID of the codeSystem from which the code is drawn (2.16.840.1.113883.6.1), and the codeSystemName (LOINC).

HL7 Data Types Release 1 requires the codeSystem attribute unless the underlying data type is “Coded Simple” or “CS”, in which case it is prohibited. The displayName and the codeSystemName are optional, but recommended, in all cases.

The above example would be properly expressed as follows.

Figure 7: XML expression of a single-code binding

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"/>

<!-- or -->

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"

displayName="Problem List"

codeSystemName=”LOINC”/>

A full discussion of the representation of vocabulary is outside the scope of this document; for more information, see the *HL7 Version 3 Interoperability Standards,* Normative Edition 2010[[10]](#footnote-10) sections on Abstract Data Types and XML Data Types R1.

There is a discrepancy in the implementation of translation code versus the original code between HL7 Data Types R1 and the convention agreed upon for this specification. The R1 data type requires the original code in the root. This implementation guide specifies the standard code in the root, whether it is original or a translation. This discrepancy is resolved in HL7 Data Types R2.

Figure 8: Translation code example

<code code='206525008’

displayName='neonatal necrotizing enterocolitis'  
 codeSystem='2.16.840.1.113883.6.96'

codeSystemName='SNOMED CT'>

<translation code='NEC-1'

displayName='necrotizing enterocolitis'

codeSystem='2.16.840.1.113883.19'/>

</code>

Null Flavor

Information technology solutions store and manage data, but sometimes data are not available: an item may be unknown, not relevant, or not computable or measureable. In HL7, a *flavor* of null, or nullFlavor, describes the reason for missing data.

For example, if a patient arrives at an Emergency Department unconscious and with no identification, we would use a null flavor to represent the lack of information. The patient’s birth date would be represented with a null flavor of “NAV”, which is the code for “temporarily unavailable”. When the patient regains consciousness or a relative arrives, we expect to know the patient’s birth date.

Figure 9: nullFlavor example

<birthTime nullFlavor=”NAV”/> <!--coding an unknown birthdate-->

Use null flavors for unknown, required, or optional attributes:

NI No information. This is the most general and default null flavor.

NA Not applicable. Known to have no proper value (e.g., last menstrual period for a male).

UNK Unknown. A proper value is applicable, but is not known.

ASKU Asked, but not known. Information was sought, but not found (e.g., the patient was asked but did not know).

NAV Temporarily unavailable. The information is not available, but is expected to be available later.

NASK Not asked. The patient was not asked.

MSK There is information on this item available but it has not been provided by the sender due to security, privacy, or other reasons. There may be an alternate mechanism for gaining access to this information.

This above list contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the nullFlavor vocabulary domain in the CDA normative edition[[11]](#footnote-11).

Any SHALLconformance statement may use nullFlavor, unless the attribute is required or the nullFlavor is explicitly disallowed. SHOULD and MAY conformance statement may also use nullFlavor.

Figure 10: Attribute required

1. SHALL contain exactly one [1..1] **code/@code**="11450-4" Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:7878)

or

2**.** SHALL contain exactly one [1..1] **effectiveTime/@value** (CONF:5256).

Figure 11: Allowed nullFlavors when element is required (with xml examples)

1. SHALL contain at least one [1..\*] id

2. SHALL contain exactly one [1..1] code

3. SHALL contain exactly one [1..1] effectiveTime

<entry>

<observation classCode="OBS" moodCode="EVN">

<id nullFlavor="**NI**"/>

<code nullFlavor="**OTH**">

<originalText>New Grading system</originalText>

</code>

<statusCode code="completed"/>

<effectiveTime nullFlavor="**UNK**"/>

<value xsi:type="CD" nullFlavor="NAV">

<originalText>Spiculated mass grade 5</originalText>

</value>

</observation>

</entry>

Figure 12: nullFlavor explicitly disallowed

1.SHALL contain exactly one [1..1] **effectiveTime** (CONF:5256).

a. SHALL NOT contain [0..0] nullFlavor (CONF:52580).

Unknown Information

If a sender wants to state that a piece of information is unknown, the following principles apply:

1. If the sender doesn’t know an attribute of an act, that attribute can be null.

Figure 13: Unknown medication example

<entry>

**<text>patient was given a medication but I do not know what it was</text>**

<substanceAdministration moodCode="EVN" classCode="SBADM">

<consumable>

<manufacturedProduct>

<manufacturedLabeledDrug>

<code **nullFlavor="NI"**/>

</manufacturedLabeledDrug>

</manufacturedProduct>

</consumable>

</substanceAdministration>

</entry>

2. If the sender doesn’t know if an act occurred, the nullFlavor is on the act (detail could include specific allergy, drug, etc.).

Figure 14: Unkown medication use of anticoagulant drug example

<entry>

<substanceAdministration moodCode="EVN" classCode="SBADM" **nullFlavor="NI">**

**<text>I do not know whether or not patient received an anticoagulant**

**drug</text>**

<consumable>

<manufacturedProduct>

<manufacturedLabeledDrug>

**<code code="81839001" displayName="anticoagulant drug"**

**codeSystem="2.16.840.1.113883.6.96"**

**codeSystemName="SNOMED CT"/>**

</manufacturedLabeledDrug>  
 </manufacturedProduct>  
 </consumable>  
 </substanceAdministration>  
</entry>

3. If the sender wants to state ‘no known’, a negationInd can be used on the corresponding act (substanceAdministration, Procedure, etc.)

Figure 15: No known medications example

<entry>

<substanceAdministration moodCode="EVN" classCode="SBADM" **negationInd=”true”>**

**<text>No known medications</text>**

<consumable>

<manufacturedProduct>

<manufacturedLabeledDrug>

**<code code="410942007" displayName="drug or medication"**

**codeSystem="2.16.840.1.113883.6.96"**

**codeSystemName="SNOMED CT"/>**

</manufacturedLabeledDrug>

</manufacturedProduct>

</consumable>

</substanceAdministration>

</entry>

Asserting an Act Did Not Occur with a Reason

The negationInd attribute, if true, specifies that the act indicated was observed to not have occurred (which is subtly but importantly different from having not been observed). NegationInd='true' is an acceptable way to make a clinical assertion that something did not occur, for example, "no gestational diabetes".

A nested reason for the act not being done can be represented through the use of an entryRelationship clinical statement with an actRelationship type of “RSON”.

Figure 16: Asserting an act did not occur with reason

<entry>

<substanceAdministration classCode="SBADM" moodCode="EVN" negationInd="true">

<templateId root="2.16.840.1.113883.10.20.22.4.52"/>

<statusCode code="completed"/>

<effectiveTime nullFlavor="NI"/>

<doseQuantity nullFlavor="NI"/>

<consumable>

<manufacturedProduct>

<templateId root="2.16.840.1.113883.10.20.22.4.54"/>

<!-- \*\*\*\*\*\*\*\* Immunization Medication Information \*\*\*\*\*\*\*\* -->

<manufacturedMaterial>

<code code="88" codeSystem="2.16.840.1.113883.6.59"

displayName="Influenza virus vaccine" codeSystemName="CVX">

</code>

</manufacturedMaterial>

</manufacturedProduct>

</consumable>

<entryRelationship typeCode="RSON">

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.24.3.88"/>

<code code="410666004"

codeSystem="2.16.840.1.113883.6.96"

displayName="reason"

codeSystemName="SNOMED CT"/>

<value xsi:type="CD"

code="275984001"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="Immunization refused"/>

</observation>

</entryRelationship>

</substanceAdministration>

</entry>

Data Types

All data types used in a CDA document are described in the CDA R2 normative edition[[12]](#footnote-12). All attributes of a data type are allowed unless explicitly prohibited by this specification.

## XML Conventions Used in This Guide

XPath Notation

Instead of the traditional dotted notation used by HL7 to represent Reference Information Model (RIM) classes, this document uses XML Path Language (XPath) notation[[13]](#footnote-13) in conformance statements and elsewhere to identify the Extensible Markup Language (XML) elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document.

Xpath statements appear in this document in a monospace font.

XPath syntax selects nodes from an XML document using a path containing the context of the node(s). The path is constructed from node names and attribute names (prefixed by a ‘@’) and catenated with a ‘/’ symbol.

Figure 17: XML document example

<author>

<assignedAuthor>

...

<code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'

code='17561000' displayName='Cardiologist' />

</assignedAuthor>

</author>

In the above example, the code attribute of the code could be selected with the XPath expression in the next figure.

Figure 18: XPath expression example

author/assignedAuthor/code/@code

XML Examples and Sample Documents

Extensible Mark-up Language (XML) examples appear in figures in this document in this monospace font. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in the example below.

Figure 19: ClinicalDocument example

<ClinicalDocument xmls="urn:h17-org:v3">

...

</ClinicalDocument>

Within the narrative, XML element (code, assignedAuthor, etc.) and attribute (SNOMED CT, 17561000, etc.) names also appear in this monospace font.

This package includes complete sample documents as listed in the [Content of the Package](#T_Contents_of_the_Package) table below.

## Content of the Package

The following files comprise this package.

Table 1: Content of the Package

|  |  |
| --- | --- |
| Filename | Description |
| Filename.pdf | This guide |
| IGName\_voc.xls | Vocabulary spreadsheet |
| SampleName.xml | The sample …. |
|  |  |
| CDA.xsl | Stylesheet for display of BCTS instances |

# document level Templates

US Realm Header [Closed for comments; published July 2012]

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.22.1.1(open)]

This section describes constraints that apply to the header for all documents within the scope of this implementation guide. Header constraints specific to each document type are described in the appropriate document-specific section below.

1. SHALL contain exactly one [1..1] realmCode="US" (CONF:16791).
2. SHALL contain exactly one [1..1] typeId (CONF:5361).
   1. This typeId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.1.3" (CONF:5250).
   2. This typeId SHALL contain exactly one [1..1] @extension="POCD\_HD000040" (CONF:5251).
3. SHALL contain exactly one [1..1] templateId (CONF:5252) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.1.1" (CONF:10036).
4. SHALL contain exactly one [1..1] id (CONF:5363).
   1. This id SHALL be a globally unique identifier for the document (CONF:9991).
5. SHALL contain exactly one [1..1] code (CONF:5253).
   1. This code SHALL specify the particular kind of document (e.g. History and Physical, Discharge Summary, Progress Note) (CONF:9992).
6. SHALL contain exactly one [1..1] title (CONF:5254).
   1. Can either be a locally defined name or the display name corresponding to clinicalDocument/code (CONF:5255).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:5256).
   1. The content SHALL be a conformant US Realm Date and Time (DTM.US.FIELDED) (2.16.840.1.113883.10.20.22.5.4) (CONF:16865).
8. SHALL contain exactly one [1..1] confidentialityCode, which SHOULD be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC 2010-04-21 (CONF:5259).
9. SHALL contain exactly one [1..1] languageCode, which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC (CONF:5372).
10. MAY contain zero or one [0..1] setId (CONF:5261).
    1. If setId is present versionNumber SHALL be present (CONF:6380). [[14]](#footnote-14)
11. MAY contain zero or one [0..1] versionNumber (CONF:5264).
    1. If versionNumber is present setId SHALL be present (CONF:6387). [[15]](#footnote-15)

Table 2: Basic Confidentiality Kind Value Set

| Value Set: HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC 2010-04-21 | | |
| --- | --- | --- |
| Code System(s): | Confidentiality Code 2.16.840.1.113883.5.25 | |
| Code | Code System | Print Name |
| N | Confidentiality Code | Normal |
| R | Confidentiality Code | Restricted |
| V | Confidentiality Code | Very Restricted |

Table 3: Language Value Set (excerpt)

| Value Set: Language 2.16.840.1.113883.1.11.11526 DYNAMIC | | |
| --- | --- | --- |
| Code System(s): | Internet Society Language 2.16.840.1.113883.1.11.11526 | |
| Description: | A value set of codes defined by Internet RFC 4646 (replacing RFC 3066). Please see ISO 639 language code set maintained by Library of Congress for enumeration of language codes  <http://www.ietf.org/rfc/rfc4646.txt> | |
| Code | Code System | Print Name |
| en | Internet Society Language | english |
| fr | Internet Society Language | french |
| ar | Internet Society Language | arabic |
| en-US | Internet Society Language | English, US |
| es-US | Internet Society Language | Spanish, US |
| … |  |  |

Figure 20: US Realm header example

<realmCode

code="US"/>

<typeId

root="2.16.840.1.113883.1.3"

extension="POCD\_HD000040"/>

<!-- US General Header Template -->

<templateId

root="2.16.840.1.113883.10.20.22.1.1"/>

<!-- \*\*\* Note: The next templateId, code and title will differ depending on what type of document is being sent. \*\*\* -->

<!-- conforms to the document specific requirements -->

<templateId

root="2.16.840.1.113883.10.20.22.1.2"/>

<id

extension="TT988"

root="2.16.840.1.113883.19.5.99999.1"/>

<code

codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC"

code="34133-9"

displayName="Summarization of Episode Note"/>

<title>Community Health and Hospitals: Health Summary</title>

<effectiveTime

value="201209150000-0400"/>

<confidentialityCode

code="N"

codeSystem="2.16.840.1.113883.5.25"/>

<languageCode

code="en-US"/>

<setId

extension="sTT988"

root="2.16.840.1.113883.19.5.99999.19"/>

<versionNumber

value="1"/>

Figure 21: effectiveTime with time zone example

<!-- the syntax is "YYYYMMDDHHMMSS.UUUU[+|-ZZzz]" where digits can be omitted

the right side to express less precision. -->

<effectiveTime value=”201107061227-08”/>

<!-- July 6, 2011, 12:27, 8 hours before UTC -->

RecordTarget

The recordTarget records the patient whose health information is described by the clinical document; it must contain at least one patientRole element.

1. SHALL contain at least one [1..\*] recordTarget (CONF:5266).
   1. Such recordTargets SHALL contain exactly one [1..1] patientRole (CONF:5267).
      1. This patientRole SHALL contain at least one [1..\*] id (CONF:5268).
      2. This patientRole SHALL contain at least one [1..\*] addr (CONF:5271).
         1. The content of addr SHALL be a conformant US Realm Address (AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10412).
      3. This patientRole SHALL contain at least one [1..\*] telecom (CONF:5280).
         1. Such telecoms SHOULD contain exactly one [1..1] @use, which SHALL be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 DYNAMIC (CONF:5375).

#### Patient

* + 1. This patientRole SHALL contain exactly one [1..1] patient (CONF:5283).
       1. This patient SHALL contain exactly one [1..1] name (CONF:5284).
          1. The content of name SHALL be a conformant US Realm Patient Name (PTN.US.FIELDED) (2.16.840.1.113883.10.20.22.5.1) (CONF:10411).
       2. This patient SHALL contain exactly one [1..1] administrativeGenderCode, which SHALL be selected from ValueSet Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 DYNAMIC (CONF:6394).
       3. This patient SHALL contain exactly one [1..1] birthTime (CONF:5298).
          1. SHALL be precise to year (CONF:5299).
          2. SHOULD be precise to day (CONF:5300).
       4. This patient SHOULD contain zero or one [0..1] maritalStatusCode, which SHALL be selected from ValueSet Marital Status Value Set 2.16.840.1.113883.1.11.12212 DYNAMIC (CONF:5303).
       5. This patient MAY contain zero or one [0..1] religiousAffiliationCode, which SHALL be selected from ValueSet Religious Affiliation Value Set 2.16.840.1.113883.1.11.19185 DYNAMIC (CONF:5317).
       6. This patient MAY contain zero or one [0..1] raceCode, which SHALL be selected from ValueSet Race Value Set 2.16.840.1.113883.1.11.14914 DYNAMIC (CONF:5322).
       7. This patient MAY contain zero or one [0..1] ethnicGroupCode, which SHALL be selected from ValueSet EtnicityGroup 2.16.840.1.114222.4.11.837 DYNAMIC (CONF:5323).
       8. This patient MAY contain zero or more [0..\*] sdtc:raceCode, where the @code SHALL be selected from ValueSet Race Value Set 2.16.840.1.113883.1.11.14914 DYNAMIC (CONF:7263).

#### Guardian

* + - 1. This patient MAY contain zero or more [0..\*] guardian (CONF:5325).
         1. The guardian, if present, SHOULD contain zero or one [0..1] code, which SHALL be selected from ValueSet PersonalRelationshipRoleType 2.16.840.1.113883.1.11.19563 DYNAMIC (CONF:5326).
         2. The guardian, if present, SHOULD contain zero or more [0..\*] addr (CONF:5359).

The content of addr SHALL be a conformant US Realm Address (AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10413).

* + - * 1. The guardian, if present, MAY contain zero or more [0..\*] telecom (CONF:5382).

The telecom, if present, SHOULD contain exactly one [1..1] @use, which SHALL be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 DYNAMIC (CONF:7993).

* + - * 1. The guardian, if present, SHALL contain exactly one [1..1] guardianPerson (CONF:5385).

This guardianPerson SHALL contain at least one [1..\*] name (CONF:5386).

The content of name SHALL be a conformant US Realm Person Name (PN.US.FIELDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10414).

#### Birthplace

* + - 1. This patient MAY contain zero or one [0..1] birthplace (CONF:5395).
         1. The birthplace, if present, SHALL contain exactly one [1..1] place (CONF:5396).

This place SHALL contain exactly one [1..1] addr (CONF:5397).

This addr SHOULD contain zero or one [0..1] country, where the @code SHALL be selected from ValueSet CountryValueSet 2.16.840.1.113883.3.88.12.80.63 DYNAMIC (CONF:5404).

This addr MAY contain zero or one [0..1] postalCode, where the @code SHALL be selected from ValueSet PostalCodeValueSet 2.16.840.1.113883.3.88.12.80.2 DYNAMIC (CONF:5403).

If country is US, this addr SHALL contain exactly one [1..1] state, which SHALL be selected from ValueSet 2.16.840.1.113883.3.88.12.80.1 StateValueSet DYNAMIC (CONF:5402).

#### LanguageCommunication

* + - 1. This patient SHOULD contain zero or more [0..\*] languageCommunication (CONF:5406).
         1. The languageCommunication, if present, SHALL contain exactly one [1..1] languageCode, which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC (CONF:5407).
         2. The languageCommunication, if present, MAY contain zero or one [0..1] modeCode, which SHALL be selected from ValueSet LanguageAbilityMode Value Set 2.16.840.1.113883.1.11.12249 DYNAMIC (CONF:5409).
         3. The languageCommunication, if present, SHOULD contain zero or one [0..1] proficiencyLevelCode, which SHALL be selected from ValueSet LanguageAbilityProficiency 2.16.840.1.113883.1.11.12199 DYNAMIC (CONF:9965).
         4. The languageCommunication, if present, MAY contain zero or one [0..1] preferenceInd (CONF:5414).

#### ProviderOrganization

* + 1. This patientRole MAY contain zero or one [0..1] providerOrganization (CONF:5416).
       1. The providerOrganization, if present, SHALL contain at least one [1..\*] id (CONF:5417).
          1. Such ids SHOULD contain zero or one [0..1] @root="2.16.840.1.113883.4.6" National Provider Identifier (CONF:16820).
       2. The providerOrganization, if present, SHALL contain at least one [1..\*] name (CONF:5419).
       3. The providerOrganization, if present, SHALL contain at least one [1..\*] telecom (CONF:5420).
          1. Such telecoms SHOULD contain exactly one [1..1] @use, which SHALL be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 DYNAMIC (CONF:7994).
       4. The providerOrganization, if present, SHALL contain at least one [1..\*] addr (CONF:5422).
          1. The content of addr SHALL be a conformant US Realm Address (AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10415).

#### 226BRecordTarget Value Sets

Table 4: Telecom Use (US Realm Header) Value Set

| Value Set: Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 DYNAMIC | | |
| --- | --- | --- |
| Code System(s): | AddressUse 2.16.840.1.113883.5.1119 | |
| Code | Code System | Print Name |
| HP | AddressUse | primary home |
| WP | AddressUse | work place |
| MC | AddressUse | mobile contact |
| HV | AddressUse | vacation home |

Table 5: Administrative Gender (HL7) Value Set

|  |  |  |
| --- | --- | --- |
| Value Set: Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 DYNAMIC | | |
| Code System(s): AdministrativeGender 2.16.840.1.113883.5.1 | | |
| Code | Code System | Print Name |
| F | AdministrativeGender | Female |
| M | AdministrativeGender | Male |
| UN | AdministrativeGender | Undifferentiated |

Table 6: Marital Status Value Set

| Value Set: HL7 Marital Status 2.16.840.1.113883.1.11.12212 DYNAMIC | | |
| --- | --- | --- |
| Code System(s): | MaritalStatus 2.16.840.1.113883.5.2 | |
| Code | Code System | Print Name |
| A | MaritalStatus | Annulled |
| D | MaritalStatus | Divorced |
| I | MaritalStatus | Interlocutory |
| L | MaritalStatus | Legally Separated |
| M | MaritalStatus | Married |
| P | MaritalStatus | Polygamous |
| S | MaritalStatus | Never Married |
| T | MaritalStatus | Domestic partner |
| W | MaritalStatus | Widowed |

Table 7: Religious Affiliation Value Set (excerpt)

| Value Set: HL7 Religious Affiliation 2.16.840.1.113883.1.11.19185 DYNAMIC | | |
| --- | --- | --- |
| Code System(s): | ReligiousAffiliation 2.16.840.1.113883.5.1076 | |
| Description: | A value set of codes that reflect spiritual faith affiliation  <http://www.hl7.org/memonly/downloads/v3edition.cfm#V32008> | |
| Code | Code System | Print Name |
| 1026 | ReligiousAffiliation | Judaism |
| 1020 | ReligiousAffiliation | Hinduism |
| 1041 | ReligiousAffiliation | Roman Catholic Church |
| … |  |  |

Table 8: Race Value Set (excerpt)

| Value Set: Race 2.16.840.1.113883.1.11.14914 DYNAMIC | | |
| --- | --- | --- |
| Code System(s): | Race and Ethnicity - CDC 2.16.840.1.113883.6.238 | |
| Description: | A Value Set of codes for Classifying data based upon race.  Race is always reported at the discretion of the person for whom this attribute is reported, and reporting must be completed according to Federal guidelines for race reporting. Any code descending from the Race concept (1000-9) in that terminology may be used in the exchange  <http://phinvads.cdc.gov/vads/ViewCodeSystemConcept.action?oid=2.16.840.1.113883.6.238&code=1000-9> | |
| Code | Code System | Print Name |
| 1002-5 | Race and Ethnicity- CDC | American Indian or Alaska Native |
| 2028-9 | Race and Ethnicity- CDC | Asian |
| 2054-5 | Race and Ethnicity- CDC | Black or African American |
| 2076-8 | Race and Ethnicity- CDC | Native Hawaiian or Other Pacific Islander |
| 2106-3 | Race and Ethnicity- CDC | White |
| ... |  |  |

Table 9: Ethnicity Value Set

| Value Set: Ethnicity Value Set 2.16.840.1.114222.4.11.837 DYNAMIC | | |
| --- | --- | --- |
| Code System(s): | Race and Ethnicity - CDC 2.16.840.1.113883.6.238 | |
| Code | Code System | Print Name |
| 2135-2 | Race and Ethnicity Code Sets | Hispanic or Latino |
| 2186-5 | Race and Ethnicity Code Sets | Not Hispanic or Latino |

Table 10: Personal Relationship Role Type Value Set (excerpt)

| Value Set: Personal Relationship Role Type 2.16.840.1.113883.1.11.19563 DYNAMIC | | |
| --- | --- | --- |
| Code System(s): | RoleCode 2.16.840.1.113883.5.111 | |
| Description: | A Personal Relationship records the role of a person in relation to another person. This value set is to be used when recording the relationships between different people who are not necessarily related by family ties, but also includes family relationships.  <http://www.hl7.org/memonly/downloads/v3edition.cfm#V32008> | |
| Code | Code System | Print Name |
| HUSB | RoleCode | husband |
| WIFE | RoleCode | wife |
| FRND | RoleCode | friend |
| SISINLAW | RoleCode | sister-in-law |
| … |  |  |

Table 11: State Value Set (excerpt)

| Value Set: StateValueSet 2.16.840.1.113883.3.88.12.80.1 DYNAMIC | | |
| --- | --- | --- |
| Code System(s): | FIPS 5-2 (State) 2.16.840.1.113883.6.92 | |
| Description: | Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987  <http://www.itl.nist.gov/fipspubs/fip5-2.htm> | |
| Code | Code System | Print Name |
| AL | FIPS 5-2 (State Alpha Codes) | Alabama |
| AK | FIPS 5-2 (State Alpha Codes) | Alaska |
| AZ | FIPS 5-2 (State Alpha Codes) | Arizona |
| AR | FIPS 5-2 (State Alpha Codes) | Arkansas |
| … |  |  |

Table 12: Postal Code Value Set (excerpt)

| Value Set: PostalCodeValueSet 2.16.840.1.113883.3.88.12.80.2 DYNAMIC | | |
| --- | --- | --- |
| Code System(s): | US Postal Codes 2.16.840.1.113883.6.231 | |
| Description: | A value set of codes postal (ZIP) Code of an address in the United States.  <http://zip4.usps.com/zip4/welcome.jsp> | |
| Code | Code System | Print Name |
| 19009 | US Postal Codes | Bryn Athyn, PA |
| 92869-1736 | US Postal Codes | Orange, CA |
| 32830-8413 | US Postal Codes | Lake Buena Vista, FL |
| … |  |  |

Table 13: Country Value Set (excerpt)

| Value Set: CountryValueSet 2.16.840.1.113883.3.88.12.80.63 DYNAMIC | | |
| --- | --- | --- |
| Code System(s): | ISO 3166-1 Country Codes: 1.0.3166.1 | |
| Description: | A value set of codes for the representation of names of countries, territories and areas of geographical interest.  Note: This table provides the ISO 3166-1 code elements available in the alpha-2 code of ISO's country code standard  <http://www.iso.org/iso/country_codes/iso_3166_code_lists.htm> | |
| Code | Code System | Print Name |
| AW | ISO 3166-1 Country Codes | Aruba |
| IL | ISO 3166-1 Country Codes | Israel |
| KZ | ISO 3166-1 Country Codes | Kazakhstan |
| US | ISO 3166-1 Country Codes | United States |
| … |  |  |

Table 14: Language Ability Value Set

| Value Set: HL7 LanguageAbilityMode 2.16.840.1.113883.1.11.12249 DYNAMIC | | |
| --- | --- | --- |
| Code System(s): | LanguageAbilityMode 2.16.840.1.113883.5.60 | |
| Description: | A value representing the method of expression of the language. | |
| Code | Code System | Print Name |
| ESGN | LanguageAbilityMode | Expressed signed |
| ESP | LanguageAbilityMode | Expressed spoken |
| EWR | LanguageAbilityMode | Expressed written |
| RSGN | LanguageAbilityMode | Received signed |
| RSP | LanguageAbilityMode | Received spoken |
| RWR | LanguageAbilityMode | Received written |

Table 15: Language Ability Proficiency Value Set

| Value Set: LanguageAbilityProficiency 2.16.840.1.113883.1.11.12199 DYNAMIC | | |
| --- | --- | --- |
| Code System(s): | LanguageAbilityProficiency 2.16.840.1.113883.5.61 | |
| Description: | A value representing the level of proficiency in a language. | |
| Code | Code System | Print Name |
| E | LanguageAbilityProficiency | Excellent |
| F | LanguageAbilityProficiency | Fair |
| G | LanguageAbilityProficiency | Good |
| P | LanguageAbilityProficiency | Poor |

#### 227BRecordTarget Example

Figure 22: recordTarget example

<recordTarget>

<patientRole>

<id

extension="998991"

root="2.16.840.1.113883.19.5.99999.2"/>

<!-- Fake ID using HL7 example OID. -->

<id

extension="111-00-2330"

root="2.16.840.1.113883.4.1"/>

<!-- Fake Social Security Number using the actual SSN OID. -->

<addr

use="HP">

<!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

<streetAddressLine>1357 Amber Drive</streetAddressLine>

<city>Beaverton</city>

<state>OR</state>

<postalCode>97867</postalCode>

<country>US</country>

<!-- US is "United States" from ISO 3166-1 Country Codes:

1.0.3166.1 -->

</addr>

<telecom

value="tel:(816)276-6909"

use="HP"/>

<!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->

<patient>

<name

use="L">

<!-- L is "Legal" from HL7 EntityNameUse 2.16.840.1.113883.5.45 -->

<given>Isabella</given>

<given>Isa</given>

<!-- CL is "Call me" from HL7 EntityNamePartQualifier

2.16.840.1.113883.5.43 -->

<family>Jones</family>

</name>

<administrativeGenderCode

code="F"

codeSystem="2.16.840.1.113883.5.1"

displayName="Female"/>

<birthTime

value="20050501"/>

<maritalStatusCode

code="M"

displayName="Married"

codeSystem="2.16.840.1.113883.5.2"

codeSystemName="MaritalStatusCode"/>

<religiousAffiliationCode

code="1013"

displayName="Christian (non-Catholic, non-specific)"

codeSystemName="HL7 Religious Affiliation"

codeSystem="2.16.840.1.113883.5.1076"/>

<raceCode

code="1966-1"

displayName="Aleut"

codeSystem="2.16.840.1.113883.6.238"

codeSystemName="Race &amp; Ethnicity - CDC"/>

<ethnicGroupCode

code="2186-5"

displayName="Not Hispanic or Latino"

codeSystem="2.16.840.1.113883.6.238"

codeSystemName="Race &amp; Ethnicity - CDC"/>

<guardian>

<code

code="GRPRN"

displayName="GrandParent"

codeSystem="2.16.840.1.113883.5.111"

codeSystemName="HL7 Role code"/>

<addr

use="HP">

<!-- HP is "primary home" from codeSystem

2.16.840.1.113883.5.1119 -->

<streetAddressLine>1357 Amber Drive</streetAddressLine>

<city>Beaverton</city>

<state>OR</state>

<postalCode>97867</postalCode>

<country>US</country>

<!-- US is "United States" from ISO 3166-1 Country Codes:

1.0.3166.1 -->

</addr>

<telecom

value="tel:(816)276-6909"

use="HP"/>

<guardianPerson>

<name>

<given>Ralph</given>

<family>Jones</family>

</name>

</guardianPerson>

</guardian>

<birthplace>

<place>

<addr>

<city>Beaverton</city>

<state>OR</state>

<postalCode>97867</postalCode>

<country>US</country>

</addr>

</place>

</birthplace>

<languageCommunication>

<languageCode

code="en"/>

<modeCode

code="ESP"

displayName="Expressed spoken"

codeSystem="2.16.840.1.113883.5.60"

codeSystemName="LanguageAbilityMode"/>

<preferenceInd

value="true"/>

</languageCommunication>

</patient>

<providerOrganization>

<id

root="2.16.840.1.113883.19.5.9999.1393"/>

<name>Community Health and Hospitals</name>

<telecom

use="WP"

value="tel: 555-555-5000"/>

<addr>

<streetAddressLine>1001 Village Avenue</streetAddressLine>

<city>Portland</city>

<state>OR</state>

<postalCode>99123</postalCode>

<country>US</country>

</addr>

</providerOrganization>

</patientRole>

</recordTarget>

Author

The author element represents the creator of the clinical document. The author may be a device, or a person.

1. SHALL contain at least one [1..\*] author (CONF:5444).
   1. Such authors SHALL contain exactly one [1..1] time (CONF:5445).
      1. The content SHALL be a conformant US Realm Date and Time (DTM.US.FIELDED) (2.16.840.1.113883.10.20.22.5.4) (CONF:16866).
   2. Such authors SHALL contain exactly one [1..1] assignedAuthor (CONF:5448).
      1. This assignedAuthor SHALL contain exactly one [1..1] id (CONF:5449) such that it
         1. SHALL contain exactly one [1..1] @root (CONF:16786).
            1. If this assignedAuthor is an assignedPerson the assignedAuthor id SHALL contain exactly one [1..1] @root="2.16.840.1.113883.4.6" National Provider Identifier (CONF:19521).
      2. This assignedAuthor SHOULD contain zero or one [0..1] code (CONF:16787).
         1. The code, if present, SHOULD contain exactly one [1..1] @code, which SHOULD be selected from ValueSet Healthcare Provider Taxonomy (HIPAA) 2.16.840.1.114222.4.11.1066 DYNAMIC (CONF:16788).
      3. This assignedAuthor SHALL contain at least one [1..\*] addr (CONF:5452).
         1. The content SHALL be a conformant US Realm Address (AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:16871).
      4. This assignedAuthor SHALL contain at least one [1..\*] telecom (CONF:5428).
         1. Such telecoms SHOULD contain exactly one [1..1] @use, which SHALL be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 DYNAMIC (CONF:7995).
      5. This assignedAuthor SHOULD contain zero or one [0..1] assignedPerson (CONF:5430).
         1. The assignedPerson, if present, SHALL contain at least one [1..\*] name (CONF:16789).
            1. The content SHALL be a conformant US Realm Person Name (PN.US.FIELDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:16872).
      6. This assignedAuthor SHOULD contain zero or one [0..1] assignedAuthoringDevice (CONF:16783).
         1. The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] manufacturerModelName (CONF:16784).
         2. The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] softwareName (CONF:16785).
      7. There SHALL be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice (CONF:16790).

Figure 23: Person author example

<author>

<time

value="20050329224411+0500"/>

<assignedAuthor>

<id

extension="99999999"

root="2.16.840.1.113883.4.6"/>

<code

code="200000000X"

codeSystem="2.16.840.1.113883.6.101"

displayName="Allopathic &amp; Osteopathic Physicians"/>

<addr>

<streetAddressLine>1002 Healthcare Drive </streetAddressLine>

<city>Portland</city>

<state>OR</state>

<postalCode>99123</postalCode>

<country>US</country>

</addr>

<telecom

use="WP"

value="tel:555-555-1002"/>

<assignedPerson>

<name>

<given>Henry</given>

<family>Seven</family>

</name>

</assignedPerson>

</assignedAuthor>

</author>

Figure 24: Device author example

<author>

<time value="20050329224411+0500"/>

<assignedAuthor>

<id extension="KP00017dev" root="2.16.840.1.113883.19.5"/>

<addr>

<streetAddressLine>21 North Ave.</streetAddressLine>

<city>Burlington</city>

<state>MA</state>

<postalCode>02368</postalCode>

<country>US</country>

</addr>

<telecom use="WP" value="tel:(555)555-1003"/>

<assignedAuthoringDevice>

<manufacturerModelName>Good Health Medical

Device</manufacturerModelName >

<softwareName>Good Health Report Generator</softwareName >

</ assignedAuthoringDevice >

</assignedAuthor>

</author>

DataEnterer

The dataEnterer element represents the person who transferred the content, written or dictated by someone else, into the clinical document. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own interpretation, and the dataEnterer adds that information to the electronic system. In other words, a dataEnterer transfers information from one source to another (e.g., transcription from paper form to electronic system).

1. MAY contain zero or one [0..1] dataEnterer (CONF:5441).
   1. The dataEnterer, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:5442).
      1. This assignedEntity SHALL contain at least one [1..\*] id (CONF:5443).
         1. Such ids SHOULD contain zero or one [0..1] @root="2.16.840.1.113883.4.6" National Provider Identifier (CONF:16821).
      2. This assignedEntity SHALL contain at least one [1..\*] addr (CONF:5460).
         1. The content of addr SHALL be a conformant US Realm Address (AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10417).
      3. This assignedEntity SHALL contain at least one [1..\*] telecom (CONF:5466).
         1. Such telecoms SHOULD contain exactly one [1..1] @use, which SHALL be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 DYNAMIC (CONF:7996).
      4. This assignedEntity SHALL contain exactly one [1..1] assignedPerson (CONF:5469).
         1. This assignedPerson SHALL contain at least one [1..\*] name (CONF:5470).
            1. The content of name SHALL be a conformant US Realm Person Name (PN.US.FIELDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10418).
      5. This assignedEntity MAY contain zero or one [0..1] code which SHOULD be selected from coding system NUCC Health Care Provider Taxonomy 2.16.840.1.113883.6.101 (CONF:9944).

Figure 25: dataEnterer example

<dataEnterer>

<assignedEntity>

<id

root="2.16.840.1.113883.4.6"

extension="999999943252"/>

<addr>

<streetAddressLine>1001 Village Avenue</streetAddressLine>

<city>Portland</city>

<state>OR</state>

<postalCode>99123</postalCode>

<country>US</country>

</addr>

<telecom

use="WP"

value="tel:555-555-1002"/>

<assignedPerson>

<name>

<given>Henry</given>

<family>Seven</family>

</name>

</assignedPerson>

</assignedEntity>

</dataEnterer>

Informant

The informant element describes the source of the information in a medical document.

Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.

When the informant is a personal relation, that informant is represented in the relatedEntity element. The code element of the relatedEntity describes the relationship between the informant and the patient. The relationship between the informant and the patient needs to be described to help the receiver of the clinical document understand the information in the document.

1. MAY contain zero or more [0..\*] informant (CONF:8001).
   1. The informant, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:8002).
      1. This assignedEntity SHOULD contain zero or more [0..\*] id (CONF:9945).
         1. If assignedEntity/id is a provider then this id, SHOULD include zero or one [0..1] id where id/@root ="2.16.840.1.113883.4.6" National Provider Identifier (CONF:9946).
      2. This assignedEntity SHOULD contain at least one [1..\*] addr (CONF:8220).
         1. The content of addr SHALL be a conformant US Realm Address (AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10419).
      3. This assignedEntity SHALL contain exactly one [1..1] assignedPerson (CONF:8221).
         1. This assignedPerson SHALL contain at least one [1..\*] name (CONF:8222).
            1. The content of name SHALL be a conformant US Realm Person Name (PN.US.FIELDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10420).
      4. Ii. This assignedEntity MAY contain zero or one [0..1] code which SHOULD be selected from coding system NUCC Health Care Provider Taxonomy 2.16.840.1.113883.6.101 (CONF:9947).

Figure 26: Informant with assignedEntity example

<informant>

<assignedEntity>

<id

extension="KP00017"

root="2.16.840.1.113883.19.5"/>

<addr>

<streetAddressLine>1001 Village Avenue</streetAddressLine>

<city>Portland</city>

<state>OR</state>

<postalCode>99123</postalCode>

<country>US</country>

</addr>

<telecom

use="WP"

value="tel:555-555-1002"/>

<assignedPerson>

<name>

<given>Henry</given>

<family>Seven</family>

</name>

</assignedPerson>

</assignedEntity>

</informant>

Custodian

The custodian element represents the organization that is in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document. Every CDA document has exactly one custodian. The custodian participation satisfies the CDA definition of Stewardship. Because CDA is an exchange standard and may not represent the original form of the authenticated document (e.g., CDA could include scanned copy of original), the custodian represents the steward of the original source document. The custodian may be the document originator, a health information exchange, or other responsible party.

1. SHALL contain exactly one [1..1] custodian (CONF:5519).
   1. This custodian SHALL contain exactly one [1..1] assignedCustodian (CONF:5520).
      1. This assignedCustodian SHALL contain exactly one [1..1] representedCustodianOrganization (CONF:5521).
         1. This representedCustodianOrganization SHALL contain at least one [1..\*] id (CONF:5522).
            1. Such ids SHOULD contain zero or one [0..1] @root="2.16.840.1.113883.4.6" National Provider Identifier (CONF:16822).
         2. This representedCustodianOrganization SHALL contain exactly one [1..1] name (CONF:5524).
         3. This representedCustodianOrganization SHALL contain exactly one [1..1] telecom (CONF:5525).
            1. This telecom SHOULD contain exactly one [1..1] @use, which SHALL be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 DYNAMIC (CONF:7998).
         4. This representedCustodianOrganization SHALL contain at least one [1..\*] addr (CONF:5559).
            1. The content of addr SHALL be a conformant US Realm Address (AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10421).

Figure 27: Custodian example

<custodian>

<assignedCustodian>

<representedCustodianOrganization>

<id

extension="99999999"

root="2.16.840.1.113883.4.6"/>

<name>Community Health and Hospitals</name>

<telecom

value="tel: 555-555-1002"

use="WP"/>

<addr

use="WP">

<streetAddressLine>1002 Healthcare Drive </streetAddressLine>

<city>Portland</city>

<state>OR</state>

<postalCode>99123</postalCode>

<country>US</country>

</addr>

</representedCustodianOrganization>

</assignedCustodian>

</custodian>

InformationRecipient

The informationRecipient element records the intended recipient of the information at the time the document is created. For example, in cases where the intended recipient of the document is the patient's health chart, set the receivedOrganization to be the scoping organization for that chart.

1. MAY contain zero or more [0..\*] informationRecipient (CONF:5565).
   1. The informationRecipient, if present, SHALL contain exactly one [1..1] intendedRecipient (CONF:5566).
      1. This intendedRecipient MAY contain zero or one [0..1] informationRecipient (CONF:5567).
         1. The informationRecipient, if present, SHALL contain at least one [1..\*] name (CONF:5568).
            1. The content of name SHALL be a conformant US Realm Person Name (PN.US.FIELDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10427).
      2. This intendedRecipient MAY contain zero or one [0..1] receivedOrganization (CONF:5577).
         1. The receivedOrganization, if present, SHALL contain exactly one [1..1] name (CONF:5578).

Figure 28: informationRecipient example

<informationRecipient>

<intendedRecipient>

<informationRecipient>

<name>

<given>Henry</given>

<family>Seven</family>

</name>

</informationRecipient>

<receivedOrganization>

<name>Community Health and Hospitals</name>

</receivedOrganization>

</intendedRecipient>

</informationRecipient>

LegalAuthenticator

The legalAuthenticator identifies the single person legally responsible for the document and must be present if the document has been legally authenticated. (Note that per the following section, there may also be one or more document authenticators.)

Based on local practice, clinical documents may be released before legal authentication. This implies that a clinical document that does not contain this element has not been legally authenticated.

The act of legal authentication requires a certain privilege be granted to the legal authenticator depending upon local policy. All clinical documents have the potential for legal authentication, given the appropriate credentials.

Local policies may choose to delegate the function of legal authentication to a device or system that generates the clinical document. In these cases, the legal authenticator is a person accepting responsibility for the document, not the generating device or system.

Note that the legal authenticator, if present, must be a person.

1. SHOULD contain zero or one [0..1] legalAuthenticator (CONF:5579).
   1. The legalAuthenticator, if present, SHALL contain exactly one [1..1] time (CONF:5580).
      1. The content SHALL be a conformant US Realm Date and Time (DTM.US.FIELDED) (2.16.840.1.113883.10.20.22.5.4) (CONF:16873).
   2. The legalAuthenticator, if present, SHALL contain exactly one [1..1] signatureCode (CONF:5583).
      1. This signatureCode SHALL contain exactly one [1..1] @code="S" (CodeSystem: Participationsignature 2.16.840.1.113883.5.89 STATIC) (CONF:5584).
   3. The legalAuthenticator, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:5585).
      1. This assignedEntity SHALL contain at least one [1..\*] id (CONF:5586).
         1. Such ids MAY contain zero or one [0..1] @root="2.16.840.1.113883.4.6" National Provider Identifier (CONF:16823).
      2. This assignedEntity MAY contain zero or one [0..1] code, which SHOULD be selected from ValueSet Healthcare Provider Taxonomy (HIPAA) 2.16.840.1.114222.4.11.1066 STATIC (CONF:17000).
      3. This assignedEntity SHALL contain at least one [1..\*] addr (CONF:5589).
         1. The content of addr SHALL be a conformant US Realm Address (AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10429).
      4. This assignedEntity SHALL contain at least one [1..\*] telecom (CONF:5595).
         1. Such telecoms SHOULD contain exactly one [1..1] @use, which SHALL be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 DYNAMIC (CONF:7999).
      5. This assignedEntity SHALL contain exactly one [1..1] assignedPerson (CONF:5597).
         1. This assignedPerson SHALL contain at least one [1..\*] name (CONF:5598).
            1. The content of name SHALL be a conformant US Realm Person Name (PN.US.FIELDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10430).

Figure 29: legalAuthenticator example

<legalAuthenticator>

<time

value="20090227130000+0500"/>

<signatureCode

code="S"/>

<assignedEntity>

<id

extension="999999999"

root="2.16.840.1.113883.4.6"/>

<addr>

<streetAddressLine>1001 Village Avenue</streetAddressLine>

<city>Portland</city>

<state>OR</state>

<postalCode>99123</postalCode>

<country>US</country>

</addr>

<telecom

use="WP"

value="tel:555-555-1002"/>

<assignedPerson>

<name>

<given>Henry</given>

<family>Seven</family>

</name>

</assignedPerson>

</assignedEntity>

</legalAuthenticator>

Authenticator

The authenticator identifies a participant or participants who attested to the accuracy of the information in the document.

1. MAY contain zero or more [0..\*] authenticator (CONF:5607).
   1. The authenticator, if present, SHALL contain exactly one [1..1] time (CONF:5608).
      1. The content SHALL be a conformant US Realm Date and Time (DTM.US.FIELDED) (2.16.840.1.113883.10.20.22.5.4) (CONF:16874).
   2. The authenticator, if present, SHALL contain exactly one [1..1] signatureCode (CONF:5610).
      1. This signatureCode SHALL contain exactly one [1..1] @code="S" (CodeSystem: Participationsignature 2.16.840.1.113883.5.89 STATIC) (CONF:5611).
   3. The authenticator, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:5612).
      1. This assignedEntity SHALL contain at least one [1..\*] id (CONF:5613).
         1. Such ids SHOULD contain zero or one [0..1] @root="2.16.840.1.113883.4.6" National Provider Identifier (CONF:16824).
      2. This assignedEntity MAY contain zero or one [0..1] code (CONF:16825).
         1. The code, if present, MAY contain zero or one [0..1] @code, which SHOULD be selected from ValueSet Healthcare Provider Taxonomy (HIPAA) 2.16.840.1.114222.4.11.1066 STATIC (CONF:16826).
      3. This assignedEntity SHALL contain at least one [1..\*] addr (CONF:5616).
         1. The content of addr SHALL be a conformant US Realm Address (AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10425).
      4. This assignedEntity SHALL contain at least one [1..\*] telecom (CONF:5622).
         1. Such telecoms SHOULD contain exactly one [1..1] @use, which SHALL be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 DYNAMIC (CONF:8000).
      5. This assignedEntity SHALL contain exactly one [1..1] assignedPerson (CONF:5624).
         1. This assignedPerson SHALL contain at least one [1..\*] name (CONF:5625).
            1. The content of name SHALL be a conformant US Realm Person Name (PN.US.FIELDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10424).

Figure 30: Authenticator example

<authenticator>

<time

value="20090227130000+0500"/>

<signatureCode

code="S"/>

<assignedEntity>

<id

extension="999999999"

root="2.16.840.1.113883.4.6"/>

<addr>

<streetAddressLine>1001 Village Avenue</streetAddressLine>

<city>Portland</city>

<state>OR</state>

<postalCode>99123</postalCode>

<country>US</country>

</addr>

<telecom

use="WP"

value="tel:555-555-1002"/>

<assignedPerson>

<name>

<given>Henry</given>

<family>Seven</family>

</name>

</assignedPerson>

</assignedEntity>

</authenticator>

Participant (Support)

The participant element identifies other supporting participants, including parents, relatives, caregivers, insurance policyholders, guarantors, and other participants related in some way to the patient.

A supporting person or organization is an individual or an organization with a relationship to the patient. A supporting person who is playing multiple roles would be recorded in multiple participants (e.g., emergency contact and next-of-kin)

1. MAY contain zero or more [0..\*] participant (CONF:10003).
   1. The participant, if present, MAY contain zero or one [0..1] time (CONF:10004).
   2. Such participants, if present, SHALL have an associatedPerson or scopingOrganization element under participant/associatedEntity (CONF:10006).
   3. Unless otherwise specified by the document specific header constraints, when participant/@typeCode is IND, associatedEntity/@classCode SHALL be selected from ValueSet 2.16.840.1.113883.11.20.9.33 INDRoleclassCodes STATIC 2011-09-30 (CONF:10007).

Table 16: IND Role classCode Value Set

| Value Set: INDRoleclassCodes 2.16.840.1.113883.11.20.9.33 STATIC 2011-09-30 | | |
| --- | --- | --- |
| Code System(s): | RoleClass 2.16.840.1.113883.5.110 | |
| Code | Code System | Print Name |
| PRS | RoleClass | personal relationship |
| NOK | RoleClass | next of kin |
| CAREGIVER | RoleClass | caregiver |
| AGNT | RoleClass | agent |
| GUAR | RoleClass | guarantor |
| ECON | RoleClass | emergency contact |

Figure 31: Participant example for a supporting person

<participant

typeCode="IND">

<time

xsi:type="IVL\_TS">

<low

value="19590101"/>

<high

value="20111025"/>

</time>

<associatedEntity

classCode="NOK">

<code

code="MTH"

codeSystem="2.16.840.1.113883.5.111"/>

<addr>

<streetAddressLine>17 Daws Rd.</streetAddressLine>

<city>Beaverton</city>

<state>OR</state>

<postalCode>97867</postalCode>

<country>US</country>

</addr>

<telecom

value="tel:(999)555-1212"

use="WP"/>

<associatedPerson>

<name>

<prefix>Mrs.</prefix>

<given>Martha</given>

<family>Jones</family>

</name>

</associatedPerson>

</associatedEntity>

</participant>

InFulfillmentOf

The inFulfillmentOf element represents orders that are fulfilled by this document.

1. MAY contain zero or more [0..\*] inFulfillmentOf (CONF:9952).
   1. The inFulfillmentOf, if present, SHALL contain exactly one [1..1] order (CONF:9953).
      1. This order SHALL contain at least one [1..\*] id (CONF:9954).

DocumentationOf/serviceEvent

A serviceEvent represents the main act, such as a colonoscopy or a cardiac stress study, being documented. In a continuity of care document, CCD, the serviceEvent is a provision of healthcare over a period of time. In a provision of healthcare serviceEvent, the care providers, PCP or other longitudinal providers, are recorded within the serviceEvent. If the document is about a single encounter, the providers associated can be recorded in the componentOf/encompassingEncounter.

1. MAY contain zero or more [0..\*] documentationOf (CONF:14835).
   1. The documentationOf, if present, SHALL contain exactly one [1..1] serviceEvent (CONF:14836).
      1. This serviceEvent SHALL contain exactly one [1..1] effectiveTime (CONF:14837).
         1. This effectiveTime SHALL contain exactly one [1..1] low (CONF:14838).
      2. This serviceEvent SHOULD contain zero or more [0..\*] performer (CONF:14839).
         1. The performer, if present, SHALL contain exactly one [1..1] @typeCode (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 STATIC) (CONF:14840).
            1. The performer participant represents clinicians who actually and principally carry out the serviceEvent. In a transfer of care this represents the healthcare providers involved in the current or pertinent historical care of the patient. Preferably, the patient’s key healthcare care team members would be listed, particularly their primary physician and any active consulting physicians, therapists, and counselors (CONF:16753).
         2. The performer, if present, MAY contain zero or one [0..1] functionCode (CONF:16818).
            1. The functionCode, if present, SHOULD contain zero or one [0..1] @codeSystem, which SHOULD be selected from CodeSystem participationFunction (2.16.840.1.113883.5.88) STATIC (CONF:16819).
         3. The performer, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:14841).
            1. This assignedEntity SHALL contain at least one [1..\*] id (CONF:14846).

Such ids SHOULD contain zero or one [0..1] @root="2.16.840.1.113883.4.6" National Provider Identifier (CONF:14847).

* + - * 1. This assignedEntity SHOULD contain zero or one [0..1] code (CONF:14842).

The code, if present, SHALL contain exactly one [1..1] @code, which SHOULD be selected from CodeSystem NUCCProviderTaxonomy (2.16.840.1.113883.6.101) STATIC (CONF:14843).

Figure 32: DocumentationOf example

<documentationOf

typeCode="DOC">

<serviceEvent

classCode="PCPR">

<code

code="73761001"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="Colonoscopy"/>

<effectiveTime>

<low

value="201209080000-0400"/>

<high

value="201209150000-0400"/>

</effectiveTime>

<performer

typeCode="PRF">

<functionCode

code="PP"

displayName="Primary Care Provider"

codeSystem="2.16.840.1.113883.12.443"

codeSystemName="Provider Role">

<originalText>Primary Care Provider</originalText>

</functionCode>

<time>

<low

value="201209080000-0400"/>

<high

value="201209150000-0400"/>

</time>

<assignedEntity>

<id

extension="PseudoMD-1"

root="2.16.840.1.113883.4.6"/>

<code

code="200000000X"

displayName="Allopathic and Osteopathic Physicians"

codeSystemName="Provider Codes"

codeSystem="2.16.840.1.113883.6.101"/>

<addr>

<streetAddressLine>1001 Village Avenue</streetAddressLine>

<city>Portland</city>

<state>OR</state>

<postalCode>99123</postalCode>

<country>US</country>

</addr>

<telecom

value="tel:+1-555-555-5000"

use="WP"/>

<assignedPerson>

<name>

<prefix>Dr.</prefix>

<given>Henry</given>

<family>Seven</family>

</name>

</assignedPerson>

<representedOrganization>

<id

root="2.16.840.1.113883.19.5.9999.1393"/>

<name>Community Health and Hospitals</name>

<telecom

value="tel:+1-555-555-5000"

use="WP"/>

<addr>

<streetAddressLine>1001 Village Avenue</streetAddressLine>

<city>Portland</city>

<state>OR</state>

<postalCode>99123</postalCode>

<country>US</country>

</addr>

</representedOrganization>

</assignedEntity>

</performer>

</serviceEvent>

</documentationOf>

Authorization/consent

The header can record information about the patient’s consent.

The type of consent (e.g., a consent to perform the related serviceEvent) is conveyed in consent/code. Consents in the header have been finalized (consent/statusCode must equal Completed) and should be on file. This specification does not address how Privacy Consent’ is represented, but does not preclude the inclusion of ‘Privacy Consent’.

1. MAY contain zero or more [0..\*] authorization (CONF:16792) such that it
   1. SHALL contain exactly one [1..1] consent (CONF:16793).
      1. This consent MAY contain zero or more [0..\*] id (CONF:16794).
      2. This consent MAY contain zero or one [0..1] code (CONF:16795).
         1. The type of consent (e.g., a consent to perform the related serviceEvent) is conveyed in consent/code (CONF:16796).
      3. This consent SHALL contain exactly one [1..1] statusCode (CONF:16797).
         1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:16798).

Figure 33: Procedure note consent example

<authorization typeCode="AUTH">

<consent classCode="CONS" moodCode="EVN">

<id root="629deb70-5306-11df-9879-0800200c9a66" />

<code codeSystem=" 2.16.840.1.113883.6.1" codeSystemName="LOINC"

code="64293-4" displayName="Procedure consent"/>

<statusCode code="completed"/>

</consent>

</authorization>

ComponentOf

The componentOf element contains the encompassing encounter for this document. The encompassing encounter represents the setting of the clinical encounter during which the document act(s) or ServiceEvent occurred.

In order to represent providers associated with a specific encounter, they are recorded within the encompassingEncounter as participants.

In a CCD the encompassingEncounter may be used when documenting a specific encounter and its participants. All relevant encounters in a CCD may be listed in the encounters section.

1. MAY contain zero or one [0..1] componentOf (CONF:9955).
   1. The componentOf, if present, SHALL contain exactly one [1..1] encompassingEncounter (CONF:9956).
      1. This encompassingEncounter SHALL contain at least one [1..\*] id (CONF:9959).
      2. This encompassingEncounter SHALL contain exactly one [1..1] effectiveTime (CONF:9958).

US Realm Address (AD.US.FIELDED)

[AD: templateId 2.16.840.1.113883.10.20.22.5.2 (open)]

Reusable ""address"" template, designed for use in US Realm CDA Header.

1. SHOULD contain exactly one [1..1] @use, which SHALL be selected from ValueSet PostalAddressUse 2.16.840.1.113883.1.11.10637 STATIC 2005-05-01 (CONF:7290).
2. SHOULD contain zero or one [0..1] country, where the @code SHALL be selected from ValueSet CountryValueSet 2.16.840.1.113883.3.88.12.80.63 DYNAMIC (CONF:7295).
3. SHOULD contain zero or one [0..1] state (ValueSet: StateValueSet 2.16.840.1.113883.3.88.12.80.1 DYNAMIC) (CONF:7293).
   1. State is required if the country is US. If country is not specified, its assumed to be US. If country is something other than US, the state MAY be present but MAY be bound to different vocabularies (CONF:10024).
4. SHALL contain exactly one [1..1] city (CONF:7292).
5. SHOULD contain zero or one [0..1] postalCode (ValueSet: PostalCodeValueSet 2.16.840.1.113883.3.88.12.80.2 DYNAMIC) (CONF:7294).
   1. PostalCode is required if the country is US. If country is not specified, its assumed to be US. If country is something other than US, the postalCode MAY be present but MAY be bound to different vocabularies (CONF:10025).
6. SHALL contain at least one and not more than 4 streetAddressLine (CONF:7291).
7. SHALL NOT have mixed content except for white space (<CONF:7296>).

Table 17: PostalAddressUse Value Set

| Value Set: PostalAddressUse 2.16.840.1.113883.1.11.10637 STATIC 2005-05-01 | | |
| --- | --- | --- |
| Code System(s): | AddressUse 2.16.840.1.113883.5.1119 | |
| Code | Code System | Print Name |
| BAD | AddressUse | bad address |
| DIR | AddressUse | direct |
| H | AddressUse | home address |
| HP | AddressUse | primary home |
| HV | AddressUse | vacation home |
| PHYS | AddressUse | physical visit address |
| PST | AddressUse | postal address |
| PUB | AddressUse | public |
| TMP | AddressUse | temporary |
| WP | AddressUse | work place |

US Realm Date and Time (DTM.US.FIELDED)

[TS: templateId 2.16.840.1.113883.10.20.22.5.4 (open)]

The US Realm Clinical Document Date and Time datatype flavor records date and time information. If no time zone offset is provided, you can make no assumption about time, unless you have made a local exchange agreement.

1. SHALL be precise to the day (CONF:10127).
2. SHOULD be precise to the minute (CONF:10128).
3. MAY be precise to the second (CONF:10129).
4. If more precise than day, SHOULD include time-zone offset (CONF:10130).

US Realm Patient Name (PTN.US.FIELDED)

[PN: templateId 2.16.840.1.113883.10.20.22.5.1 (open)]

The US Realm Patient Name datatype flavor is a set of reusable constraints that can be used for the patient or any other person. It requires a first (given) and last (family) name. If a patient or person has only one name part (e.g., patient with first name only) place the name part in the field required by the organization. Use the appropriate nullFlavor, ""Not Applicable"" (NA), in the other field.

For information on mixed content see the Extensible Markup Language reference (http://www.w3c.org/TR/2008/REC-xml-20081126/).

1. MAY contain zero or one [0..1] @use, which SHALL be selected from ValueSet EntityNameUse 2.16.840.1.113883.1.11.15913 STATIC 2005-05-01 (CONF:7154).
2. SHALL contain exactly one [1..1] family (CONF:7159).
   1. This family MAY contain zero or one [0..1] @qualifier, which SHALL be selected from ValueSet EntityPersonNamePartQualifier 2.16.840.1.113883.11.20.9.26 STATIC 2011-09-30 (CONF:7160).
3. SHALL contain at least one [1..\*] given (CONF:7157).
   1. Such givens MAY contain zero or one [0..1] @qualifier, which SHALL be selected from ValueSet EntityPersonNamePartQualifier 2.16.840.1.113883.11.20.9.26 STATIC 2011-09-30 (CONF:7158).
   2. The second occurrence of given (given[2]) if provided, SHALL include middle name or middle initial (CONF:7163).
4. MAY contain zero or more [0..\*] prefix (CONF:7155).
   1. The prefix, if present, MAY contain zero or one [0..1] @qualifier, which SHALL be selected from ValueSet EntityPersonNamePartQualifier 2.16.840.1.113883.11.20.9.26 STATIC 2011-09-30 (CONF:7156).
5. MAY contain zero or one [0..1] suffix (CONF:7161).
   1. The suffix, if present, MAY contain zero or one [0..1] @qualifier, which SHALL be selected from ValueSet EntityPersonNamePartQualifier 2.16.840.1.113883.11.20.9.26 STATIC 2011-09-30 (CONF:7162).
6. SHALL NOT have mixed content except for white space (<CONF:7278>).

Table 18: EntityNameUse Value Set

| Value Set: EntityNameUse 2.16.840.1.113883.1.11.15913 STATIC 2005-05-01 | | |
| --- | --- | --- |
| Code System(s): | EntityNameUse 2.16.840.1.113883.5.45 | |
| Code | Code System | Print Name |
| A | EntityNameUse | Artist/Stage |
| ABC | EntityNameUse | Alphabetic |
| ASGN | EntityNameUse | Assigned |
| C | EntityNameUse | License |
| I | EntityNameUse | Indigenous/Tribal |
| IDE | EntityNameUse | Ideographic |
| L | EntityNameUse | Legal |
| P | EntityNameUse | Pseudonym |
| PHON | EntityNameUse | Phonetic |
| R | EntityNameUse | Religious |
| SNDX | EntityNameUse | Soundex |
| SRCH | EntityNameUse | Search |
| SYL | EntityNameUse | Syllabic |

Table 19: EntityPersonNamePersonPartQualifier Value Set

| Value Set: EntityPersonNamePartQualifier 2.16.840.1.113883.11.20.9.26 STATIC   2011-09-30 | | |
| --- | --- | --- |
| Code System(s): | EntityNamePartQualifier 2.16.840.1.113883.5.43 | |
| Code | Code System | Print Name |
| AC | EntityNamePartQualifier | academic |
| AD | EntityNamePartQualifier | adopted |
| BR | EntityNamePartQualifier | birth |
| CL | EntityNamePartQualifier | callme |
| IN | EntityNamePartQualifier | initial |
| NB | EntityNamePartQualifier | nobility |
| PR | EntityNamePartQualifier | professional |
| SP | EntityNamePartQualifier | spouse |
| TITLE | EntityNamePartQualifier | title |
| VV | EntityNamePartQualifier | voorvoegsel |

US Realm Person Name (PN.US.FIELDED)

[PN: templateId 2.16.840.1.113883.10.20.22.5.1.1 (open)]

The US Realm Clinical Document Person Name datatype flavor is a set of reusable constraints that can be used for Persons.

1. SHALL contain exactly one [1..1] name (CONF:9368).
   1. The content of name SHALL be either a conformant Patient Name (PTN.US.FIELDED), or a string (CONF:9371).

Clinical Oncology Treatment Plan and Summary

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.30.1.1 (open)]

Table 20: Clinical Oncology Treatment Plan and Summary Contexts

| Used By: | Contains Entries: |
| --- | --- |
|  | [Allergies Section (entries optional)](#S_Allergies_Section_entries_optional)  [Encounters Section BCTPS](#Encounters_Section_BCTPS)  [Family History Section BCTPS](#Family_History_Section_BCTPS)  [Functional Status Section BCTPS](#Functional_Status_Section_BCTPS)  [Medications Section BCTPS](#S_Medications_Section_BCTPS)  [Plan of Care Section BCTPS](#S_Plan_of_Care_Section_BCTPS)  [Problem Section BCTPS](#S_Problem_Section_BCTPS)  [Procedures Section BCTPS](#Procedures_Section_BCTPS_)  [Results Section BCTPS](#Results_Section_BCTPS)  [Vital Signs Section BCTPS](#Vital_Signs_Section_BCTPS) |

This document template conforms to the US Realm Header and contains additional constraints for the Clinical Oncology Treatment Plan and Summary.

Notes: Need to discuss sections that are required vs optional.

Table 21: Clinical Oncology Treatment Plan and Summary Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | ClinicalDocument[templateId/@root = '2.16.840.1.113883.10.20.30.1.1'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [19232](#C_19232) |  |
|  | @root | 1..1 | SHALL |  | [19233](#C_19233) | 2.16.840.1.113883.10.20.30.1.1 |
|  | code | 1..1 | SHALL |  | [19234](#C_19234) |  |
|  | @code | 1..1 | SHALL |  | [19235](#C_19235) | 2.16.840.1.113883.6.1 (LOINC) = CLONC-X |
|  | title | 1..1 | SHALL |  | [19236](#C_19236) |  |
|  | recordTarget | 1..1 | SHALL |  | [19237](#C_19237) |  |
|  | patientRole | 1..1 | SHALL |  | [19238](#C_19238) |  |
|  | id | 1..\* | SHALL |  | [19240](#C_19240) |  |
|  | telecom | 1..\* | SHALL |  | [19241](#C_19241) |  |
|  | providerOrganization | 1..1 | SHALL |  | [19692](#C_19692) |  |
|  | telecom | 1..\* | SHALL |  | [19693](#C_19693) |  |
|  | addr | 1..1 | SHALL |  | [19694](#C_19694) |  |
|  | legalAuthenticator | 1..1 | SHALL |  | [19695](#C_19695) |  |
|  | participant | 1..\* | SHALL |  | [19662](#C_19662) |  |
|  | associatedEntity | 1..1 | SHALL |  | [19663](#C_19663) |  |
|  | telecom | 1..\* | SHALL |  | [19664](#C_19664) |  |
|  | associatedPerson | 1..1 | SHALL |  | [19665](#C_19665) |  |
|  | name | 1..1 | SHALL |  | [19696](#C_19696) |  |
|  | family | 1..1 | SHALL |  | [19697](#C_19697) |  |
|  | given | 1..1 | SHALL |  | [19698](#C_19698) |  |
|  | documentationOf | 1..1 | SHALL |  | [19242](#C_19242) |  |
|  | serviceEvent | 1..1 | SHALL |  | [19243](#C_19243) |  |
|  | @classCode | 1..1 | SHALL |  | [19322](#C_19322) | PCPR |
|  | code | 1..1 | SHALL |  | [19323](#C_19323) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 801460020 |
|  | performer | 1..\* | SHALL |  | [19244](#C_19244) |  |
|  | assignedEntity | 1..1 | SHALL |  | [19245](#C_19245) |  |
|  | code | 1..1 | SHALL |  | [20955](#C_20955) |  |
|  | @code | 0..1 | SHOULD |  | [20956](#C_20956) | 2.16.840.1.114222.4.11.1066 (Healthcare Provider Taxonomy (HIPAA)) |
|  | addr | 1..1 | SHALL |  | [19699](#C_19699) |  |
|  | telecom | 0..\* | SHOULD |  | [19256](#C_19256) |  |
|  | assignedPerson | 0..1 | SHOULD |  | [19326](#C_19326) |  |
|  | name | 1..\* | SHALL |  | [19327](#C_19327) |  |
|  | family | 1..1 | SHALL |  | [19700](#C_19700) |  |
|  | given | 1..1 | SHALL |  | [19701](#C_19701) |  |
|  | component | 1..1 | SHALL |  | [19501](#C_19501) |  |
|  | structuredBody | 1..1 | SHALL |  | [19502](#C_19502) |  |
|  | component | 1..1 | SHALL |  | [19503](#C_19503) |  |
|  | section | 1..1 | SHALL |  | [23357](#C_23357) |  |
|  | component | 1..1 | SHALL |  | [25978](#C_25978) |  |
|  | section | 1..1 | SHALL |  | [25979](#C_25979) |  |
|  | component | 1..1 | SHALL |  | [25980](#C_25980) |  |
|  | section | 1..1 | SHALL |  | [25981](#C_25981) |  |
|  | component | 1..1 | SHALL |  | [26317](#C_26317) |  |
|  | section | 1..1 | SHALL |  | [26319](#C_26319) |  |
|  | component | 1..1 | SHALL |  | [26320](#C_26320) |  |
|  | section | 1..1 | SHALL |  | [26321](#C_26321) |  |
|  | component | 1..1 | SHALL |  | [26322](#C_26322) |  |
|  | section | 1..1 | SHALL |  | [26323](#C_26323) |  |
|  | component | 1..1 | SHALL |  | [26324](#C_26324) |  |
|  | section | 1..1 | SHALL |  | [26325](#C_26325) |  |
|  | component | 1..1 | SHALL |  | [26326](#C_26326) |  |
|  | section | 1..1 | SHALL |  | [26327](#C_26327) |  |
|  | component | 1..1 | SHALL |  | [26444](#C_26444) |  |
|  | section | 1..1 | SHALL |  | [26445](#C_26445) |  |
|  | component | 0..1 | MAY |  | [26446](#C_26446) |  |
|  | section | 1..1 | SHALL |  | [26447](#C_26447) |  |

1. Conforms to [US Realm Header](#D_US_Realm_Header) template (2.16.840.1.113883.10.20.22.1.1).
2. SHALL contain exactly one [1..1] templateId (CONF:19232) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.1.1" (CONF:19233).
3. SHALL contain exactly one [1..1] code (CONF:19234).
   1. This code SHALL contain exactly one [1..1] @code="CLONC-X" Treatment Plan and Summary (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:19235).

The clinical document title describes the type of Oncology Treatment Plan and Summary. For example: “Breast Cancer Adjuvant Treatment Plan and Summary”. The document title should not conflict with the ClinicalDocument code or further document specification defined through the documentationOf/serviceEvent or an encompassingEncounter.

1. SHALL contain exactly one [1..1] title (CONF:19236).
2. SHALL contain exactly one [1..1] recordTarget (CONF:19237).
   1. This recordTarget SHALL contain exactly one [1..1] patientRole (CONF:19238).

At least one patient ID would represent the patient medical record number (MRN).

* + 1. This patientRole SHALL contain at least one [1..\*] id (CONF:19240).
    2. This patientRole SHALL contain at least one [1..\*] telecom (CONF:19241).
    3. This patientRole SHALL contain exactly one [1..1] providerOrganization (CONF:19692).
       1. This providerOrganization SHALL contain at least one [1..\*] telecom (CONF:19693).
       2. This providerOrganization SHALL contain exactly one [1..1] addr (CONF:19694).

1. SHALL contain exactly one [1..1] legalAuthenticator (CONF:19695).

The participant element identifies supporting participants, including parents, relatives, caregivers, and other participants related in some way to the patient. The type of support person is identified with the associatedEntity/classCode as defined in the Participant (Support) (link) in the US realm header. In BCTP it is also required to specify contact person’s name and phone.

1. SHALL contain at least one [1..\*] participant (CONF:19662).
   1. Such participants SHALL contain exactly one [1..1] associatedEntity (CONF:19663).
      1. This associatedEntity SHALL contain at least one [1..\*] telecom (CONF:19664).
      2. This associatedEntity SHALL contain exactly one [1..1] associatedPerson (CONF:19665).
         1. This associatedPerson SHALL contain exactly one [1..1] name (CONF:19696).
            1. This name SHALL contain exactly one [1..1] family (CONF:19697).
            2. This name SHALL contain exactly one [1..1] given (CONF:19698).

This documentationOf/serviceEvent represents the time period over which care was provided. It contains information about the providers involved in the cancer care of the patient during the period of care being summarized.

1. SHALL contain exactly one [1..1] documentationOf (CONF:19242).
   1. This documentationOf SHALL contain exactly one [1..1] serviceEvent (CONF:19243).
      1. This serviceEvent SHALL contain exactly one [1..1] @classCode="PCPR" Care Provision (CONF:19322).
      2. This serviceEvent SHALL contain exactly one [1..1] code="801460020" Breast Cancer Treatment (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:19323).
      3. This serviceEvent SHALL contain at least one [1..\*] performer (CONF:19244).
         1. Such performers SHALL contain exactly one [1..1] assignedEntity (CONF:19245).
            1. This assignedEntity SHALL contain exactly one [1..1] code (CONF:20955).

This code SHOULD contain zero or one [0..1] @code (ValueSet: Healthcare Provider Taxonomy (HIPAA) 2.16.840.1.114222.4.11.1066) (CONF:20956).

This provider address represents the site where patient received treatment from this provider.

* + - * 1. This assignedEntity SHALL contain exactly one [1..1] addr (CONF:19699).
        2. This assignedEntity SHOULD contain zero or more [0..\*] telecom (CONF:19256).
        3. This assignedEntity SHOULD contain zero or one [0..1] assignedPerson (CONF:19326).

The assignedPerson, if present, SHALL contain at least one [1..\*] name (CONF:19327).

Such names SHALL contain exactly one [1..1] family (CONF:19700).

Such names SHALL contain exactly one [1..1] given (CONF:19701).

1. SHALL contain exactly one [1..1] component (CONF:19501).
   1. This component SHALL contain exactly one [1..1] structuredBody (CONF:19502).
      1. This structuredBody SHALL contain exactly one [1..1] component (CONF:19503) such that it
         1. SHALL contain exactly one [1..1] [Allergies Section (entries optional)](#S_Allergies_Section_entries_optional) (templateId:2.16.840.1.113883.10.20.22.2.6) (CONF:23357).
      2. This structuredBody SHALL contain exactly one [1..1] component (CONF:25978) such that it
         1. SHALL contain exactly one [1..1] [Medications Section BCTPS](#S_Medications_Section_BCTPS) (templateId:2.16.840.1.113883.10.20.30.2.7) (CONF:25979).
      3. This structuredBody SHALL contain exactly one [1..1] component (CONF:25980) such that it
         1. SHALL contain exactly one [1..1] [Family History Section BCTPS](#Family_History_Section_BCTPS) (templateId:2.16.840.1.113883.10.20.30.2.3) (CONF:25981).
      4. This structuredBody SHALL contain exactly one [1..1] component (CONF:26317) such that it
         1. SHALL contain exactly one [1..1] [Problem Section BCTPS](#S_Problem_Section_BCTPS) (templateId:2.16.840.1.113883.10.20.30.2.1) (CONF:26319).
      5. This structuredBody SHALL contain exactly one [1..1] component (CONF:26320) such that it
         1. SHALL contain exactly one [1..1] [Procedures Section BCTPS](#Procedures_Section_BCTPS_) (templateId:2.16.840.1.113883.10.20.30.2.4) (CONF:26321).
      6. This structuredBody SHALL contain exactly one [1..1] component (CONF:26322) such that it
         1. SHALL contain exactly one [1..1] [Results Section BCTPS](#Results_Section_BCTPS) (templateId:2.16.840.1.113883.10.20.30.2.2) (CONF:26323).
      7. This structuredBody SHALL contain exactly one [1..1] component (CONF:26324) such that it
         1. SHALL contain exactly one [1..1] [Vital Signs Section BCTPS](#Vital_Signs_Section_BCTPS) (templateId:2.16.840.1.113883.10.20.30.2.5) (CONF:26325).
      8. This structuredBody SHALL contain exactly one [1..1] component (CONF:26326) such that it
         1. SHALL contain exactly one [1..1] [Plan of Care Section BCTPS](#S_Plan_of_Care_Section_BCTPS) (templateId:2.16.840.1.113883.10.20.30.2.6) (CONF:26327).
      9. This structuredBody SHALL contain exactly one [1..1] component (CONF:26444) such that it
         1. SHALL contain exactly one [1..1] [Functional Status Section BCTPS](#Functional_Status_Section_BCTPS) (templateId:2.16.840.1.113883.10.20.30.2.8) (CONF:26445).
      10. This structuredBody MAY contain zero or one [0..1] component (CONF:26446) such that it
          1. SHALL contain exactly one [1..1] [Encounters Section BCTPS](#Encounters_Section_BCTPS) (templateId:2.16.840.1.113883.10.20.30.2.9 ) (CONF:26447).

# section-level template

Allergies Section (entries optional) [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.6 (open)]

Table 22: Allergies Section (entries optional) Contexts

| Used By: | Contains Entries: |
| --- | --- |
|  | [Allergy Problem Act](#E_Allergy_Problem_Act) |

This section lists and describes any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives) used to assure the safety of health care delivery. At a minimum, it should list currently active and any relevant historical allergies and adverse reactions.

Table 23: Allergies Section (entries optional) Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.22.2.6'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [7800](#C_7800) |  |
|  | @root | 1..1 | SHALL |  | [10378](#C_10378) | 2.16.840.1.113883.10.20.22.2.6 |
|  | code | 1..1 | SHALL |  | [15345](#C_15345) |  |
|  | @code | 1..1 | SHALL |  | [15346](#C_15346) | 2.16.840.1.113883.6.1 (LOINC) = 48765-2 |
|  | title | 1..1 | SHALL |  | [7802](#C_7802) |  |
|  | text | 1..1 | SHALL |  | [7803](#C_7803) |  |
|  | entry | 0..\* | SHOULD |  | [7804](#C_7804) |  |
|  | act | 1..1 | SHALL |  | [15444](#C_15444) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:7800) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.6" (CONF:10378).
2. SHALL contain exactly one [1..1] code (CONF:15345).
   1. This code SHALL contain exactly one [1..1] @code="48765-2" Allergies, adverse reactions, alerts (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:15346).
3. SHALL contain exactly one [1..1] title (CONF:7802).
4. SHALL contain exactly one [1..1] text (CONF:7803).
5. SHOULD contain zero or more [0..\*] entry (CONF:7804) such that it
   1. SHALL contain exactly one [1..1] [Allergy Problem Act](#E_Allergy_Problem_Act) (templateId:2.16.840.1.113883.10.20.22.4.30) (CONF:15444).

Encounters Section (entries optional) [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.22 (open)]

Table 24: Encounters Section (entries optional) Contexts

| Used By: | Contains Entries: |
| --- | --- |
|  | [Encounter Activities](#E_Encounter_Activities) |

This section lists and describes any healthcare encounters pertinent to the patient’s current health status or historical health history. An Encounter is an interaction, regardless of the setting, between a patient and a practitioner who is vested with primary responsibility for diagnosing, evaluating, or treating the patient’s condition. It may include visits, appointments, as well as non-face-to-face interactions. It is also a contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment. This section may contain all encounters for the time period being summarized, but should include notable encounters.

Table 25: Encounters Section (entries optional) Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.22.2.22'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [7940](#C_7940) |  |
|  | @root | 1..1 | SHALL |  | [10386](#C_10386) | 2.16.840.1.113883.10.20.22.2.22 |
|  | code | 1..1 | SHALL |  | [15461](#C_15461) |  |
|  | @code | 1..1 | SHALL |  | [15462](#C_15462) | 2.16.840.1.113883.6.1 (LOINC) = 46240-8 |
|  | title | 1..1 | SHALL |  | [7942](#C_7942) |  |
|  | text | 1..1 | SHALL |  | [7943](#C_7943) |  |
|  | entry | 0..\* | SHOULD |  | [7951](#C_7951) |  |
|  | encounter | 1..1 | SHALL |  | [15465](#C_15465) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:7940) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.22" (CONF:10386).
2. SHALL contain exactly one [1..1] code (CONF:15461).
   1. This code SHALL contain exactly one [1..1] @code="46240-8" Encounters (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:15462).
3. SHALL contain exactly one [1..1] title (CONF:7942).
4. SHALL contain exactly one [1..1] text (CONF:7943).
5. SHOULD contain zero or more [0..\*] entry (CONF:7951) such that it
   1. SHALL contain exactly one [1..1] [Encounter Activities](#E_Encounter_Activities) (templateId:2.16.840.1.113883.10.20.22.4.49) (CONF:15465).

Encounters Section BCTPS

[section: templateId 2.16.840.1.113883.10.20.30.2.9 (open)]

Table 26: Encounters Section BCTPS Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Clinical Oncology Treatment Plan and Summary](#D_Clinical_Oncology_Treatment_Plan_and_) (optional) | [Hospitalization for Toxicity](#Hospitalization_for_Toxicity) |

This section contains encounters related to the patient's cancer treatment plan and summary. This section should describe inpatient encounters resulting from toxicity due to chemotherapy as well as other notable encounters.

Table 27: Encounters Section BCTPS Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.30.2.9 '] | | | | | |
|  | templateId | 1..1 | SHALL |  | [26309](#C_26309) |  |
|  | @root | 1..1 | SHALL |  | [26310](#C_26310) | 2.16.840.1.113883.10.20.30.2.9 |
|  | entry | 1..\* | SHALL |  | [26315](#C_26315) |  |
|  | encounter | 1..1 | SHALL |  | [26316](#C_26316) |  |

1. Conforms to [Encounters Section (entries optional)](#S_Encounters_Section_entries_optional) template (2.16.840.1.113883.10.20.22.2.22).
2. SHALL contain exactly one [1..1] templateId (CONF:26309) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.2.9 " (CONF:26310).
3. SHALL contain at least one [1..\*] entry (CONF:26315) such that it
   1. SHALL contain exactly one [1..1] [Hospitalization for Toxicity](#Hospitalization_for_Toxicity) (templateId:2.16.840.1.113883.10.20.30.3.36) (CONF:26316).

Figure 34: Encounters section BCTPS example

<templateId root="2.16.840.1.113883.10.20.30.2.9"/>

<code code="46240-8" codeSystem="2.16.840.1.113883.6.1"/>

<title>ENCOUNTERS</title>

<text>

<table border="1" width="100%">

<thead>

<tr>

<th>Encounter</th>

<th>Location</th>

<th>Admission Date</th>

<th>Discharge Date</th>

<th>Reason</th>

</tr>

</thead>

<tbody>

<tr>

<td>Inpatient encounter</td>

<td>Good Health Hospital</td>

<td>Apr 07, 2012</td>

<td>Apr 10, 2012</td>

<td>Toxicity due to chemotherapy</td>

</tr>

</tbody>

</table>

</text>

<entry typeCode="DRIV">

<encounter classCode="ENC" moodCode="EVN">

<!-- Consolidated CDA encounter activities template -->

<templateId root="2.16.840.1.113883.10.20.22.4.49"/>

<!-- Hospitalization for toxicity template -->

<templateId root="2.16.840.1.113883.10.20.30.3.36"/>

<id root="dd21f8ce-4cb4-43f7-b735-e64eb02b927c"/>

<code codeSystem="2.16.840.1.113883.5.4" code="IMP"

displayName="Inpatient encounter"/>

<effectiveTime>

<!-- Dates of admission and discharge -->

<low value="20120407"/>

<high value="20120410"/>

</effectiveTime>

<participant typeCode="LOC">

<!-- Location participation template -->

<templateId root="2.16.840.1.113883.10.20.1.45"/>

<participantRole classCode="SDLOC">

<id root="2.16.840.1.113883.19.5"/>

<playingEntity classCode="PLC">

<name>Good Health Hospital</name>

</playingEntity>

</participantRole>

</participant>

…

</entry>

Family History Section[Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.15 (open)]

Table 28: Family History Section Contexts

| Used By: | Contains Entries: |
| --- | --- |
|  | [Family History Organizer](#E_Family_History_Organizer) |

This section contains data defining the patient’s genetic relatives in terms of possible or relevant health risk factors that have a potential impact on the patient’s healthcare risk profile.

Table 29: Family History Section Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.22.2.15'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [7932](#C_7932) |  |
|  | @root | 1..1 | SHALL |  | [10388](#C_10388) | 2.16.840.1.113883.10.20.22.2.15 |
|  | code | 1..1 | SHALL |  | [15469](#C_15469) |  |
|  | @code | 1..1 | SHALL |  | [15470](#C_15470) | 2.16.840.1.113883.6.1 (LOINC) = 10157-6 |
|  | title | 1..1 | SHALL |  | [7934](#C_7934) |  |
|  | text | 1..1 | SHALL |  | [7935](#C_7935) |  |
|  | entry | 0..\* | MAY |  | [7955](#C_7955) |  |
|  | organizer | 1..1 | SHALL |  | [15471](#C_15471) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:7932) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.15" (CONF:10388).
2. SHALL contain exactly one [1..1] code (CONF:15469).
   1. This code SHALL contain exactly one [1..1] @code="10157-6" Family History (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:15470).
3. SHALL contain exactly one [1..1] title (CONF:7934).
4. SHALL contain exactly one [1..1] text (CONF:7935).
5. MAY contain zero or more [0..\*] entry (CONF:7955) such that it
   1. SHALL contain exactly one [1..1] [Family History Organizer](#E_Family_History_Organizer) (templateId:2.16.840.1.113883.10.20.22.4.45) (CONF:15471).

Family History Section BCTPS

[Section: templateId 2.16.840.1.113883.10.20.30.2.3 (open)]

Table 30: Family History Section BCTPS Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Clinical Oncology Treatment Plan and Summary](#D_Clinical_Oncology_Treatment_Plan_and_) (required) | [Family History of Cancer None](#Family_History_of_Cancer_None)  [Family History Organizer](#E_Family_History_Organizer)  [Family History Pedigree](#E_Family_History_Pedigree) |

This section contains the patient's family history (pedigree) information. It also allows assertion of no family history of cancer. The HL7 Family History (Pedigree) Model is required to be referenced as an external observation, and a nullFlavor can be sent if there is no pedigree available to point to. No oncology family history may also be represented.

Table 31: Family History Section BCTPS Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Section[templateId/@root = '2.16.840.1.113883.10.20.30.2.3'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [25967](#C_25967) |  |
|  | @root | 1..1 | SHALL |  | [25968](#C_25968) | 2.16.840.1.113883.10.20.30.2.3 |
|  | entry | 0..1 | MAY |  | [26011](#C_26011) |  |
|  | observation | 1..1 | SHALL |  | [26027](#C_26027) |  |
|  | entry | 1..1 | SHALL |  | [26759](#C_26759) |  |
|  | act | 1..1 | SHALL |  | [26760](#C_26760) |  |
|  | entry | 1..\* | SHALL |  | [26761](#C_26761) |  |
|  | organizer | 1..1 | SHALL |  | [26762](#C_26762) |  |

1. Conforms to [Family History Section](#S_Family_History_Section) template (2.16.840.1.113883.10.20.22.2.15).
2. SHALL contain exactly one [1..1] templateId (CONF:25967) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.2.3" (CONF:25968).
3. MAY contain zero or one [0..1] entry (CONF:26011) such that it
   1. SHALL contain exactly one [1..1] [Family History of Cancer None](#Family_History_of_Cancer_None) (templateId:2.16.840.1.113883.10.20.30.3.11) (CONF:26027).
4. SHALL contain exactly one [1..1] entry (CONF:26759) such that it
   1. SHALL contain exactly one [1..1] [Family History Pedigree](#E_Family_History_Pedigree) (templateId:2.16.840.1.113883.10.20.30.3.48) (CONF:26760).
5. SHALL contain at least one [1..\*] entry (CONF:26761) such that it
   1. SHALL contain exactly one [1..1] [Family History Organizer](#E_Family_History_Organizer) (templateId:2.16.840.1.113883.10.20.22.4.45) (CONF:26762).

Figure 35: Family history section BCTPS example

<section>

<templateId root="2.16.840.1.113883.10.20.30.2.3"/>

<code code="10157-6" displayName="History of family member diseases" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>

<title>FAMILY HISTORY</title>

<text>

<list>

<item>FamilyPedigreeModel </item>

<item>From Avon Center Appointment Number 299 </item>

</list>

<linkHtml href=<https://www.google.com/webhp?source=search_app>

name="Test Patient Pedigree Model"></linkHtml>

<table border="1" width="100%">

<thead>

<tr>

<th>Relative</th>

<th>Diagnosis</th>

<th>Age At Onset</th>

</tr>

</thead>

<tbody>

<tr>

<td>Biological Mother</td>

<td>Left Breast Cancer</td>

<td>50</td>

</tr>

<tr>

<td>Biological Father</td>

<td>Prostate Cancer</td>

<td>57</td>

</tr>

</tbody>

</table>

</text>

...

</section>

Functional Status Section[Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.14 (open)]

Table 32: Functional Status Section Contexts

| Used By: | Contains Entries: |
| --- | --- |
|  | [Assessment Scale Observation](#E_Assessment_Scale_Observation)  [Caregiver Characteristics](#E_Caregiver_Characteristics)  [Cognitive Status Problem Observation](#E_Cognitive_Status_Problem_Observation)  [Cognitive Status Result Observation](#E_Cognitive_Status_Result_Observation)  [Cognitive Status Result Organizer](#E_Cognitive_Status_Result_Organizer)  [Functional Status Problem Observation](#E_Functional_Status_Problem_Observation)  [Functional Status Result Observation](#E_Functional_Status_Result_Observation)  [Functional Status Result Organizer](#E_Functional_Status_Result_Organizer)  [Highest Pressure Ulcer Stage](#E_Highest_Pressure_Ulcer_Stage)  [Non-Medicinal Supply Activity](#E_NonMedicinal_Supply_Activity)  [Number of Pressure Ulcers Observation](#E_Number_of_Pressure_Ulcers_Observation)  [Pressure Ulcer Observation](#E_Pressure_Ulcer_Observation_) |

The Functional Status section describes the patient’s physical state, status of functioning, and environmental status at the time the document was created.

A patient’s physical state may include information regarding the patient’s physical findings as they relate to problems, including but not limited to:

• Pressure Ulcers

• Amputations

• Heart murmur

• Ostomies

A patient’s functional status may include information regarding the patient relative to their general functional and cognitive ability, including:

• Ambulatory ability

• Mental status or competency

• Activities of Daily Living (ADLs), including bathing, dressing, feeding, grooming

• Home or living situation having an effect on the health status of the patient

• Ability to care for self

• Social activity, including issues with social cognition, participation with friends and acquaintances other than family members

• Occupation activity, including activities partly or directly related to working, housework or volunteering, family and home responsibilities or activities related to home and family

• Communication ability, including issues with speech, writing or cognition required for communication

• Perception, including sight, hearing, taste, skin sensation, kinesthetic sense, proprioception, or balance

A patient’s environmental status may include information regarding the patient’s current exposures from their daily environment, including but not limited to:

• Airborne hazards such as second-hand smoke, volatile organic compounds, dust, or other allergens

• Radiation

• Safety hazards in home, such as throw rugs, poor lighting, lack of railings/grab bars, etc.

• Safety hazards at work, such as communicable diseases, excessive heat, excessive noise, etc.

The patient's functional status may be expressed as a problem or as a result observation. A functional or cognitive status problem observation describes a patient’s problem, symptoms or condition. A functional or cognitive status result observation may include observations resulting from an assessment scale, evaluation or question and answer assessment.

Any deviation from normal function displayed by the patient and recorded in the record should be included. Of particular interest are those limitations that would interfere with self-care or the medical therapeutic process in any way. In addition, a note of normal function, an improvement, or a change in functioning status may be included.

Table 33: Functional Status Section Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.22.2.14'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [7920](#C_7920) |  |
|  | @root | 1..1 | SHALL |  | [10389](#C_10389) | 2.16.840.1.113883.10.20.22.2.14 |
|  | code | 1..1 | SHALL |  | [14578](#C_14578) |  |
|  | @code | 1..1 | SHALL |  | [14579](#C_14579) | 2.16.840.1.113883.6.1 (LOINC) = 47420-5 |
|  | title | 1..1 | SHALL |  | [7922](#C_7922) |  |
|  | text | 1..1 | SHALL |  | [7923](#C_7923) |  |
|  | entry | 0..\* | MAY |  | [14414](#C_14414) |  |
|  | organizer | 1..1 | SHALL |  | [14415](#C_14415) |  |
|  | entry | 0..\* | MAY |  | [14416](#C_14416) |  |
|  | organizer | 1..1 | SHALL |  | [14417](#C_14417) |  |
|  | entry | 0..\* | MAY |  | [14418](#C_14418) |  |
|  | observation | 1..1 | SHALL |  | [14419](#C_14419) |  |
|  | entry | 0..\* | MAY |  | [14420](#C_14420) |  |
|  | observation | 1..1 | SHALL |  | [14421](#C_14421) |  |
|  | entry | 0..\* | MAY |  | [14422](#C_14422) |  |
|  | observation | 1..1 | SHALL |  | [14423](#C_14423) |  |
|  | entry | 0..\* | MAY |  | [14424](#C_14424) |  |
|  | observation | 1..1 | SHALL |  | [14425](#C_14425) |  |
|  | entry | 0..\* | MAY |  | [14426](#C_14426) |  |
|  | observation | 1..1 | SHALL |  | [14427](#C_14427) |  |
|  | entry | 0..\* | MAY |  | [14580](#C_14580) |  |
|  | observation | 1..1 | SHALL |  | [14581](#C_14581) |  |
|  | entry | 0..\* | MAY |  | [14582](#C_14582) |  |
|  | observation | 1..1 | SHALL |  | [14583](#C_14583) |  |
|  | entry | 0..\* | MAY |  | [16777](#C_16777) |  |
|  | observation | 1..1 | SHALL |  | [16778](#C_16778) |  |
|  | entry | 0..\* | MAY |  | [16779](#C_16779) |  |
|  | observation | 1..1 | SHALL |  | [16780](#C_16780) |  |
|  | entry | 0..\* | MAY |  | [16781](#C_16781) |  |
|  | observation | 1..1 | SHALL |  | [16782](#C_16782) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:7920) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.14" (CONF:10389).
2. SHALL contain exactly one [1..1] code (CONF:14578).
   1. This code SHALL contain exactly one [1..1] @code="47420-5" Functional Status (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:14579).
3. SHALL contain exactly one [1..1] title (CONF:7922).
4. SHALL contain exactly one [1..1] text (CONF:7923).
5. MAY contain zero or more [0..\*] entry (CONF:14414) such that it
   1. SHALL contain exactly one [1..1] [Functional Status Result Organizer](#E_Functional_Status_Result_Organizer) (templateId:2.16.840.1.113883.10.20.22.4.66) (CONF:14415).
6. MAY contain zero or more [0..\*] entry (CONF:14416) such that it
   1. SHALL contain exactly one [1..1] [Cognitive Status Result Organizer](#E_Cognitive_Status_Result_Organizer) (templateId:2.16.840.1.113883.10.20.22.4.75) (CONF:14417).
7. MAY contain zero or more [0..\*] entry (CONF:14418) such that it
   1. SHALL contain exactly one [1..1] [Functional Status Result Observation](#E_Functional_Status_Result_Observation) (templateId:2.16.840.1.113883.10.20.22.4.67) (CONF:14419).
8. MAY contain zero or more [0..\*] entry (CONF:14420) such that it
   1. SHALL contain exactly one [1..1] [Cognitive Status Result Observation](#E_Cognitive_Status_Result_Observation) (templateId:2.16.840.1.113883.10.20.22.4.74) (CONF:14421).
9. MAY contain zero or more [0..\*] entry (CONF:14422) such that it
   1. SHALL contain exactly one [1..1] [Functional Status Problem Observation](#E_Functional_Status_Problem_Observation) (templateId:2.16.840.1.113883.10.20.22.4.68) (CONF:14423).
10. MAY contain zero or more [0..\*] entry (CONF:14424) such that it
    1. SHALL contain exactly one [1..1] [Cognitive Status Problem Observation](#E_Cognitive_Status_Problem_Observation) (templateId:2.16.840.1.113883.10.20.22.4.73) (CONF:14425).
11. MAY contain zero or more [0..\*] entry (CONF:14426) such that it
    1. SHALL contain exactly one [1..1] [Caregiver Characteristics](#E_Caregiver_Characteristics) (templateId:2.16.840.1.113883.10.20.22.4.72) (CONF:14427).
12. MAY contain zero or more [0..\*] entry (CONF:14580) such that it
    1. SHALL contain exactly one [1..1] [Assessment Scale Observation](#E_Assessment_Scale_Observation) (templateId:2.16.840.1.113883.10.20.22.4.69) (CONF:14581).
13. MAY contain zero or more [0..\*] entry (CONF:14582) such that it
    1. SHALL contain exactly one [1..1] [Non-Medicinal Supply Activity](#E_NonMedicinal_Supply_Activity) (templateId:2.16.840.1.113883.10.20.22.4.50) (CONF:14583).
14. MAY contain zero or more [0..\*] entry (CONF:16777) such that it
    1. SHALL contain exactly one [1..1] [Pressure Ulcer Observation](#E_Pressure_Ulcer_Observation_) (templateId:2.16.840.1.113883.10.20.22.4.70) (CONF:16778).
15. MAY contain zero or more [0..\*] entry (CONF:16779) such that it
    1. SHALL contain exactly one [1..1] [Number of Pressure Ulcers Observation](#E_Number_of_Pressure_Ulcers_Observation) (templateId:2.16.840.1.113883.10.20.22.4.76) (CONF:16780).
16. MAY contain zero or more [0..\*] entry (CONF:16781) such that it
    1. SHALL contain exactly one [1..1] [Highest Pressure Ulcer Stage](#E_Highest_Pressure_Ulcer_Stage) (templateId:2.16.840.1.113883.10.20.22.4.77) (CONF:16782).

Functional Status Section BCTPS

[section: templateId 2.16.840.1.113883.10.20.30.2.8 (open)]

Table 34: Functional Status Section BCTPS Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Clinical Oncology Treatment Plan and Summary](#D_Clinical_Oncology_Treatment_Plan_and_) (required) | [Neurotoxicity Impairment of ADLs](#Neurotoxicity_Impairment_of_ADLs) |

This section describes the patient’s physical state, functioning status, and environmental status at the time the document was created. In particular, impairments to activities of daily living from neurotoxicity due to chemotherapy are noted within this section.

Table 35: Functional Status Section BCTPS Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.30.2.8'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [26375](#C_26375) |  |
|  | @root | 1..1 | SHALL |  | [26376](#C_26376) | 2.16.840.1.113883.10.20.30.2.8 |
|  | entry | 0..\* | MAY |  | [26440](#C_26440) |  |
|  | observation | 1..1 | SHALL |  | [26441](#C_26441) |  |

1. Conforms to [Functional Status Section](#S_Functional_Status_Section) template (2.16.840.1.113883.10.20.22.2.14).
2. SHALL contain exactly one [1..1] templateId (CONF:26375) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.2.8" (CONF:26376).
3. MAY contain zero or more [0..\*] entry (CONF:26440) such that it
   1. SHALL contain exactly one [1..1] [Neurotoxicity Impairment of ADLs](#Neurotoxicity_Impairment_of_ADLs) (templateId:2.16.840.1.113883.10.20.30.3.37) (CONF:26441).

Figure 36: Functional status section BCTPS example

<section>

<templateId root="2.16.840.1.113883.10.20.30.2.8"/>

<code code="47420-5" codeSystem="2.16.840.1.113883.6.1"/>

<title>FUNCTIONAL STATUS</title>

<text>

<table border="1" width="100%">

<thead>

<tr>

<th>Finding</th>

<th>Onset Date</th>

</tr>

</thead>

<tbody>

<tr>

<td><content ID="activity1">Difficulty initiating walking

caused by neurotoxicity</content></td>

<td>May 12, 2012</td>

</tr>

</tbody>

</table>

</text>

<entry typeCode="DRIV">

<observation classCode="OBS" moodCode="EVN">

<!-- Consolidated CDA functional status problem observation

template -->

<templateId root="2.16.840.1.113883.10.20.22.4.68"/>

<!-- Neurotoxicity impairment of activities of daily living

template -->

<templateId root="2.16.840.1.113883.10.20.30.3.37"/>

<id root="0a2405dd-7629-40e4-abb7-8eb12432e450"/>

<code codeSystem="2.16.840.1.113883.6.96" code="248536006"

displayName="finding of functional performance and activity"/>

<statusCode code="completed"/>

<effectiveTime>

<low value="20120512"/>

</effectiveTime>

<value xsi:type="CD" code="282207002"

codeSystem="2.16.840.1.113883.6.96" displayName="Difficulty

initiating walking"/>

<!-- actRelationshipTypeCode "CAUS" is "has etiology for", therefore

requires inversion Indicator -->

<entryRelationship typeCode="CAUS" inversionInd="true">

<observation classCode="OBS" moodCode="EVN">

<!-- This is could reference the id of the detailed reaction

observation in the chemo regimen or in Allergies/Adverse

events section -->

<id root="ea3d6016-7d2c-450f-aa0c-e18f1bffbbe0"/>

<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"

codeSystemName="HL7ActCode"/>

<statusCode code="completed"/>

<value xsi:type="CD" code="1946603"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"

displayName="Neurotoxocity"/>

</observation>

</entryRelationship>

</observation>

</entry>

...

</section>

Medications Section (entries optional) [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.1 (open)]

Table 36: Medications Section (entries optional) Contexts

| Used By: | Contains Entries: |
| --- | --- |
|  | [Medication Activity](#E_Medication_Activity) |

The Medications section defines a patient's current medications and pertinent medication history. At a minimum, the currently active medications are to be listed, with an entire medication history as an option. The section may also include a patient's prescription and dispense history.

This section requires that there be either an entry indicating the subject is not known to be on any medications, or that there be entries summarizing the subject's medications.

Table 37: Medications Section (entries optional) Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.22.2.1'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [7791](#C_7791) |  |
|  | @root | 1..1 | SHALL |  | [10432](#C_10432) | 2.16.840.1.113883.10.20.22.2.1 |
|  | code | 1..1 | SHALL |  | [15385](#C_15385) |  |
|  | @code | 1..1 | SHALL |  | [15386](#C_15386) | 2.16.840.1.113883.6.1 (LOINC) = 10160-0 |
|  | title | 1..1 | SHALL |  | [7793](#C_7793) |  |
|  | text | 1..1 | SHALL |  | [7794](#C_7794) |  |
|  | entry | 0..\* | SHOULD |  | [7795](#C_7795) |  |
|  | substanceAdministration | 1..1 | SHALL |  | [15984](#C_15984) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:7791) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.1" (CONF:10432).
2. SHALL contain exactly one [1..1] code (CONF:15385).
   1. This code SHALL contain exactly one [1..1] @code="10160-0" History of medication use (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:15386).
3. SHALL contain exactly one [1..1] title (CONF:7793).
4. SHALL contain exactly one [1..1] text (CONF:7794).
5. SHOULD contain zero or more [0..\*] entry (CONF:7795) such that it
   1. SHALL contain exactly one [1..1] [Medication Activity](#E_Medication_Activity) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:15984).
   2. If medication use is unknown, the appropriate nullFlavor MAY be present (see unknown information in Section 1) (CONF:10076).

Medications Section BCTPS

[Section: templateId 2.16.840.1.113883.10.20.30.2.7 (open)]

Table 38: Medications Section BCTPS Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Clinical Oncology Treatment Plan and Summary](#D_Clinical_Oncology_Treatment_Plan_and_) (required) | [Anthracycline Medication Activity](#Anthracycline_Medication_Activity)  [Chemotherapy Regimen](#E_Chemotherapy_Regimen)  [Endocrine Medication Activity](#Endocrine_Medication_Activity)  [Trastuzumab Medication Activity](#Trastuzumab_Medication_Activity) |

This section contains therapies administered during a cancer treatment for a patient, e.g., chemotherapy regimens, hormonal therapy, and the targeted drug Trastuzumab (Herceptin) therapy. Other medications are not precluded.

Table 39: Medications Section BCTPS Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Section[templateId/@root = '2.16.840.1.113883.10.20.30.2.7'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [23764](#C_23764) |  |
|  | @root | 1..1 | SHALL |  | [23765](#C_23765) | 2.16.840.1.113883.10.20.30.2.7 |
|  | entry | 0..1 | SHOULD |  | [23837](#C_23837) |  |
|  | @typeCode | 1..1 | SHALL |  | [24044](#C_24044) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = DRIV |
|  | procedure | 1..1 | SHALL |  | [23952](#C_23952) |  |
|  | entry | 0..1 | MAY |  | [23966](#C_23966) |  |
|  | @typeCode | 1..1 | SHALL |  | [24045](#C_24045) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = DRIV |
|  | substanceAdministration | 1..1 | SHALL |  | [26245](#C_26245) |  |
|  | entry | 0..1 | MAY |  | [23968](#C_23968) |  |
|  | @typeCode | 0..1 | MAY |  | [24046](#C_24046) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = DRIV |
|  | substanceAdministration | 1..1 | SHALL |  | [23970](#C_23970) |  |
|  | entry | 0..\* | MAY |  | [25964](#C_25964) |  |
|  | @typeCode | 1..1 | SHALL |  | [25965](#C_25965) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = DRIV |
|  | substanceAdministration | 1..1 | SHALL |  | [25966](#C_25966) |  |

1. Conforms to [Medications Section (entries optional)](#S_Medications_Section_entries_optional) template (2.16.840.1.113883.10.20.22.2.1).
2. SHALL contain exactly one [1..1] templateId (CONF:23764) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.2.7" (CONF:23765).
3. SHOULD contain zero or one [0..1] entry (CONF:23837) such that it
   1. SHALL contain exactly one [1..1] @typeCode="DRIV" derived (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24044).
   2. SHALL contain exactly one [1..1] [Chemotherapy Regimen](#E_Chemotherapy_Regimen) (templateId:2.16.840.1.113883.10.20.30.3.1) (CONF:23952).
4. MAY contain zero or one [0..1] entry (CONF:23966) such that it
   1. SHALL contain exactly one [1..1] @typeCode="DRIV" derived (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24045).
   2. SHALL contain exactly one [1..1] [Endocrine Medication Activity](#Endocrine_Medication_Activity) (templateId:2.16.840.1.113883.10.20.30.3.23) (CONF:26245).
5. MAY contain zero or one [0..1] entry (CONF:23968) such that it
   1. MAY contain zero or one [0..1] @typeCode="DRIV" derived (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24046).
   2. SHALL contain exactly one [1..1] [Trastuzumab Medication Activity](#Trastuzumab_Medication_Activity) (templateId:2.16.840.1.113883.10.20.30.3.40) (CONF:23970).
6. MAY contain zero or more [0..\*] entry (CONF:25964) such that it
   1. SHALL contain exactly one [1..1] @typeCode="DRIV" derived (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:25965).
   2. SHALL contain exactly one [1..1] [Anthracycline Medication Activity](#Anthracycline_Medication_Activity) (templateId:2.16.840.1.113883.10.20.30.3.24) (CONF:25966).

Figure 37:Medications section BCTPS example

<section>

<templateId root="2.16.840.1.113883.10.20.30.2.7"/>

<code code="10160-0" codeSystem="2.16.840.1.113883.6.1"

displayName="History of medication use" codeSystemName="LOINC"/>

<title>MEDICATIONS</title>

<text>

<table border="1" width="100%">

<thead>

<tr>

<th>Chemotherapy Regimen</th>

<th>Drug</th>

<th colspan="2">Dates</th>

</tr>

<tr>

<th> </th>

<th> </th>

<th>START</th>

<th>END</th>

</tr>

</thead>

<tbody>

<tr>

<td>TAC Regimen</td>

<td>For 4 months</td>

<td>1/6/10</td>

<td>5/6/10</td>

</tr>

<tr>

<td/>

<td>Docetaxel (Taxotere) every 21 days for 4 months</td>

<td>1/6/10</td>

<td>4/21/10</td>

</tr>

<tr>

<td/>

<td>Doxorubicin (Adriamycin)every 21 days for 4 months</td>

<td>1/6/10</td>

<td>4/21/10</td>

</tr>

<tr>

<td/>

<td>Cyclophosphamide every 21 days for 4 months</td>

<td>1/6/10</td>

<td>4/21/10</td>

</tr>

</tbody>

</table>

<paragraph/>

<table border="1" width="100%">

…

</entry>

</section>

Plan of Care Section[Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.10 (open)]

Table 40: Plan of Care Section Contexts

| Used By: | Contains Entries: |
| --- | --- |
|  | [Instructions](#E_Instructions)  [Plan of Care Activity Act](#E_Plan_of_Care_Activity_Act)  [Plan of Care Activity Encounter](#E_Plan_of_Care_Activity_Encounter)  [Plan of Care Activity Observation](#E_Plan_of_Care_Activity_Observation)  [Plan of Care Activity Procedure](#E_Plan_of_Care_Activity_Procedure)  [Plan of Care Activity Substance Administration](#E_Plan_of_Care_Activity_Substance_Admini)  [Plan of Care Activity Supply](#E_Plan_of_Care_Activity_Supply) |

The Plan of Care section contains data that defines pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only, which are indicated by the @moodCode of the entries within this section. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current care of the patient should be listed unless constrained due to privacy issues. The plan may also contain information about ongoing care of the patient and information regarding goals and clinical reminders. Clinical reminders are placed here to provide prompts for disease prevention and management, patient safety, and health-care quality improvements, including widely accepted performance measures. The plan may also indicate that patient education will be provided.

Table 41: Plan of Care Section Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.22.2.10'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [7723](#C_7723) |  |
|  | @root | 1..1 | SHALL |  | [10435](#C_10435) | 2.16.840.1.113883.10.20.22.2.10 |
|  | code | 1..1 | SHALL |  | [14749](#C_14749) |  |
|  | @code | 1..1 | SHALL |  | [14750](#C_14750) | 2.16.840.1.113883.6.1 (LOINC) = 18776-5 |
|  | title | 1..1 | SHALL |  | [16986](#C_16986) |  |
|  | text | 1..1 | SHALL |  | [7725](#C_7725) |  |
|  | entry | 0..\* | MAY |  | [7726](#C_7726) |  |
|  | observation | 1..1 | SHALL |  | [14751](#C_14751) |  |
|  | entry | 0..\* | MAY |  | [8805](#C_8805) |  |
|  | observation | 1..1 | SHALL |  | [14752](#C_14752) |  |
|  | entry | 0..\* | MAY |  | [8807](#C_8807) |  |
|  | observation | 1..1 | SHALL |  | [14753](#C_14753) |  |
|  | entry | 0..\* | MAY |  | [8809](#C_8809) |  |
|  | observation | 1..1 | SHALL |  | [14754](#C_14754) |  |
|  | entry | 0..\* | MAY |  | [8811](#C_8811) |  |
|  | observation | 1..1 | SHALL |  | [14755](#C_14755) |  |
|  | entry | 0..\* | MAY |  | [8813](#C_8813) |  |
|  | observation | 1..1 | SHALL |  | [14756](#C_14756) |  |
|  | entry | 0..\* | MAY |  | [14695](#C_14695) |  |
|  | act | 1..1 | SHALL |  | [16751](#C_16751) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:7723) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.10" (CONF:10435).
2. SHALL contain exactly one [1..1] code (CONF:14749).
   1. This code SHALL contain exactly one [1..1] @code="18776-5" Plan of Care (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:14750).
3. SHALL contain exactly one [1..1] title (CONF:16986).
4. SHALL contain exactly one [1..1] text (CONF:7725).
5. MAY contain zero or more [0..\*] entry (CONF:7726) such that it
   1. SHALL contain exactly one [1..1] [Plan of Care Activity Act](#E_Plan_of_Care_Activity_Act) (templateId:2.16.840.1.113883.10.20.22.4.39) (CONF:14751).
6. MAY contain zero or more [0..\*] entry (CONF:8805) such that it
   1. SHALL contain exactly one [1..1] [Plan of Care Activity Encounter](#E_Plan_of_Care_Activity_Encounter) (templateId:2.16.840.1.113883.10.20.22.4.40) (CONF:14752).
7. MAY contain zero or more [0..\*] entry (CONF:8807) such that it
   1. SHALL contain exactly one [1..1] [Plan of Care Activity Observation](#E_Plan_of_Care_Activity_Observation) (templateId:2.16.840.1.113883.10.20.22.4.44) (CONF:14753).
8. MAY contain zero or more [0..\*] entry (CONF:8809) such that it
   1. SHALL contain exactly one [1..1] [Plan of Care Activity Procedure](#E_Plan_of_Care_Activity_Procedure) (templateId:2.16.840.1.113883.10.20.22.4.41) (CONF:14754).
9. MAY contain zero or more [0..\*] entry (CONF:8811) such that it
   1. SHALL contain exactly one [1..1] [Plan of Care Activity Substance Administration](#E_Plan_of_Care_Activity_Substance_Admini) (templateId:2.16.840.1.113883.10.20.22.4.42) (CONF:14755).
10. MAY contain zero or more [0..\*] entry (CONF:8813) such that it
    1. SHALL contain exactly one [1..1] [Plan of Care Activity Supply](#E_Plan_of_Care_Activity_Supply) (templateId:2.16.840.1.113883.10.20.22.4.43) (CONF:14756).
11. MAY contain zero or more [0..\*] entry (CONF:14695) such that it
    1. SHALL contain exactly one [1..1] [Instructions](#E_Instructions) (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:16751).

Plan of Care Section BCTPS

[section: templateId 2.16.840.1.113883.10.20.30.2.6 (open)]

Table 42: Plan of Care Section BCTPS Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Clinical Oncology Treatment Plan and Summary](#D_Clinical_Oncology_Treatment_Plan_and_) (required) | [Chemotherapy Regimen Plans](#E_Chemotherapy_Regimen_Plans)  [Plan of Care Activity Reconstruction Procedure](#E_Plan_of_Care_Activity_Reconstruction_)  [Plan of Care Radiation Activity](#E_Plan_of_Care_Radiation_Activity) |

This section contains information about planned radiation, chemotherapy, and reconstruction procedures for the patient. It is limited to prospective, unfulfilled or incomplete orders, and requests only, which are indicated by the @moodCode of the entries within this section.

Table 43: Plan of Care Section BCTPS Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.30.2.6'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [24087](#C_24087) |  |
|  | @root | 1..1 | SHALL |  | [26271](#C_26271) | 2.16.840.1.113883.10.20.30.2.6 |
|  | entry | 0..1 | SHOULD |  | [24099](#C_24099) |  |
|  | procedure | 1..1 | SHALL |  | [24130](#C_24130) |  |
|  | entry | 0..1 | SHOULD |  | [24101](#C_24101) |  |
|  | procedure | 1..1 | SHALL |  | [24131](#C_24131) |  |
|  | entry | 0..1 | SHOULD |  | [24103](#C_24103) |  |
|  | act | 1..1 | SHALL |  | [24132](#C_24132) |  |

1. Conforms to [Plan of Care Section](#S_Plan_of_Care_Section) template (2.16.840.1.113883.10.20.22.2.10).
2. SHALL contain exactly one [1..1] templateId (CONF:24087) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.2.6" (CONF:26271).
3. SHOULD contain zero or one [0..1] entry (CONF:24099) such that it
   1. SHALL contain exactly one [1..1] [Chemotherapy Regimen Plans](#E_Chemotherapy_Regimen_Plans) (templateId:2.16.840.1.113883.10.20.30.3.30) (CONF:24130).
4. SHOULD contain zero or one [0..1] entry (CONF:24101) such that it
   1. SHALL contain exactly one [1..1] [Plan of Care Activity Reconstruction Procedure](#E_Plan_of_Care_Activity_Reconstruction_) (templateId:2.16.840.1.113883.10.20.30.3.31) (CONF:24131).
5. SHOULD contain zero or one [0..1] entry (CONF:24103) such that it
   1. SHALL contain exactly one [1..1] [Plan of Care Radiation Activity](#E_Plan_of_Care_Radiation_Activity) (templateId:2.16.840.1.113883.10.20.30.3.32) (CONF:24132).

Figure 38: Plan of care BCTPS example

<section>

<templateId root="2.16.840.1.113883.10.20.30.2.6"/>

<!-- \*\*\*\* Plan of Care section template \*\*\*\* -->

<code code="18776-5" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC"

displayName="Treatment plan"/>

<title>PLAN OF CARE</title>

<text>

<table border="1" width="100%">

<thead>

<tr>

<th>Planned Activity</th>

<th>Planned Date</th>

</tr>

</thead>

<tbody>

<tr>

<th>TAC chemotherapy regimen</th>

<th>For 4 months from 1/6/10 to 5/6/10</th>

</tr>

</tbody>

<tbody>

<tr>

<td>Reconstruction</td>

<td>January 5, 2013</td>

</tr>

</tbody>

<tbody>

<tr>

<td>Radiation Therapy Recommended or

Ordered</td>

<td>January 21, 2013</td>

</tr>

</tbody>

</table>

</text>

<!-- Modeling: 69960004 cancer chemotherapy regimen(procedure) with

name of regimen in:originalText and component entryRelationships with the

chemo agent-->

<!--Plan of Care Chemotherapy regimen similar to medication section except

Mood is Plan of Care moodCode(SubstanceAdministration/Supply)

with only the applicable contained templates-->

<entry typeCode="DRIV">

<procedure classCode="PROC" moodCode="INT">

<!-- Plan of Care Activity Procedure-->

<templateId root="2.16.840.1.113883.10.20.22.4.41"/>

<!-- Chemotherapy regimen plans template-->

<templateId root="2.16.840.1.113883.10.20.30.3.30"/>

<id root="2baf9dc1-6d92-4ed0-8b4a-ad556adb90fe"/>

<code code="69960004"

codeSystem="2.16.840.1.113883.6.96"

displayName="cancer chemotherapy regimen">

…

</entry>

...

</section>

Problem Section (entries optional) [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.5 (open)]

Table 44: Problem Section (entries optional) Contexts

| Used By: | Contains Entries: |
| --- | --- |
|  | [Problem Concern Act (Condition)](#E_Problem_Concern_Act_Condition) |

This section lists and describes all relevant clinical problems at the time the document is generated. At a minimum, all pertinent current and historical problems should be listed.

Table 45: Problem Section (entries optional) Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.22.2.5'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [7877](#C_7877) |  |
|  | @root | 1..1 | SHALL |  | [10440](#C_10440) | 2.16.840.1.113883.10.20.22.2.5 |
|  | code | 1..1 | SHALL |  | [15407](#C_15407) |  |
|  | @code | 1..1 | SHALL |  | [15408](#C_15408) | 2.16.840.1.113883.6.1 (LOINC) = 11450-4 |
|  | title | 1..1 | SHALL |  | [7879](#C_7879) |  |
|  | text | 1..1 | SHALL |  | [7880](#C_7880) |  |
|  | entry | 0..\* | SHOULD |  | [7881](#C_7881) |  |
|  | act | 1..1 | SHALL |  | [15505](#C_15505) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:7877) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.5" (CONF:10440).
2. SHALL contain exactly one [1..1] code (CONF:15407).
   1. This code SHALL contain exactly one [1..1] @code="11450-4" Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:15408).
3. SHALL contain exactly one [1..1] title (CONF:7879).
4. SHALL contain exactly one [1..1] text (CONF:7880).
5. SHOULD contain zero or more [0..\*] entry (CONF:7881).
   1. The entry, if present, SHALL contain exactly one [1..1] [Problem Concern Act (Condition)](#E_Problem_Concern_Act_Condition) (templateId:2.16.840.1.113883.10.20.22.4.3) (CONF:15505).

Problem Section BCTPS

[Section: templateId 2.16.840.1.113883.10.20.30.2.1 (open)]

Table 46: Problem Section BCTPS Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Clinical Oncology Treatment Plan and Summary](#D_Clinical_Oncology_Treatment_Plan_and_) (required) | [Breast Cancer Concern Act](#Breast_Cancer_Concern_Act)  [Last menstrual period](#E_Last_menstrual_period) |

This section contains a breast cancer concern act which contains information specific to a breast cancer diagnosis such as tumor type, staging, and location. This section may include additional problem concern acts that represent information about the patient's comorbid conditions and post-treatment disease status.

Table 47: Problem Section BCTPS Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Section[templateId/@root = '2.16.840.1.113883.10.20.30.2.1'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [19335](#C_19335) |  |
|  | @root | 1..1 | SHALL |  | [19336](#C_19336) | 2.16.840.1.113883.10.20.30.2.1 |
|  | entry | 1..1 | SHALL |  | [19456](#C_19456) |  |
|  | act | 1..1 | SHALL |  | [21929](#C_21929) |  |
|  | entry | 0..1 | MAY |  | [22074](#C_22074) |  |
|  | observation | 1..1 | SHALL |  | [22075](#C_22075) |  |

1. Conforms to [Problem Section (entries optional)](#S_Problem_Section_entries_optional) template (2.16.840.1.113883.10.20.22.2.5).
2. SHALL contain exactly one [1..1] templateId (CONF:19335) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.2.1" (CONF:19336).
3. SHALL contain at least one [1..\*] entry (CONF:19456) such that it
   1. SHALL contain exactly one [1..1] [Breast Cancer Concern Act](#Breast_Cancer_Concern_Act) (templateId:2.16.840.1.113883.10.20.30.3.6) (CONF:21929).
4. MAY contain zero or one [0..1] entry (CONF:22074) such that it
   1. SHALL contain exactly one [1..1] [Last menstrual period](#E_Last_menstrual_period) (templateId:2.16.840.1.113883.10.20.30.3.34) (CONF:22075).

Figure 39: Problem section BCTPS example

<section>

<templateId root="2.16.840.1.113883.10.20.30.2.1"/>

<code code="11450-4" displayName="Problem Section"

codeSystem="2.16.840.1.113883.6.1"/>

<title>PROBLEMS</title>

<text>

<paragraph>Infiltrating duct carcinoma of breast

(disorder), left breast

Diagnosis Date: January 04, 2012</paragraph>

<paragraph/>

<table border="1" width="100%">

<thead>

<tr>

<th>Type of Staging</th>

<th>Stage</th>

</tr>

</thead>

<tbody>

<tr>

<td>Overall Clinical Stage</td>

<td>IA</td>

</tr>

<tr>

<td>Tumor Stage</td>

<td>T2</td>

</tr>

<tr>

<td>Node Stage</td>

<td>N1</td>

</tr>

<tr>

<td>Metastasis Stage</td>

<td>M1</td>

</tr>

</tbody>

</table>

<content/>

<paragraph>Post Treatment Status: Recurrent

disease</paragraph>

<paragraph>Last Menstrual Period: November 28,

2012</paragraph>

<paragraph> Co-Morbid Conditions: Asthma Since January

3, 2012</paragraph>

</text>

<entry>

<!-- \*\* Breast Cancer Concern Act \*\* -->

...

</entry>

...

</section>

Procedures Section (entries optional) [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.7 (open)]

Table 48: Procedures Section (entries optional) Contexts

| Used By: | Contains Entries: |
| --- | --- |
|  | [Procedure Activity Act](#E_Procedure_Activity_Act)  [Procedure Activity Observation](#E_Procedure_Activity_Observation)  [Procedure Activity Procedure](#E_Procedure_Activity_Procedure) |

This section defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time the document is generated. The section is intended to include notable procedures, but can contain all procedures for the period of time being summarized. The common notion of ""procedure"" is broader than that specified by the HL7 Version 3 Reference Information Model (RIM). Therefore this section contains procedure templates represented with three RIM classes: Act. Observation, and Procedure. Procedure act is for procedures the alter that physical condition of a patient (Splenectomy). Observation act is for procedures that result in new information about a patient but do not cause physical alteration (EEG). Act is for all other types of procedures (dressing change).

The length of an encounter is documented in the documentationOf/encompassingEncounter/effectiveTime and length of service in documentationOf/ServiceEvent/effectiveTime.

Table 49: Procedures Section (entries optional) Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.22.2.7'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [6270](#C_6270) |  |
|  | @root | 1..1 | SHALL |  | [6271](#C_6271) | 2.16.840.1.113883.10.20.22.2.7 |
|  | code | 1..1 | SHALL |  | [15423](#C_15423) |  |
|  | @code | 1..1 | SHALL |  | [15424](#C_15424) | 2.16.840.1.113883.6.1 (LOINC) = 47519-4 |
|  | title | 1..1 | SHALL |  | [17184](#C_17184) |  |
|  | text | 1..1 | SHALL |  | [6273](#C_6273) |  |
|  | entry | 0..\* | MAY |  | [6274](#C_6274) |  |
|  | procedure | 1..1 | SHALL |  | [15509](#C_15509) |  |
|  | entry | 0..1 | MAY |  | [6278](#C_6278) |  |
|  | observation | 1..1 | SHALL |  | [15510](#C_15510) |  |
|  | entry | 0..1 | MAY |  | [8533](#C_8533) |  |
|  | act | 1..1 | SHALL |  | [15511](#C_15511) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:6270) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.7" (CONF:6271).
2. SHALL contain exactly one [1..1] code (CONF:15423).
   1. This code SHALL contain exactly one [1..1] @code="47519-4" History of Procedures (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:15424).
3. SHALL contain exactly one [1..1] title (CONF:17184).
4. SHALL contain exactly one [1..1] text (CONF:6273).
5. MAY contain zero or more [0..\*] entry (CONF:6274) such that it
   1. SHALL contain exactly one [1..1] [Procedure Activity Procedure](#E_Procedure_Activity_Procedure) (templateId:2.16.840.1.113883.10.20.22.4.14) (CONF:15509).
6. MAY contain zero or one [0..1] entry (CONF:6278) such that it
   1. SHALL contain exactly one [1..1] [Procedure Activity Observation](#E_Procedure_Activity_Observation) (templateId:2.16.840.1.113883.10.20.22.4.13) (CONF:15510).
7. MAY contain zero or one [0..1] entry (CONF:8533) such that it
   1. SHALL contain exactly one [1..1] [Procedure Activity Act](#E_Procedure_Activity_Act) (templateId:2.16.840.1.113883.10.20.22.4.12) (CONF:15511).

Procedures Section BCTPS

[Section: templateId 2.16.840.1.113883.10.20.30.2.4 (open)]

Table 50: Procedures Section BCTPS Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Clinical Oncology Treatment Plan and Summary](#D_Clinical_Oncology_Treatment_Plan_and_) (required) | [Breast Cancer Procedures](#E_Breast_Cancer_Procedures)  [Radiation Therapy Care Completed](#Radiation_Therapy_Care_Completed) |

This section contains information about breast cancer related procedures and treatments such as radiation therapy care.

Table 51: Procedures Section BCTPS Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Section[templateId/@root = '2.16.840.1.113883.10.20.30.2.4'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [23138](#C_23138) |  |
|  | @root | 1..1 | SHALL |  | [23139](#C_23139) | 2.16.840.1.113883.10.20.30.2.4 |
|  | entry | 1..\* | SHALL |  | [23135](#C_23135) |  |
|  | procedure | 1..1 | SHALL |  | [23137](#C_23137) |  |
|  | entry | 0..1 | SHOULD |  | [23189](#C_23189) |  |
|  | act | 1..1 | SHALL |  | [23190](#C_23190) |  |

1. Conforms to [Procedures Section (entries optional)](#S_Procedures_Section_entries_optional) template (2.16.840.1.113883.10.20.22.2.7).
2. SHALL contain exactly one [1..1] templateId (CONF:23138) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.2.4" (CONF:23139).
3. SHALL contain at least one [1..\*] entry (CONF:23135) such that it
   1. SHALL contain exactly one [1..1] [Breast Cancer Procedures](#E_Breast_Cancer_Procedures) (templateId:2.16.840.1.113883.10.20.30.3.12) (CONF:23137).
4. SHOULD contain zero or one [0..1] entry (CONF:23189) such that it
   1. SHALL contain exactly one [1..1] [Radiation Therapy Care Completed](#Radiation_Therapy_Care_Completed) (templateId:2.16.840.1.113883.10.20.30.3.16) (CONF:23190).

Figure 40: Procedures section BCTPS example

<section>

<templateId root="2.16.840.1.113883.10.20.30.2.4"/>

<code code="47519-4" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC"

displayName="HISTORY OF PROCEDURES"/>

<title>PROCEDURES</title>

<text>

<table border="1" width="100%">

<thead>

<tr>

<th>Procedure</th>

<th> Date</th>

<th>Biopsy Procedure if applicable</th>

<th>Location of Biopsy Procedure</th>

<th>Notable Surgical Findings/Comments</th>

</tr>

</thead>

<tbody>

<tr>

<td>Left Breast Mastectomy</td>

<td>October 30, 2012</td>

<td>Modified radical</td>

<td>Left Breast</td>

<td>none</td>

</tr>

</tbody>

<tbody>

<tr>

<td>Axillary lymph node procedure</td>

<td>September 30, 2012</td>

<td>Deep axillary lymphadenectomy</td>

<td>left axillary region</td>

<td>3 out of 6 nodes positive from sample collected by</td>

</tr>

</tbody>

<tbody>

<tr>

<td>Mammoplasty</td>

<td>November 30, 2012</td>

<td>Breast reconstruction with TRAM flap</td>

<td></td>

<td></td>

</tr>

</tbody>

<tbody>

<tr>

<td>Radiation Therapy for Adjuvant intent</td>

<td>August 9, 2012 to September 9, 2012</td>

<td/>

<td/>

<td/>

</text>

<entry>

<!-- \*\* Breast Cancer Procedures \*\* -->

...

</entry>

</section>

Results Section (entries optional) [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.3 (open)]

Table 52: Results Section (entries optional) Contexts

| Used By: | Contains Entries: |
| --- | --- |
|  | [Result Organizer](#E_Result_Organizer) |

The Results section contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes observations such as hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, echocardiography, nuclear medicine, pathology, and procedure observations. The section often includes notable results such as abnormal values or relevant trends, and could contain all results for the period of time being documented.

Laboratory results are typically generated by laboratories providing analytic services in areas such as chemistry, hematology, serology, histology, cytology, anatomic pathology, microbiology, and/or virology. These observations are based on analysis of specimens obtained from the patient and submitted to the laboratory.

Imaging results are typically generated by a clinician reviewing the output of an imaging procedure, such as where a cardiologist reports the left ventricular ejection fraction based on the review of a cardiac echocardiogram.

Procedure results are typically generated by a clinician to provide more granular information about component observations made during a procedure, such as where a gastroenterologist reports the size of a polyp observed during a colonoscopy.

Table 53: Results Section (entries optional) Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.22.2.3'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [7116](#C_7116) |  |
|  | @root | 1..1 | SHALL |  | [9136](#C_9136) | 2.16.840.1.113883.10.20.22.2.3 |
|  | code | 1..1 | SHALL |  | [15431](#C_15431) |  |
|  | @code | 1..1 | SHALL |  | [15432](#C_15432) | 2.16.840.1.113883.6.1 (LOINC) = 30954-2 |
|  | title | 1..1 | SHALL |  | [8891](#C_8891) |  |
|  | text | 1..1 | SHALL |  | [7118](#C_7118) |  |
|  | entry | 0..\* | SHOULD |  | [7119](#C_7119) |  |
|  | organizer | 1..1 | SHALL |  | [15515](#C_15515) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:7116) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.3" (CONF:9136).
2. SHALL contain exactly one [1..1] code (CONF:15431).
   1. This code SHALL contain exactly one [1..1] @code="30954-2" Relevant diagnostic tests and/or laboratory data (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:15432).
3. SHALL contain exactly one [1..1] title (CONF:8891).
4. SHALL contain exactly one [1..1] text (CONF:7118).
5. SHOULD contain zero or more [0..\*] entry (CONF:7119) such that it
   1. SHALL contain exactly one [1..1] [Result Organizer](#E_Result_Organizer) (templateId:2.16.840.1.113883.10.20.22.4.1) (CONF:15515).

Results Section BCTPS

[Section: templateId 2.16.840.1.113883.10.20.30.2.2 (open)]

Table 54: Results Section BCTPS Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Clinical Oncology Treatment Plan and Summary](#D_Clinical_Oncology_Treatment_Plan_and_) (required) | [Cardiac Function Observation](#Cardiac_Function_Observation)  [Receptor Status Organizer](#E_Receptor_Status_Organizer) |

This section contains the result of observations for laboratory or diagnostic studies performed on patients with breast cancer (e.g., pre and post chemotherapy cardiac diagnostic studies, and hormone receptor status results).

Table 55: Results Section BCTPS Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Section[templateId/@root = '2.16.840.1.113883.10.20.30.2.2'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [23515](#C_23515) |  |
|  | @root | 1..1 | SHALL |  | [23516](#C_23516) | 2.16.840.1.113883.10.20.30.2.2 |
|  | entry | 1..1 | SHALL |  | [23517](#C_23517) |  |
|  | organizer | 1..1 | SHALL |  | [23518](#C_23518) |  |
|  | entry | 1..\* | SHALL |  | [23519](#C_23519) |  |
|  | observation | 1..1 | SHALL |  | [23520](#C_23520) |  |

1. Conforms to [Results Section (entries optional)](#S_Results_Section_entries_optional) template (2.16.840.1.113883.10.20.22.2.3).
2. SHALL contain exactly one [1..1] templateId (CONF:23515) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.2.2" (CONF:23516).
3. SHALL contain exactly one [1..1] entry (CONF:23517) such that it
   1. SHALL contain exactly one [1..1] [Receptor Status Organizer](#E_Receptor_Status_Organizer) (templateId:2.16.840.1.113883.10.20.30.3.17) (<CONF:23518>).
4. SHALL contain exactly one [1..1] entry uch that it
   1. SHALL contain exactly one [1..1] [Molecular Diagnostic Testing Organizer](#E_Receptor_Status_Organizer) (templateId:2.16.840.1.113883.10.20.30.3.XXXX)
5. SHALL contain at least one [1..\*] entry (CONF:23519) such that it
   1. SHALL contain exactly one [1..1] [Cardiac Function Observation](#Cardiac_Function_Observation) (templateId:2.16.840.1.113883.10.20.30.3.21) (CONF:23520).

Figure 41: Results section BCTPS example

<section>

<templateId root="2.16.840.1.113883.10.20.30.2.2"/>

<code code="30954-2" codeSystem="2.16.840.1.113883.6.1"/>

<title>RESULTS</title>

<text>

<table border="1" width="100%">

<thead>

<tr>

<th>Test</th>

<th>Date</th>

<th>Result</th>

</tr>

</thead>

<tbody>

<tr>

<td>Oncotype DX Recurrence Score</td>

<td>March 23, 2012</td>

<td>9</td>

</tr>

<tr>

<td>ER Status</td>

<td>March 23, 2012</td>

<td>Positive</td>

</tr>

<tr>

<td>PR Status</td>

<td>March 23, 2012</td>

<td>Borderline Low</td>

</tr>

<tr>

<td>HER2 Status</td>

<td>March 23, 2012</td>

<td>Positive</td>

</tr>

<tr>

<td> MUGA</td>

<td>March 23, 2012</td>

<td>EF=76%</td>

</tr>

<tr>

<td> Cardiac Ejection Fraction</td>

<td>July 4, 2012</td>

<td>EF=39%</td>

</tr>

<tr>

<td> Cardiac Ejection Fraction</td>

<td>November 4, 2012</td>

<td>EF=30%</td>

</tr>

</tbody>

</table>

</text>

...

</section>

Vital Signs Section (entries optional) [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.4 (open)]

Table 56: Vital Signs Section (entries optional) Contexts

| Used By: | Contains Entries: |
| --- | --- |
|  | [Vital Signs Organizer](#E_Vital_Signs_Organizer) |

The Vital Signs section contains relevant vital signs for the context and use case of the document type, such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, and pulse oximetry. The section should include notable vital signs such as the most recent, maximum and/or minimum, baseline, or relevant trends.

Vital signs are represented in the same way as other results, but are aggregated into their own section to follow clinical conventions.

Table 57: Vital Signs Section (entries optional) Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.22.2.4'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [7268](#C_7268) |  |
|  | @root | 1..1 | SHALL |  | [10451](#C_10451) | 2.16.840.1.113883.10.20.22.2.4 |
|  | code | 1..1 | SHALL |  | [15242](#C_15242) |  |
|  | @code | 1..1 | SHALL |  | [15243](#C_15243) | 2.16.840.1.113883.6.1 (LOINC) = 8716-3 |
|  | title | 1..1 | SHALL |  | [9966](#C_9966) |  |
|  | text | 1..1 | SHALL |  | [7270](#C_7270) |  |
|  | entry | 0..\* | SHOULD |  | [7271](#C_7271) |  |
|  | organizer | 1..1 | SHALL |  | [15517](#C_15517) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:7268) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.4" (CONF:10451).
2. SHALL contain exactly one [1..1] code (CONF:15242).
   1. This code SHALL contain exactly one [1..1] @code="8716-3" Vital Signs (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:15243).
3. SHALL contain exactly one [1..1] title (CONF:9966).
4. SHALL contain exactly one [1..1] text (CONF:7270).
5. SHOULD contain zero or more [0..\*] entry (CONF:7271) such that it
   1. SHALL contain exactly one [1..1] [Vital Signs Organizer](#E_Vital_Signs_Organizer) (templateId:2.16.840.1.113883.10.20.22.4.26) (CONF:15517).

Vital Signs Section BCTPS

[section: templateId 2.16.840.1.113883.10.20.30.2.5 (open)]

Table 58: Vital Signs Section BCTPS Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Clinical Oncology Treatment Plan and Summary](#D_Clinical_Oncology_Treatment_Plan_and_) (required) | [Vital Signs Organizer BCTPS](#E_Vital_Signs_Organizer_BCTPS) |

This section contains height, weight and body surface area findings.

Table 59: Vital Signs Section BCTPS Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.30.2.5'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [24842](#C_24842) |  |
|  | @root | 1..1 | SHALL |  | [24843](#C_24843) | 2.16.840.1.113883.10.20.30.2.5 |
|  | entry | 1..\* | SHALL |  | [24848](#C_24848) |  |
|  | organizer | 1..1 | SHALL |  | [24906](#C_24906) |  |

1. Conforms to [Vital Signs Section (entries optional)](#S_Vital_Signs_Section_entries_optional) template (2.16.840.1.113883.10.20.22.2.4).
2. SHALL contain exactly one [1..1] templateId (CONF:24842) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.2.5" (CONF:24843).
3. SHALL contain at least one [1..\*] entry (CONF:24848) such that it
   1. SHALL contain exactly one [1..1] [Vital Signs Organizer BCTPS](#E_Vital_Signs_Organizer_BCTPS) (templateId:2.16.840.1.113883.10.20.30.3.25) (CONF:24906).

Figure 42: Vital signs section BCTPS example

<section>

<templateId root="2.16.840.1.113883.10.20.30.2.5"/>

<code code="8716-3" displayName="Physical Findings - Vital signs"

codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC">

<originalText>Vital Signs</originalText>

</code>

<title>VITAL SIGNS</title>

<text>

<table border="1" width="100%">

<thead>

<tr>

<th>Vital</th>

<th>Value</th>

<th>Date</th>

</tr>

</thead>

<tbody>

<tr>

<td ID="O-3" align="left">Body Height</td>

<td>152.4 cm</td>

<td>Apr 7, 2012</td>

</tr>

<tr>

<td ID="O-4" align="left">Body Weight</td>

<td>45 kg</td>

<td>Apr 7, 2012</td>

</tr>

<tr>

<td ID="O-5" align="left">Body Surface

Area</td>

<td>1.31 m2</td>

<td>Apr 7, 2012</td>

</tr>

</tbody>

</table>

</text>

<entry typeCode="DRIV">

<organizer classCode="CLUSTER" moodCode="EVN">

<!-- Vital signs organizer template from Consolidation templateID-->

<templateId root="2.16.840.1.113883.10.20.22.4.26"/>

<!-- Vital signs organizer BCTPS templateID-->

<templateId root="2.16.840.1.113883.10.20.30.3.25"/>

<id root="16f81685-cb5b-470b-9823-fca324968479"/>

<code code="46680005" codeSystem="2.16.840.1.113883.6.96"

…

</entry>

</section>

# entry-level templates

Age Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.31 (open)]

Table 60: Age Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Problem Observation](#E_Problem_Observation) (optional)  [Family History Observation](#E_Family_History_Observation) (optional) |  |

This Age Observation represents the subject's age at onset of an event or observation. The age of a relative in a Family History Observation at the time of that observation could also be inferred by comparing RelatedSubject/subject/birthTime with Observation/effectiveTime. However, a common scenario is that a patient will know the age of a relative when the relative had a certain condition or when the relative died, but will not know the actual year (e.g., "grandpa died of a heart attack at the age of 50"). Often times, neither precise dates nor ages are known (e.g. "cousin died of congenital heart disease as an infant").

Table 61: Age Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.31'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7613](#C_7613) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [7614](#C_7614) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [7899](#C_7899) |  |
|  | @root | 1..1 | SHALL |  | [10487](#C_10487) | 2.16.840.1.113883.10.20.22.4.31 |
|  | code | 1..1 | SHALL |  | [7615](#C_7615) |  |
|  | @code | 1..1 | SHALL |  | [16776](#C_16776) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 445518008 |
|  | statusCode | 1..1 | SHALL |  | [15965](#C_15965) |  |
|  | @code | 1..1 | SHALL |  | [15966](#C_15966) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | value | 1..1 | SHALL | PQ | [7617](#C_7617) |  |
|  | @unit | 1..1 | SHALL | CS | [7618](#C_7618) | 2.16.840.1.113883.11.20.9.21 (AgePQ\_UCUM) |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7613).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7614).
3. SHALL contain exactly one [1..1] templateId (CONF:7899) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.31" (CONF:10487).
4. SHALL contain exactly one [1..1] code (CONF:7615).
   1. This code SHALL contain exactly one [1..1] @code="445518008" Age At Onset (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:16776).
5. SHALL contain exactly one [1..1] statusCode (CONF:15965).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:15966).
6. SHALL contain exactly one [1..1] value with @xsi:type="PQ" (CONF:7617).
   1. This value SHALL contain exactly one [1..1] @unit, which SHALL be selected from ValueSet AgePQ\_UCUM 2.16.840.1.113883.11.20.9.21 DYNAMIC (CONF:7618).

Table 62: AgePQ\_UCUM

|  |  |  |
| --- | --- | --- |
| Value Set: AgePQ\_UCUM 2.16.840.1.113883.11.20.9.21 | | |
| Code | Code System | Print Name |
| min | UCUM | Minute |
| h | UCUM | Hour |
| d | UCUM | Day |
| wk | UCUM | Week |
| mo | UCUM | Month |
| a | UCUM | Year |

Allergy Problem Act [Closed for comments; published July 2012]

[act: templateId 2.16.840.1.113883.10.20.22.4.30 (open)]

Table 63: Allergy Problem Act Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Allergies Section (entries optional)](#S_Allergies_Section_entries_optional) (optional) | [Allergy - Intolerance Observation](#E_Allergy__Intolerance_Observation) |

This clinical statement act represents a concern relating to a patient's allergies or adverse events. A concern is a term used when referring to patient's problems that are related to one another. Observations of problems or other clinical statements captured at a point in time are wrapped in a Allergy Problem Act, or ""Concern"" act, which represents the ongoing process tracked over time. This outer Allergy Problem Act (representing the ""Concern"") can contain nested problem observations or other nested clinical statements relevant to the allergy concern.

Table 64: Allergy Problem Act Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | act[templateId/@root = '2.16.840.1.113883.10.20.22.4.30'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7469](#C_7469) | 2.16.840.1.113883.5.6 (HL7ActClass) = ACT |
|  | @moodCode | 1..1 | SHALL |  | [7470](#C_7470) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [7471](#C_7471) |  |
|  | @root | 1..1 | SHALL |  | [10489](#C_10489) | 2.16.840.1.113883.10.20.22.4.30 |
|  | id | 1..\* | SHALL |  | [7472](#C_7472) |  |
|  | code | 1..1 | SHALL |  | [7477](#C_7477) |  |
|  | @code | 1..1 | SHALL |  | [19158](#C_19158) | 2.16.840.1.113883.6.1 (LOINC) = 48765-2 |
|  | statusCode | 1..1 | SHALL |  | [7485](#C_7485) |  |
|  | @code | 1..1 | SHALL |  | [19086](#C_19086) | 2.16.840.1.113883.11.20.9.19 (ProblemAct statusCode) |
|  | effectiveTime | 1..1 | SHALL |  | [7498](#C_7498) |  |
|  | entryRelationship | 1..\* | SHALL |  | [7509](#C_7509) |  |
|  | @typeCode | 1..1 | SHALL |  | [7915](#C_7915) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | observation | 1..1 | SHALL |  | [14925](#C_14925) |  |

1. SHALL contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7469).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7470).
3. SHALL contain exactly one [1..1] templateId (CONF:7471) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.30" (CONF:10489).
4. SHALL contain at least one [1..\*] id (CONF:7472).
5. SHALL contain exactly one [1..1] code (CONF:7477).
   1. This code SHALL contain exactly one [1..1] @code="48765-2" Allergies, adverse reactions, alerts (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:19158).
6. SHALL contain exactly one [1..1] statusCode (CONF:7485).
   1. This statusCode SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet ProblemAct statusCode 2.16.840.1.113883.11.20.9.19 STATIC 2011-09-09 (CONF:19086).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:7498).
   1. If statusCode/@code="active" Active, then effectiveTime SHALL contain [1..1] low (CONF:7504).
   2. If statusCode/@code="completed" Completed, then effectiveTime SHALL contain [1..1] high (CONF:10085).
8. SHALL contain at least one [1..\*] entryRelationship (CONF:7509) such that it
   1. SHALL contain exactly one [1..1] @typeCode="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7915).
   2. SHALL contain exactly one [1..1] [Allergy - Intolerance Observation](#E_Allergy__Intolerance_Observation) (templateId:2.16.840.1.113883.10.20.22.4.7) (CONF:14925).

Table 65: ProblemAct statusCode

|  |  |  |
| --- | --- | --- |
| Value Set: ProblemAct statusCode 2.16.840.1.113883.11.20.9.19 | | |
| Code | Code System | Print Name |
| completed | ActStatus | Completed |
| aborted | ActStatus | Aborted |
| active | ActStatus | Active |
| suspended | ActStatus | Suspended |

Allergy Status Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.28 (open)]

Table 66: Allergy Status Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Allergy - Intolerance Observation](#E_Allergy__Intolerance_Observation) (optional)  [Substance or Device Allergy - Intolerance Observation](#E_Substance_or_Device_Allergy__Intolera) (optional) |  |

This template represents the status of the allergy indicating whether it is active, no longer active, or is an historic allergy. There can be only one allergy status observation per alert observation.

Table 67: Allergy Status Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.28'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7318](#C_7318) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [7319](#C_7319) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [7317](#C_7317) |  |
|  | @root | 1..1 | SHALL |  | [10490](#C_10490) | 2.16.840.1.113883.10.20.22.4.28 |
|  | code | 1..1 | SHALL |  | [7320](#C_7320) |  |
|  | @code | 1..1 | SHALL |  | [19131](#C_19131) | 2.16.840.1.113883.6.1 (LOINC) = 33999-4 |
|  | statusCode | 1..1 | SHALL |  | [7321](#C_7321) |  |
|  | @code | 1..1 | SHALL |  | [19087](#C_19087) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | value | 1..1 | SHALL | CE | [7322](#C_7322) | 2.16.840.1.113883.3.88.12.80.68 (Problem Status Value Set) |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7318).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7319).
3. SHALL contain exactly one [1..1] templateId (CONF:7317) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.28" (CONF:10490).
4. SHALL contain exactly one [1..1] code (CONF:7320).
   1. This code SHALL contain exactly one [1..1] @code="33999-4" Status (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:19131).
5. SHALL contain exactly one [1..1] statusCode (CONF:7321).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19087).
6. SHALL contain exactly one [1..1] value with @xsi:type="CE", where the @code SHALL be selected from ValueSet Problem Status Value Set 2.16.840.1.113883.3.88.12.80.68 DYNAMIC (CONF:7322).

Table 68: Problem Status Value Set

|  |  |  |
| --- | --- | --- |
| Value Set: Problem Status Value Set 2.16.840.1.113883.3.88.12.80.68 | | |
| Code | Code System | Print Name |
| 55561003 | SNOMED-CT | Active |
| 73425007 | SNOMED-CT | Iinactive |
| 413322009 | SNOMED-CT | Resolved |

Assessment Scale Observation[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.69 (open)]

Table 69: Assessment Scale Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Functional Status Section](#S_Functional_Status_Section) (optional)  [Functional Status Result Observation](#E_Functional_Status_Result_Observation) (optional)  [Cognitive Status Result Observation](#E_Cognitive_Status_Result_Observation) (optional)  [Functional Status Problem Observation](#E_Functional_Status_Problem_Observation) (optional)  [Cognitive Status Problem Observation](#E_Cognitive_Status_Problem_Observation) (optional) | [Assessment Scale Supporting Observation](#E_Assessment_Scale_Supporting_Observati) |

An assessment scale is a collection of observations that together yield a summary evaluation of a particular condition. Examples include the Braden Scale (assesses pressure ulcer risk), APACHE Score (estimates mortality in critically ill patients), Mini-Mental Status Exam (assesses cognitive function), APGAR Score (assesses the health of a newborn), and Glasgow Coma Scale (assesses coma and impaired consciousness.)

Table 70: Assessment Scale Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.69'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [14434](#C_14434) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [14435](#C_14435) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [14436](#C_14436) |  |
|  | @root | 1..1 | SHALL |  | [14437](#C_14437) | 2.16.840.1.113883.10.20.22.4.69 |
|  | id | 1..\* | SHALL |  | [14438](#C_14438) |  |
|  | code | 1..1 | SHALL |  | [14439](#C_14439) |  |
|  | derivationExpr | 0..1 | MAY |  | [14637](#C_14637) |  |
|  | statusCode | 1..1 | SHALL |  | [14444](#C_14444) |  |
|  | @code | 1..1 | SHALL |  | [19088](#C_19088) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 1..1 | SHALL |  | [14445](#C_14445) |  |
|  | value | 1..1 | SHALL |  | [14450](#C_14450) |  |
|  | interpretationCode | 0..\* | MAY |  | [14459](#C_14459) |  |
|  | translation | 0..\* | MAY |  | [14888](#C_14888) |  |
|  | author | 0..\* | MAY |  | [14460](#C_14460) |  |
|  | entryRelationship | 0..\* | SHOULD |  | [14451](#C_14451) |  |
|  | @typeCode | 1..1 | SHALL |  | [16741](#C_16741) | COMP |
|  | observation | 1..1 | SHALL |  | [16742](#C_16742) |  |
|  | referenceRange | 0..\* | MAY |  | [16799](#C_16799) |  |
|  | observationRange | 1..1 | SHALL |  | [16800](#C_16800) |  |
|  | text | 0..1 | SHOULD |  | [16801](#C_16801) |  |
|  | reference | 0..1 | SHOULD |  | [16802](#C_16802) |  |
|  | @value | 0..1 | MAY |  | [16803](#C_16803) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:14434).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14435).
3. SHALL contain exactly one [1..1] templateId (CONF:14436) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.69" (CONF:14437).
4. SHALL contain at least one [1..\*] id (CONF:14438).
5. SHALL contain exactly one [1..1] code (CONF:14439).
   1. SHOULD be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) identifying the assessment scale (CONF:14440).

Such derivation expression can contain a text calculation of how the components total up to the summed score

1. MAY contain zero or one [0..1] derivationExpr (CONF:14637).
2. SHALL contain exactly one [1..1] statusCode (CONF:14444).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19088).

Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards)

1. SHALL contain exactly one [1..1] effectiveTime (CONF:14445).
2. SHALL contain exactly one [1..1] value (CONF:14450).
3. MAY contain zero or more [0..\*] interpretationCode (CONF:14459).
   1. The interpretationCode, if present, MAY contain zero or more [0..\*] translation (CONF:14888).
4. MAY contain zero or more [0..\*] author (CONF:14460).
5. SHOULD contain zero or more [0..\*] entryRelationship (CONF:14451) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" has component (CONF:16741).
   2. SHALL contain exactly one [1..1] [Assessment Scale Supporting Observation](#E_Assessment_Scale_Supporting_Observati) (templateId:2.16.840.1.113883.10.20.22.4.86) (CONF:16742).

The referenceRange/observationRange/text, if present, MAY contain a description of the scale (e.g. for a Pain Scale 1 to 10: 1 to 3 = little pain, 4 to 7= moderate pain, 8 to 10 = severe pain)

1. MAY contain zero or more [0..\*] referenceRange (CONF:16799).
   1. The referenceRange, if present, SHALL contain exactly one [1..1] observationRange (CONF:16800).
      1. This observationRange SHOULD contain zero or one [0..1] text (CONF:16801).
         1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:16802).
            1. The reference, if present, MAY contain zero or one [0..1] @value (CONF:16803).

This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:16804).

Assessment Scale Supporting Observation[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.86 (open)]

Table 71: Assessment Scale Supporting Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Assessment Scale Observation](#E_Assessment_Scale_Observation) (optional) |  |

An Assessment Scale Supporting observation represents the components of a scale used in an Assessment Scale Observation. The individual parts that make up the component may be a group of cognitive or functional status observations.

Table 72: Assessment Scale Supporting Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.86'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [16715](#C_16715) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [16716](#C_16716) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [16722](#C_16722) |  |
|  | @root | 1..1 | SHALL |  | [16723](#C_16723) | 2.16.840.1.113883.10.20.22.4.86 |
|  | id | 1..\* | SHALL |  | [16724](#C_16724) |  |
|  | code | 1..1 | SHALL |  | [19178](#C_19178) |  |
|  | @code | 1..1 | SHALL |  | [19179](#C_19179) |  |
|  | statusCode | 1..1 | SHALL |  | [16720](#C_16720) |  |
|  | @code | 1..1 | SHALL |  | [19089](#C_19089) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | value | 1..\* | SHALL |  | [16754](#C_16754) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:16715).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:16716).
3. SHALL contain exactly one [1..1] templateId (CONF:16722) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.86" (CONF:16723).
4. SHALL contain at least one [1..\*] id (CONF:16724).
5. SHALL contain exactly one [1..1] code (CONF:19178).
   1. This code SHALL contain exactly one [1..1] @code (CONF:19179).
      1. Such that the @code SHALL be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) and represents components of the scale (CONF:19180).
6. SHALL contain exactly one [1..1] statusCode (CONF:16720).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19089).
7. SHALL contain at least one [1..\*] value (CONF:16754).
   1. If xsi:type="CD" , MAY have a translation code to further specify the source if the instrument has an applicable code system and valueSet for the integer (CONF:14639) (CONF:16755).

Caregiver Characteristics [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.72 (open)]

Table 73: Caregiver Characteristics Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Functional Status Section](#S_Functional_Status_Section) (optional)  [Functional Status Result Observation](#E_Functional_Status_Result_Observation) (optional)  [Cognitive Status Result Observation](#E_Cognitive_Status_Result_Observation) (optional)  [Functional Status Problem Observation](#E_Functional_Status_Problem_Observation) (optional)  [Cognitive Status Problem Observation](#E_Cognitive_Status_Problem_Observation) (optional) |  |

This clinical statement represents a caregiver’s willingness to provide care and the abilities of that caregiver to provide assistance to a patient in relation to a specific need.

Table 74: Caregiver Characteristics Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.72'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [14219](#C_14219) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [14220](#C_14220) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [14221](#C_14221) |  |
|  | @root | 1..1 | SHALL |  | [14222](#C_14222) | 2.16.840.1.113883.10.20.22.4.72 |
|  | id | 1..\* | SHALL |  | [14223](#C_14223) |  |
|  | code | 1..1 | SHALL |  | [14230](#C_14230) |  |
|  | statusCode | 1..1 | SHALL |  | [14233](#C_14233) |  |
|  | @code | 1..1 | SHALL |  | [19090](#C_19090) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | value | 1..1 | SHALL |  | [14599](#C_14599) |  |
|  | participant | 1..\* | SHALL |  | [14227](#C_14227) |  |
|  | time | 0..1 | MAY |  | [14830](#C_14830) |  |
|  | low | 1..1 | SHALL |  | [14831](#C_14831) |  |
|  | high | 0..1 | MAY |  | [14832](#C_14832) |  |
|  | participantRole | 1..1 | SHALL |  | [14228](#C_14228) |  |
|  | @classCode | 1..1 | SHALL |  | [14229](#C_14229) | IND |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:14219).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14220).
3. SHALL contain exactly one [1..1] templateId (CONF:14221) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.72" (CONF:14222).
4. SHALL contain at least one [1..\*] id (CONF:14223).
5. SHALL contain exactly one [1..1] code (CONF:14230).
6. SHALL contain exactly one [1..1] statusCode (CONF:14233).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19090).
7. SHALL contain exactly one [1..1] value (CONF:14599).
   1. Where the @code SHALL be selected from LOINC (codeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:14600).
8. SHALL contain at least one [1..\*] participant (CONF:14227).
   1. Such participants MAY contain zero or one [0..1] time (CONF:14830).
      1. The time, if present, SHALL contain exactly one [1..1] low (CONF:14831).
      2. The time, if present, MAY contain zero or one [0..1] high (CONF:14832).
   2. Such participants SHALL contain exactly one [1..1] participantRole (CONF:14228).
      1. This participantRole SHALL contain exactly one [1..1] @classCode="IND" (CONF:14229).

Chemotherapy Dose Reduction

[Observation: templateId 2.16.840.1.113883.10.20.30.3.39 (open)]

Table 75: Chemotherapy Dose Reduction Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Anthracycline Medication Activity](#Anthracycline_Medication_Activity) (optional)  [Chemotherapy Medication Activity](#E_Chemotherapy_Medication_Activity) (optional) |  |

This clinical statement represents a chemotherapy drug dose reduction and the reason for the dose reduction.

Notes: Issue: the SNOMED code is "treatment dose changed" and not necessarily restricts to dose reduction. Discussion point: Consider only having multiple chemotherapy regimens/meds with doses and dates, as opposed to additional detail stating this is a dose reduction. Value set issue: is there a need for coded value set for "Reason for Dosing Reduction"? or simply a free text entry? if coded list, needs the list of reasons.

Table 76: Chemotherapy Dose Reduction Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.39'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [23614](#C_23614) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [23615](#C_23615) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [23616](#C_23616) |  |
|  | @root | 1..1 | SHALL |  | [23617](#C_23617) | 2.16.840.1.113883.10.20.30.3.39 |
|  | code | 1..1 | SHALL |  | [23618](#C_23618) |  |
|  | @code | 1..1 | SHALL |  | [23619](#C_23619) | ASSERTION |
|  | @codeSystem | 1..1 | SHALL |  | [24943](#C_24943) | 2.16.840.1.113883.5.4 (HL7ActCode) = 2.16.840.1.113883.5.4 |
|  | statusCode | 1..1 | SHALL |  | [23620](#C_23620) |  |
|  | @code | 1..1 | SHALL |  | [23621](#C_23621) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 0..1 | MAY |  | [23622](#C_23622) |  |
|  | low | 1..1 | SHALL |  | [23623](#C_23623) |  |
|  | value | 1..1 | SHALL | CD | [23624](#C_23624) |  |
|  | @code | 1..1 | SHALL |  | [23625](#C_23625) | 445528004 |
|  | @codeSystem | 1..1 | SHALL |  | [24944](#C_24944) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |
|  | entryRelationship | 0..\* | SHOULD |  | [23626](#C_23626) |  |
|  | @typeCode | 1..1 | SHALL |  | [23627](#C_23627) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON |
|  | observation | 1..1 | SHALL |  | [23628](#C_23628) |  |
|  | @classCode | 1..1 | SHALL |  | [23629](#C_23629) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [23630](#C_23630) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | code | 1..1 | SHALL |  | [23631](#C_23631) |  |
|  | @code | 1..1 | SHALL |  | [23632](#C_23632) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 373832009 |
|  | statusCode | 1..1 | SHALL |  | [23633](#C_23633) |  |
|  | @code | 1..1 | SHALL |  | [23634](#C_23634) | 2.16.840.1.113883.5.14 (ActStatus) = Completed |
|  | value | 0..1 | SHOULD | CD | [23635](#C_23635) |  |
|  | @code | 1..1 | SHALL |  | [23636](#C_23636) | 2.16.840.1.113883.11.20.11.6 (Reason for Dosing Reduction) |

1. SHALL contain exactly one [1..1] @classCode="OBS" observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23614).
2. SHALL contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23615).
3. SHALL contain exactly one [1..1] templateId (CONF:23616).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.39" (CONF:23617).
4. SHALL contain exactly one [1..1] code (CONF:23618).
   1. This code SHALL contain exactly one [1..1] @code="ASSERTION" Assertion (CONF:23619).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.5.4" (CodeSystem: HL7ActCode 2.16.840.1.113883.5.4) (CONF:24943).
5. SHALL contain exactly one [1..1] statusCode (CONF:23620).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23621).
6. MAY contain zero or one [0..1] effectiveTime (CONF:23622).
   1. The effectiveTime, if present, SHALL contain exactly one [1..1] low (CONF:23623).
7. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:23624).
   1. This value SHALL contain exactly one [1..1] @code="445528004" treatment dose changed (CONF:23625).
   2. This value SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:24944).
8. SHOULD contain zero or more [0..\*] entryRelationship (CONF:23626).
   1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="RSON" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:23627).
   2. The entryRelationship, if present, SHALL contain exactly one [1..1] observation (CONF:23628).
      1. This observation SHALL contain exactly one [1..1] @classCode="OBS" observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23629).
      2. This observation SHALL contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23630).
      3. This observation SHALL contain exactly one [1..1] code (CONF:23631).
         1. This code SHALL contain exactly one [1..1] @code="373832009" reason for change in planned chemotherapy treatment (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23632).
      4. This observation SHALL contain exactly one [1..1] statusCode (CONF:23633).
         1. This statusCode SHALL contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23634).
      5. This observation SHOULD contain zero or one [0..1] value with @xsi:type="CD" (CONF:23635).
         1. The value, if present, SHALL contain exactly one [1..1] @code (ValueSet: Reason for Dosing Reduction 2.16.840.1.113883.11.20.11.6) (CONF:23636).

<templateId root="2.16.840.1.113883.10.20.30.3.39"/>

<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>

<statusCode code="completed"/>

<effectiveTime>

<low nullFlavor="NI"/>

</effectiveTime>

<value xsi:type="CD" code="445528004" displayName="treatment dose changed"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>

<entryRelationship typeCode="RSON">

<observation classCode="OBS" moodCode="EVN">

<code code="373832009" displayName="reason for change in planned

chemotherapy treatment"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED

CT"></code>

<statusCode code="completed"/>

<effectiveTime>

<low nullFlavor="NI"/>

</effectiveTime>

<!-- Reason for Dosing Reduction value set

"2.16.840.1.113883.11.20.11.6"-->

<value xsi:type="CD" nullFlavor="NI"/>

</observation>

</entryRelationship>

Figure 43: Chemotherapy dose reduction example

Chemotherapy Regimen

[Procedure: templateId 2.16.840.1.113883.10.20.30.3.1 (open)]

Table 77: Chemotherapy Regimen Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Medications Section BCTPS](#S_Medications_Section_BCTPS) (optional) | [Chemotherapy Medication Activity](#E_Chemotherapy_Medication_Activity)  [Clinical Drug Trial](#Clinical_Drug_Trial)  [Drug Therapy Discontinued](#Drug_Therapy_Discontinued)  [Possible Side Effects](#Possible_Side_Effects)  [Therapy Side Effects](#Therapy_Side_Effects) |

This clinical statement represents the course of chemotherapy administered to a patient. The code/originalText element identifies the regimen used.

Notes: Discussion Points: For "possible side effects", should possible side effects be in the plan of care section where medications planned will be documented. Included as MAY here. Is it beneficial for the possible side effects template be in both since different regimens may be planned than one that was/is being administered. Anthracycline (specifically called out in the BCTPS) is included as a MAY inside this chemo regimen template. Should this be a top level SBADM template, separate from the regimen. If not, why is it emphasized over other chemotherapeutic meds?

Table 78: Chemotherapy Regimen Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Procedure[templateId/@root = '2.16.840.1.113883.10.20.30.3.1'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [19522](#C_19522) | 2.16.840.1.113883.5.6 (HL7ActClass) = PROC |
|  | @moodCode | 1..1 | SHALL |  | [19523](#C_19523) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [19524](#C_19524) |  |
|  | @root | 1..1 | SHALL |  | [19525](#C_19525) | 2.16.840.1.113883.10.20.30.3.1 |
|  | id | 1..\* | SHALL |  | [19526](#C_19526) |  |
|  | code | 1..1 | SHALL |  | [19527](#C_19527) |  |
|  | @code | 1..1 | SHALL |  | [19528](#C_19528) | 69960004 |
|  | @codeSystem | 1..1 | SHALL |  | [24946](#C_24946) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |
|  | originalText | 1..1 | SHALL |  | [23842](#C_23842) |  |
|  | statusCode | 1..1 | SHALL |  | [19530](#C_19530) |  |
|  | @code | 1..1 | SHALL |  | [19531](#C_19531) | 2.16.840.1.113883.5.14 (ActStatus) |
|  | effectiveTime | 1..1 | SHALL |  | [19535](#C_19535) |  |
|  | low | 1..1 | SHALL |  | [23843](#C_23843) |  |
|  | high | 1..1 | SHALL |  | [23844](#C_23844) |  |
|  | entryRelationship | 0..\* | SHOULD |  | [23929](#C_23929) |  |
|  | @typeCode | 1..1 | SHALL |  | [23930](#C_23930) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | substanceAdministration | 1..1 | SHALL |  | [23931](#C_23931) |  |
|  | entryRelationship | 0..1 | MAY |  | [23935](#C_23935) |  |
|  | @typeCode | 1..1 | SHALL |  | [23936](#C_23936) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | act | 1..1 | SHALL |  | [23937](#C_23937) |  |
|  | entryRelationship | 0..1 | MAY |  | [23938](#C_23938) |  |
|  | @typeCode | 1..1 | SHALL |  | [23939](#C_23939) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | observation | 1..1 | SHALL |  | [23940](#C_23940) |  |
|  | entryRelationship | 0..\* | SHOULD |  | [23947](#C_23947) |  |
|  | @typeCode | 1..1 | SHALL |  | [23948](#C_23948) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = MFST |
|  | @inversionInd | 1..1 | SHALL |  | [23949](#C_23949) | true |
|  | observation | 1..1 | SHALL |  | [23950](#C_23950) |  |
|  | entryRelationship | 0..\* | MAY |  | [24041](#C_24041) |  |
|  | @typeCode | 1..1 | SHALL |  | [24042](#C_24042) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | act | 1..1 | SHALL |  | [24043](#C_24043) |  |

1. SHALL contain exactly one [1..1] @classCode="PROC" procedure (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:19522).
2. SHALL contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:19523).
3. SHALL contain exactly one [1..1] templateId (CONF:19524) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.1" (CONF:19525).
4. SHALL contain at least one [1..\*] id (CONF:19526).
5. SHALL contain exactly one [1..1] code (CONF:19527).
   1. This code SHALL contain exactly one [1..1] @code="69960004" cancer chemotherapy regimen (CONF:19528).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:24946).

The code is a generic SNOMED-CT code for "cancer chemotherapy regimen", the originalText will be used for the specific regimen name.

* 1. This code SHALL contain exactly one [1..1] originalText (CONF:23842).

1. SHALL contain exactly one [1..1] statusCode (CONF:19530).

If the entire regimen is done, the statusCode should be "completed".

* 1. This statusCode SHALL contain exactly one [1..1] @code (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:19531).

The effectiveTime is used to represent the date the regimen began and ended. The effectiveTime/high can be nulled if the regimen is not completed when the note is generated.

1. SHALL contain exactly one [1..1] effectiveTime (CONF:19535).
   1. This effectiveTime SHALL contain exactly one [1..1] low (CONF:23843).
   2. This effectiveTime SHALL contain exactly one [1..1] high (CONF:23844).
2. SHOULD contain zero or more [0..\*] entryRelationship (CONF:23929) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:23930).
   2. SHALL contain exactly one [1..1] [Chemotherapy Medication Activity](#E_Chemotherapy_Medication_Activity) (templateId:2.16.840.1.113883.10.20.30.3.44) (CONF:23931).
3. MAY contain zero or one [0..1] entryRelationship (CONF:23935) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:23936).
   2. SHALL contain exactly one [1..1] [Clinical Drug Trial](#Clinical_Drug_Trial) (templateId:2.16.840.1.113883.10.20.30.3.4) (CONF:23937).
4. MAY contain zero or one [0..1] entryRelationship (CONF:23938) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:23939).
   2. SHALL contain exactly one [1..1] [Drug Therapy Discontinued](#Drug_Therapy_Discontinued) (templateId:2.16.840.1.113883.10.20.30.3.43) (CONF:23940).
5. SHOULD contain zero or more [0..\*] entryRelationship (CONF:23947) such that it
   1. SHALL contain exactly one [1..1] @typeCode="MFST" is manifestation (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:23948).
   2. SHALL contain exactly one [1..1] @inversionInd="true" (CONF:23949).
   3. SHALL contain exactly one [1..1] [Therapy Side Effects](#Therapy_Side_Effects) (templateId:2.16.840.1.113883.10.20.30.3.42) (CONF:23950).
6. MAY contain zero or more [0..\*] entryRelationship (CONF:24041) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24042).
   2. SHALL contain exactly one [1..1] [Possible Side Effects](#Possible_Side_Effects) (templateId:2.16.840.1.113883.10.20.30.3.35) (CONF:24043).

Figure 44: Chemotherapy regimen example

<templateId root="2.16.840.1.113883.10.20.30.3.1"/>

<id root="230a5fb5-1ada-11e0-ac64-0800200c9a66"/>

<code code="69960004" codeSystem="2.16.840.1.113883.6.96"

displayName="cancer chemotherapy regimen">

<!-- SHALL originalText, the originalText is specific regimen name-->

<originalText>TAC chemotherapy regimen</originalText>

</code>

<statusCode code="completed"/>

<!-- SHALL effectiveTime [1..1]-->

<!-- 5 of 3-week cycle, for 4 months from 1/6/10 to 4/21/10 -->

<effectiveTime xsi:type="IVL\_TS">

<!-- Date chemotherapy started -->

<low value="20120106"/>

<!-- Date chemotherapy ended -->

<high value="20120421"/>

</effectiveTime>

<!-- MAY [0..\*] entryRelationship chemotherapy medication Activity. -->

<!-- 1st instance: Docetaxel (Taxotere) -->

<entryRelationship typeCode="COMP">

<substanceAdministration classCode="SBADM" moodCode="EVN">

<!-- Consolidated CDA Medication Activity templateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.16"/>

<!--Chemotherapy Medication Activity 2.16.840.1.113883.10.20.30.3.44-->

<templateId root="2.16.840.1.113883.10.20.30.3.44"/>

<id root="cd3c85ed-c3df-4e23-97c9-80c9fd084ba6"/>

<statusCode code="completed"/>

<!-- 3 weeks a cycle, 5 cycles, over 4 months. Started 2012/01/06,

Stopped 2012/04/21-->

<effectiveTime xsi:type="IVL\_TS">

<low value="20120106"/>

<high value="20120421"/>

</effectiveTime>

<!-- Frequency of the chemotherapy. 3 weeks/cycle -->

<effectiveTime xsi:type="PIVL\_TS" operator="A">

<period value="21" unit="d"/>

</effectiveTime>

<routeCode code="C38276" displayName="intravenous"

codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="National

Cancer Institute (NCI) Thesaurus"/>

<consumable>

<manufacturedProduct classCode="MANU">

<!-- Consolidated CDA Medication Information

(manufacturedMaterial) -->

<templateId root="2.16.840.1.113883.10.20.22.4.23"/>

<manufacturedMaterial>

<code codeSystem="2.16.840.1.113883.6.88"

codeSystemName="RXNorm"

code="414983" displayName="docetaxel 13.3 MG/ML

Injectable Solution">

<originalText>docetaxel 13.3 MG/ML Injectable

Solution</originalText>

</code>

…

Chemotherapy Regimen Plans

[Procedure: templateId 2.16.840.1.113883.10.20.30.3.30 (open)]

Table 79: Chemotherapy Regimen Plans Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Plan of Care Section BCTPS](#S_Plan_of_Care_Section_BCTPS) (optional) | [Chemotherapy Medication Activity](#E_Chemotherapy_Medication_Activity)  [Clinical Drug Trial](#Clinical_Drug_Trial)  [Possible Side Effects](#Possible_Side_Effects) |

This clinical statement represents a Chemotherapy Regimen Plan that describes a patient’s future course of chemotherapy. In the code/originalText element text entered identifies the regimen to be used.

Table 80: Chemotherapy Regimen Plans Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Procedure[templateId/@root = '2.16.840.1.113883.10.20.30.3.30'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [24047](#C_24047) | 2.16.840.1.113883.5.6 (HL7ActClass) = PROC |
|  | @moodCode | 1..1 | SHALL |  | [24048](#C_24048) | 2.16.840.1.113883.11.20.9.24 (Plan of Care moodCode (SubstanceAdministration/Supply)) |
|  | templateId | 1..1 | SHALL |  | [24049](#C_24049) |  |
|  | @root | 1..1 | SHALL |  | [24050](#C_24050) | 2.16.840.1.113883.10.20.30.3.30 |
|  | id | 1..\* | SHALL |  | [24051](#C_24051) |  |
|  | code | 1..1 | SHALL |  | [24052](#C_24052) |  |
|  | @code | 1..1 | SHALL |  | [24053](#C_24053) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 69960004 |
|  | originalText | 1..1 | SHALL |  | [24054](#C_24054) |  |
|  | statusCode | 1..1 | SHALL |  | [24055](#C_24055) |  |
|  | @code | 1..1 | SHALL |  | [24056](#C_24056) | 2.16.840.1.113883.5.14 (ActStatus) = new |
|  | effectiveTime | 1..1 | SHALL |  | [24057](#C_24057) |  |
|  | low | 1..1 | SHALL |  | [24058](#C_24058) |  |
|  | high | 1..1 | SHALL |  | [24059](#C_24059) |  |
|  | entryRelationship | 0..\* | SHOULD |  | [24060](#C_24060) |  |
|  | @typeCode | 1..1 | SHALL |  | [24061](#C_24061) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | substanceAdministration | 1..1 | SHALL |  | [24062](#C_24062) |  |
|  | entryRelationship | 0..1 | MAY |  | [24066](#C_24066) |  |
|  | @typeCode | 1..1 | SHALL |  | [24067](#C_24067) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | act | 1..1 | SHALL |  | [24068](#C_24068) |  |
|  | entryRelationship | 0..\* | MAY |  | [24076](#C_24076) |  |
|  | @typeCode | 1..1 | SHALL |  | [24077](#C_24077) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | act | 1..1 | SHALL |  | [24078](#C_24078) |  |

1. SHALL contain exactly one [1..1] @classCode="PROC" procedure (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:24047).
2. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet Plan of Care moodCode (SubstanceAdministration/Supply) 2.16.840.1.113883.11.20.9.24 STATIC (CONF:24048).
3. SHALL contain exactly one [1..1] templateId (CONF:24049) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.30" (CONF:24050).
4. SHALL contain at least one [1..\*] id (CONF:24051).
5. SHALL contain exactly one [1..1] code (CONF:24052).
   1. This code SHALL contain exactly one [1..1] @code="69960004" cancer chemotherapy regimen (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:24053).

The originalText element captures the name of the regimen plan.

* 1. This code SHALL contain exactly one [1..1] originalText (CONF:24054).

1. SHALL contain exactly one [1..1] statusCode (CONF:24055).
   1. This statusCode SHALL contain exactly one [1..1] @code="new" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:24056).

The effectiveTime is used to represent when the regimen plan is expected to begin and end.

1. SHALL contain exactly one [1..1] effectiveTime (CONF:24057).
   1. This effectiveTime SHALL contain exactly one [1..1] low (CONF:24058).
   2. This effectiveTime SHALL contain exactly one [1..1] high (CONF:24059).
2. SHOULD contain zero or more [0..\*] entryRelationship (CONF:24060) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24061).
   2. SHALL contain exactly one [1..1] [Chemotherapy Medication Activity](#E_Chemotherapy_Medication_Activity) (templateId:2.16.840.1.113883.10.20.30.3.44) (CONF:24062).
3. MAY contain zero or one [0..1] entryRelationship (CONF:24066) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24067).
   2. SHALL contain exactly one [1..1] [Clinical Drug Trial](#Clinical_Drug_Trial) (templateId:2.16.840.1.113883.10.20.30.3.4) (CONF:24068).
4. MAY contain zero or more [0..\*] entryRelationship (CONF:24076) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24077).
   2. SHALL contain exactly one [1..1] [Possible Side Effects](#Possible_Side_Effects) (templateId:2.16.840.1.113883.10.20.30.3.35) (CONF:24078).

Table 81: Plan of Care moodCode (SubstanceAdministration/Supply)

|  |  |  |
| --- | --- | --- |
| Value Set: Plan of Care moodCode (SubstanceAdministration/Supply) 2.16.840.1.113883.11.20.9.24 | | |
| Code | Code System | Print Name |
| INT | ActMood | Intent |
| PRMS | ActMood | Promise |
| PRP | ActMood | Proposal |
| RQO | ActMood | Request |

Figure 45: Chemotherpay regimen plans example

<templateId root="2.16.840.1.113883.10.20.30.3.30"/>

<id root="2baf9dc1-6d92-4ed0-8b4a-ad556adb90fe"/>

<code code="69960004" codeSystem="2.16.840.1.113883.6.96"

displayName="cancer chemotherapy regimen">

<originalText>TAC chemotherapy regimen</originalText>

</code>

<statusCode code="new"/>

<!-- Expected start and end dates of entire regimen plan -->

<effectiveTime xsi:type="IVL\_TS">

<low value="20100106"/>

<high value="20100506"/>

</effectiveTime>

<!-- Taxotere (Docetaxel) -->

<entryRelationship typeCode="COMP">

<substanceAdministration classCode="SBADM" moodCode="INT">

<!-- Consolidated CDA Plan of Care Activity Substance Administration-->

<templateId root="2.16.840.1.113883.10.20.22.4.42"/>

<id root="393083d6-01d1-423c-b253-3e2658241287"/>

<statusCode code="active"/>

<!-- every 21 days for 4 months from 1/6/10 to 5/6/10 -->

<effectiveTime xsi:type="IVL\_TS">

<low value="20100106"/>

<high value="20100506"/>

</effectiveTime>

<effectiveTime xsi:type="PIVL\_TS">

<period value="21" unit="d"/>

</effectiveTime>

<routeCode code="C38276" codeSystem="2.16.840.1.113883.3.26.1.1"

displayName="Intravenous route"

codeSystemName="FDA RouteOfAdministration"/>

<consumable>

<manufacturedProduct>

<!-- Consolidated CDA Medication Information

(manufacturedMaterial) -->

<templateId root="2.16.840.1.113883.10.20.22.4.23"/>

<manufacturedMaterial>

<code code="72962" codeSystem="2.16.840.1.113883.6.88"

codeSystemName="RXNorm" displayName="Docetaxel">

<originalText>Docetaxel</originalText>

</code>

<!-- Brand Name -->

<name>Taxotere</name>

</manufacturedMaterial>

</manufacturedProduct>

</consumable>

</substanceAdministration>

</entryRelationship>

<!-- Doxorubicin (Adriamycin) -->

<entryRelationship typeCode="COMP">

...

Clinical Drug Trial

[Act: templateId 2.16.840.1.113883.10.20.30.3.4 (open)]

Table 82: Clinical Drug Trial Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Chemotherapy Regimen](#E_Chemotherapy_Regimen) (optional)  [Chemotherapy Regimen Plans](#E_Chemotherapy_Regimen_Plans) (optional) |  |

This clinical statement represents a treatment (e.g., chemotherapy administered) that is part of a clinical trial.

Table 83: Clinical Drug Trial Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Act[templateId/@root = '2.16.840.1.113883.10.20.30.3.4'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [23859](#C_23859) | 2.16.840.1.113883.5.6 (HL7ActClass) = ACT |
|  | @moodCode | 1..1 | SHALL |  | [23860](#C_23860) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [23861](#C_23861) |  |
|  | @root | 1..1 | SHALL |  | [23862](#C_23862) | 2.16.840.1.113883.10.20.30.3.4 |
|  | code | 1..1 | SHALL |  | [23876](#C_23876) |  |
|  | @code | 1..1 | SHALL |  | [23877](#C_23877) | 185922005 |
|  | @codeSystem | 1..1 | SHALL |  | [26246](#C_26246) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |
|  | statusCode | 1..1 | SHALL |  | [23863](#C_23863) |  |
|  | @code | 1..1 | SHALL |  | [23864](#C_23864) | 2.16.840.1.113883.5.14 (ActStatus) = completed |

Figure 46: Clinical Drug Trial Example

<!-- Clinical drug trial 2.16.840.1.113883.10.20.30.3.4 -->

<entryRelationship typeCode="REFR">

<act classCode="ACT" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.30.3.4"/>

<code code="185922005" displayName="clinical drug trials"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT"/>

<statusCode code="completed"/>

</act>

</entryRelationship>

<!-- MAY [0..1] chemotherapy treatment stopped and reason-->

<!-- Drug Therapy Discontinued 2.16.840.1.113883.10.20.30.3.43 -->

<entryRelationship typeCode="REFR">

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.30.3.43"/>

<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>

<statusCode code="completed"/>

<effectiveTime>

<low nullFlavor="NI"/>

</effectiveTime>

<value xsi:type="CD" code="274512008" displayName="drug therapy

discontinued"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>

<!-- SHOULD [0..\*] reasons for stopping -->

<entryRelationship typeCode="RSON">

<observation classCode="OBS" moodCode="EVN">

<code code="373832009" displayName="reason for change in

planned chemotherapy treatment"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED

CT"></code>

<statusCode code="completed"/>

<effectiveTime>

<low nullFlavor="NI"/>

</effectiveTime>

<value xsi:type="CD" nullFlavor="NI"/>

</observation>

</entryRelationship>

</observation>

</entryRelationship>

<!-- SHOULD contain [0..\*] actual reaction (toxicities) occurred during the

therapy -->

<!-- Therapy Side Effects 2.16.840.1.113883.10.20.30.3.42 -->

<entryRelationship typeCode="MFST" inversionInd="true">

<!-- SHALL [1..1] Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->

<observation classCode="OBS" moodCode="EVN">

<!-- C-CDA Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->

<templateId root="2.16.840.1.113883.10.20.22.4.9"/>

...

<entryRelationship typeCode="MFST" inversionInd="true">

<!-- SHALL [1..1] Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->

<observation classCode="OBS" moodCode="EVN">

<!-- C-CDA Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->

<templateId root="2.16.840.1.113883.10.20.22.4.9"/>

<!--therapy side effects observation 2.16.840.1.113883.10.20.30.3.42-->

<templateId root="2.16.840.1.113883.10.20.30.3.42"/>

...

Drug Therapy Discontinued

[Observation: templateId 2.16.840.1.113883.10.20.30.3.43 (open)]

Table 87: Drug Therapy Discontinued Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Chemotherapy Regimen](#E_Chemotherapy_Regimen) (optional) |  |

This clinical statement represents drug therapy was stopped and the reason why it was discontinued.

Notes: Value set issue: the complete list of codes for "Reasons for Stopping Chemotherapy" value set needs to be defined and reviewed. (Some example codes are entered for now)

Table 88: Drug Therapy Discontinued Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.43'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [23906](#C_23906) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [23907](#C_23907) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [23908](#C_23908) |  |
|  | @root | 1..1 | SHALL |  | [23909](#C_23909) | 2.16.840.1.113883.10.20.30.3.43 |
|  | code | 1..1 | SHALL |  | [23910](#C_23910) |  |
|  | @code | 1..1 | SHALL |  | [23911](#C_23911) | 2.16.840.1.113883.5.4 (ActCode) = ASSERTION |
|  | statusCode | 1..1 | SHALL |  | [23912](#C_23912) |  |
|  | @code | 1..1 | SHALL |  | [23913](#C_23913) | 2.16.840.1.113883.5.14 (ActStatus) = Completed |
|  | effectiveTime | 1..1 | SHOULD |  | [23914](#C_23914) |  |
|  | low | 1..1 | SHALL |  | [23915](#C_23915) |  |
|  | value | 1..1 | SHALL | CD | [23916](#C_23916) |  |
|  | @code | 1..1 | SHALL |  | [23917](#C_23917) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 274512008 |
|  | entryRelationship | 0..\* | SHOULD |  | [23918](#C_23918) |  |
|  | @typeCode | 1..1 | SHALL |  | [23919](#C_23919) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON |
|  | observation | 1..1 | SHALL |  | [23920](#C_23920) |  |
|  | @classCode | 1..1 | SHALL |  | [23921](#C_23921) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [23922](#C_23922) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | statusCode | 1..1 | SHALL |  | [23923](#C_23923) |  |
|  | @code | 1..1 | SHALL |  | [23924](#C_23924) | 2.16.840.1.113883.5.14 (ActStatus) = Completed |
|  | effectiveTime | 0..1 | MAY |  | [23925](#C_23925) |  |
|  | low | 1..1 | SHALL |  | [23926](#C_23926) |  |
|  | value | 1..1 | SHALL | CD | [23927](#C_23927) |  |
|  | @code | 1..1 | SHALL |  | [23928](#C_23928) | 2.16.840.1.113883.11.20.11.11 (Reason for Stopping Chemotherapy) |

1. SHALL contain exactly one [1..1] @classCode="OBS" observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23906).
2. SHALL contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23907).
3. SHALL contain exactly one [1..1] templateId (CONF:23908) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.43" (CONF:23909).
4. SHALL contain exactly one [1..1] code (CONF:23910).
   1. This code SHALL contain exactly one [1..1] @code="ASSERTION" Assertion (CodeSystem: ActCode 2.16.840.1.113883.5.4) (CONF:23911).
5. SHALL contain exactly one [1..1] statusCode (CONF:23912).
   1. This statusCode SHALL contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23913).
6. SHOULD contain exactly one [1..1] effectiveTime (CONF:23914).
   1. This effectiveTime SHALL contain exactly one [1..1] low (CONF:23915).
7. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:23916).
   1. This value SHALL contain exactly one [1..1] @code="274512008" drug therapy discontinued (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23917).
8. SHOULD contain zero or more [0..\*] entryRelationship (CONF:23918).
   1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="RSON" has reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:23919).
   2. The entryRelationship, if present, SHALL contain exactly one [1..1] observation (CONF:23920).
      1. This observation SHALL contain exactly one [1..1] @classCode="OBS" observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23921).
      2. This observation SHALL contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23922).
      3. This observation SHALL contain exactly one [1..1] statusCode (CONF:23923).
         1. This statusCode SHALL contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23924).
      4. This observation MAY contain zero or one [0..1] effectiveTime (CONF:23925).
         1. The effectiveTime, if present, SHALL contain exactly one [1..1] low (CONF:23926).
      5. This observation SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:23927).
         1. This value SHALL contain exactly one [1..1] @code (ValueSet: Reason for Stopping Chemotherapy 2.16.840.1.113883.11.20.11.11) (CONF:23928).

Table 89: Reason for Stopping Chemotherapy

|  |  |  |
| --- | --- | --- |
| Value Set: Reason for Stopping Chemotherapy 2.16.840.1.113883.11.20.11.11 | | |
| Code | Code System | Print Name |
| 419099009 | SNOMED-CT | dead |
| 62014003 | SNOMED-CT | adverse reaction to drug |
| 182868002 | SNOMED-CT | treatment stopped - alternative therapy undertaken |
| 399307001 | SNOMED-CT | lost to follow-up |
| 105480006 | SNOMED-CT | refusal of treatment by patient |
| 182992009 | SNOMED-CT | treatment completed |

Figure 47: Drug theraphy discontinued example

<!-- Drug Therapy Discontinued 2.16.840.1.113883.10.20.30.3.43 -->

<entryRelationship typeCode="REFR">

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.30.3.43"/>

<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>

<statusCode code="completed"/>

<effectiveTime>

<low nullFlavor="NI"/>

</effectiveTime>

<value xsi:type="CD" code="274512008" displayName="drug therapy

discontinued"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>

<!-- SHOULD [0..\*] reasons for stopping -->

<entryRelationship typeCode="RSON">

<observation classCode="OBS" moodCode="EVN">

<code code="373832009" displayName="reason for change in

planned chemotherapy treatment"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED

CT"></code>

<statusCode code="completed"/>

<effectiveTime>

<low nullFlavor="NI"/>

</effectiveTime>

<!-- need to create valueSet "Reason for Stopping Chemotherapy"

2.16.840.1.113883.11.20.11.11-->

<value xsi:type="CD" nullFlavor="NI"/>

</observation>

</entryRelationship>

</observation>

</entryRelationship>

<!-- SHOULD contain [0..\*] actual reaction (toxicities) occurred during the

therapy -->

Drug Vehicle [Closed for comments; published July 2012]

[participantRole: templateId 2.16.840.1.113883.10.20.22.4.24 (open)]

Table 90: Drug Vehicle Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Medication Activity](#E_Medication_Activity) (optional) |  |

This template represents the vehicle (e.g. saline, dextrose) for administering a medication.

Table 91: Drug Vehicle Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | participantRole[templateId/@root = '2.16.840.1.113883.10.20.22.4.24'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7490](#C_7490) | 2.16.840.1.113883.5.110 (RoleClass) = MANU |
|  | templateId | 1..1 | SHALL |  | [7495](#C_7495) |  |
|  | @root | 1..1 | SHALL |  | [10493](#C_10493) | 2.16.840.1.113883.10.20.22.4.24 |
|  | code | 1..1 | SHALL |  | [19137](#C_19137) |  |
|  | @code | 1..1 | SHALL |  | [19138](#C_19138) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 412307009 |
|  | playingEntity | 1..1 | SHALL |  | [7492](#C_7492) |  |
|  | code | 1..1 | SHALL |  | [7493](#C_7493) |  |
|  | name | 0..1 | MAY |  | [7494](#C_7494) |  |

1. SHALL contain exactly one [1..1] @classCode="MANU" (CodeSystem: RoleClass 2.16.840.1.113883.5.110 STATIC) (CONF:7490).
2. SHALL contain exactly one [1..1] templateId (CONF:7495) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.24" (CONF:10493).
3. SHALL contain exactly one [1..1] code (CONF:19137).
   1. This code SHALL contain exactly one [1..1] @code="412307009" Drug Vehicle (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:19138).
4. SHALL contain exactly one [1..1] playingEntity (CONF:7492).

This playingEntity/code is used to supply a coded term for the drug vehicle.

* 1. This playingEntity SHALL contain exactly one [1..1] code (CONF:7493).
  2. This playingEntity MAY contain zero or one [0..1] name (CONF:7494).
     1. This playingEntity/name MAY be used for the vehicle name in text, such as Normal Saline (CONF:10087).

Encounter Activities[Closed for comments; published July 2012]

[encounter: templateId 2.16.840.1.113883.10.20.22.4.49 (open)]

Table 92: Encounter Activities Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Encounters Section (entries optional)](#S_Encounters_Section_entries_optional) (optional) | [Encounter Diagnosis](#E_Encounter_Diagnosis)  [Indication](#E_Indication)  [Service Delivery Location](#E_Service_Delivery_Location) |

This clinical statement describes the interactions between the patient and clinicians. Interactions include in-person encounters, telephone conversations, and email exchanges.

Table 93: Encounter Activities Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
| Green Encounter Activities | encounter[templateId/@root = '2.16.840.1.113883.10.20.22.4.49'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [8710](#C_8710) | 2.16.840.1.113883.5.6 (HL7ActClass) = ENC |
|  | @moodCode | 1..1 | SHALL |  | [8711](#C_8711) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [8712](#C_8712) |  |
|  | @root | 1..1 | SHALL |  | [26353](#C_26353) | 2.16.840.1.113883.10.20.22.4.49 |
| encounterID | id | 1..\* | SHALL |  | [8713](#C_8713) |  |
| encounterType | code | 0..1 | SHOULD |  | [8714](#C_8714) | 2.16.840.1.113883.3.88.12.80.32 (EncounterTypeCode) |
|  | originalText | 0..1 | SHOULD |  | [8719](#C_8719) |  |
|  | reference | 0..1 | SHOULD |  | [15970](#C_15970) |  |
|  | @value | 0..1 | SHOULD |  | [15971](#C_15971) |  |
| encounterFreeTextType | reference/@value | 0..1 | SHOULD |  | [8720](#C_8720) |  |
| encounterDateTime | effectiveTime | 1..1 | SHALL |  | [8715](#C_8715) |  |
|  | performer | 0..\* | MAY |  | [8725](#C_8725) |  |
| encounterProvider | assignedEntity | 1..1 | SHALL |  | [8726](#C_8726) |  |
|  | code | 0..1 | MAY |  | [8727](#C_8727) |  |
| facilityLocation | participant | 0..\* | MAY |  | [8738](#C_8738) |  |
|  | @typeCode | 1..1 | SHALL |  | [8740](#C_8740) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = LOC |
|  | participantRole | 1..1 | SHALL |  | [14903](#C_14903) |  |
| reasonForVisit | entryRelationship | 0..\* | MAY |  | [8722](#C_8722) |  |
|  | @typeCode | 1..1 | SHALL |  | [8723](#C_8723) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON |
|  | observation | 1..1 | SHALL |  | [14899](#C_14899) |  |
|  | entryRelationship | 0..\* | MAY |  | [15492](#C_15492) |  |
|  | act | 1..1 | SHALL |  | [15973](#C_15973) |  |

1. SHALL contain exactly one [1..1] @classCode="ENC" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8710).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:8711).
3. SHALL contain exactly one [1..1] templateId (CONF:8712) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.49" (CONF:26353).
4. SHALL contain at least one [1..\*] id (CONF:8713).
5. SHOULD contain zero or one [0..1] code, which SHOULD be selected from ValueSet EncounterTypeCode 2.16.840.1.113883.3.88.12.80.32 DYNAMIC (CONF:8714).
   1. The code, if present, SHOULD contain zero or one [0..1] originalText (CONF:8719).
      1. The originalText, if present, SHOULD contain zero or one [0..1] reference (CONF:15970).
         1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15971).
            1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15972).
      2. The originalText, if present, SHOULD contain zero or one [0..1] reference/@value (CONF:8720).
6. SHALL contain exactly one [1..1] effectiveTime (CONF:8715).
7. MAY contain zero or more [0..\*] performer (CONF:8725).
   1. The performer, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:8726).
      1. This assignedEntity MAY contain zero or one [0..1] code (CONF:8727).
8. MAY contain zero or more [0..\*] participant (CONF:8738) such that it
   1. SHALL contain exactly one [1..1] @typeCode="LOC" Location (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:8740).
   2. SHALL contain exactly one [1..1] [Service Delivery Location](#E_Service_Delivery_Location) (templateId:2.16.840.1.113883.10.20.22.4.32) (CONF:14903).
9. MAY contain zero or more [0..\*] entryRelationship (CONF:8722) such that it
   1. SHALL contain exactly one [1..1] @typeCode="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:8723).
   2. SHALL contain exactly one [1..1] [Indication](#E_Indication) (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:14899).
10. MAY contain zero or more [0..\*] entryRelationship (CONF:15492) such that it
    1. SHALL contain exactly one [1..1] [Encounter Diagnosis](#E_Encounter_Diagnosis) (templateId:2.16.840.1.113883.10.20.22.4.80) (CONF:15973).
11. MAY contain zero or one [0..1] sdtc:dischargeDispositionCode, which SHALL be selected from ValueSet 2.16.840.1.113883.3.88.12.80.33 NUBC UB-04 FL17-Patient Status DYNAMIC or, if access to NUBC is unavailable, from CodeSystem 2.16.840.1.113883.12.112 HL7 Discharge Disposition. The prefix sdtc: SHALL be bound to the namespace “urn:hl7-org:sdtc”. The use of the namespace provides a necessary extension to CDA R2 for the use of the dischargeDispositionCode element (CONF:9929).

Hospitalization for Toxicity

[encounter: templateId 2.16.840.1.113883.10.20.30.3.36 (open)]

Table 94: Hospitalization for Toxicity Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Encounters Section BCTPS](#Encounters_Section_BCTPS) (required) | [Indication](#E_Indication) |

This clinical statement represents an inpatient hospitalization that occurred because of toxicity due to chemotherapy. The HL7 encounter code "IMP" (inpatient) identifies an inpatient encounter. The HL7 actRelationship typeCode "RSON" (reason) captures the reason for the inpatient hospitalization as toxicity due to chemotherapy. There can be additional entry relationships that describe what the clinical toxicities or problems were.

Notes: 1) May need to update to include a reason for hospitalization for toxicity that conforms to Indication with a specific value set rather than just re-using the existing indications template. 2) Encounter/code is constrained to the generic HL7 IMP (Inpatient Encounter) which meets the requirement. The C-CDA encounter activity template recommends (SHOULD) that CPT codes be used. There is no generic "Inpatient encounter" CPT code)

Table 95: Hospitalization for Toxicity Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | encounter[templateId/@root = '2.16.840.1.113883.10.20.30.3.36'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [26330](#C_26330) |  |
|  | @root | 1..1 | SHALL |  | [26331](#C_26331) | 2.16.840.1.113883.10.20.30.3.36 |
|  | code | 1..1 | SHALL |  | [26333](#C_26333) |  |
|  | @code | 1..1 | SHALL |  | [26442](#C_26442) | 2.16.840.1.113883.5.4 (ActCode) = IMP |
|  | @codeSystem | 1..1 | SHALL |  | [26443](#C_26443) | 2.16.840.1.113883.5.4 |
|  | entryRelationship | 1..1 | SHALL |  | [26346](#C_26346) |  |
|  | @typeCode | 1..1 | SHALL |  | [26347](#C_26347) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON |
|  | observation | 1..1 | SHALL |  | [26374](#C_26374) |  |

1. Conforms to [Encounter Activities](#E_Encounter_Activities) template (2.16.840.1.113883.10.20.22.4.49).
2. SHALL contain exactly one [1..1] templateId (CONF:26330) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.36" (CONF:26331).
3. SHALL contain exactly one [1..1] code (CONF:26333).
   1. This code SHALL contain exactly one [1..1] @code="IMP" Inpatient encounter (CodeSystem: ActCode 2.16.840.1.113883.5.4) (CONF:26442).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.5.4" actCode (CONF:26443).
4. SHALL contain exactly one [1..1] entryRelationship (CONF:26346) such that it
   1. SHALL contain exactly one [1..1] @typeCode="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:26347).
   2. SHALL contain exactly one [1..1] [Indication](#E_Indication) (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:26374).

Figure 48: Hospitalization for toxicity example

<templateId root="2.16.840.1.113883.10.20.30.3.36"/>

<id root="dd21f8ce-4cb4-43f7-b735-e64eb02b927c"/>

<code codeSystem="2.16.840.1.113883.5.4" code="IMP" displayName="Inpatient encounter"/>

<effectiveTime>

<!-- Dates of admission and discharge -->

<low value="20120407"/>

<high value="20120410"/>

</effectiveTime>

<participant typeCode="LOC">

<!-- Location participation template -->

<templateId root="2.16.840.1.113883.10.20.1.45"/>

<participantRole classCode="SDLOC">

<id root="2.16.840.1.113883.19.5"/>

<playingEntity classCode="PLC">

<name>Good Health Hospital</name>

</playingEntity>

</participantRole>

</participant>

<!-- This states that the reason for admission was due to chemotherapy toxicity

-->

<entryRelationship typeCode="RSON">

<observation classCode="OBS" moodCode="EVN">

<!-- Consolidated CDA Indication template -->

<templateId root="2.16.840.1.113883.10.20.22.4.19"/>

<!-- Observation ID equals an ID on the problem list -->

<id root="43faccd9-5b6e-45f3-b007-856e96b3d84d"/>

<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />

<statusCode code="completed" />

<value xsi:type="CD" code="399213007"

codeSystem="2.16.840.1.113883.6.96" displayName="toxicity due to

chemotherapy"/>

</observation>

</entryRelationship>

Encounter Diagnosis[Closed for comments; published July 2012]

[act: templateId 2.16.840.1.113883.10.20.22.4.80 (open)]

Table 96: Encounter Diagnosis Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Encounter Activities](#E_Encounter_Activities) (optional) | [Problem Observation](#E_Problem_Observation) |

This template wraps relevant problems or diagnoses at the close of a visit or that need to be followed after the visit. If the encounter is associated with a Hospital Discharge, the Hospital Discharge Diagnosis must be used. This entry requires at least one Problem Observation entry.

Table 97: Encounter Diagnosis Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | act[templateId/@root = '2.16.840.1.113883.10.20.22.4.80'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [14889](#C_14889) | 2.16.840.1.113883.5.6 (HL7ActClass) = ACT |
|  | @moodCode | 1..1 | SHALL |  | [14890](#C_14890) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [14895](#C_14895) |  |
|  | @root | 1..1 | SHALL |  | [14896](#C_14896) | 2.16.840.1.113883.10.20.22.4.80 |
|  | code | 1..1 | SHALL |  | [19182](#C_19182) |  |
|  | @code | 1..1 | SHALL |  | [19183](#C_19183) | 2.16.840.1.113883.6.1 (LOINC) = 29308-4 |
|  | entryRelationship | 1..\* | SHALL |  | [14892](#C_14892) |  |
|  | @typeCode | 1..1 | SHALL |  | [14893](#C_14893) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | observation | 1..1 | SHALL |  | [14898](#C_14898) |  |

1. SHALL contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:14889).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14890).
3. SHALL contain exactly one [1..1] templateId (CONF:14895) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.80" (CONF:14896).
4. SHALL contain exactly one [1..1] code (CONF:19182).
   1. This code SHALL contain exactly one [1..1] @code="29308-4" Diagnosis (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:19183).
5. SHALL contain at least one [1..\*] entryRelationship (CONF:14892) such that it
   1. SHALL contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:14893).
   2. SHALL contain exactly one [1..1] [Problem Observation](#E_Problem_Observation) (templateId:2.16.840.1.113883.10.20.22.4.4) (CONF:14898).

Family History Death Observation[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.47 (open)]

Table 98: Family History Death Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Family History Observation](#E_Family_History_Observation) (optional) |  |

This clinical statement records whether the family member is deceased.

Table 99: Family History Death Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.47'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [8621](#C_8621) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [8622](#C_8622) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [8623](#C_8623) |  |
|  | @root | 1..1 | SHALL |  | [10495](#C_10495) | 2.16.840.1.113883.10.20.22.4.47 |
|  | code | 1..1 | SHALL |  | [19141](#C_19141) |  |
|  | @code | 1..1 | SHALL |  | [19142](#C_19142) | 2.16.840.1.113883.5.4 (ActCode) = ASSERTION |
|  | statusCode | 1..1 | SHALL |  | [8625](#C_8625) |  |
|  | @code | 1..1 | SHALL |  | [19097](#C_19097) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | value | 1..1 | SHALL | CD | [8626](#C_8626) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 419099009 |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8621).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:8622).
3. SHALL contain exactly one [1..1] templateId (CONF:8623) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.47" (CONF:10495).
4. SHALL contain exactly one [1..1] code (CONF:19141).
   1. This code SHALL contain exactly one [1..1] @code="ASSERTION" Assertion (CodeSystem: ActCode 2.16.840.1.113883.5.4 STATIC) (CONF:19142).
5. SHALL contain exactly one [1..1] statusCode (CONF:8625).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19097).
6. SHALL contain exactly one [1..1] value="419099009" Dead with @xsi:type="CD" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:8626).

Family History Observation[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.46 (open)]

Table 100: Family History Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Family History Organizer](#E_Family_History_Organizer) (required) | [Age Observation](#E_Age_Observation)  [Family History Death Observation](#E_Family_History_Death_Observation) |

Family History Observations related to a particular family member are contained within a Family History Organizer. The effectiveTime in the Family History Observation is the biologically or clinically relevant time of the observation. The biologically or clinically relevant time is the time at which the observation holds (is effective) for the family member (the subject of the observation).

Table 101: Family History Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
| Green Family History Observation | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.46'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [8586](#C_8586) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [8587](#C_8587) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [8599](#C_8599) |  |
|  | @root | 1..1 | SHALL |  | [10496](#C_10496) | 2.16.840.1.113883.10.20.22.4.46 |
|  | id | 1..\* | SHALL |  | [8592](#C_8592) |  |
|  | code | 1..1 | SHALL |  | [8589](#C_8589) | 2.16.840.1.113883.3.88.12.3221.7.2 (Problem Type) |
|  | statusCode | 1..1 | SHALL |  | [8590](#C_8590) |  |
|  | @code | 1..1 | SHALL |  | [19098](#C_19098) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 0..1 | SHOULD |  | [8593](#C_8593) |  |
|  | value | 1..1 | SHALL | CD | [8591](#C_8591) | 2.16.840.1.113883.3.88.12.3221.7.4 (Problem Value Set) |
|  | entryRelationship | 0..1 | MAY |  | [8675](#C_8675) |  |
|  | @typeCode | 1..1 | SHALL |  | [8676](#C_8676) | 2.16.840.1.113883.5.90 (HL7ParticipationType) = SUBJ |
|  | @inversionInd | 1..1 | SHALL |  | [8677](#C_8677) | true |
|  | observation | 1..1 | SHALL |  | [15526](#C_15526) |  |
|  | entryRelationship | 0..1 | MAY |  | [8678](#C_8678) |  |
|  | @typeCode | 1..1 | SHALL |  | [8679](#C_8679) | 2.16.840.1.113883.5.90 (HL7ParticipationType) = CAUS |
|  | observation | 1..1 | SHALL |  | [15527](#C_15527) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8586).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:8587).
3. SHALL contain exactly one [1..1] templateId (CONF:8599) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.46" (CONF:10496).
4. SHALL contain at least one [1..\*] id (CONF:8592).
5. SHALL contain exactly one [1..1] code, which SHOULD be selected from ValueSet Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 STATIC 2012-06-01 (CONF:8589).
6. SHALL contain exactly one [1..1] statusCode (CONF:8590).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19098).
7. SHOULD contain zero or one [0..1] effectiveTime (CONF:8593).
8. SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHALL be selected from ValueSet Problem Value Set 2.16.840.1.113883.3.88.12.3221.7.4 DYNAMIC (CONF:8591).
9. MAY contain zero or one [0..1] entryRelationship (CONF:8675) such that it
   1. SHALL contain exactly one [1..1] @typeCode="SUBJ" Subject (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 STATIC) (CONF:8676).
   2. SHALL contain exactly one [1..1] @inversionInd="true" True (CONF:8677).
   3. SHALL contain exactly one [1..1] [Age Observation](#E_Age_Observation) (templateId:2.16.840.1.113883.10.20.22.4.31) (CONF:15526).
10. MAY contain zero or one [0..1] entryRelationship (CONF:8678) such that it
    1. SHALL contain exactly one [1..1] @typeCode="CAUS" Causal or Contributory (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 STATIC) (CONF:8679).
    2. SHALL contain exactly one [1..1] [Family History Death Observation](#E_Family_History_Death_Observation) (templateId:2.16.840.1.113883.10.20.22.4.47) (CONF:15527).

Table 102: Problem Type

|  |  |  |
| --- | --- | --- |
| Value Set: Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 | | |
| Code | Code System | Print Name |
| 404684003 | SNOMED-CT | Finding |
| 409586006 | SNOMED-CT | Complaint |
| 282291009 | SNOMED-CT | Diagnosis |
| 64572001 | SNOMED-CT | Condition |
| 248536006 | SNOMED-CT | Finding of functional performance and activity |
| 418799008 | SNOMED-CT | Symptom |
| 55607006 | SNOMED-CT | Problem |
| 373930000 | SNOMED-CT | Cognitive function finding |

Family History of Cancer None

[Observation: templateId 2.16.840.1.113883.10.20.30.3.11 (open)]

Table 103: Family History of Cancer None Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Family History Section BCTPS](#Family_History_Section_BCTPS) (optional) |  |

This clinical statement asserts that the patient does not have a family history of cancer.

Table 104: Family History of Cancer None Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.11'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [26013](#C_26013) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [26014](#C_26014) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | @negationInd | 1..1 | SHALL |  | [26015](#C_26015) | true |
|  | templateId | 1..1 | SHALL |  | [26016](#C_26016) |  |
|  | @root | 1..1 | SHALL |  | [26017](#C_26017) | 2.16.840.1.113883.10.20.30.3.11 |
|  | code | 1..1 | SHALL |  | [26018](#C_26018) |  |
|  | @code | 1..1 | SHALL |  | [26019](#C_26019) | ASSERTION |
|  | @codeSystem | 1..1 | SHALL |  | [26020](#C_26020) | 2.16.840.1.113883.5.4 |
|  | text | 0..1 | SHOULD |  | [26021](#C_26021) | No family history of cancer |
|  | statusCode | 1..1 | SHALL |  | [26022](#C_26022) |  |
|  | @code | 1..1 | SHALL |  | [26023](#C_26023) | 2.16.840.1.113883.5.14 (ActStatus) = Completed |
|  | value | 1..1 | SHALL | CD | [26024](#C_26024) |  |
|  | @code | 1..1 | SHALL |  | [26025](#C_26025) | 275937001 |
|  | @codeSystem | 1..1 | SHALL |  | [26026](#C_26026) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |

1. SHALL contain exactly one [1..1] @classCode="OBS" observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:26013).
2. SHALL contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:26014).
3. SHALL contain exactly one [1..1] @negationInd="true" (CONF:26015).
4. SHALL contain exactly one [1..1] templateId (CONF:26016) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.11" (CONF:26017).
5. SHALL contain exactly one [1..1] code (CONF:26018).
   1. This code SHALL contain exactly one [1..1] @code="ASSERTION" Assertion (CONF:26019).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.5.4" (CONF:26020).
6. SHOULD contain zero or one [0..1] text="No family history of cancer" (CONF:26021).
7. SHALL contain exactly one [1..1] statusCode (CONF:26022).
   1. This statusCode SHALL contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:26023).
8. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:26024).
   1. This value SHALL contain exactly one [1..1] @code="275937001" family history of cancer (CONF:26025).
   2. This value SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:26026).

Figure 49: Family history of cancer none example

<entry>

<!-- MAY contain an assertion of no Family History of Cancer -->

<observation classCode="OBS" moodCode="EVN" negationInd="true">

<!-- Family History of Cancer - None -->

<templateId root="2.16.840.1.113883.10.20.30.3.11"/>

<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"

codeSystemName="HL7ActCode"/>

<text> No Family History of Cancer</text>

<statusCode code="completed"/>

<!-- SHALL single value binding -->

<value xsi:type="CD" code="275937001"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"

displayName="family history of cancer"/>

</observation>

</entry

Family History Organizer [Closed for comments; published July 2012]

[organizer: templateId 2.16.840.1.113883.10.20.22.4.45 (open)]

Table 105: Family History Organizer Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Family History Section](#S_Family_History_Section) (optional) | [Family History Observation](#E_Family_History_Observation) |

The Family History Organizer associates a set of observations with a family member. For example, the Family History Organizer can group a set of observations about the patient’s father.

Table 106: Family History Organizer Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
| Green Family History Organizer | organizer[templateId/@root = '2.16.840.1.113883.10.20.22.4.45'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [8600](#C_8600) | 2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER |
|  | @moodCode | 1..1 | SHALL |  | [8601](#C_8601) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [8604](#C_8604) |  |
|  | @root | 1..1 | SHALL |  | [10497](#C_10497) | 2.16.840.1.113883.10.20.22.4.45 |
|  | statusCode | 1..1 | SHALL |  | [8602](#C_8602) |  |
|  | @code | 1..1 | SHALL |  | [19099](#C_19099) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
| familyMemberDemographics | subject | 1..1 | SHALL |  | [8609](#C_8609) |  |
|  | relatedSubject | 1..1 | SHALL |  | [15244](#C_15244) |  |
|  | @classCode | 1..1 | SHALL |  | [15245](#C_15245) | 2.16.840.1.113883.5.41 (EntityClass) = PRS |
|  | code | 1..1 | SHALL |  | [15246](#C_15246) |  |
|  | @code | 1..1 | SHALL |  | [15247](#C_15247) | 2.16.840.1.113883.1.11.19579 (Family Member Value Set) |
|  | subject | 0..1 | SHOULD |  | [15248](#C_15248) |  |
|  | administrativeGenderCode | 1..1 | SHALL |  | [15974](#C_15974) |  |
|  | @code | 1..1 | SHALL |  | [15975](#C_15975) | 2.16.840.1.113883.1.11.1 (Administrative Gender (HL7 V3)) |
|  | birthTime | 0..1 | SHOULD |  | [15976](#C_15976) |  |
| familyMemberMedicalHistory | component | 1..\* | SHALL |  | [8607](#C_8607) |  |
|  | observation | 1..1 | SHALL |  | [16888](#C_16888) |  |

1. SHALL contain exactly one [1..1] @classCode="CLUSTER" Cluster (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8600).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:8601).
3. SHALL contain exactly one [1..1] templateId (CONF:8604) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.45" (CONF:10497).
4. SHALL contain exactly one [1..1] statusCode (CONF:8602).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19099).
5. SHALL contain exactly one [1..1] subject (CONF:8609).
   1. This subject SHALL contain exactly one [1..1] relatedSubject (CONF:15244).
      1. This relatedSubject SHALL contain exactly one [1..1] @classCode="PRS" Person (CodeSystem: EntityClass 2.16.840.1.113883.5.41 STATIC) (CONF:15245).
      2. This relatedSubject SHALL contain exactly one [1..1] code (CONF:15246).
         1. This code SHALL contain exactly one [1..1] @code, which SHOULD be selected from ValueSet Family Member Value Set 2.16.840.1.113883.1.11.19579 DYNAMIC (CONF:15247).
      3. This relatedSubject SHOULD contain zero or one [0..1] subject (CONF:15248).
         1. The subject, if present, SHALL contain exactly one [1..1] administrativeGenderCode (CONF:15974).
            1. This administrativeGenderCode SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 STATIC (CONF:15975).
         2. The subject, if present, SHOULD contain zero or one [0..1] birthTime (CONF:15976).
         3. The subject SHOULD contain zero or more [0..\*] sdtc:id. The prefix sdtc: SHALL be bound to the namespace “urn:hl7-org:sdtc”. The use of the namespace provides a necessary extension to CDA R2 for the use of the id element (CONF:15249).
         4. The subject MAY contain zero or one sdtc:deceasedInd. The prefix sdtc: SHALL be bound to the namespace “urn:hl7-org:sdtc”. The use of the namespace provides a necessary extension to CDA R2 for the use of the deceasedInd element (CONF:15981).
         5. The subject MAY contain zero or one sdtc:deceasedTime. The prefix sdtc: SHALL be bound to the namespace “urn:hl7-org:sdtc”. The use of the namespace provides a necessary extension to CDA R2 for the use of the deceasedTime element (CONF:15982).
         6. The age of a relative at the time of a family history observation SHOULD be inferred by comparing RelatedSubject/subject/birthTime with Observation/effectiveTime (CONF:15983).
6. SHALL contain at least one [1..\*] component (CONF:8607).
   1. Such components SHALL contain exactly one [1..1] [Family History Observation](#E_Family_History_Observation) (templateId:2.16.840.1.113883.10.20.22.4.46) (CONF:16888).

Figure 50: Family History Organizer - Hx of Cancer Example

<entry typeCode="DRIV">  
 <!-- mother -->  
 <organizer moodCode="EVN" classCode="CLUSTER">  
 <!--Consolidated CDA FAMILY HISTORY ORGANIZER TemplateID-->  
 <templateId root="2.16.840.1.113883.10.20.22.4.45"/>  
 <statusCode code="completed"/>   
 <!-- Example using HL7 Family Member Value Set. -->  
 <subject>   
 <relatedSubject classCode="PRS">  
 <code code="MTH" displayName="Mother"  
 codeSystemName="HL7 FamilyMember"  
 codeSystem="2.16.840.1.113883.5.111">  
 <translation code="9947008" displayName="Biological mother"  
 codeSystemName="SNOMED"  
 codeSystem="2.16.840.1.113883.6.96"/>  
 </code>  
 <subject>  
 <sdtc:id root="2.16.840.1.113883.19.5.99999.2"

extension="99999"/>  
 <id xmlns="urn:hl7-org:sdtc"

root="2.16.840.1.113883.19.5.99999.2" extension="1234"/>  
 <administrativeGenderCode code="F"  
 codeSystem="2.16.840.1.113883.5.1" displayName="Female"/>  
 <birthTime value="1930"/>   
 </subject>  
 </relatedSubject>  
 </subject>  
 <component>  
 <observation classCode="OBS" moodCode="EVN">  
 <!--Consolidated CDA FAMILY HISTORY OBSERVATION TemplateID-->  
 <templateId root="2.16.840.1.113883.10.20.22.4.46"/>  
 <id root="5bfe3ec0-5c8b-11db-b0de-0800200c9a66"/>  
 <code code="55607006" displayName="Problem"  
 codeSystemName="SNOMED CT"  
 codeSystem="2.16.840.1.113883.6.96"/>  
 <statusCode code="completed"/>  
 <effectiveTime value="1980"/>  
 <value xsi:type="CD" code="46635009"  
 codeSystem="2.16.840.1.113883.6.96" displayName="Left Breast

Cancer"/>  
 </observation>  
 </component>  
 </organizer>  
</entry>

Table 107: Family Member Value Set

|  |  |  |
| --- | --- | --- |
| Value Set: Family Member Value Set 2.16.840.1.113883.1.11.19579 | | |
| Code | Code System | Print Name |
| ADOPT | RoleCode | adopted child |
| AUNT | RoleCode | aunt |
| CHILD | RoleCode | Child |
| CHLDINLAW | RoleCode | child in-law |
| COUSN | RoleCode | cousin |
| DOMPART | RoleCode | domestic partner |
| FAMMEMB | RoleCode | Family Member |
| CHLDFOST | RoleCode | foster child |
| GRNDCHILD | RoleCode | grandchild |
| GRPRN | RoleCode | Grandparent |
| GPARNT | RoleCode | grandparent |
| GGRPRN | RoleCode | great grandparent |
| HSIB | RoleCode | half-sibling |
| MAUNT | RoleCode | MaternalAunt |
| MCOUSN | RoleCode | MaternalCousin |
| MGRPRN | RoleCode | MaternalGrandparent |
| MGGRPRN | RoleCode | MaternalGreatgrandparent |
| MUNCLE | RoleCode | MaternalUncle |
| NCHILD | RoleCode | natural child |
| NPRN | RoleCode | natural parent |
| NSIB | RoleCode | natural sibling |
| NIENEPH | RoleCode | niece/nephew |
| PRN | RoleCode | Parent |
| PRNINLAW | RoleCode | parent in-law |
| PAUNT | RoleCode | PaternalAunt |
| PCOUSN | RoleCode | PaternalCousin |
| PGRPRN | RoleCode | PaternalGrandparent |
| PGGRPRN | RoleCode | PaternalGreatgrandparent |
| PUNCLE | RoleCode | PaternalUncle |
| SIB | RoleCode | Sibling |
| SIBINLAW | RoleCode | sibling in-law |
| SIGOTHR | RoleCode | significant other |
| SPS | RoleCode | spouse |
| STEP | RoleCode | step child |
| STPPRN | RoleCode | step parent |
| STPSIB | RoleCode | step sibling |
| UNCLE | RoleCode | uncle |

Table 108: Administrative Gender (HL7 V3)

|  |  |  |
| --- | --- | --- |
| Value Set: Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 | | |
| Code | Code System | Print Name |
| F | AdministrativeGender | Female |
| M | AdministrativeGender | Male |
| UN | AdministrativeGender | Undifferentiated |

Family History Pedigree

[Act: templateId 2.16.840.1.113883.10.20.30.3.48 (open)]

Table 99: Family History Pedigree Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Family History Section BCTPS](#Family_History_Section_BCTPS) (required) |  |

This clinical statement contains the pedigree of the patient by pointing to the HL7 Pedigree Model as an external observation. If there is no pedigree available, a nullFlavor can be sent.

Table 100: Family History Pedigree Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Act[templateId/@root = '2.16.840.1.113883.10.20.30.3.48'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [26743](#C_26743) | 2.16.840.1.113883.5.6 (HL7ActClass) = ACT |
|  | @moodCode | 1..1 | SHALL |  | [26744](#C_26744) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [26745](#C_26745) |  |
|  | @root | 1..1 | SHALL |  | [26746](#C_26746) | 2.16.840.1.113883.10.20.30.3.48 |
|  | code | 1..1 | SHALL |  | [26747](#C_26747) |  |
|  | @code | 1..1 | SHALL |  | [26748](#C_26748) | 10157-6 |
|  | @codeSystem | 1..1 | SHALL |  | [26749](#C_26749) | 2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
|  | reference | 1..1 | SHALL |  | [26750](#C_26750) |  |
|  | @typeCode | 1..1 | SHALL |  | [26751](#C_26751) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | externalObservation | 1..1 | SHALL |  | [26752](#C_26752) |  |
|  | @classCode | 1..1 | SHALL |  | [26753](#C_26753) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [26754](#C_26754) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | id | 1..\* | SHALL |  | [26755](#C_26755) |  |
|  | text | 0..1 | SHOULD |  | [26756](#C_26756) |  |
|  | reference | 0..1 | SHOULD |  | [26757](#C_26757) |  |
|  | @value | 1..1 | SHALL |  | [26758](#C_26758) |  |

1. SHALL contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:26743).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:26744).
3. SHALL contain exactly one [1..1] templateId (CONF:26745) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.48" (CONF:26746).
4. SHALL contain exactly one [1..1] code (CONF:26747).
   1. This code SHALL contain exactly one [1..1] @code="10157-6" History of family member diseases  (CONF:26748).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:26749).
5. SHALL contain exactly one [1..1] reference (CONF:26750) such that it
   1. SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:26751).
   2. SHALL contain exactly one [1..1] externalObservation (CONF:26752).
      1. This externalObservation SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:26753).
      2. This externalObservation SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:26754).

The id attribute shall hold the id of a Pedigree instance.

* + 1. This externalObservation SHALL contain at least one [1..\*] id (CONF:26755).
    2. This externalObservation SHOULD contain zero or one [0..1] text (CONF:26756).
       1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:26757).
          1. The reference, if present, SHALL contain exactly one [1..1] @value (CONF:26758).

Figure 51: CDA Family History Pedigree

<act classCode="ACT" moodCode="EVN">  
 <!-- CDA FAMILY HISTORY PEDIGREE TemplateID -->  
 <templateId root="2.16.840.1.113883.10.20.30.3.48"/>  
 <code code="10157-6" displayName="History of family member diseases" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>  
 <reference typeCode="REFR">  
 <externalObservation classCode="OBS" moodCode="EVN">  
 <!-- Example id -->  
 <id root="2.16.840.1.113883.6.117" extension="299" assigningAuthorityName="Avon Center Appointment Number"/>  
 <text mediaType="text">FamilyPedigreeModel   
 <reference value="https://www.google.com/webhp?source=search\_app"/>  
 </text>  
 </externalObservation>  
 </reference>  
</act>

Health Status Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.5 (closed)]

Table 111: Health Status Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Problem Observation](#E_Problem_Observation) (optional) |  |

The Health Status Observation records information about the current health status of the patient.

Table 112: Health Status Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.5'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [9057](#C_9057) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [9072](#C_9072) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [16756](#C_16756) |  |
|  | @root | 1..1 | SHALL |  | [16757](#C_16757) | 2.16.840.1.113883.10.20.22.4.5 |
|  | code | 1..1 | SHALL |  | [19143](#C_19143) |  |
|  | @code | 1..1 | SHALL |  | [19144](#C_19144) | 2.16.840.1.113883.6.1 (LOINC) = 11323-3 |
|  | text | 0..1 | SHOULD |  | [9270](#C_9270) |  |
|  | reference | 0..1 | SHOULD |  | [15529](#C_15529) |  |
|  | @value | 0..1 | SHOULD |  | [15530](#C_15530) |  |
|  | statusCode | 1..1 | SHALL |  | [9074](#C_9074) |  |
|  | @code | 1..1 | SHALL |  | [19103](#C_19103) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | value | 1..1 | SHALL | CD | [9075](#C_9075) | 2.16.840.1.113883.1.11.20.12 (HealthStatus) |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:9057).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:9072).
3. SHALL contain exactly one [1..1] templateId (CONF:16756) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.5" (CONF:16757).
4. SHALL contain exactly one [1..1] code (CONF:19143).
   1. This code SHALL contain exactly one [1..1] @code="11323-3" Health status (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:19144).
5. SHOULD contain zero or one [0..1] text (CONF:9270).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:15529).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15530).
         1. SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15531).
6. SHALL contain exactly one [1..1] statusCode (CONF:9074).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19103).
7. SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHALL be selected from ValueSet HealthStatus 2.16.840.1.113883.1.11.20.12 DYNAMIC (CONF:9075).

Table 113: HealthStatus

|  |  |  |
| --- | --- | --- |
| Value Set: HealthStatus 2.16.840.1.113883.1.11.20.12 | | |
| Code | Code System | Print Name |
| 81323004 | SNOMED-CT | Alive and well |
| 313386006 | SNOMED-CT | In remission |
| 162467007 | SNOMED-CT | Symptom free |
| 161901003 | SNOMED-CT | Chronically ill |
| 271593001 | SNOMED-CT | Severely ill |
| 21134002 | SNOMED-CT | Disabled |
| 161045001 | SNOMED-CT | Severely disabled |
| 419099009 | SNOMED-CT | Deceased |

Highest Pressure Ulcer Stage[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.77 (open)]

Table 114: Highest Pressure Ulcer Stage Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Functional Status Section](#S_Functional_Status_Section) (optional) |  |

This observation contains a description of the wound tissue of the most severe or highest staged pressure ulcer observed on a patient.

Table 115: Highest Pressure Ulcer Stage Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.77'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [14726](#C_14726) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [14727](#C_14727) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [14728](#C_14728) |  |
|  | @root | 1..1 | SHALL |  | [14729](#C_14729) | 2.16.840.1.113883.10.20.22.4.77 |
|  | id | 1..\* | SHALL |  | [14730](#C_14730) |  |
|  | code | 1..1 | SHALL |  | [14731](#C_14731) |  |
|  | @code | 1..1 | SHALL |  | [14732](#C_14732) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 420905001 |
|  | value | 1..1 | SHALL |  | [14733](#C_14733) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:14726).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14727).
3. SHALL contain exactly one [1..1] templateId (CONF:14728) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.77" (CONF:14729).
4. SHALL contain at least one [1..\*] id (CONF:14730).
5. SHALL contain exactly one [1..1] code (CONF:14731).
   1. This code SHALL contain exactly one [1..1] @code="420905001" Highest Pressure Ulcer Stage (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:14732).
6. SHALL contain exactly one [1..1] value (CONF:14733).

Immunization Medication Information[Closed for comments; published July 2012]

[manufacturedProduct: templateId 2.16.840.1.113883.10.20.22.4.54 (open)]

Table 116: Immunization Medication Information Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Medication Supply Order](#E_Medication_Supply_Order) (optional)  [Medication Dispense](#E_Medication_Dispense) (optional) |  |

The Immunization Medication Information represents product information about the immunization substance. The vaccine manufacturer and vaccine lot number are typically recorded in the medical record and should be included if known.

Notes: reference: http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/D/vacc\_admin.pdf

Table 117: Immunization Medication Information Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
| Green Immunization Medication Information | manufacturedProduct[templateId/@root = '2.16.840.1.113883.10.20.22.4.54'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [9002](#C_9002) | 2.16.840.1.113883.5.110 (RoleClass) = MANU |
|  | templateId | 1..1 | SHALL |  | [9004](#C_9004) |  |
|  | @root | 1..1 | SHALL |  | [10499](#C_10499) | 2.16.840.1.113883.10.20.22.4.54 |
|  | id | 0..\* | MAY |  | [9005](#C_9005) |  |
|  | manufacturedMaterial | 1..1 | SHALL |  | [9006](#C_9006) |  |
| codedProductName | code | 1..1 | SHALL |  | [9007](#C_9007) | 2.16.840.1.113883.3.88.12.80.22 (Vaccine Administered Value Set) |
| freeTextProductName | originalText | 0..1 | SHOULD |  | [9008](#C_9008) |  |
|  | reference | 0..1 | SHOULD |  | [15555](#C_15555) |  |
|  | @value | 0..1 | SHOULD |  | [15556](#C_15556) |  |
|  | translation | 0..\* | MAY | SET<PQR> | [9011](#C_9011) |  |
| lotNumber | lotNumberText | 0..1 | SHOULD |  | [9014](#C_9014) |  |
| drugManufacturer | manufacturerOrganization | 0..1 | SHOULD |  | [9012](#C_9012) |  |

1. SHALL contain exactly one [1..1] @classCode="MANU" (CodeSystem: RoleClass 2.16.840.1.113883.5.110 STATIC) (CONF:9002).
2. SHALL contain exactly one [1..1] templateId (CONF:9004) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.54" (CONF:10499).
3. MAY contain zero or more [0..\*] id (CONF:9005).
4. SHALL contain exactly one [1..1] manufacturedMaterial (CONF:9006).
   1. This manufacturedMaterial SHALL contain exactly one [1..1] code, which SHALL be selected from ValueSet Vaccine Administered Value Set 2.16.840.1.113883.3.88.12.80.22 DYNAMIC (CONF:9007).
      1. This code SHOULD contain zero or one [0..1] originalText (CONF:9008).
         1. The originalText, if present, SHOULD contain zero or one [0..1] reference (CONF:15555).
            1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15556).

This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15557).

* + 1. This code MAY contain zero or more [0..\*] translation (CONF:9011).
       1. Translations can be used to represent generic product name, packaged product code, etc (CONF:16887).
  1. This manufacturedMaterial SHOULD contain zero or one [0..1] lotNumberText (CONF:9014).

1. SHOULD contain zero or one [0..1] manufacturerOrganization (CONF:9012).

Indication[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.19 (open)]

Table 118: Indication Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Medication Activity](#E_Medication_Activity) (optional)  [Procedure Activity Procedure](#E_Procedure_Activity_Procedure) (optional)  [Procedure Activity Act](#E_Procedure_Activity_Act) (optional)  [Procedure Activity Observation](#E_Procedure_Activity_Observation) (optional)  [Encounter Activities](#E_Encounter_Activities) (optional)  [Hospitalization for Toxicity](#Hospitalization_for_Toxicity) (required) |  |

The Indication Observation documents the rationale for an activity. It can do this with the id element to reference a problem recorded elsewhere in the document or with a code and value to record the problem type and problem within the Indication. For example, the indication for a prescription of a painkiller might be a headache that is documented in the Problems Section.

Table 119: Indication Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.19'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7480](#C_7480) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [7481](#C_7481) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [7482](#C_7482) |  |
|  | @root | 1..1 | SHALL |  | [10502](#C_10502) | 2.16.840.1.113883.10.20.22.4.19 |
|  | id | 1..1 | SHALL |  | [7483](#C_7483) |  |
|  | code | 1..1 | SHALL |  | [16886](#C_16886) | 2.16.840.1.113883.3.88.12.3221.7.2 (Problem Type) |
|  | statusCode | 1..1 | SHALL |  | [7487](#C_7487) |  |
|  | @code | 1..1 | SHALL |  | [19105](#C_19105) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 0..1 | SHOULD |  | [7488](#C_7488) |  |
|  | value | 0..1 | SHOULD | CD | [7489](#C_7489) |  |
|  | @nullFlavor | 0..1 | MAY |  | [15990](#C_15990) |  |
|  | @code | 0..1 | SHOULD |  | [15985](#C_15985) | 2.16.840.1.113883.3.88.12.3221.7.4 (Problem Value Set) |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7480).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7481).
3. SHALL contain exactly one [1..1] templateId (CONF:7482) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.19" (CONF:10502).
4. SHALL contain exactly one [1..1] id (CONF:7483).
   1. Set the observation/id equal to an ID on the problem list to signify that problem as an indication (CONF:16885).
5. SHALL contain exactly one [1..1] code, which SHOULD be selected from ValueSet Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 STATIC 2012-06-01 (CONF:16886).
6. SHALL contain exactly one [1..1] statusCode (CONF:7487).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19105).
7. SHOULD contain zero or one [0..1] effectiveTime (CONF:7488).
8. SHOULD contain zero or one [0..1] value with @xsi:type="CD" (CONF:7489).
   1. The value, if present, MAY contain zero or one [0..1] @nullFlavor (CONF:15990).
      1. If the diagnosis is unknown or the SNOMED code is unknown, @nullFlavor SHOULD be “UNK”. If the code is something other than SNOMED, @nullFlavor SHOULD be “OTH” and the other code SHOULD be placed in the translation element (CONF:15991).
   2. The value, if present, SHOULD contain zero or one [0..1] @code, which SHOULD be selected from ValueSet Problem Value Set 2.16.840.1.113883.3.88.12.3221.7.4 DYNAMIC (CONF:15985).

Table 120: Problem Type

|  |  |  |
| --- | --- | --- |
| Value Set: Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 | | |
| Code | Code System | Print Name |
| 404684003 | SNOMED-CT | Finding |
| 409586006 | SNOMED-CT | Complaint |
| 282291009 | SNOMED-CT | Diagnosis |
| 64572001 | SNOMED-CT | Condition |
| 248536006 | SNOMED-CT | Finding of functional performance and activity |
| 418799008 | SNOMED-CT | Symptom |
| 55607006 | SNOMED-CT | Problem |
| 373930000 | SNOMED-CT | Cognitive function finding |

Reasons for Radiation Therapy

[Observation: templateId 2.16.840.1.113883.10.20.30.3.46 (open)]

Table 121: Reasons for Radiation Therapy Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Radiation Therapy Care Completed](#Radiation_Therapy_Care_Completed) (optional) |  |

This clinical statement represents the reason for radiation therapy.

Notes: Design Note: Value Set for Reasons for Radiation Care 2.16.840.1.113883.11.20.11.10 is pending.

Table 122: Reasons for Radiation Therapy Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.46'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [26003](#C_26003) |  |
|  | @root | 1..1 | SHALL |  | [26004](#C_26004) | 2.16.840.1.113883.10.20.30.3.46 |
|  | id | 1..\* | SHALL |  | [26005](#C_26005) |  |
|  | code | 1..1 | SHALL |  | [26006](#C_26006) |  |
|  | @code | 1..1 | SHALL |  | [26007](#C_26007) | 2.16.840.1.113883.5.4 (ActCode) = ASSERTION |
|  | value | 1..1 | SHALL | CD | [26009](#C_26009) | 2.16.840.1.113883.11.20.11.10 ( Reasons for Radiation Therapy Care (temp)) |

1. Conforms to [Indication](#E_Indication) template (2.16.840.1.113883.10.20.22.4.19).
2. SHALL contain exactly one [1..1] templateId (CONF:26003) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.46" (CONF:26004).
3. SHALL contain at least one [1..\*] id (CONF:26005).
4. SHALL contain exactly one [1..1] code (CONF:26006).
   1. This code SHALL contain exactly one [1..1] @code="ASSERTION" Assertion (CodeSystem: ActCode 2.16.840.1.113883.5.4) (CONF:26007).
5. SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHALL be selected from ValueSet Reasons for Radiation Therapy Care (temp) 2.16.840.1.113883.11.20.11.10 (CONF:26009).

Table 123: Reasons for Radiation Therapy Care (temp)

|  |  |  |
| --- | --- | --- |
| Value Set: Reasons for Radiation Therapy Care (temp) 2.16.840.1.113883.11.20.11.10 | | |
| Code | Code System | Print Name |
| 373846009 | SNOMED-CT | adjuvant - intent |
| 103735009 | SNOMED-CT | palliative care |

Figure 52: Reasons for Radiation Therapy

<entryRelationship typeCode="RSON">

<observation classCode="OBS" moodCode="EVN">

<!--Consolidated CDA Indication TemplateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.19"/>

<!-- Reason for Radiation Therapy TemplateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.46"/>

<id root="569c8703-dace-488e-ab3f-ad62d62f765d"/>

<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"

codeSystemName="HL7ActCode"/>

<statusCode code="completed"/>

<effectiveTime value="20120809"/>

<value xsi:type="CD" codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="373846009"

displayName="adjuvant - intent "/>

</observation>

</entryRelationship>

Instructions[Closed for comments; published July 2012]

[act: templateId 2.16.840.1.113883.10.20.22.4.20 (open)]

Table 124: Instructions Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Medication Activity](#E_Medication_Activity) (optional)  [Medication Supply Order](#E_Medication_Supply_Order) (optional)  [Procedure Activity Procedure](#E_Procedure_Activity_Procedure) (optional)  [Plan of Care Section](#S_Plan_of_Care_Section) (optional)  [Procedure Activity Act](#E_Procedure_Activity_Act) (optional)  [Procedure Activity Observation](#E_Procedure_Activity_Observation) (optional) |  |

The Instructions template can be used in several ways, such as to record patient instructions within a Medication Activity or to record fill instructions within a supply order. The act/code defines the type of instruction. Though not defined in this template, a Vaccine Information Statement (VIS) document could be referenced through act/reference/externalDocument, and patient awareness of the instructions can be represented with the generic participant and the participant/awarenessCode.

Table 125: Instructions Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | act[templateId/@root = '2.16.840.1.113883.10.20.22.4.20'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7391](#C_7391) | 2.16.840.1.113883.5.6 (HL7ActClass) = ACT |
|  | @moodCode | 1..1 | SHALL |  | [7392](#C_7392) | 2.16.840.1.113883.5.1001 (ActMood) = INT |
|  | templateId | 1..1 | SHALL |  | [7393](#C_7393) |  |
|  | @root | 1..1 | SHALL |  | [10503](#C_10503) | 2.16.840.1.113883.10.20.22.4.20 |
|  | code | 1..1 | SHALL |  | [16884](#C_16884) | 2.16.840.1.113883.11.20.9.34 (Patient Education) |
|  | text | 0..1 | SHOULD |  | [7395](#C_7395) |  |
|  | reference | 0..1 | SHOULD |  | [15577](#C_15577) |  |
|  | @value | 0..1 | SHOULD |  | [15578](#C_15578) |  |
|  | statusCode | 1..1 | SHALL |  | [7396](#C_7396) |  |
|  | @code | 1..1 | SHALL |  | [19106](#C_19106) | 2.16.840.1.113883.5.14 (ActStatus) = completed |

1. SHALL contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7391).
2. SHALL contain exactly one [1..1] @moodCode="INT" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7392).
3. SHALL contain exactly one [1..1] templateId (CONF:7393) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.20" (CONF:10503).
4. SHALL contain exactly one [1..1] code, which SHOULD be selected from ValueSet Patient Education 2.16.840.1.113883.11.20.9.34 DYNAMIC (CONF:16884).
5. SHOULD contain zero or one [0..1] text (CONF:7395).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:15577).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15578).
         1. This @value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15579).
6. SHALL contain exactly one [1..1] statusCode (CONF:7396).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19106).

Table 126: Patient Education

|  |  |  |
| --- | --- | --- |
| Value Set: Patient Education 2.16.840.1.113883.11.20.9.34 | | |
| Code | Code System | Print Name |
| 311401005 | SNOMED-CT | Patient Education |
| 171044003 | SNOMED-CT | Immunization Education |
| 243072006 | SNOMED-CT | Cancer Education |

Possible Side Effects

[Act: templateId 2.16.840.1.113883.10.20.30.3.35 (open)]

Table 127: Possible Side Effects Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Chemotherapy Regimen](#E_Chemotherapy_Regimen) (optional)  [Chemotherapy Regimen Plans](#E_Chemotherapy_Regimen_Plans) (optional) |  |

This clinical statement represents the possible side effects of a chemotherapy treatment.

Table 128: Possible Side Effects Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Act[templateId/@root = '2.16.840.1.113883.10.20.30.3.35'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [24027](#C_24027) | 2.16.840.1.113883.5.6 (HL7ActClass) = ACT |
|  | @moodCode | 1..1 | SHALL |  | [24028](#C_24028) | 2.16.840.1.113883.5.1001 (ActMood) = INT |
|  | templateId | 1..1 | SHALL |  | [24029](#C_24029) |  |
|  | @root | 1..1 | SHALL |  | [24030](#C_24030) | 2.16.840.1.113883.10.20.30.3.35 |
|  | code | 1..1 | SHALL |  | [24031](#C_24031) |  |
|  | @code | 1..1 | SHALL |  | [24032](#C_24032) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 396080005 |
|  | entryRelationship | 1..1 | SHALL |  | [24033](#C_24033) |  |
|  | @typeCode | 1..1 | SHALL |  | [24034](#C_24034) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | observation | 1..1 | SHALL |  | [24035](#C_24035) |  |
|  | code | 1..1 | SHALL |  | [24036](#C_24036) |  |
|  | @code | 1..1 | SHALL |  | [24037](#C_24037) | 2.16.840.1.113883.5.4 (ActCode) = ASSERTION |
|  | statusCode | 1..1 | SHALL |  | [24038](#C_24038) |  |
|  | @code | 1..1 | SHALL |  | [24039](#C_24039) | 2.16.840.1.113883.5.14 (ActStatus) = Completed |
|  | value | 1..1 | SHALL | CD | [24040](#C_24040) | 2.16.840.1.113883.11.20.11.9 (Chemotherapy Side Effects) |

1. Conforms to [Instructions](#E_Instructions) template (2.16.840.1.113883.10.20.22.4.20).
2. SHALL contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:24027).
3. SHALL contain exactly one [1..1] @moodCode="INT" intent (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:24028).
4. SHALL contain exactly one [1..1] templateId (CONF:24029) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.35" (CONF:24030).
5. SHALL contain exactly one [1..1] code (CONF:24031).
   1. This code SHALL contain exactly one [1..1] @code="396080005" medication side effects education (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:24032).
6. SHALL contain exactly one [1..1] entryRelationship (CONF:24033).
   1. This entryRelationship SHALL contain exactly one [1..1] @typeCode="SUBJ" has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24034).
   2. This entryRelationship SHALL contain exactly one [1..1] observation (CONF:24035).
      1. This observation SHALL contain exactly one [1..1] code (CONF:24036).
         1. This code SHALL contain exactly one [1..1] @code="ASSERTION" Assertion (CodeSystem: ActCode 2.16.840.1.113883.5.4) (CONF:24037).
      2. This observation SHALL contain exactly one [1..1] statusCode (CONF:24038).
         1. This statusCode SHALL contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:24039).
      3. This observation SHALL contain exactly one [1..1] value with @xsi:type="CD" (ValueSet: Chemotherapy Side Effects 2.16.840.1.113883.11.20.11.9) (CONF:24040).

Table 129: Chemotherapy Side Effects

|  |  |  |
| --- | --- | --- |
| Value Set: Chemotherapy Side Effects 2.16.840.1.113883.11.20.11.9 | | |
| Code | Code System | Print Name |
| 278040002 | SNOMED-CT | loss of hair |
| 422587007 | SNOMED-CT | nausea |
| 386033004 | SNOMED-CT | neuropathy |
| 165423001 | SNOMED-CT | red blood cell count low |
| 84229001 | SNOMED-CT | fatigue |
| 170951000 | SNOMED-CT | menopause symptoms present |

Figure 53: Possible side effect example

<!-- Possible Side Effects 2.16.840.1.113883.10.20.30.3.35 -->

<entryRelationship typeCode="SUBJ">

<!-- Instructions template requires intent mood -->

<act classCode="ACT" moodCode="INT">

<!-- C-CDA Instructions Template -->

<templateId root="2.16.840.1.113883.10.20.22.4.20"/>

<!-- Possible Side Effects Template -->

<templateId root="2.16.840.1.113883.10.20.30.3.35"/>

<code code="396080005"

displayName="medication side effects education"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT"/>

<statusCode code="completed"/>

<!-- SHALL 1..\* entryRelationship (possible side effects) -->

<entryRelationship typeCode="SUBJ">

<!-- SHALL observation in definition mood -->

<observation classCode="OBS" moodCode="DEF">

<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>

<statusCode code="completed"/>

<!-- SHOULD bound to value set of common breast cancer regimen

side effects: e.g., alopecia (hair loss) -->

<!-- Chemotherapy Side Effects 2.16.840.1.113883.11.20.11.9 -->

<value xsi:type="CD" code="56317004"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED

CT"

displayName="alopecia"/>

</observation>

</entryRelationship>

</act>

</entryRelationship>

Last menstrual period

[Observation: templateId 2.16.840.1.113883.10.20.30.3.34 (open)]

Table 130: Last menstrual period Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Problem Section BCTPS](#S_Problem_Section_BCTPS) (required) |  |

This clinical statement represents the date of menstrual period of the patient. If known, the first day of last menstrual period should be captured. An effective time is required to determine if the menstrual period occured before or after treatment.

Notes: ALTERNATE DESIGN NOTE: The data element is described as "The first day of the last menstrual period" which could be captured with the snomed-CT code: 161713000 "last menstrual period -1st day". The concern with being this specific is that it would require that the date be captured out to the day (YYYYMMDD) which may not always be known by the patient.

Table 131: Last menstrual period Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.34'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [21960](#C_21960) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [21961](#C_21961) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [21962](#C_21962) |  |
|  | @root | 1..1 | SHALL |  | [21963](#C_21963) | 2.16.840.1.113883.10.20.30.3.34 |
|  | id | 1..\* | SHALL |  | [22066](#C_22066) |  |
|  | code | 1..1 | SHALL |  | [21964](#C_21964) |  |
|  | @code | 1..1 | SHALL |  | [21965](#C_21965) | 21840007 |
|  | @codeSystem | 1..1 | SHALL |  | [23237](#C_23237) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |
|  | statusCode | 1..1 | SHALL |  | [21966](#C_21966) |  |
|  | @code | 1..1 | SHALL |  | [21967](#C_21967) | Completed |
|  | effectiveTime | 1..1 | SHALL |  | [22065](#C_22065) |  |
|  | value | 1..1 | SHALL | TS | [21968](#C_21968) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:21960).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:21961).
3. SHALL contain exactly one [1..1] templateId (CONF:21962) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.34" (CONF:21963).
4. SHALL contain at least one [1..\*] id (CONF:22066).
5. SHALL contain exactly one [1..1] code (CONF:21964).
   1. This code SHALL contain exactly one [1..1] @code="21840007" Date of Last Menstrual Period (CONF:21965).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23237).
6. SHALL contain exactly one [1..1] statusCode (CONF:21966).
   1. This statusCode SHALL contain exactly one [1..1] @code="Completed" Completed (CONF:21967).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:22065).
8. SHALL contain exactly one [1..1] value with @xsi:type="TS" (CONF:21968).

Figure 54: Last menstrual period example

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.30.3.34"/>

<id root="11f83a4d-344e-4c62-ac97-4ef857616562"/>

<code code="21840007" codeSystem="2.16.840.1.113883.6.1"

displayName="Date of last menstrual period"/>

<statusCode code="completed"/>

<effectiveTime value="20121128"/>

<!-- SHALL xsi:type TS (do not restrict date specificity -->

<value xsi:type="TS" value="20121104"/>

</observation>

Medication Activity [Closed for comments; published July 2012]

[substanceAdministration: templateId 2.16.840.1.113883.10.20.22.4.16 (open)]

| Used By: | Contains Entries: |
| --- | --- |
| [Reaction Observation](#E_Reaction_Observation) (optional)  [Procedure Activity Procedure](#E_Procedure_Activity_Procedure) (optional)  [Medications Section (entries optional)](#S_Medications_Section_entries_optional) (optional)  [Procedure Activity Act](#E_Procedure_Activity_Act) (optional)  [Procedure Activity Observation](#E_Procedure_Activity_Observation) (optional) | [Drug Vehicle](#E_Drug_Vehicle)  [Indication](#E_Indication)  [Instructions](#E_Instructions)  [Medication Dispense](#E_Medication_Dispense)  [Medication Information](#E_Medication_Information)  [Medication Supply Order](#E_Medication_Supply_Order)  [Precondition for Substance Administration](#E_Precondition_for_Substance_Administrat)  [Reaction Observation](#E_Reaction_Observation) |

Table 132: Medication Activity Contexts

A medication activity describes substance administrations that have actually occurred (e.g. pills ingested or injections given) or are intended to occur (e.g. ""take 2 tablets twice a day for the next 10 days""). Medication activities in ""INT"" mood are reflections of what a clinician intends a patient to be taking. Medication activities in ""EVN"" mood reflect actual use.

Medication timing is complex. This template requires that there be a substanceAdministration/effectiveTime valued with a time interval, representing the start and stop dates. Additional effectiveTime elements are optional, and can be used to represent frequency and other aspects of more detailed dosing regimens.

Table 133: Medication Activity Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
| Green Medication Activity | substanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.22.4.16'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7496](#C_7496) | 2.16.840.1.113883.5.6 (HL7ActClass) = SBADM |
|  | @moodCode | 1..1 | SHALL |  | [7497](#C_7497) | 2.16.840.1.113883.11.20.9.18 (MoodCodeEvnInt) |
|  | templateId | 1..1 | SHALL |  | [7499](#C_7499) |  |
|  | @root | 1..1 | SHALL |  | [10504](#C_10504) | 2.16.840.1.113883.10.20.22.4.16 |
|  | id | 1..\* | SHALL |  | [7500](#C_7500) |  |
| deliveryMethod | code | 0..1 | MAY |  | [7506](#C_7506) |  |
| freeTextSig | text | 0..1 | SHOULD |  | [7501](#C_7501) |  |
|  | reference | 0..1 | SHOULD |  | [15977](#C_15977) |  |
|  | @value | 0..1 | SHOULD |  | [15978](#C_15978) |  |
|  | statusCode | 1..1 | SHALL |  | [7507](#C_7507) |  |
|  | effectiveTime | 1..1 | SHALL |  | [7508](#C_7508) |  |
| indicateMedicationStarted | low | 1..1 | SHALL |  | [7511](#C_7511) |  |
| indicateMedicationStopped | high | 1..1 | SHALL |  | [7512](#C_7512) |  |
| administrationTiming | effectiveTime | 0..1 | SHOULD |  | [7513](#C_7513) |  |
|  | @operator | 1..1 | SHALL |  | [9106](#C_9106) | A |
|  | repeatNumber | 0..1 | MAY |  | [7555](#C_7555) |  |
| route | routeCode | 0..1 | MAY |  | [7514](#C_7514) | 2.16.840.1.113883.3.88.12.3221.8.7 (Medication Route FDA Value Set) |
| site | approachSiteCode | 0..1 | MAY | SET<CD> | [7515](#C_7515) | 2.16.840.1.113883.3.88.12.3221.8.9 (Body Site Value Set) |
| dose | doseQuantity | 0..1 | SHOULD |  | [7516](#C_7516) |  |
|  | @unit | 0..1 | SHOULD |  | [7526](#C_7526) | 2.16.840.1.113883.1.11.12839 (UnitsOfMeasureCaseSensitive) |
|  | rateQuantity | 0..1 | MAY |  | [7517](#C_7517) |  |
|  | @unit | 1..1 | SHALL |  | [7525](#C_7525) | 2.16.840.1.113883.1.11.12839 (UnitsOfMeasureCaseSensitive) |
| doseRestriction | maxDoseQuantity | 0..1 | MAY | RTO<PQ, PQ> | [7518](#C_7518) |  |
| productForm | administrationUnitCode | 0..1 | MAY |  | [7519](#C_7519) | 2.16.840.1.113883.3.88.12.3221.8.11 (Medication Product Form Value Set) |
| medicationInformation | consumable | 1..1 | SHALL |  | [7520](#C_7520) |  |
|  | manufacturedProduct | 1..1 | SHALL |  | [16085](#C_16085) |  |
|  | performer | 0..1 | MAY |  | [7522](#C_7522) |  |
| vehicle | participant | 0..\* | MAY |  | [7523](#C_7523) |  |
|  | @typeCode | 1..1 | SHALL |  | [7524](#C_7524) | 2.16.840.1.113883.5.90 (HL7ParticipationType) = CSM |
|  | participantRole | 1..1 | SHALL |  | [16086](#C_16086) |  |
| indication | entryRelationship | 0..\* | MAY |  | [7536](#C_7536) |  |
|  | @typeCode | 1..1 | SHALL |  | [7537](#C_7537) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON |
|  | observation | 1..1 | SHALL |  | [16087](#C_16087) |  |
| patientInstructions | entryRelationship | 0..1 | MAY |  | [7539](#C_7539) |  |
|  | @typeCode | 1..1 | SHALL |  | [7540](#C_7540) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | @inversionInd | 1..1 | SHALL |  | [7542](#C_7542) | true |
|  | act | 1..1 | SHALL |  | [16088](#C_16088) |  |
| orderInformation | entryRelationship | 0..1 | MAY |  | [7543](#C_7543) |  |
|  | @typeCode | 1..1 | SHALL |  | [7547](#C_7547) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | supply | 1..1 | SHALL |  | [16089](#C_16089) |  |
| fulfillmentInstructions | entryRelationship | 0..\* | MAY |  | [7549](#C_7549) |  |
|  | @typeCode | 1..1 | SHALL |  | [7553](#C_7553) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | supply | 1..1 | SHALL |  | [16090](#C_16090) |  |
| reaction | entryRelationship | 0..1 | MAY |  | [7552](#C_7552) |  |
|  | @typeCode | 1..1 | SHALL |  | [7544](#C_7544) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = CAUS |
|  | observation | 1..1 | SHALL |  | [16091](#C_16091) |  |
|  | precondition | 0..\* | MAY |  | [7546](#C_7546) |  |
|  | @typeCode | 1..1 | SHALL |  | [7550](#C_7550) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = PRCN |
|  | criterion | 1..1 | SHALL |  | [16092](#C_16092) |  |

1. SHALL contain exactly one [1..1] @classCode="SBADM" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7496).
2. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 STATIC 2011-04-03 (CONF:7497).
3. SHALL contain exactly one [1..1] templateId (CONF:7499) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.16" (CONF:10504).
4. SHALL contain at least one [1..\*] id (CONF:7500).
5. MAY contain zero or one [0..1] code (CONF:7506).
6. SHOULD contain zero or one [0..1] text (CONF:7501).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:15977).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15978).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15979).
7. SHALL contain exactly one [1..1] statusCode (CONF:7507).
8. SHALL contain exactly one [1..1] effectiveTime (CONF:7508) such that it
   1. SHALL contain exactly one [1..1] low (CONF:7511).
   2. SHALL contain exactly one [1..1] high (CONF:7512).
9. SHOULD contain zero or one [0..1] effectiveTime (CONF:7513) such that it
   1. SHALL contain exactly one [1..1] @operator="A" (CONF:9106).
   2. SHALL contain exactly one [1..1] @xsi:type=”PIVL\_TS” or “EIVL\_TS” (CONF:9105).
10. MAY contain zero or one [0..1] repeatNumber (CONF:7555).
    1. In "INT" (intent) mood, the repeatNumber defines the number of allowed administrations. For example, a repeatNumber of "3" means that the substance can be administered up to 3 times. In "EVN" (event) mood, the repeatNumber is the number of occurrences. For example, a repeatNumber of "3" in a substance administration event means that the current administration is the 3rd in a series (CONF:16877).
11. MAY contain zero or one [0..1] routeCode, which SHALL be selected from ValueSet Medication Route FDA Value Set 2.16.840.1.113883.3.88.12.3221.8.7 DYNAMIC (CONF:7514).
12. MAY contain zero or one [0..1] approachSiteCode, where the @code SHALL be selected from ValueSet Body Site Value Set 2.16.840.1.113883.3.88.12.3221.8.9 DYNAMIC (CONF:7515).
13. SHOULD contain zero or one [0..1] doseQuantity (CONF:7516).
    1. The doseQuantity, if present, SHOULD contain zero or one [0..1] @unit, which SHALL be selected from ValueSet UnitsOfMeasureCaseSensitive 2.16.840.1.113883.1.11.12839 DYNAMIC (CONF:7526).
    2. Pre-coordinated consumable: If the consumable code is a pre-coordinated unit dose (e.g. "metoprolol 25mg tablet") then doseQuantity is a unitless number that indicates the number of products given per administration (e.g. "2", meaning 2 x "metoprolol 25mg tablet") (CONF:16878).
    3. Not pre-coordinated consumable: If the consumable code is not pre-coordinated (e.g. is simply "metoprolol"), then doseQuantity must represent a physical quantity with @unit, e.g. "25" and "mg", specifying the amount of product given per administration (CONF:16879).
14. MAY contain zero or one [0..1] rateQuantity (CONF:7517).
    1. The rateQuantity, if present, SHALL contain exactly one [1..1] @unit, which SHALL be selected from ValueSet UnitsOfMeasureCaseSensitive 2.16.840.1.113883.1.11.12839 DYNAMIC (CONF:7525).
15. MAY contain zero or one [0..1] maxDoseQuantity (CONF:7518).
16. MAY contain zero or one [0..1] administrationUnitCode, which SHALL be selected from ValueSet Medication Product Form Value Set 2.16.840.1.113883.3.88.12.3221.8.11 DYNAMIC (CONF:7519).
17. SHALL contain exactly one [1..1] consumable (CONF:7520).
    1. This consumable SHALL contain exactly one [1..1] [Medication Information](#E_Medication_Information) (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:16085).
18. MAY contain zero or one [0..1] performer (CONF:7522).
19. MAY contain zero or more [0..\*] participant (CONF:7523) such that it
    1. SHALL contain exactly one [1..1] @typeCode="CSM" (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 STATIC) (CONF:7524).
    2. SHALL contain exactly one [1..1] [Drug Vehicle](#E_Drug_Vehicle) (templateId:2.16.840.1.113883.10.20.22.4.24) (CONF:16086).
20. MAY contain zero or more [0..\*] entryRelationship (CONF:7536) such that it
    1. SHALL contain exactly one [1..1] @typeCode="RSON" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7537).
    2. SHALL contain exactly one [1..1] [Indication](#E_Indication) (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:16087).
21. MAY contain zero or one [0..1] entryRelationship (CONF:7539) such that it
    1. SHALL contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7540).
    2. SHALL contain exactly one [1..1] @inversionInd="true" True (CONF:7542).
    3. SHALL contain exactly one [1..1] [Instructions](#E_Instructions) (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:16088).
22. MAY contain zero or one [0..1] entryRelationship (CONF:7543) such that it
    1. SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7547).
    2. SHALL contain exactly one [1..1] [Medication Supply Order](#E_Medication_Supply_Order) (templateId:2.16.840.1.113883.10.20.22.4.17) (CONF:16089).
23. MAY contain zero or more [0..\*] entryRelationship (CONF:7549) such that it
    1. SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7553).
    2. SHALL contain exactly one [1..1] [Medication Dispense](#E_Medication_Dispense) (templateId:2.16.840.1.113883.10.20.22.4.18) (CONF:16090).
24. MAY contain zero or one [0..1] entryRelationship (CONF:7552) such that it
    1. SHALL contain exactly one [1..1] @typeCode="CAUS" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7544).
    2. SHALL contain exactly one [1..1] [Reaction Observation](#E_Reaction_Observation) (templateId:2.16.840.1.113883.10.20.22.4.9) (CONF:16091).
25. MAY contain zero or more [0..\*] precondition (CONF:7546) such that it
    1. SHALL contain exactly one [1..1] @typeCode="PRCN" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7550).
    2. SHALL contain exactly one [1..1] [Precondition for Substance Administration](#E_Precondition_for_Substance_Administrat) (templateId:2.16.840.1.113883.10.20.22.4.25) (CONF:16092).
26. Medication Activity SHOULD include doseQuantity OR rateQuantity (CONF:7529).

Table 134: MoodCodeEvnInt

|  |  |  |
| --- | --- | --- |
| Value Set: MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 | | |
| Code | Code System | Print Name |
| EVN | ActMood | Event |
| INT | ActMood | Intent |

Anthracycline Medication Activity

[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.30.3.24 (open)]

Table 135: Anthracycline Medication Activity Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Medications Section BCTPS](#S_Medications_Section_BCTPS) (optional) | [Anthracycline Medication Information](#Anthracycline_Medication_Information)  [Chemotherapy Dose Reduction](#Chemotherapy_Dose_Reduction) |

This clinical statement represents Anthracycline administered post the chemotherapy treatment.

Notes: @classCode SBADM is not exporting

Table 136: Anthracycline Medication Activity Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | SubstanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.30.3.24'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [23637](#C_23637) | 2.16.840.1.113883.5.6 (HL7ActClass) = SBADM |
|  | @moodCode | 1..1 | SHALL |  | [23638](#C_23638) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [23639](#C_23639) |  |
|  | @root | 1..1 | SHALL |  | [23640](#C_23640) | 2.16.840.1.113883.10.20.30.3.24 |
|  | statusCode | 1..1 | SHALL |  | [23641](#C_23641) |  |
|  | @code | 1..1 | SHALL |  | [23642](#C_23642) | 2.16.840.1.113883.5.14 (ActStatus) = Completed |
|  | routeCode | 1..1 | SHALL |  | [23643](#C_23643) |  |
|  | @code | 1..1 | SHALL |  | [23644](#C_23644) | 2.16.840.1.113883.3.88.12.3221.8.7 (Medication Route FDA Value Set) |
|  | doseQuantity | 1..1 | SHALL |  | [23645](#C_23645) |  |
|  | @unit | 1..1 | SHALL |  | [23646](#C_23646) | 2.16.840.1.113883.1.11.12839 (UnitsOfMeasureCaseSensitive) |
|  | consumable | 1..1 | SHALL |  | [23647](#C_23647) |  |
|  | entryRelationship | 0..1 | MAY |  | [23648](#C_23648) |  |
|  | @typeCode | 1..1 | SHALL |  | [23649](#C_23649) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | observation | 1..1 | SHALL |  | [23650](#C_23650) |  |

1. Conforms to [Medication Activity](#E_Medication_Activity) template (2.16.840.1.113883.10.20.22.4.16).
2. SHALL contain exactly one [1..1] @classCode="SBADM" SubstanceAdministration (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23637).
3. SHALL contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23638).
4. SHALL contain exactly one [1..1] templateId (CONF:23639) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.24" (CONF:23640).
5. SHALL contain exactly one [1..1] statusCode (CONF:23641).
   1. This statusCode SHALL contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23642).
6. SHALL contain exactly one [1..1] routeCode (CONF:23643).
   1. This routeCode SHALL contain exactly one [1..1] @code (ValueSet: Medication Route FDA Value Set 2.16.840.1.113883.3.88.12.3221.8.7 DYNAMIC) (CONF:23644).
7. SHALL contain exactly one [1..1] doseQuantity (CONF:23645).
   1. This doseQuantity SHALL contain exactly one [1..1] @unit (ValueSet: UnitsOfMeasureCaseSensitive 2.16.840.1.113883.1.11.12839 DYNAMIC) (CONF:23646).
8. SHALL contain exactly one [1..1] [Anthracycline Medication Information](#Anthracycline_Medication_Information) (templateId:2.16.840.1.113883.10.20.30.3.33) (CONF:23647).
9. MAY contain zero or one [0..1] entryRelationship (CONF:23648) such that it
   1. SHALL contain exactly one [1..1] @typeCode="REFR" refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:23649).
   2. SHALL contain exactly one [1..1] [Chemotherapy Dose Reduction](#Chemotherapy_Dose_Reduction) (templateId:2.16.840.1.113883.10.20.30.3.39) (CONF:23650).

Figure 55: Anthracycline medication activity example

<templateId root="2.16.840.1.113883.10.20.30.3.24"/>

<id root="39c22143-e9f2-42b7-b117-d1f0d454b0d9"/>

<!-- SHALL completed -->

<statusCode code="completed"/>

<!-- 3 weeks a cycle, 5 cycles, over 4 months. Started 2012/01/06, Stoped 2012/04/21-->

<effectiveTime xsi:type="IVL\_TS">

<low value="20120106"/>

<high value="20120421"/>

</effectiveTime>

<!-- Frequency of the chemotherapy. 3 weeks/cycle -->

<effectiveTime xsi:type="PIVL\_TS" operator="A">

<period value="21" unit="d"/>

</effectiveTime>

<!-- SHALL [1..1] route -->

<routeCode code="C38276" displayName="intravenous" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="National Cancer Institute (NCI) Thesaurus"/>

<!-- SHALL [1..1] dose -->

<!--UCUM code: mg/m2 MilliGramsPerSquareMeter-->

<doseQuantity value="50" unit="mg/m2"/>

<consumable>

<manufacturedProduct classCode="MANU">

<!-- Consolidated CDA Medication Information (manufacturedMaterial) -->

<templateId root="2.16.840.1.113883.10.20.22.4.23"/>

<!-- Anthracycline Medication Information (manufacturedMaterial) -->

<templateId root="2.16.840.1.113883.10.20.30.3.33"/>

<!-- SHALL binding to valueSet of Anthracycline drugs -->

<manufacturedMaterial>

<code codeSystem="2.16.840.1.113883.6.88"

codeSystemName="RxNorm" code="107037"

displayName="Doxorubicin 1 MG/ML Irrigation Solution">

<originalText>Doxorubicin 1 MG/ML Irrigation

Solution</originalText>

</code>

<!-- Brand Name -->

<name>Adriamycin</name>

</manufacturedMaterial>

</manufacturedProduct>

</consumable>

<!-- MAY [0..1] chemotherapy drug dose reduction template 2.16.840.1.113883.10.20.30.3.39-->

<entryRelationship typeCode="REFR">

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.30.3.39"/>

<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>

<statusCode code="completed"/>

<effectiveTime>

<low nullFlavor="NI"/>

</effectiveTime>

<value xsi:type="CD" code="445528004" displayName="treatment dose

changed"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>

...

Chemotherapy Medication Activity

[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.30.3.44 (open)]

Table 137: Chemotherapy Medication Activity Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Chemotherapy Regimen](#E_Chemotherapy_Regimen) (optional)  [Chemotherapy Regimen Plans](#E_Chemotherapy_Regimen_Plans) (optional) | [Chemotherapy Dose Reduction](#Chemotherapy_Dose_Reduction)  [Medication Information](#E_Medication_Information) |

This clinical statement represents details about the chemotherapeutic agent that is part of a chemotherapy regimen procedure. An effectiveTime of xsi:type of IVL\_TS with a low and high are required to represent the duration the agent covers. An effectiveTime of xsi:type PIVL\_TS with a period value is required to represent the dose. The ManufacturedMaterial code is drawn from Rx Norm. The ManufacturedMaterial/OriginalText states the generic name. The ManufacturedMaterial/name represents the brand name.

Notes: The question is whether we need to keep the Anthracycline specific template, which is constrained to Anthracycline drugs, or to simply use this generic template to capture all chemotherapy drugs.

Table 138: Chemotherapy Medication Activity Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | SubstanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.30.3.44'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [23845](#C_23845) | 2.16.840.1.113883.5.6 (HL7ActClass) = SBADM |
|  | @moodCode | 1..1 | SHALL |  | [23846](#C_23846) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [23847](#C_23847) |  |
|  | @root | 1..1 | SHALL |  | [23848](#C_23848) | 2.16.840.1.113883.10.20.30.3.44 |
|  | statusCode | 1..1 | SHALL |  | [23849](#C_23849) |  |
|  | @code | 1..1 | SHALL |  | [23850](#C_23850) | 2.16.840.1.113883.5.14 (ActStatus) = Completed |
|  | effectiveTime | 1..1 | SHALL | IVL\_TS | [26227](#C_26227) |  |
|  | low | 1..1 | SHALL |  | [26228](#C_26228) |  |
|  | high | 1..1 | SHALL |  | [26229](#C_26229) |  |
|  | effectiveTime | 1..1 | SHALL |  | [26240](#C_26240) |  |
|  | routeCode | 1..1 | SHALL |  | [23851](#C_23851) |  |
|  | @code | 1..1 | SHALL |  | [23852](#C_23852) | 2.16.840.1.113883.3.88.12.3221.8.7 (Medication Route FDA Value Set) |
|  | doseQuantity | 1..1 | SHALL |  | [23853](#C_23853) |  |
|  | @unit | 1..1 | SHALL |  | [23854](#C_23854) | 2.16.840.1.113883.1.11.12839 (UnitsOfMeasureCaseSensitive) = 1 |
|  | consumable | 1..1 | SHALL |  | [23855](#C_23855) |  |
|  | entryRelationship | 0..1 | MAY |  | [23856](#C_23856) |  |
|  | @typeCode | 1..1 | SHALL |  | [23857](#C_23857) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | observation | 1..1 | SHALL |  | [23858](#C_23858) |  |

1. Conforms to [Medication Activity](#E_Medication_Activity) template (2.16.840.1.113883.10.20.22.4.16).
2. SHALL contain exactly one [1..1] @classCode="SBADM" SubstanceAdministration (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23845).
3. SHALL contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23846).
4. SHALL contain exactly one [1..1] templateId (CONF:23847) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.44" (CONF:23848).
5. SHALL contain exactly one [1..1] statusCode (CONF:23849).
   1. This statusCode SHALL contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23850).

effectiveTime with data type of IVL\_TS is required to represent duration of chemotherapy, e.g., for 4 months.

1. SHALL contain exactly one [1..1] effectiveTime (CONF:26227) such that it
   1. SHALL contain exactly one [1..1] low (CONF:26228).
   2. SHALL contain exactly one [1..1] high (CONF:26229).
2. SHALL contain exactly one [1..1] effectiveTime (CONF:26240) such that it

effectiveTime of data type PIVL\_TS is required to represent dosing frequency of chemotherapy. The period attribute indicates how often the dose is given, e.g., chemotherapy administered every 3 weeks.

* 1. SHALL contain [1..1] @xsi:type=PIVL\_TS (CONF:26239) (CONF:26241).

1. SHALL contain exactly one [1..1] routeCode (CONF:23851).
   1. This routeCode SHALL contain exactly one [1..1] @code (ValueSet: Medication Route FDA Value Set 2.16.840.1.113883.3.88.12.3221.8.7 DYNAMIC) (CONF:23852).
2. SHALL contain exactly one [1..1] doseQuantity (CONF:23853).
   1. This doseQuantity SHALL contain exactly one [1..1] @unit="1" (ValueSet: UnitsOfMeasureCaseSensitive 2.16.840.1.113883.1.11.12839 DYNAMIC) (CONF:23854).
3. SHALL contain exactly one [1..1] [Medication Information](#E_Medication_Information) (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:23855).
4. MAY contain zero or one [0..1] entryRelationship (CONF:23856) such that it
   1. SHALL contain exactly one [1..1] @typeCode="REFR" refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:23857).
   2. SHALL contain exactly one [1..1] [Chemotherapy Dose Reduction](#Chemotherapy_Dose_Reduction) (templateId:2.16.840.1.113883.10.20.30.3.39) (CONF:23858).

Figure 56: Chemotherapy medication activity example

<templateId root="2.16.840.1.113883.10.20.30.3.44"/>

<id root="cd3c85ed-c3df-4e23-97c9-80c9fd084ba6"/>

<statusCode code="completed"/>

<!-- 3 weeks a cycle, 5 cycles, over 4 months. Started 2012/01/06, Stoped 2012/04/21-->

<effectiveTime xsi:type="IVL\_TS">

<low value="20120106"/>

<high value="20120421"/>

</effectiveTime>

<!-- Frequency of the chemotherapy. 3 weeks/cycle -->

<effectiveTime xsi:type="PIVL\_TS" operator="A">

<period value="21" unit="d"/>

</effectiveTime>

<routeCode code="C38276" displayName="intravenous" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="National Cancer Institute (NCI) Thesaurus"/>

<consumable>

<manufacturedProduct classCode="MANU">

<!-- Consolidated CDA Medication Information (manufacturedMaterial) -->

<templateId root="2.16.840.1.113883.10.20.22.4.23"/>

<manufacturedMaterial>

<code codeSystem="2.16.840.1.113883.6.88" codeSystemName="RXNorm"

code="414983" displayName="docetaxel 13.3 MG/ML Injectable

Solution">

<originalText>docetaxel 13.3 MG/ML Injectable

Solution</originalText>

</code>

<!-- Brand Name -->

<name>Taxotere</name>

</manufacturedMaterial>

</manufacturedProduct>

</consumable>

<!-- MAY [0..1] chemotherapy dose reduction template 2.16.840.1.113883.10.20.30.3.39-->

<entryRelationship typeCode="REFR">

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.30.3.39"/>

<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>

<statusCode code="completed"/>

<effectiveTime>

<low nullFlavor="NI"/>

</effectiveTime>

<value xsi:type="CD" code="445528004" displayName="treatment dose

changed"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>

<entryRelationship typeCode="RSON">

<observation classCode="OBS" moodCode="EVN">

<code code="373832009" displayName="reason for change in

planned chemotherapy treatment"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED

CT"></code>

<statusCode code="completed"/>

<effectiveTime>

<low nullFlavor="NI"/>

...

Endocrine Medication Activity

[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.30.3.23 (open)]

Table 139: Endocrine Medication Activity Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Medications Section BCTPS](#S_Medications_Section_BCTPS) (optional) | [Endocrine Medication Information](#E_Endocrine_Medication_Information) |

This clinical statement represents the medications used for endocrine therapy in cancer treatment.

Table 140: Endocrine Medication Activity Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | SubstanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.30.3.23'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [23776](#C_23776) | 2.16.840.1.113883.5.6 (HL7ActClass) = SBADM |
|  | @moodCode | 1..1 | SHALL |  | [23777](#C_23777) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [23778](#C_23778) |  |
|  | @root | 1..1 | SHALL |  | [23779](#C_23779) | 2.16.840.1.113883.10.20.30.3.23 |
|  | statusCode | 1..1 | SHALL |  | [23780](#C_23780) |  |
|  | @code | 1..1 | SHALL |  | [23781](#C_23781) | 2.16.840.1.113883.5.14 (ActStatus) = Completed |
|  | consumable | 1..1 | SHALL |  | [23794](#C_23794) |  |

1. Conforms to [Medication Activity](#E_Medication_Activity) template (2.16.840.1.113883.10.20.22.4.16).
2. SHALL contain exactly one [1..1] @classCode="SBADM" SubstanceAdministration (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23776).
3. SHALL contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23777).
4. SHALL contain exactly one [1..1] templateId (CONF:23778) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.23" (CONF:23779).
5. SHALL contain exactly one [1..1] statusCode (CONF:23780).
   1. This statusCode SHALL contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23781).
6. SHALL contain exactly one [1..1] [Endocrine Medication Information](#E_Endocrine_Medication_Information) (templateId:2.16.840.1.113883.10.20.30.3.22) (CONF:23794).

Figure 57: Endocrine medication activity example

<templateId root="2.16.840.1.113883.10.20.30.3.23"/>

<id root="68fa3c6c-24a7-4e64-be9c-a3a6619e065e"/>

<statusCode code="completed"/>

<!-- start date and a duration, e.g., start 2012/01/01, for 3 years. The end date is a future date. -->

<effectiveTime xsi:type="IVL\_TS">

<low value="20120101"/>

<high value="20121231"/>

</effectiveTime>

<consumable>

<manufacturedProduct classCode="MANU">

<!-- Consolidated CDA Medication Information (manufacturedMaterial) -->

<templateId root="2.16.840.1.113883.10.20.22.4.23"/>

<!-- Endocrine Medication Information (manufacturedMaterial)

2.16.840.1.113883.10.20.30.3.22 -->

<templateId root="2.16.840.1.113883.10.20.30.3.22"/>

<!-- Endocrine Drug Value Set 2.16.840.1.113883.11.20.11.7 -->

<manufacturedMaterial>

<code codeSystem="2.16.840.1.113883.6.88" codeSystemName="RXNorm"

code="313195" displayName="Tamoxifen 20 MG Oral Tablet">

<originalText>Tamoxifen 20 MG Oral Tablet</originalText>

</code>

</manufacturedMaterial>

</manufacturedProduct>

</consumable>

Trastuzumab Medication Activity

[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.30.3.40 (open)]

Table 141: Trastuzumab Medication Activity Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Medications Section BCTPS](#S_Medications_Section_BCTPS) (optional) | [Trastuzumab Medication Information](#E_Trastuzumab_Medication_Information) |

This clinical statement represents the Trastuzumab (Herceptin) administered during cancer treatment.

Table 142: Trastuzumab Medication Activity Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | SubstanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.30.3.40'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [23830](#C_23830) | 2.16.840.1.113883.5.6 (HL7ActClass) = SBADM |
|  | @moodCode | 1..1 | SHALL |  | [23831](#C_23831) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [23832](#C_23832) |  |
|  | @root | 1..1 | SHALL |  | [23833](#C_23833) | 2.16.840.1.113883.10.20.30.3.40 |
|  | statusCode | 1..1 | SHALL |  | [23834](#C_23834) |  |
|  | @code | 1..1 | SHALL |  | [23835](#C_23835) | 2.16.840.1.113883.5.14 (ActStatus) = Completed |
|  | consumable | 1..1 | SHALL |  | [23836](#C_23836) |  |

1. Conforms to [Medication Activity](#E_Medication_Activity) template (2.16.840.1.113883.10.20.22.4.16).
2. SHALL contain exactly one [1..1] @classCode="SBADM" SubstanceAdministration (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23830).
3. SHALL contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23831).
4. SHALL contain exactly one [1..1] templateId (CONF:23832) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.40" (CONF:23833).
5. SHALL contain exactly one [1..1] statusCode (CONF:23834).
   1. This statusCode SHALL contain exactly one [1..1] @code="Completed" Coompleted (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23835).
6. SHALL contain exactly one [1..1] [Trastuzumab Medication Information](#E_Trastuzumab_Medication_Information) (templateId:2.16.840.1.113883.10.20.30.3.41) (CONF:23836).

Figure 58: Trastuzumab medication activity example

<templateId root="2.16.840.1.113883.10.20.30.3.40"/>

<id root="059b73aa-97af-437f-8b31-9d47e2284395"/>

<statusCode code="completed"/>

<!-- once every 3 weeks over 4 months (roughly). Exact dates: Started 2012/01/06, Stoped 2012/04/21-->

<effectiveTime xsi:type="IVL\_TS">

<low value="20120106"/>

<high value="20120421"/>

</effectiveTime>

<!-- Frequency of the chemotherapy. 3 weeks/cycle -->

<effectiveTime xsi:type="PIVL\_TS" operator="A">

<period value="21" unit="d"/>

</effectiveTime>

<consumable>

<manufacturedProduct classCode="MANU">

<!-- Consolidated CDA Medication Information (manufacturedMaterial) -->

<templateId root="2.16.840.1.113883.10.20.22.4.23"/>

<!-- Trastuzumab (Herceptin) Medication Information 2.16.840.1.113883.10.20.30.3.41-->

<templateId root="2.16.840.1.113883.10.20.30.3.41"/>

<!-- SHOULD binding to valueSet of herceptin drugs -->

<!-- Trastuzumab drug Value Set 2.16.840.1.113883.11.20.11.8 -->

<manufacturedMaterial>

<code codeSystem="2.16.840.1.113883.6.88" codeSystemName="RXNorm"

code="806573" displayName="trastuzumab 22 MG/ML Injectable Solution">

<originalText>trastuzumab 22 MG/ML Injectable Solution</originalText>

</code>

</manufacturedMaterial>

</manufacturedProduct>

</consumable>

Medication Dispense [Closed for comments; published July 2012]

[supply: templateId 2.16.840.1.113883.10.20.22.4.18 (open)]

Table 143: Medication Dispense Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Medication Activity](#E_Medication_Activity) (optional) | [Immunization Medication Information](#E_Immunization_Medication_Information)  [Medication Information](#E_Medication_Information)  [Medication Supply Order](#E_Medication_Supply_Order) |

This template records the act of supplying medications (i.e., dispensing).

Table 144: Medication Dispense Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
| Green Medication Dispense | supply[templateId/@root = '2.16.840.1.113883.10.20.22.4.18'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7451](#C_7451) | 2.16.840.1.113883.5.6 (HL7ActClass) = SPLY |
|  | @moodCode | 1..1 | SHALL |  | [7452](#C_7452) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [7453](#C_7453) |  |
|  | @root | 1..1 | SHALL |  | [10505](#C_10505) | 2.16.840.1.113883.10.20.22.4.18 |
| prescriptionNumber | id | 1..\* | SHALL |  | [7454](#C_7454) |  |
|  | statusCode | 1..1 | SHALL |  | [7455](#C_7455) | 2.16.840.1.113883.3.88.12.80.64 (Medication Fill Status) |
| dispenseDate | effectiveTime | 0..1 | SHOULD |  | [7456](#C_7456) |  |
| fillNumber | repeatNumber | 0..1 | SHOULD |  | [7457](#C_7457) |  |
| quantityDispensed | quantity | 0..1 | SHOULD |  | [7458](#C_7458) |  |
|  | product | 0..1 | MAY |  | [7459](#C_7459) |  |
|  | manufacturedProduct | 1..1 | SHALL |  | [15607](#C_15607) |  |
|  | product | 0..1 | MAY |  | [9331](#C_9331) |  |
|  | manufacturedProduct | 1..1 | SHALL |  | [15608](#C_15608) |  |
|  | performer | 0..1 | MAY |  | [7461](#C_7461) |  |
| provider | assignedEntity | 1..1 | SHALL |  | [7467](#C_7467) |  |
|  | addr | 0..1 | SHOULD |  | [7468](#C_7468) |  |
| orderInformation | entryRelationship | 0..1 | MAY |  | [7473](#C_7473) |  |
|  | @typeCode | 1..1 | SHALL |  | [7474](#C_7474) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | supply | 1..1 | SHALL |  | [15606](#C_15606) |  |

1. SHALL contain exactly one [1..1] @classCode="SPLY" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7451).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7452).
3. SHALL contain exactly one [1..1] templateId (CONF:7453) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.18" (CONF:10505).
4. SHALL contain at least one [1..\*] id (CONF:7454).
5. SHALL contain exactly one [1..1] statusCode, which SHALL be selected from ValueSet Medication Fill Status 2.16.840.1.113883.3.88.12.80.64 DYNAMIC (CONF:7455).
6. SHOULD contain zero or one [0..1] effectiveTime (CONF:7456).
7. SHOULD contain zero or one [0..1] repeatNumber (CONF:7457).
   1. In "EVN" (event) mood, the repeatNumber is the number of occurrences. For example, a repeatNumber of "3" in a dispense act means that the current dispensation is the 3rd (CONF:16876).
8. SHOULD contain zero or one [0..1] quantity (CONF:7458).
9. MAY contain zero or one [0..1] product (CONF:7459) such that it
   1. SHALL contain exactly one [1..1] [Medication Information](#E_Medication_Information) (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:15607).
10. MAY contain zero or one [0..1] product (CONF:9331) such that it
    1. SHALL contain exactly one [1..1] [Immunization Medication Information](#E_Immunization_Medication_Information) (templateId:2.16.840.1.113883.10.20.22.4.54) (CONF:15608).
11. MAY contain zero or one [0..1] performer (CONF:7461).
    1. The performer, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:7467).
       1. This assignedEntity SHOULD contain zero or one [0..1] addr (CONF:7468).
          1. The content of addr SHALL be a conformant US Realm Address (AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10565).
12. MAY contain zero or one [0..1] entryRelationship (CONF:7473) such that it
    1. SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7474).
    2. SHALL contain exactly one [1..1] [Medication Supply Order](#E_Medication_Supply_Order) (templateId:2.16.840.1.113883.10.20.22.4.17) (CONF:15606).
13. A supply act SHALL contain one product/Medication Information or one product/Immunization Medication Information template (CONF:9333).

Table 145: Medication Fill Status

|  |  |  |
| --- | --- | --- |
| Value Set: Medication Fill Status 2.16.840.1.113883.3.88.12.80.64 | | |
| Code | Code System | Print Name |
| aborted | ActStatus | Aborted |
| completed | ActStatus | Completed |

Medication Information[Closed for comments; published July 2012]

[manufacturedProduct: templateId 2.16.840.1.113883.10.20.22.4.23 (open)]

Table 146: Medication Information Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Medication Activity](#E_Medication_Activity) (required)  [Medication Supply Order](#E_Medication_Supply_Order) (optional)  [Medication Dispense](#E_Medication_Dispense) (optional)  [Chemotherapy Medication Activity](#E_Chemotherapy_Medication_Activity) (required) |  |

The medication can be recorded as a pre-coordinated product strength, product form, or product concentration (e.g., ""metoprolol 25mg tablet"", ""amoxicillin 400mg/5mL suspension""); or not pre-coordinated (e.g., ""metoprolol product"").

Table 147: Medication Information Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
| Green Medication Information | manufacturedProduct[templateId/@root = '2.16.840.1.113883.10.20.22.4.23'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7408](#C_7408) | 2.16.840.1.113883.5.110 (RoleClass) = MANU |
|  | templateId | 1..1 | SHALL |  | [7409](#C_7409) |  |
|  | @root | 1..1 | SHALL |  | [10506](#C_10506) | 2.16.840.1.113883.10.20.22.4.23 |
|  | id | 0..\* | MAY |  | [7410](#C_7410) |  |
|  | manufacturedMaterial | 1..1 | SHALL |  | [7411](#C_7411) |  |
| codedProductName | code | 1..1 | SHALL |  | [7412](#C_7412) | 2.16.840.1.113883.3.88.12.80.17 (Medication Clinical Drug Name Value Set) |
| freeTextProductName | originalText | 0..1 | SHOULD |  | [7413](#C_7413) |  |
|  | reference | 0..1 | SHOULD |  | [15986](#C_15986) |  |
|  | @value | 0..1 | SHOULD |  | [15987](#C_15987) |  |
| codedBrandName | translation | 0..\* | MAY | SET<PQR> | [7414](#C_7414) |  |
| drugManufacturer | manufacturerOrganization | 0..1 | MAY |  | [7416](#C_7416) |  |

1. SHALL contain exactly one [1..1] @classCode="MANU" (CodeSystem: RoleClass 2.16.840.1.113883.5.110 STATIC) (CONF:7408).
2. SHALL contain exactly one [1..1] templateId (CONF:7409) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.23" (CONF:10506).
3. MAY contain zero or more [0..\*] id (CONF:7410).
4. SHALL contain exactly one [1..1] manufacturedMaterial (CONF:7411).
   1. This manufacturedMaterial SHALL contain exactly one [1..1] code, which SHALL be selected from ValueSet Medication Clinical Drug Name Value Set 2.16.840.1.113883.3.88.12.80.17 DYNAMIC (CONF:7412).
      1. This code SHOULD contain zero or one [0..1] originalText (CONF:7413).
         1. The originalText, if present, SHOULD contain zero or one [0..1] reference (CONF:15986).
            1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15987).

This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15988).

* + 1. This code MAY contain zero or more [0..\*] translation (CONF:7414).
       1. Translations can be used to represent generic product name, packaged product code, etc (CONF:16875).

1. MAY contain zero or one [0..1] manufacturerOrganization (CONF:7416).

Anthracycline Medication Information

[Consumable: templateId 2.16.840.1.113883.10.20.30.3.33 (open)]

Table 148: Anthracycline Medication Information Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Anthracycline Medication Activity](#Anthracycline_Medication_Activity) (required) |  |

This clinical statement represents the anthracycline medication such as doxorubicin and epirubicin for anticancer treatment.

Notes: Value set issue: the complete list of anthracycline drugs that will be contained in the "Anthracycline Medication Clinical Drug" value set needs to be defined and reviewed. (Some example codes are now contained in the value set).

Table 149: Anthracycline Medication Information Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Consumable[templateId/@root = '2.16.840.1.113883.10.20.30.3.33'] | | | | | |
|  | manufacturedProduct | 1..1 | SHALL |  | [23395](#C_23395) |  |
|  | templateId | 1..1 | SHALL |  | [23790](#C_23790) |  |
|  | @root | 1..1 | SHALL |  | [23791](#C_23791) | 2.16.840.1.113883.10.20.30.3.33 |
|  | manufacturedMaterial | 1..1 | SHALL |  | [23396](#C_23396) |  |
|  | code | 1..1 | SHALL |  | [23397](#C_23397) |  |
|  | @code | 1..1 | SHALL |  | [23398](#C_23398) | 2.16.840.1.113883.11.20.11.1 (Anthracycline Medication Clinical Drug) |

1. Conforms to [Medication Information](#E_Medication_Information) template (2.16.840.1.113883.10.20.22.4.23).
2. SHALL contain exactly one [1..1] manufacturedProduct (CONF:23395).
   1. This manufacturedProduct SHALL contain exactly one [1..1] templateId (CONF:23790) such that it
      1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.33" (CONF:23791).
   2. This manufacturedProduct SHALL contain exactly one [1..1] manufacturedMaterial (CONF:23396).
      1. This manufacturedMaterial SHALL contain exactly one [1..1] code (CONF:23397).
         1. This code SHALL contain exactly one [1..1] @code (ValueSet: Anthracycline Medication Clinical Drug 2.16.840.1.113883.11.20.11.1) (CONF:23398).

Table 150: Anthracycline Medication Clinical Drug

|  |  |  |
| --- | --- | --- |
| Value Set: Anthracycline Medication Clinical Drug 2.16.840.1.113883.11.20.11.1 | | |
| Code | Code System | Print Name |
| 242001 | RxNorm | Daunorubicin 2 MG/ML Injectable Solution |
| 309650 | RxNorm | Daunorubicin 5 MG/ML Injectable Solution |
| 646830 | RxNorm | Daunorubicin Liposomal 2 MG/ML Injectable Solution |
| 107036 | RxNorm | Doxorubicin 0.5 MG/ML Irrigation Solution |
| 107037 | RxNorm | Doxorubicin 1 MG/ML Irrigation Solution |
| 310025 | RxNorm | Doxorubicin 5 MG/ML Injectable Solution |
| 310024 | RxNorm | Doxorubicin 2 MG/ML Injectable Solution |
| 107040 | RxNorm | Epirubicin 0.6 MG/ML Irrigation Solution |
| 836382 | RxNorm | Epirubicin Hydrochloride 1 MG/ML Irrigation Solution |
| 836378 | RxNorm | Epirubicin Hydrochloride 2 MG/ML Injectable Solution |
| 849900 | RxNorm | Epirubicin Hydrochloride 10 MG/ML Injectable Solution |
| 836389 | RxNorm | Epirubicin Hydrochloride 2 MG/ML Irrigation Solution |
| 849902 | RxNorm | Epirubicin Hydrochloride 50 MG/ML Injectable Solution |

Figure 59: Anthracycline medication information example

<manufacturedProduct classCode="MANU">

<!-- Consolidated CDA Medication Information (manufacturedMaterial) -->

<templateId root="2.16.840.1.113883.10.20.22.4.23"/>

<!-- Anthracycline Medication Information (manufacturedMaterial) -->

<templateId root="2.16.840.1.113883.10.20.30.3.33"/>

<!-- SHALL binding to valueSet of Anthracycline drugs -->

<manufacturedMaterial>

<code codeSystem="2.16.840.1.113883.6.88"

codeSystemName="RxNorm" code="107037"

displayName="Doxorubicin 1 MG/ML Irrigation Solution">

<originalText>Doxorubicin 1 MG/ML Irrigation

Solution</originalText>

</code>

<!-- Brand Name -->

<name>Adriamycin</name>

</manufacturedMaterial>

</manufacturedProduct>

Endocrine Medication Information

[Consumable: templateId 2.16.840.1.113883.10.20.30.3.22 (open)]

Table 151: Endocrine Medication Information Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Endocrine Medication Activity](#Endocrine_Medication_Activity) (required) |  |

This clinical statement represents the information about endocrine drugs such as tamoxifen.

Notes: Value set issue: the complete list of codes that will be contained in the "Endocrine Drugs Value Set" need to be defined and reviewed.

Table 152: Endocrine Medication Information Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Consumable[templateId/@root = '2.16.840.1.113883.10.20.30.3.22'] | | | | | |
|  | manufacturedProduct | 1..1 | SHALL |  | [23782](#C_23782) |  |
|  | templateId | 1..1 | SHALL |  | [23783](#C_23783) |  |
|  | @root | 1..1 | SHALL |  | [23784](#C_23784) | 2.16.840.1.113883.10.20.30.3.22 |
|  | manufacturedMaterial | 1..1 | SHALL |  | [23785](#C_23785) |  |
|  | code | 1..1 | SHALL |  | [26244](#C_26244) | 2.16.840.1.113883.11.20.11.7 (Endocrine Drug) |

1. Conforms to [Medication Information](#E_Medication_Information) template (2.16.840.1.113883.10.20.22.4.23).
2. SHALL contain exactly one [1..1] manufacturedProduct (CONF:23782).
   1. This manufacturedProduct SHALL contain exactly one [1..1] templateId (CONF:23783) such that it
      1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.22" (CONF:23784).
   2. This manufacturedProduct SHALL contain exactly one [1..1] manufacturedMaterial (CONF:23785).
      1. This manufacturedMaterial SHALL contain exactly one [1..1] code, which SHALL be selected from ValueSet Endocrine Drug 2.16.840.1.113883.11.20.11.7 (CONF:26244).

Table 153: Endocrine Drug

|  |  |  |
| --- | --- | --- |
| Value Set: Endocrine Drug 2.16.840.1.113883.11.20.11.7 | | |
| Code | Code System | Print Name |
| 198240 | RxNorm | Nolvadex (tamoxifen) |
| 217010 | RxNorm | Evista (raloxifene) |
| 155082 | RxNorm | Fareston (toremifene) |

Figure 60: Endocrine medication information example

<manufacturedProduct classCode="MANU">

<!-- Consolidated CDA Medication Information (manufacturedMaterial) -->

<templateId root="2.16.840.1.113883.10.20.22.4.23"/>

<!-- Endocrine Medication Information (manufacturedMaterial)

2.16.840.1.113883.10.20.30.3.22 -->

<templateId root="2.16.840.1.113883.10.20.30.3.22"/>

<!-- Endocrine Drug Value Set 2.16.840.1.113883.11.20.11.7 -->

<manufacturedMaterial>

<code codeSystem="2.16.840.1.113883.6.88" codeSystemName="RXNorm"

code="313195" displayName="Tamoxifen 20 MG Oral Tablet">

<originalText>Tamoxifen 20 MG Oral Tablet</originalText>

</code>

</manufacturedMaterial>

</manufacturedProduct>

Trastuzumab Medication Information

[Consumable: templateId 2.16.840.1.113883.10.20.30.3.41 (open)]

Table 154: Trastuzumab Medication Information Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Trastuzumab Medication Activity](#Trastuzumab_Medication_Activity) (required) |  |

This clinical statement represents information about trastuzumab (Herceptin) used for cancer treatment.

Notes: Value set issue: need to define and review the complete list of codes for "Trastuzumab Drug" value set. (Currently only added RxNorm code "806573 trastuzumab 22 MG/ML Injectable Solution" as an example).

Table 155: Trastuzumab Medication Information Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Consumable[templateId/@root = '2.16.840.1.113883.10.20.30.3.41'] | | | | | |
|  | manufacturedProduct | 1..1 | SHALL |  | [23824](#C_23824) |  |
|  | templateId | 1..1 | SHALL |  | [23825](#C_23825) |  |
|  | @root | 1..1 | SHALL |  | [23826](#C_23826) | 2.16.840.1.113883.10.20.30.3.41 |
|  | manufacturedMaterial | 1..1 | SHALL |  | [23827](#C_23827) |  |
|  | code | 1..1 | SHALL |  | [23828](#C_23828) |  |
|  | @code | 1..1 | SHALL |  | [23829](#C_23829) | 2.16.840.1.113883.11.20.11.8 (Trastuzumab Drug) |

1. Conforms to [Medication Information](#E_Medication_Information) template (2.16.840.1.113883.10.20.22.4.23).
2. SHALL contain exactly one [1..1] manufacturedProduct (CONF:23824).
   1. This manufacturedProduct SHALL contain exactly one [1..1] templateId (CONF:23825) such that it
      1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.41" (CONF:23826).
   2. This manufacturedProduct SHALL contain exactly one [1..1] manufacturedMaterial (CONF:23827).
      1. This manufacturedMaterial SHALL contain exactly one [1..1] code (CONF:23828).
         1. This code SHALL contain exactly one [1..1] @code (ValueSet: Trastuzumab Drug 2.16.840.1.113883.11.20.11.8 DYNAMIC) (CONF:23829).

Table 156: Trastuzumab Drug

|  |  |  |
| --- | --- | --- |
| Value Set: Trastuzumab Drug 2.16.840.1.113883.11.20.11.8 | | |
| Code | Code System | Print Name |
| 806573 | RxNorm | trastuzumab 22 MG/ML Injectable Solution |

Figure 61: Trastuzumab medication information example

<manufacturedProduct classCode="MANU">

<!-- Consolidated CDA Medication Information (manufacturedMaterial) -->

<templateId root="2.16.840.1.113883.10.20.22.4.23"/>

<!-- Trastuzumab (Herceptin) Medication Information

2.16.840.1.113883.10.20.30.3.41-->

<templateId root="2.16.840.1.113883.10.20.30.3.41"/>

<!-- SHOULD binding to valueSet of herceptin drugs -->

<!-- Trastuzumab drug Value Set 2.16.840.1.113883.11.20.11.8 -->

<manufacturedMaterial>

<code codeSystem="2.16.840.1.113883.6.88" codeSystemName="RXNorm"

code="806573" displayName="trastuzumab 22 MG/ML Injectable

Solution">

<originalText>trastuzumab 22 MG/ML Injectable

Solution</originalText>

</code>

</manufacturedMaterial>

</manufacturedProduct>

Medication Supply Order [Closed for comments; published July 2012]

[supply: templateId 2.16.840.1.113883.10.20.22.4.17 (open)]

Table 157: Medication Supply Order Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Medication Activity](#E_Medication_Activity) (optional)  [Medication Dispense](#E_Medication_Dispense) (optional) | [Immunization Medication Information](#E_Immunization_Medication_Information)  [Instructions](#E_Instructions)  [Medication Information](#E_Medication_Information) |

This template records the intent to supply a patient with medications.

Table 158: Medication Supply Order Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | supply[templateId/@root = '2.16.840.1.113883.10.20.22.4.17'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7427](#C_7427) | 2.16.840.1.113883.5.6 (HL7ActClass) = SPLY |
|  | @moodCode | 1..1 | SHALL |  | [7428](#C_7428) | 2.16.840.1.113883.5.1001 (ActMood) = INT |
|  | templateId | 1..1 | SHALL |  | [7429](#C_7429) |  |
|  | @root | 1..1 | SHALL |  | [10507](#C_10507) | 2.16.840.1.113883.10.20.22.4.17 |
|  | id | 1..\* | SHALL |  | [7430](#C_7430) |  |
|  | statusCode | 1..1 | SHALL |  | [7432](#C_7432) |  |
|  | effectiveTime | 0..1 | SHOULD | IVL\_TS | [15143](#C_15143) |  |
|  | high | 1..1 | SHALL |  | [15144](#C_15144) |  |
|  | repeatNumber | 0..1 | SHOULD |  | [7434](#C_7434) |  |
|  | quantity | 0..1 | SHOULD |  | [7436](#C_7436) |  |
|  | product | 0..1 | MAY |  | [7439](#C_7439) |  |
|  | manufacturedProduct | 1..1 | SHALL |  | [16093](#C_16093) |  |
|  | product | 0..1 | MAY |  | [9334](#C_9334) |  |
|  | manufacturedProduct | 1..1 | SHALL |  | [16094](#C_16094) |  |
|  | author | 0..1 | MAY |  | [7438](#C_7438) |  |
|  | entryRelationship | 0..1 | MAY |  | [7442](#C_7442) |  |
|  | @typeCode | 1..1 | SHALL |  | [7444](#C_7444) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | @inversionInd | 1..1 | SHALL |  | [7445](#C_7445) | true |
|  | act | 1..1 | SHALL |  | [16095](#C_16095) |  |

1. SHALL contain exactly one [1..1] @classCode="SPLY" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7427).
2. SHALL contain exactly one [1..1] @moodCode="INT" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7428).
3. SHALL contain exactly one [1..1] templateId (CONF:7429) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.17" (CONF:10507).
4. SHALL contain at least one [1..\*] id (CONF:7430).
5. SHALL contain exactly one [1..1] statusCode (CONF:7432).
6. SHOULD contain zero or one [0..1] effectiveTime (CONF:15143) such that it
   1. SHALL contain exactly one [1..1] high (CONF:15144).
7. SHOULD contain zero or one [0..1] repeatNumber (CONF:7434).
   1. In "INT" (intent) mood, the repeatNumber defines the number of allowed fills. For example, a repeatNumber of "3" means that the substance can be supplied up to 3 times (or, can be dispensed, with 2 refills) (CONF:16869).
8. SHOULD contain zero or one [0..1] quantity (CONF:7436).
9. MAY contain zero or one [0..1] product (CONF:7439) such that it
   1. SHALL contain exactly one [1..1] [Medication Information](#E_Medication_Information) (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:16093).
10. MAY contain zero or one [0..1] product (CONF:9334) such that it
    1. SHALL contain exactly one [1..1] [Immunization Medication Information](#E_Immunization_Medication_Information) (templateId:2.16.840.1.113883.10.20.22.4.54) (CONF:16094).
       1. A supply act SHALL contain one product/Medication Information or one product/Immunization Medication Information template (CONF:16870).
11. MAY contain zero or one [0..1] author (CONF:7438).
12. MAY contain zero or one [0..1] entryRelationship (CONF:7442).
    1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7444).
    2. The entryRelationship, if present, SHALL contain exactly one [1..1] @inversionInd="true" True (CONF:7445).
    3. The entryRelationship, if present, SHALL contain exactly one [1..1] [Instructions](#E_Instructions) (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:16095).

Non-Medicinal Supply Activity [Closed for comments; published July 2012]

[supply: templateId 2.16.840.1.113883.10.20.22.4.50 (open)]

Table 159: Non-Medicinal Supply Activity Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Functional Status Section](#S_Functional_Status_Section) (optional)  [Functional Status Result Observation](#E_Functional_Status_Result_Observation) (optional)  [Cognitive Status Result Observation](#E_Cognitive_Status_Result_Observation) (optional)  [Functional Status Problem Observation](#E_Functional_Status_Problem_Observation) (optional)  [Cognitive Status Problem Observation](#E_Cognitive_Status_Problem_Observation) (optional) | [Product Instance](#E_Product_Instance) |

This template records non-medicinal supplies provided, such as medical equipment

Table 160: Non-Medicinal Supply Activity Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | supply[templateId/@root = '2.16.840.1.113883.10.20.22.4.50'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [8745](#C_8745) | 2.16.840.1.113883.5.6 (HL7ActClass) = SPLY |
|  | @moodCode | 1..1 | SHALL |  | [8746](#C_8746) | 2.16.840.1.113883.11.20.9.18 (MoodCodeEvnInt) |
|  | templateId | 1..1 | SHALL |  | [8747](#C_8747) |  |
|  | @root | 1..1 | SHALL |  | [10509](#C_10509) | 2.16.840.1.113883.10.20.22.4.50 |
|  | id | 1..\* | SHALL |  | [8748](#C_8748) |  |
|  | statusCode | 1..1 | SHALL |  | [8749](#C_8749) |  |
|  | effectiveTime | 0..1 | SHOULD | IVL\_TS | [15498](#C_15498) |  |
|  | quantity | 0..1 | SHOULD |  | [8751](#C_8751) |  |
|  | participant | 0..1 | MAY |  | [8752](#C_8752) |  |
|  | @typeCode | 1..1 | SHALL |  | [8754](#C_8754) | 2.16.840.1.113883.5.90 (HL7ParticipationType) = PRD |
|  | participantRole | 1..1 | SHALL |  | [15900](#C_15900) |  |

1. SHALL contain exactly one [1..1] @classCode="SPLY" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8745).
2. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 STATIC 2011-04-03 (CONF:8746).
3. SHALL contain exactly one [1..1] templateId (CONF:8747) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.50" (CONF:10509).
4. SHALL contain at least one [1..\*] id (CONF:8748).
5. SHALL contain exactly one [1..1] statusCode (CONF:8749).
6. SHOULD contain zero or one [0..1] effectiveTime (CONF:15498).
   1. The effectiveTime, if present, SHOULD contain zero or one [0..1] high (CONF:16867).
7. SHOULD contain zero or one [0..1] quantity (CONF:8751).
8. MAY contain zero or one [0..1] participant (CONF:8752) such that it
   1. SHALL contain exactly one [1..1] @typeCode="PRD" Product (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 STATIC) (CONF:8754).
   2. SHALL contain exactly one [1..1] [Product Instance](#E_Product_Instance) (templateId:2.16.840.1.113883.10.20.22.4.37) (CONF:15900).

Table 161: MoodCodeEvnInt

|  |  |  |
| --- | --- | --- |
| Value Set: MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 | | |
| Code | Code System | Print Name |
| EVN | ActMood | Event |
| INT | ActMood | Intent |

Number of Pressure Ulcers Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.76 (open)]

Table 162: Number of Pressure Ulcers Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Functional Status Section](#S_Functional_Status_Section) (optional) |  |

This clinical statement enumerates the number of pressure ulcers observed in a particular stage.

Table 163: Number of Pressure Ulcers Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.76'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [14705](#C_14705) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [14706](#C_14706) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [14707](#C_14707) |  |
|  | @root | 1..1 | SHALL |  | [14708](#C_14708) | 2.16.840.1.113883.10.20.22.4.76 |
|  | id | 1..\* | SHALL |  | [14709](#C_14709) |  |
|  | code | 1..1 | SHALL |  | [14767](#C_14767) |  |
|  | @code | 1..1 | SHALL |  | [14768](#C_14768) | 2264892003 |
|  | statusCode | 1..1 | SHALL |  | [14714](#C_14714) |  |
|  | @code | 1..1 | SHALL |  | [19108](#C_19108) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 1..1 | SHALL |  | [14715](#C_14715) |  |
|  | value | 1..1 | SHALL | INT | [14771](#C_14771) |  |
|  | author | 0..1 | MAY |  | [14717](#C_14717) |  |
|  | entryRelationship | 1..1 | SHALL |  | [14718](#C_14718) |  |
|  | @typeCode | 1..1 | SHALL |  | [14719](#C_14719) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | observation | 1..1 | SHALL |  | [14720](#C_14720) |  |
|  | @classCode | 1..1 | SHALL |  | [14721](#C_14721) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [14722](#C_14722) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | value | 1..1 | SHALL | CD | [14725](#C_14725) | 2.16.840.1.113883.11.20.9.35 (Pressure Ulcer Stage) |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:14705).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14706).
3. SHALL contain exactly one [1..1] templateId (CONF:14707) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.76" (CONF:14708).
4. SHALL contain at least one [1..\*] id (CONF:14709).
5. SHALL contain exactly one [1..1] code (CONF:14767).
   1. This code SHALL contain exactly one [1..1] @code="2264892003" number of pressure ulcers (CONF:14768).
6. SHALL contain exactly one [1..1] statusCode (CONF:14714).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19108).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:14715).
8. SHALL contain exactly one [1..1] value with @xsi:type="INT" (CONF:14771).
9. MAY contain zero or one [0..1] author (CONF:14717).
10. SHALL contain exactly one [1..1] entryRelationship (CONF:14718).
    1. This entryRelationship SHALL contain exactly one [1..1] @typeCode="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:14719).
    2. This entryRelationship SHALL contain exactly one [1..1] observation (CONF:14720).
       1. This observation SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:14721).
       2. This observation SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14722).
       3. This observation SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHOULD be selected from ValueSet Pressure Ulcer Stage 2.16.840.1.113883.11.20.9.35 STATIC (CONF:14725).

Table 164: Pressure Ulcer Stage

|  |  |  |
| --- | --- | --- |
| Value Set: Pressure Ulcer Stage 2.16.840.1.113883.11.20.9.35 | | |
| Code | Code System | Print Name |
| 421076008 | SNOMED-CT | Pressure Ulcer Stage 1 |
| 420324007 | SNOMED-CT | Pressure Ulcer Stage 2 |
| 421927004 | SNOMED-CT | Pressure Ulcer Stage 3 |
| 420597008 | SNOMED-CT | Pressure Ulcer Stage 4 |
| 421594008 | SNOMED-CT | Nonstageable pressure |

Overall Stage

[Act: templateId 2.16.840.1.113883.10.20.30.3.3 (open)]

Table 165: Overall Stage Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Breast Cancer Diagnosis Observation](#E_Breast_Cancer_Diagnosis_Observation) (required) | [TNM Metastasis Staging](#E_TNM_Metastasis_Staging)  [TNM Node Staging](#E_TNM_Node_Staging)  [TNM Tumor Staging](#E_TNM_Tumor_Staging_) |

This clinical statement represents the overall stage of the patient’s cancer and may contain Tumor, Node and Metastasis (TNM) stages.

Notes: Design Note: Need to determine a high level Value Set for Clinical stage (temp) (2.16.840.1.113883.11.20.11.12).

Table 166: Overall Stage Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Act[templateId/@root = '2.16.840.1.113883.10.20.30.3.3'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [22056](#C_22056) | 2.16.840.1.113883.5.6 (HL7ActClass) = ACT |
|  | @moodCode | 1..1 | SHALL |  | [22057](#C_22057) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [19292](#C_19292) |  |
|  | @root | 1..1 | SHALL |  | [19293](#C_19293) | 2.16.840.1.113883.10.20.30.3.3 |
|  | id | 1..\* | SHALL |  | [24929](#C_24929) |  |
|  | code | 1..1 | SHALL |  | [21897](#C_21897) |  |
|  | @code | 1..1 | SHALL |  | [21898](#C_21898) | 254326001 |
|  | @codeSystem | 1..1 | SHALL |  | [23351](#C_23351) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |
|  | effectiveTime | 1..1 | SHALL |  | [22077](#C_22077) |  |
|  | entryRelationship | 1..1 | SHALL |  | [21899](#C_21899) |  |
|  | @typeCode | 1..1 | SHALL |  | [21900](#C_21900) | COMP |
|  | observation | 1..1 | SHALL |  | [24907](#C_24907) |  |
|  | @classCode | 1..1 | SHALL |  | [24908](#C_24908) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [24909](#C_24909) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | code | 1..1 | SHALL |  | [24910](#C_24910) |  |
|  | @code | 1..1 | SHALL |  | [24911](#C_24911) | 385349001 |
|  | @codeSystem | 1..1 | SHALL |  | [24912](#C_24912) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |
|  | statusCode | 1..1 | SHALL |  | [24913](#C_24913) |  |
|  | @code | 1..1 | SHALL |  | [24914](#C_24914) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | value | 1..1 | SHALL | CD | [24915](#C_24915) |  |
|  | @code | 1..1 | SHALL |  | [24916](#C_24916) | 2.16.840.1.113883.11.20.11.12 (Overall Stage) |
|  | methodCode | 1..1 | SHALL |  | [24917](#C_24917) |  |
|  | @code | 1..1 | SHALL |  | [24918](#C_24918) | 443830009 |
|  | @codeSystem | 1..1 | SHALL |  | [24919](#C_24919) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |
|  | entryRelationship | 1..1 | SHALL |  | [26213](#C_26213) |  |
|  | @typeCode | 1..1 | SHALL |  | [26214](#C_26214) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | observation | 1..1 | SHALL |  | [26215](#C_26215) |  |
|  | entryRelationship | 1..1 | SHALL |  | [26216](#C_26216) |  |
|  | @typeCode | 1..1 | SHALL |  | [26217](#C_26217) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | observation | 1..1 | SHALL |  | [26218](#C_26218) |  |
|  | entryRelationship | 1..1 | SHALL |  | [26219](#C_26219) |  |
|  | @typeCode | 1..1 | SHALL |  | [26220](#C_26220) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | observation | 1..1 | SHALL |  | [26221](#C_26221) |  |

1. SHALL contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:22056).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:22057).
3. SHALL contain exactly one [1..1] templateId (CONF:19292) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.3" (CONF:19293).
4. SHALL contain at least one [1..\*] id (CONF:24929).
5. SHALL contain exactly one [1..1] code (CONF:21897).
   1. This code SHALL contain exactly one [1..1] @code="254326001" TNM Breast Cancer Staging (CONF:21898).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23351).
6. SHALL contain exactly one [1..1] effectiveTime (CONF:22077).
7. SHALL contain exactly one [1..1] entryRelationship (CONF:21899) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" Has Component (CONF:21900).
   2. SHALL contain exactly one [1..1] observation (CONF:24907).
      1. This observation SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:24908).
      2. This observation SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:24909).
      3. This observation SHALL contain exactly one [1..1] code (CONF:24910).
         1. This code SHALL contain exactly one [1..1] @code="385349001" Clinical Stage (CONF:24911).
         2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:24912).
      4. This observation SHALL contain exactly one [1..1] statusCode (CONF:24913).
         1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:24914).
      5. This observation SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:24915).
         1. This value SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet Overall Stage 2.16.840.1.113883.11.20.11.12 (CONF:24916).
      6. This observation SHALL contain exactly one [1..1] methodCode (CONF:24917).
         1. This methodCode SHALL contain exactly one [1..1] @code="443830009" American Joint Commission on Cancer,Cancer Staging Manual,7th edition neoplasm staging system (CONF:24918).
         2. This methodCode SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:24919).
      7. This observation SHALL contain exactly one [1..1] entryRelationship (CONF:26213) such that it
         1. SHALL contain exactly one [1..1] @typeCode="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:26214).
         2. SHALL contain exactly one [1..1] [TNM Tumor Staging](#E_TNM_Tumor_Staging_) (templateId:2.16.840.1.113883.10.20.30.3.5) (CONF:26215).
      8. This observation SHALL contain exactly one [1..1] entryRelationship (CONF:26216) such that it
         1. SHALL contain exactly one [1..1] @typeCode="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:26217).
         2. SHALL contain exactly one [1..1] [TNM Node Staging](#E_TNM_Node_Staging) (templateId:2.16.840.1.113883.10.20.30.3.7) (CONF:26218).
      9. This observation SHALL contain exactly one [1..1] entryRelationship (CONF:26219) such that it
         1. SHALL contain exactly one [1..1] @typeCode="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:26220).
         2. SHALL contain exactly one [1..1] [TNM Metastasis Staging](#E_TNM_Metastasis_Staging) (templateId:2.16.840.1.113883.10.20.30.3.8) (CONF:26221).

Table 167: Overall Stage

|  |  |  |
| --- | --- | --- |
| Value Set: Overall Stage 2.16.840.1.113883.11.20.11.12 | | |
| Code | Code System | Print Name |
| 13104003 | SNOMED-CT | clinical stage I |
| 46333007 | SNOMED-CT | clinical stage I |
| 786005 | SNOMED-CT | clinical stage I |
| 15542003 | SNOMED-CT | clinical stage I |
| 35440002 | SNOMED-CT | clinical stage I |
| 56380009 | SNOMED-CT | clinical stage I |
| 17691001 | SNOMED-CT | clinical stage I |
| 60333009 | SNOMED-CT | clinical stage II |
| 52774001 | SNOMED-CT | clinical stage II |
| 17816005 | SNOMED-CT | clinical stage II |
| 39617003 | SNOMED-CT | clinical stage II |
| 112240001 | SNOMED-CT | clinical stage II |
| 69605008 | SNOMED-CT | clinical stage II |
| 90321006 | SNOMED-CT | clinical stage II |
| 50283003 | SNOMED-CT | clinical stage III |
| 73082003 | SNOMED-CT | clinical stage III |
| 64062008 | SNOMED-CT | clinical stage III |
| 48105005 | SNOMED-CT | clinical stage III |
| 55336000 | SNOMED-CT | clinical stage III |
| 33907000 | SNOMED-CT | clinical stage III |
| 64877001 | SNOMED-CT | clinical stage III |
| 2640006 | SNOMED-CT | clinical stage IV |
| 71725004 | SNOMED-CT | clinical stage IV |
| 1523005 | SNOMED-CT | clinical stage IV |
| 33177002 | SNOMED-CT | clinical stage IV |
| 52865009 | SNOMED-CT | clinical stage IV |
| 64202001 | SNOMED-CT | clinical stage IV |
| 70664003 | SNOMED-CT | clinical stage IV |

Figure 62: Overall stage example

<templateId root="2.16.840.1.113883.10.20.30.3.3"/>

<code codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="254326001"

displayName="TNM Breast Cancer Staging"/>

<effectiveTime value="20121212"/>

<!-- This entryRelationship provides details as to the clinical stage-->

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<code codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="385349001"

displayName="clinical stage"/>

<statusCode code="completed"/>

<!-- SHALL be bound to a value set of limited high level

category codes -->

<value xsi:type="CD"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="13104003"

displayName="clinical stage I"/>

<!-- SHALL method code -->

<methodCode code="443830009"

displayName="American Joint Commission on Cancer,

Cancer Staging Manual,

7th edition neoplasm staging system"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT"/>

<!-- TNM TUMOR(T) STAGING-->

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<!-- TNM - Tumor (T) STAGING templateID-->

<templateId root="2.16.840.1.113883.10.20.30.3.5"/>

<code codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="371508000"

displayName="Tumor stage"/>

<statusCode code="completed"/>

...

<!-- TNM Node(N) STAGING -->

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<!-- TNM - Node (N) STAGING TemplateID-->

<templateId root="2.16.840.1.113883.10.20.30.3.7"/>

<code codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="371494008"

displayName="stage of regional lymph node involvement

by tumor"/>

...

<!-- TNM METASTASIS(M) STAGING -->

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<!-- TNM - Metastasis (M) STAGING TemplateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.8"/>

<code codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="277208005"

displayName="M - Metastasis stages"/>

...

Plan of Care Activity Act [Closed for comments; published July 2012]

[act: templateId 2.16.840.1.113883.10.20.22.4.39 (open)]

Table 168: Plan of Care Activity Act Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Plan of Care Section](#S_Plan_of_Care_Section) (optional) |  |

This is the generic template for the Plan of Care Activity.

Table 169: Plan of Care Activity Act Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | act[templateId/@root = '2.16.840.1.113883.10.20.22.4.39'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [8538](#C_8538) | 2.16.840.1.113883.5.6 (HL7ActClass) = ACT |
|  | @moodCode | 1..1 | SHALL |  | [8539](#C_8539) | 2.16.840.1.113883.11.20.9.23 (Plan of Care moodCode (Act/Encounter/Procedure)) |
|  | templateId | 1..1 | SHALL |  | [8544](#C_8544) |  |
|  | @root | 1..1 | SHALL |  | [10510](#C_10510) | 2.16.840.1.113883.10.20.22.4.39 |
|  | id | 1..\* | SHALL |  | [8546](#C_8546) |  |

1. SHALL contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8538).
2. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30 (CONF:8539).
3. SHALL contain exactly one [1..1] templateId (CONF:8544) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.39" (CONF:10510).
4. SHALL contain at least one [1..\*] id (CONF:8546).

Table 170: Plan of Care moodCode (Act/Encounter/Procedure)

|  |  |  |
| --- | --- | --- |
| Value Set: Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 | | |
| Code | Code System | Print Name |
| INT | ActMood | Intent |
| ARQ | ActMood | Appointment Request |
| PRMS | ActMood | Promise |
| PRP | ActMood | Proposal |
| RQO | ActMood | Request |

Plan of Care Radiation Activity

[act: templateId 2.16.840.1.113883.10.20.30.3.32 (open)]

Table 171: Plan of Care Radiation Activity Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Plan of Care Section BCTPS](#S_Plan_of_Care_Section_BCTPS) (optional) |  |

This clinical statement represents a planned radiation therapy.

Table 172: Plan of Care Radiation Activity Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | act[templateId/@root = '2.16.840.1.113883.10.20.30.3.32'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [23537](#C_23537) | 2.16.840.1.113883.5.6 (HL7ActClass) = ACT |
|  | @moodCode | 1..1 | SHALL |  | [23538](#C_23538) | 2.16.840.1.113883.11.20.9.23 (Plan of Care moodCode (Act/Encounter/Procedure)) |
|  | templateId | 1..1 | SHALL |  | [23539](#C_23539) |  |
|  | @root | 1..1 | SHALL |  | [23540](#C_23540) | 2.16.840.1.113883.10.20.30.3.32 |
|  | id | 1..\* | SHALL |  | [23541](#C_23541) |  |
|  | code | 1..1 | SHALL |  | [23542](#C_23542) |  |
|  | @code | 1..1 | SHALL |  | [23543](#C_23543) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 385798007 |
|  | effectiveTime | 1..1 | SHALL |  | [23544](#C_23544) |  |

1. Conforms to [Plan of Care Activity Act](#E_Plan_of_Care_Activity_Act) template (2.16.840.1.113883.10.20.22.4.39).
2. SHALL contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:23537).
3. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30 (CONF:23538).
4. SHALL contain exactly one [1..1] templateId (CONF:23539) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.32" (CONF:23540).
5. SHALL contain at least one [1..\*] id (CONF:23541).
6. SHALL contain exactly one [1..1] code (CONF:23542).
   1. This code SHALL contain exactly one [1..1] @code="385798007" radiation therapy care (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23543).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:23544).

Table 173: Plan of Care moodCode (Act/Encounter/Procedure)

|  |  |  |
| --- | --- | --- |
| Value Set: Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 | | |
| Code | Code System | Print Name |
| INT | ActMood | Intent |
| ARQ | ActMood | Appointment Request |
| PRMS | ActMood | Promise |
| PRP | ActMood | Proposal |
| RQO | ActMood | Request |

Figure 63: Plan of care radiation activity example

<templateId root="2.16.840.1.113883.10.20.30.3.32"/>

<!-- \*\*\*\* Plan of Care Activity Act template \*\*\*\* -->

<id root="ab3365e3-97b1-4461-8a60-290d9228ea26"/>

<code code="385798007" codeSystem="2.16.840.1.113883.6.96"

displayName="radiation therapy care"/>

<statusCode code="new"/>

<effectiveTime value="20130113"/>

Plan of Care Activity Encounter [Closed for comments; published July 2012]

[encounter: templateId 2.16.840.1.113883.10.20.22.4.40 (open)]

Table 174: Plan of Care Activity Encounter Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Plan of Care Section](#S_Plan_of_Care_Section) (optional) |  |

This is the template for the Plan of Care Activity Encounter.

Table 175: Plan of Care Activity Encounter Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | encounter[templateId/@root = '2.16.840.1.113883.10.20.22.4.40'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [8564](#C_8564) | 2.16.840.1.113883.5.6 (HL7ActClass) = ENC |
|  | @moodCode | 1..1 | SHALL |  | [8565](#C_8565) | 2.16.840.1.113883.11.20.9.23 (Plan of Care moodCode (Act/Encounter/Procedure)) |
|  | templateId | 1..1 | SHALL |  | [8566](#C_8566) |  |
|  | @root | 1..1 | SHALL |  | [10511](#C_10511) | 2.16.840.1.113883.10.20.22.4.40 |
|  | id | 1..\* | SHALL |  | [8567](#C_8567) |  |

1. SHALL contain exactly one [1..1] @classCode="ENC" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8564).
2. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30 (CONF:8565).
3. SHALL contain exactly one [1..1] templateId (CONF:8566) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.40" (CONF:10511).
4. SHALL contain at least one [1..\*] id (CONF:8567).

Table 176: Plan of Care moodCode (Act/Encounter/Procedure)

|  |  |  |
| --- | --- | --- |
| Value Set: Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 | | |
| Code | Code System | Print Name |
| INT | ActMood | Intent |
| ARQ | ActMood | Appointment Request |
| PRMS | ActMood | Promise |
| PRP | ActMood | Proposal |
| RQO | ActMood | Request |

Plan of Care Activity Observation[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.44 (open)]

Table 177: Plan of Care Activity Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Plan of Care Section](#S_Plan_of_Care_Section) (optional) |  |

This is the template for the Plan of Care Activity Observation.

Table 178: Plan of Care Activity Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.44'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [8581](#C_8581) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [8582](#C_8582) | 2.16.840.1.113883.11.20.9.25 (Plan of Care moodCode (Observation)) |
|  | templateId | 1..1 | SHALL |  | [8583](#C_8583) |  |
|  | @root | 1..1 | SHALL |  | [10512](#C_10512) | 2.16.840.1.113883.10.20.22.4.44 |
|  | id | 1..\* | SHALL |  | [8584](#C_8584) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8581).
2. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet Plan of Care moodCode (Observation) 2.16.840.1.113883.11.20.9.25 STATIC 2011-09-30 (CONF:8582).
3. SHALL contain exactly one [1..1] templateId (CONF:8583) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.44" (CONF:10512).
4. SHALL contain at least one [1..\*] id (CONF:8584).

Table 179: Plan of Care moodCode (Observation)

|  |  |  |
| --- | --- | --- |
| Value Set: Plan of Care moodCode (Observation) 2.16.840.1.113883.11.20.9.25 | | |
| Code | Code System | Print Name |
| INT | ActMood | Intent |
| GOL | ActMood | Goal |
| PRMS | ActMood | Promise |
| PRP | ActMood | Proposal |
| RQO | ActMood | Request |

Plan of Care Activity Procedure[Closed for comments; published July 2012]

[procedure: templateId 2.16.840.1.113883.10.20.22.4.41 (open)]

Table 180: Plan of Care Activity Procedure Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Plan of Care Section](#S_Plan_of_Care_Section) (optional) |  |

This is the template for the Plan of Care Activity Procedure.

Table 181: Plan of Care Activity Procedure Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | procedure[templateId/@root = '2.16.840.1.113883.10.20.22.4.41'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [8568](#C_8568) | 2.16.840.1.113883.5.6 (HL7ActClass) = PROC |
|  | @moodCode | 1..1 | SHALL |  | [8569](#C_8569) | 2.16.840.1.113883.11.20.9.23 (Plan of Care moodCode (Act/Encounter/Procedure)) |
|  | templateId | 1..1 | SHALL |  | [8570](#C_8570) |  |
|  | @root | 1..1 | SHALL |  | [10513](#C_10513) | 2.16.840.1.113883.10.20.22.4.41 |
|  | id | 1..\* | SHALL |  | [8571](#C_8571) |  |

1. SHALL contain exactly one [1..1] @classCode="PROC" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8568).
2. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30 (CONF:8569).
3. SHALL contain exactly one [1..1] templateId (CONF:8570) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.41" (CONF:10513).
4. SHALL contain at least one [1..\*] id (CONF:8571).

Table 182: Plan of Care moodCode (Act/Encounter/Procedure)

|  |  |  |
| --- | --- | --- |
| Value Set: Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 | | |
| Code | Code System | Print Name |
| INT | ActMood | Intent |
| ARQ | ActMood | Appointment Request |
| PRMS | ActMood | Promise |
| PRP | ActMood | Proposal |
| RQO | ActMood | Request |

Plan of Care Activity Reconstruction Procedure

[procedure: templateId 2.16.840.1.113883.10.20.30.3.31 (open)]

Table 183: Plan of Care Activity Reconstruction Procedure Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Plan of Care Section BCTPS](#S_Plan_of_Care_Section_BCTPS) (optional) |  |

This clinical statement represents a planned breast reconstruction procedure.

Table 184: Plan of Care Activity Reconstruction Procedure Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | procedure[templateId/@root = '2.16.840.1.113883.10.20.30.3.31'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [24079](#C_24079) | 2.16.840.1.113883.5.6 (HL7ActClass) = PROC |
|  | @moodCode | 1..1 | SHALL |  | [24080](#C_24080) | 2.16.840.1.113883.11.20.9.23 (Plan of Care moodCode (Act/Encounter/Procedure)) |
|  | templateId | 1..1 | SHALL |  | [24081](#C_24081) |  |
|  | @root | 1..1 | SHALL |  | [24082](#C_24082) | 2.16.840.1.113883.10.20.30.3.31 |
|  | id | 1..\* | SHALL |  | [24083](#C_24083) |  |
|  | code | 1..1 | SHALL |  | [24084](#C_24084) | 2.16.840.1.113883.10.20.30.4.2 (Breast Cancer Procedures (Temp)) |
|  | effectiveTime | 1..1 | SHALL |  | [24086](#C_24086) |  |

1. Conforms to [Plan of Care Activity Procedure](#E_Plan_of_Care_Activity_Procedure) template (2.16.840.1.113883.10.20.22.4.41).
2. SHALL contain exactly one [1..1] @classCode="PROC" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:24079).
3. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30 (CONF:24080).
4. SHALL contain exactly one [1..1] templateId (CONF:24081) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.31" (CONF:24082).
5. SHALL contain at least one [1..\*] id (CONF:24083).
6. SHALL contain exactly one [1..1] code, which SHALL be selected from ValueSet Breast Cancer Procedures (Temp) 2.16.840.1.113883.10.20.30.4.2 (CONF:24084).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:24086).

Table 185: Plan of Care moodCode (Act/Encounter/Procedure)

|  |  |  |
| --- | --- | --- |
| Value Set: Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 | | |
| Code | Code System | Print Name |
| INT | ActMood | Intent |
| ARQ | ActMood | Appointment Request |
| PRMS | ActMood | Promise |
| PRP | ActMood | Proposal |
| RQO | ActMood | Request |

Figure 64: Plan of care activity reconstruction procedure example

<templateId root="2.16.840.1.113883.10.20.30.3.31"/>

<id root="2e606db3-66dc-4abe-8771-5cee29739935"/>

<code code="33496007" codeSystem="2.16.840.1.113883.6.96"

displayName="Reconstruction of breast"/>

<statusCode code="new"/>

<effectiveTime value="20130105"/>

Plan of Care Activity Substance Administration[Closed for comments; published July 2012]

[substanceAdministration: templateId 2.16.840.1.113883.10.20.22.4.42 (open)]

Table 186: Plan of Care Activity Substance Administration Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Plan of Care Section](#S_Plan_of_Care_Section) (optional) |  |

This is the template for the Plan of Care Activity Substance Administration

Table 187: Plan of Care Activity Substance Administration Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | substanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.22.4.42'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [8572](#C_8572) | 2.16.840.1.113883.5.6 (HL7ActClass) = SBADM |
|  | @moodCode | 1..1 | SHALL |  | [8573](#C_8573) | 2.16.840.1.113883.11.20.9.24 (Plan of Care moodCode (SubstanceAdministration/Supply)) |
|  | templateId | 1..1 | SHALL |  | [8574](#C_8574) |  |
|  | @root | 1..1 | SHALL |  | [10514](#C_10514) | 2.16.840.1.113883.10.20.22.4.42 |
|  | id | 1..\* | SHALL |  | [8575](#C_8575) |  |

1. SHALL contain exactly one [1..1] @classCode="SBADM" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8572).
2. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet Plan of Care moodCode (SubstanceAdministration/Supply) 2.16.840.1.113883.11.20.9.24 STATIC 2011-09-30 (CONF:8573).
3. SHALL contain exactly one [1..1] templateId (CONF:8574) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.42" (CONF:10514).
4. SHALL contain at least one [1..\*] id (CONF:8575).

Table 188: Plan of Care moodCode (SubstanceAdministration/Supply)

|  |  |  |
| --- | --- | --- |
| Value Set: Plan of Care moodCode (SubstanceAdministration/Supply) 2.16.840.1.113883.11.20.9.24 | | |
| Code | Code System | Print Name |
| INT | ActMood | Intent |
| PRMS | ActMood | Promise |
| PRP | ActMood | Proposal |
| RQO | ActMood | Request |

Plan of Care Activity Supply [Closed for comments; published July 2012]

[supply: templateId 2.16.840.1.113883.10.20.22.4.43 (open)]

Table 189: Plan of Care Activity Supply Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Plan of Care Section](#S_Plan_of_Care_Section) (optional) |  |

This is the template for the Plan of Care Activity Supply.

Table 190: Plan of Care Activity Supply Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | supply[templateId/@root = '2.16.840.1.113883.10.20.22.4.43'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [8577](#C_8577) | 2.16.840.1.113883.5.6 (HL7ActClass) = SPLY |
|  | @moodCode | 1..1 | SHALL |  | [8578](#C_8578) | 2.16.840.1.113883.11.20.9.24 (Plan of Care moodCode (SubstanceAdministration/Supply)) |
|  | templateId | 1..1 | SHALL |  | [8579](#C_8579) |  |
|  | @root | 1..1 | SHALL |  | [10515](#C_10515) | 2.16.840.1.113883.10.20.22.4.43 |
|  | id | 1..\* | SHALL |  | [8580](#C_8580) |  |

1. SHALL contain exactly one [1..1] @classCode="SPLY" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8577).
2. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet Plan of Care moodCode (SubstanceAdministration/Supply) 2.16.840.1.113883.11.20.9.24 STATIC 2011-09-30 (CONF:8578).
3. SHALL contain exactly one [1..1] templateId (CONF:8579) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.43" (CONF:10515).
4. SHALL contain at least one [1..\*] id (CONF:8580).

Table 191: Plan of Care moodCode (SubstanceAdministration/Supply)

|  |  |  |
| --- | --- | --- |
| Value Set: Plan of Care moodCode (SubstanceAdministration/Supply) 2.16.840.1.113883.11.20.9.24 | | |
| Code | Code System | Print Name |
| INT | ActMood | Intent |
| PRMS | ActMood | Promise |
| PRP | ActMood | Proposal |
| RQO | ActMood | Request |

Post Treatment Disease Status

[Observation: templateId 2.16.840.1.113883.10.20.30.3.29 (open)]

Table 192: Post Treatment Disease Status Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Breast Cancer Diagnosis Observation](#E_Breast_Cancer_Diagnosis_Observation) (required) |  |

This clinical statement represents the disease status of the patient after treatment.

Notes: Design Note: values for "Post Treatment Disease Status 2.16.840.1.113883.10.20.30.4.1" TBD.

Table 193: Post Treatment Disease Status Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.29'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [21934](#C_21934) | 2.16.840.1.113883.5.6 (HL7ActClass) |
|  | @moodCode | 1..1 | SHALL |  | [21935](#C_21935) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [21932](#C_21932) |  |
|  | @root | 1..1 | SHALL |  | [21933](#C_21933) | 2.16.840.1.113883.10.20.30.3.29 |
|  | id | 1..\* | SHALL |  | [21936](#C_21936) |  |
|  | code | 1..1 | SHALL |  | [21937](#C_21937) |  |
|  | @code | 1..1 | SHALL |  | [21938](#C_21938) | 128926000 |
|  | @codeSystem | 1..1 | SHALL |  | [23339](#C_23339) | 2.16.840.1.113883.6.96 (SNOMED-CT) |
|  | statusCode | 1..1 | SHALL |  | [21939](#C_21939) |  |
|  | @code | 1..1 | SHALL |  | [21940](#C_21940) | 2.16.840.1.113883.5.14 (ActStatus) = Completed |
|  | effectiveTime | 1..1 | SHALL |  | [21941](#C_21941) |  |
|  | value | 1..1 | SHALL | CD | [21942](#C_21942) |  |
|  | @code | 1..1 | SHALL |  | [22629](#C_22629) | 2.16.840.1.113883.10.20.30.4.1 (Disease Status Post Treatment) |

1. SHALL contain exactly one [1..1] @classCode (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:21934).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:21935).
3. SHALL contain exactly one [1..1] templateId (CONF:21932) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.29" (CONF:21933).
4. SHALL contain at least one [1..\*] id (CONF:21936).
5. SHALL contain exactly one [1..1] code (CONF:21937).
   1. This code SHALL contain exactly one [1..1] @code="405178006" Postprocedural recovery status (CONF:21938).
   2. This code SHALL contain exactly one [1..1] @codeSystem (CodeSystem:SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23339).
6. SHALL contain exactly one [1..1] statusCode (CONF:21939).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:21940).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:21941).
8. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:21942).
   1. This value SHALL contain exactly one [1..1] @code (ValueSet: Disease Status Post Treatment 2.16.840.1.113883.10.20.30.4.1) (CONF:22629).

Figure 65: Post treatment disease status example

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<!-- Post Treatement Disease Status TemplateID-->

<templateId root="2.16.840.1.113883.10.20.30.3.29"/>

<id nullFlavor="NI"/>

<code code="405178006"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT"

displayName="Postprocedural recovery status"/>

<statusCode code="completed"/>

<!-- SHALL -->

<effectiveTime value="20120304"/>

<!-- SHALL be bound to a dynamic value set of onco disease states -->

<value xsi:type="CD" code="58184002"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="recurrent disease"/>

</observation>

</entryRelationship>

Precondition for Substance Administration[Closed for comments; published July 2012]

[criterion: templateId 2.16.840.1.113883.10.20.22.4.25 (open)]

Table 194: Precondition for Substance Administration Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Medication Activity](#E_Medication_Activity) (optional) |  |

A criterion for administration can be used to record that the medication is to be administered only when the associated criteria are met.

Table 195: Precondition for Substance Administration Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | criterion[templateId/@root = '2.16.840.1.113883.10.20.22.4.25'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [7372](#C_7372) |  |
|  | @root | 1..1 | SHALL |  | [10517](#C_10517) | 2.16.840.1.113883.10.20.22.4.25 |
|  | code | 0..1 | SHOULD |  | [16854](#C_16854) |  |
|  | text | 0..1 | MAY |  | [7373](#C_7373) |  |
|  | value | 0..1 | SHOULD | CD | [7369](#C_7369) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:7372) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.25" (CONF:10517).
2. SHOULD contain zero or one [0..1] code (CONF:16854).
3. MAY contain zero or one [0..1] text (CONF:7373).
4. SHOULD contain zero or one [0..1] value with @xsi:type="CD" (CONF:7369).

Pressure Ulcer Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.70 (open)]

Table 196: Pressure Ulcer Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Functional Status Section](#S_Functional_Status_Section) (optional) |  |

The pressure ulcer observation contains details about the pressure ulcer such as the stage of the ulcer, location, and dimensions. If the pressure ulcer is a diagnosis, you may find this on the problem list. An example of how this would appear is in the Problem Section.

Table 197: Pressure Ulcer Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.70'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [14383](#C_14383) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [14384](#C_14384) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | @negationInd | 0..1 | MAY |  | [14385](#C_14385) |  |
|  | templateId | 1..1 | SHALL |  | [14387](#C_14387) |  |
|  | @root | 1..1 | SHALL |  | [14388](#C_14388) | 2.16.840.1.113883.10.20.22.4.70 |
|  | id | 1..\* | SHALL |  | [14389](#C_14389) |  |
|  | code | 1..1 | SHALL |  | [14759](#C_14759) |  |
|  | @code | 1..1 | SHALL |  | [14760](#C_14760) | 2.16.840.1.113883.5.4 (ActCode) = ASSERTION |
|  | text | 0..1 | SHOULD |  | [14391](#C_14391) |  |
|  | reference | 0..1 | SHOULD |  | [14392](#C_14392) |  |
|  | @value | 1..1 | SHALL |  | [15585](#C_15585) |  |
|  | statusCode | 1..1 | SHALL |  | [14394](#C_14394) |  |
|  | @code | 1..1 | SHALL |  | [19111](#C_19111) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 1..1 | SHALL |  | [14395](#C_14395) |  |
|  | value | 1..1 | SHALL | CD | [14396](#C_14396) | 2.16.840.1.113883.11.20.9.35 (Pressure Ulcer Stage) |
|  | @nullFlavor | 0..1 | MAY |  | [14397](#C_14397) |  |
|  | targetSiteCode | 0..\* | SHOULD |  | [14797](#C_14797) |  |
|  | @code | 1..1 | SHALL |  | [14798](#C_14798) | 2.16.840.1.113883.11.20.9.36 (Pressure Point ) |
|  | qualifier | 0..1 | SHOULD |  | [14799](#C_14799) |  |
|  | name | 1..1 | SHALL |  | [14800](#C_14800) |  |
|  | @code | 0..1 | SHOULD |  | [14801](#C_14801) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 272741003 |
|  | value | 1..1 | SHALL |  | [14802](#C_14802) |  |
|  | @code | 0..1 | SHOULD |  | [14803](#C_14803) | 2.16.840.1.113883.11.20.9.37 (TargetSite Qualifiers ) |
|  | entryRelationship | 0..1 | SHOULD |  | [14410](#C_14410) |  |
|  | @typeCode | 1..1 | SHALL |  | [14411](#C_14411) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | observation | 1..1 | SHALL |  | [14619](#C_14619) |  |
|  | @classCode | 1..1 | SHALL |  | [14685](#C_14685) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [14686](#C_14686) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | code | 1..1 | SHALL |  | [14620](#C_14620) |  |
|  | @code | 1..1 | SHALL |  | [14621](#C_14621) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 401238003 |
|  | value | 1..1 | SHALL | PQ | [14622](#C_14622) |  |
|  | entryRelationship | 0..1 | SHOULD |  | [14601](#C_14601) |  |
|  | @typeCode | 1..1 | SHALL |  | [14602](#C_14602) | COMP |
|  | observation | 1..1 | SHALL |  | [14623](#C_14623) |  |
|  | @classCode | 1..1 | SHALL |  | [14687](#C_14687) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [14688](#C_14688) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | code | 1..1 | SHALL |  | [14624](#C_14624) |  |
|  | @code | 1..1 | SHALL |  | [14625](#C_14625) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 401239006 |
|  | value | 1..1 | SHALL | PQ | [14626](#C_14626) |  |
|  | entryRelationship | 0..1 | SHOULD |  | [14605](#C_14605) |  |
|  | @typeCode | 1..1 | SHALL |  | [14606](#C_14606) | COMP |
|  | observation | 1..1 | SHALL |  | [14627](#C_14627) |  |
|  | @classCode | 1..1 | SHALL |  | [14689](#C_14689) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [14690](#C_14690) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | code | 1..1 | SHALL |  | [14628](#C_14628) |  |
|  | @code | 1..1 | SHALL |  | [14629](#C_14629) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 425094009 |
|  | value | 1..1 | SHALL | PQ | [14630](#C_14630) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:14383).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14384).

Use negationInd="true" to indicate that the problem was not observed.

1. MAY contain zero or one [0..1] @negationInd (CONF:14385).
2. SHALL contain exactly one [1..1] templateId (CONF:14387) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.70" (CONF:14388).
3. SHALL contain at least one [1..\*] id (CONF:14389).
4. SHALL contain exactly one [1..1] code (CONF:14759).
   1. This code SHALL contain exactly one [1..1] @code="ASSERTION" Assertion (CodeSystem: ActCode 2.16.840.1.113883.5.4 STATIC) (CONF:14760).
5. SHOULD contain zero or one [0..1] text (CONF:14391).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:14392).
      1. The reference, if present, SHALL contain exactly one [1..1] @value (CONF:15585).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15586).
6. SHALL contain exactly one [1..1] statusCode (CONF:14394).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19111).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:14395).
8. SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHOULD be selected from ValueSet Pressure Ulcer Stage 2.16.840.1.113883.11.20.9.35 STATIC (CONF:14396).
   1. This value MAY contain zero or one [0..1] @nullFlavor (CONF:14397).
      1. If the stage unknown or the SNOMED code is unknown, @nullFlavor SHOULD be “UNK”. If the code is something other than SNOMED, @nullFlavor SHOULD be “OTH” and the other code SHOULD be placed in the translation element (CONF:14398).
9. SHOULD contain zero or more [0..\*] targetSiteCode (CONF:14797).
   1. The targetSiteCode, if present, SHALL contain exactly one [1..1] @code, which SHOULD be selected from ValueSet Pressure Point 2.16.840.1.113883.11.20.9.36 STATIC (CONF:14798).
   2. The targetSiteCode, if present, SHOULD contain zero or one [0..1] qualifier (CONF:14799).
      1. The qualifier, if present, SHALL contain exactly one [1..1] name (CONF:14800).
         1. This name SHOULD contain zero or one [0..1] @code="272741003" laterality (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:14801).
      2. The qualifier, if present, SHALL contain exactly one [1..1] value (CONF:14802).
         1. This value SHOULD contain zero or one [0..1] @code, which SHOULD be selected from ValueSet TargetSite Qualifiers 2.16.840.1.113883.11.20.9.37 STATIC (CONF:14803).
10. SHOULD contain zero or one [0..1] entryRelationship (CONF:14410) such that it
    1. SHALL contain exactly one [1..1] @typeCode="COMP" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:14411).
    2. SHALL contain exactly one [1..1] observation (CONF:14619).
       1. This observation SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:14685).
       2. This observation SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14686).
       3. This observation SHALL contain exactly one [1..1] code (CONF:14620).
          1. This code SHALL contain exactly one [1..1] @code="401238003" Length of Wound (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:14621).
       4. This observation SHALL contain exactly one [1..1] value with @xsi:type="PQ" (CONF:14622).
11. SHOULD contain zero or one [0..1] entryRelationship (CONF:14601) such that it
    1. SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:14602).
    2. SHALL contain exactly one [1..1] observation (CONF:14623).
       1. This observation SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:14687).
       2. This observation SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14688).
       3. This observation SHALL contain exactly one [1..1] code (CONF:14624).
          1. This code SHALL contain exactly one [1..1] @code="401239006" Width of Wound (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:14625).
       4. This observation SHALL contain exactly one [1..1] value with @xsi:type="PQ" (CONF:14626).
12. SHOULD contain zero or one [0..1] entryRelationship (CONF:14605) such that it
    1. SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:14606).
    2. SHALL contain exactly one [1..1] observation (CONF:14627).
       1. This observation SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:14689).
       2. This observation SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14690).
       3. This observation SHALL contain exactly one [1..1] code (CONF:14628).
          1. This code SHALL contain exactly one [1..1] @code="425094009" Depth of Wound (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:14629).
       4. This observation SHALL contain exactly one [1..1] value with @xsi:type="PQ" (CONF:14630).

Table 198: Pressure Ulcer Stage

|  |  |  |
| --- | --- | --- |
| Value Set: Pressure Ulcer Stage 2.16.840.1.113883.11.20.9.35 | | |
| Code | Code System | Print Name |
| 421076008 | SNOMED-CT | Pressure Ulcer Stage 1 |
| 420324007 | SNOMED-CT | Pressure Ulcer Stage 2 |
| 421927004 | SNOMED-CT | Pressure Ulcer Stage 3 |
| 420597008 | SNOMED-CT | Pressure Ulcer Stage 4 |
| 421594008 | SNOMED-CT | Nonstageable pressure |

Table 199: Pressure Point

|  |  |  |
| --- | --- | --- |
| Value Set: Pressure Point 2.16.840.1.113883.11.20.9.36 | | |
| Code | Code System | Print Name |
| 43631005 | SNOMED-CT | occipital region structure |
| 23747009 | SNOMED-CT | skin structure of chin |
| 91774008 | SNOMED-CT | structure of right shoulder |
| 7874003 | SNOMED-CT | structure of scapular region of back; 272741003 = laterality; 24028007 = right (qualifier value) |
| 368149001 | SNOMED-CT | right elbow region structure |
| 368148009 | SNOMED-CT | left elbow region structure |
| 87141009 | SNOMED-CT | sacral vertebra structure |
| 122495006 | SNOMED-CT | thoracic spine structure |
| 122496007 | SNOMED-CT | lumbar spine structure |
| 287579007 | SNOMED-CT | right hip region structure |
| 387679003 | SNOMED-CT | left hip region structure |
| 396993003 | SNOMED-CT | right posterior iliac crest |
| 396994009 | SNOMED-CT | left posterior iliac crest |
| 46862004 | SNOMED-CT | buttock structure;272741003 = laterality;7771000 = left |
| 6757004 | SNOMED-CT | structure of right knee |
| 82169009 | SNOMED-CT | structure of left knee |
| 76853006 | SNOMED-CT | heel structure; 272741003 = laterality; 24028007 = right |
| 182304008 | SNOMED-CT | medial aspect of ankle; 272741003 = laterality; 24028007 = right |
| 182305009 | SNOMED-CT | lateral aspect of ankle; 272741003 = laterality; 24028007 = right |
| 43631005 | SNOMED-CT | occipital region structure |
| 23747009 | SNOMED-CT | skin structure of chin |
| 91774008 | SNOMED-CT | structure of right shoulder |
| 7874003 | SNOMED-CT | structure of scapular region of back; 272741003 = laterality; 24028007 = right (qualifier value) |
| 368149001 | SNOMED-CT | right elbow region structure |
| 368148009 | SNOMED-CT | left elbow region structure |
| 87141009 | SNOMED-CT | sacral vertebra structure |
| 122495006 | SNOMED-CT | thoracic spine structure |
| 122496007 | SNOMED-CT | lumbar spine structure |
| 287579007 | SNOMED-CT | right hip region structure |
| 387679003 | SNOMED-CT | left hip region structure |
| 396993003 | SNOMED-CT | right posterior iliac crest |
| 396994009 | SNOMED-CT | left posterior iliac crest |
| 46862004 | SNOMED-CT | buttock structure;272741003 = laterality;7771000 = left |
| 6757004 | SNOMED-CT | structure of right knee |
| 82169009 | SNOMED-CT | structure of left knee |
| 76853006 | SNOMED-CT | heel structure; 272741003 = laterality; 24028007 = right |
| 182304008 | SNOMED-CT | medial aspect of ankle; 272741003 = laterality; 7771000 = left |
| 182305009 | SNOMED-CT | lateral aspect of ankle; 272741003 = laterality;7771000 = left |
| 6685009 | SNOMED-CT | structure of right ankle |

Table 200: TargetSite Qualifiers

|  |  |  |
| --- | --- | --- |
| Value Set: TargetSite Qualifiers 2.16.840.1.113883.11.20.9.37 | | |
| Code | Code System | Print Name |
| 255549009 | SNOMED-CT | anterior |
| 7771000 | SNOMED-CT | left |
| 255561001 | SNOMED-CT | medial |
| 255551008 | SNOMED-CT | posterior |
| 24028007 | SNOMED-CT | right |

Problem Concern Act (Condition) [Closed for comments; published July 2012]

[act: templateId 2.16.840.1.113883.10.20.22.4.3 (open)]

Table 201: Problem Concern Act (Condition) Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Problem Section (entries optional)](#S_Problem_Section_entries_optional) (optional) | [Problem Observation](#E_Problem_Observation) |

Observations of problems or other clinical statements captured at a point in time are wrapped in a ""Concern"" act, which represents the ongoing process tracked over time. This allows for binding related observations of problems. For example, the observation of ""Acute MI"" in 2004 can be related to the observation of ""History of MI"" in 2006 because they are the same concern. The conformance statements in this section define an outer ""problem act"" (representing the ""Concern"") that can contain a nested ""problem observation"" or other nested clinical statements.

Table 202: Problem Concern Act (Condition) Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | act[templateId/@root = '2.16.840.1.113883.10.20.22.4.3'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [9024](#C_9024) | 2.16.840.1.113883.5.6 (HL7ActClass) = ACT |
|  | @moodCode | 1..1 | SHALL |  | [9025](#C_9025) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [16772](#C_16772) |  |
|  | @root | 1..1 | SHALL |  | [16773](#C_16773) | 2.16.840.1.113883.10.20.22.4.3 |
|  | id | 1..\* | SHALL |  | [9026](#C_9026) |  |
|  | code | 1..1 | SHALL |  | [9027](#C_9027) |  |
|  | @code | 1..1 | SHALL |  | [19184](#C_19184) | 2.16.840.1.113883.5.6 (HL7ActClass) = CONC |
|  | statusCode | 1..1 | SHALL |  | [9029](#C_9029) | 2.16.840.1.113883.11.20.9.19 (ProblemAct statusCode) |
|  | effectiveTime | 1..1 | SHALL |  | [9030](#C_9030) |  |
|  | low | 1..1 | SHALL |  | [9032](#C_9032) |  |
|  | high | 0..1 | SHOULD |  | [9033](#C_9033) |  |
|  | entryRelationship | 1..\* | SHALL |  | [9034](#C_9034) |  |
|  | @typeCode | 1..1 | SHALL |  | [9035](#C_9035) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | observation | 1..1 | SHALL |  | [15980](#C_15980) |  |

1. SHALL contain exactly one [1..1] @classCode="ACT" Act (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:9024).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:9025).
3. SHALL contain exactly one [1..1] templateId (CONF:16772) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.3" (CONF:16773).
4. SHALL contain at least one [1..\*] id (CONF:9026).
5. SHALL contain exactly one [1..1] code (CONF:9027).
   1. This code SHALL contain exactly one [1..1] @code="CONC" Concern (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:19184).
6. SHALL contain exactly one [1..1] statusCode, which SHALL be selected from ValueSet ProblemAct statusCode 2.16.840.1.113883.11.20.9.19 STATIC 2011-09-09 (CONF:9029).

The effectiveTime element records the starting and ending times during which the concern was active on the Problem List.

1. SHALL contain exactly one [1..1] effectiveTime (CONF:9030).
   1. This effectiveTime SHALL contain exactly one [1..1] low (CONF:9032).
   2. This effectiveTime SHOULD contain zero or one [0..1] high (CONF:9033).
2. SHALL contain at least one [1..\*] entryRelationship (CONF:9034) such that it
   1. SHALL contain exactly one [1..1] @typeCode="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:9035).
   2. SHALL contain exactly one [1..1] [Problem Observation](#E_Problem_Observation) (templateId:2.16.840.1.113883.10.20.22.4.4) (CONF:15980).

Table 203: ProblemAct statusCode

|  |  |  |
| --- | --- | --- |
| Value Set: ProblemAct statusCode 2.16.840.1.113883.11.20.9.19 | | |
| Code | Code System | Print Name |
| completed | ActStatus | Completed |
| aborted | ActStatus | Aborted |
| active | ActStatus | Active |
| suspended | ActStatus | Suspended |

Breast Cancer Concern Act

[Act: templateId 2.16.840.1.113883.10.20.30.3.6 (open)]

Table 204: Breast Cancer Concern Act Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Problem Section BCTPS](#S_Problem_Section_BCTPS) (required) | [Breast Cancer Diagnosis Observation](#E_Breast_Cancer_Diagnosis_Observation) |

This clinical statement represents the breast cancer concern and contains the diagnosis of breast cancer which includes diagnosis detail and supporting observations such as breast cancer site, tumor type, and cancer staging.

Table 205: Breast Cancer Concern Act Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Act[templateId/@root = '2.16.840.1.113883.10.20.30.3.6'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [21814](#C_21814) |  |
|  | @root | 1..1 | SHALL |  | [21815](#C_21815) | 2.16.840.1.113883.10.20.30.3.6 |
|  | entryRelationship | 1..1 | SHALL |  | [21817](#C_21817) |  |
|  | @typeCode | 1..1 | SHALL |  | [21818](#C_21818) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | observation | 1..1 | SHALL |  | [21819](#C_21819) |  |
|  | entryRelationship | 1..1 | SHALL |  | [21973](#C_21973) |  |

1. Conforms to [Problem Concern Act (Condition)](#E_Problem_Concern_Act_Condition) template (2.16.840.1.113883.10.20.22.4.3).
2. SHALL contain exactly one [1..1] templateId (CONF:21814) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.6" (CONF:21815).
3. SHALL contain exactly one [1..1] entryRelationship (CONF:21817) such that it
   1. SHALL contain exactly one [1..1] @typeCode="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:21818).
   2. SHALL contain exactly one [1..1] [Breast Cancer Diagnosis Observation](#E_Breast_Cancer_Diagnosis_Observation) (templateId:2.16.840.1.113883.10.20.30.3.2) (CONF:21819).
4. SHALL contain exactly one [1..1] entryRelationship (CONF:21973).

Figure 66: Breast cancer concern act example

<templateId root="2.16.840.1.113883.10.20.30.3.6"/>

<id root="ec8a6ff8-ed4b-4f7e-82c3-e98e58b45de7"/>

<code code="CONC" codeSystem="2.16.840.1.113883.5.6"

displayName="Concern"/>

<statusCode code="completed"/>

<effectiveTime>

<low value="20120104"/>

<high value="20120104"/>

</effectiveTime>

<!-- BREAST CANCER DIAGNOSIS OBSERVATION -->

<entryRelationship typeCode="SUBJ">

<observation classCode="OBS" moodCode="EVN">

<!-- Consolidated CDA Problem observation templateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.4"/>

<!-- Breast Cancer Diagnosis Observation templateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.2"/>

<id root="4f5e6e60-e641-4e80-ac7b-cdea1029bcce"/>

<!-- SHALL diagnosis coded -->

<code code="282291009" codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT" displayName="diagnosis"/>

<statusCode code="completed"/>

<!-- Date of diagnosis -->

<effectiveTime>

<low value="20120104"/>

</effectiveTime>

<!-- SHALL value and breast cancer snomed codes -->

<value xsi:type="CD" codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="408643008"

displayName="Infiltrating duct carcinoma of breast (disorder)"/>

<!-- SHOULD -->

<targetSiteCode code="80248007"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="left breast (body structure)"/>

<!-- OVERALL STAGE-->

<entryRelationship typeCode="SPRT">

<act classCode="ACT" moodCode="EVN">

<!-- Overall stage templateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.3"/>

<code codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="254326001"

...

<!-- TNM TUMOR(T) STAGING-->

<entryRelationship typeCode="COMP">

...

<!-- TNM Node(N) STAGING -->

<entryRelationship typeCode="COMP">

<!-- TNM METASTASIS(M) STAGING -->

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<!-- TNM – Metastasis(M) STAGING TemplateID -->

...

</entryRelationship>

Problem Observation[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.4 (open)]

Table 206: Problem Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Problem Concern Act (Condition)](#E_Problem_Concern_Act_Condition) (required)  [Encounter Diagnosis](#E_Encounter_Diagnosis) (required) | [Age Observation](#E_Age_Observation)  [Health Status Observation](#E_Health_Status_Observation)  [Problem Status](#E_Problem_Status) |

A problem is a clinical statement that a clinician has noted. In health care it is a condition that requires monitoring or diagnostic, therapeutic, or educational action. It also refers to any unmet or partially met basic human need.

A Problem Observation is required to be wrapped in an act wrapper in locations such as the Problem Section, Allergies Section, and Hospital Discharge Diagnosis Section, where the type of problem needs to be identified or the condition tracked.

A Problem Observation can be a valid ""standalone"" template instance in cases where a simple problem observation is to be sent.

The negationInd attribute, if true, specifies that the problem indicated was observed to not have occurred (which is subtly but importantly different from having not been observed). NegationInd='true' is an acceptable way to make a clinical assertion that something did not occur, for example, 'no diabetes'.

Table 207: Problem Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
| Green Problem Observation | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.4'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [9041](#C_9041) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [9042](#C_9042) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | @negationInd | 0..1 | MAY |  | [10139](#C_10139) |  |
|  | templateId | 1..1 | SHALL |  | [14926](#C_14926) |  |
|  | @root | 1..1 | SHALL |  | [14927](#C_14927) | 2.16.840.1.113883.10.20.22.4.4 |
|  | id | 1..\* | SHALL |  | [9043](#C_9043) |  |
| problemType | code | 1..1 | SHALL |  | [9045](#C_9045) | 2.16.840.1.113883.3.88.12.3221.7.2 (Problem Type) |
| problemName | text | 0..1 | SHOULD |  | [9185](#C_9185) |  |
|  | reference | 0..1 | SHOULD |  | [15587](#C_15587) |  |
|  | @value | 1..1 | SHALL |  | [15588](#C_15588) |  |
|  | statusCode | 1..1 | SHALL |  | [9049](#C_9049) |  |
|  | @code | 1..1 | SHALL |  | [19112](#C_19112) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
| problemDate | effectiveTime | 0..1 | SHOULD |  | [9050](#C_9050) |  |
|  | low | 1..1 | SHALL |  | [15603](#C_15603) |  |
|  | high | 0..1 | SHOULD |  | [15604](#C_15604) |  |
| problemCode | value | 1..1 | SHALL | CD | [9058](#C_9058) | 2.16.840.1.113883.3.88.12.3221.7.4 (Problem Value Set) |
|  | translation | 0..\* | MAY |  | [16749](#C_16749) |  |
|  | @code | 0..1 | MAY |  | [16750](#C_16750) | 2.16.840.1.113883.6.90 (ICD10CM) |
|  | @nullFlavor | 0..1 | MAY |  | [10141](#C_10141) |  |
| ageAtOnset | entryRelationship | 0..1 | MAY |  | [9059](#C_9059) |  |
|  | @typeCode | 1..1 | SHALL |  | [9060](#C_9060) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | @inversionInd | 1..1 | SHALL |  | [9069](#C_9069) | true |
|  | observation | 1..1 | SHALL |  | [15590](#C_15590) |  |
| problemStatus | entryRelationship | 0..1 | MAY |  | [9063](#C_9063) |  |
|  | @typeCode | 1..1 | SHALL |  | [9068](#C_9068) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | observation | 1..1 | SHALL |  | [15591](#C_15591) |  |
|  | entryRelationship | 0..1 | MAY |  | [9067](#C_9067) |  |
|  | @typeCode | 1..1 | SHALL |  | [9064](#C_9064) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | observation | 1..1 | SHALL |  | [15592](#C_15592) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:9041).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:9042).
3. MAY contain zero or one [0..1] @negationInd (CONF:10139).
   1. Use negationInd="true" to indicate that the problem was not observed (CONF:16880).
4. SHALL contain exactly one [1..1] templateId (CONF:14926) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.4" (CONF:14927).
5. SHALL contain at least one [1..\*] id (CONF:9043).
6. SHALL contain exactly one [1..1] code, which SHOULD be selected from ValueSet Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 STATIC 2012-06-01 (CONF:9045).
7. SHOULD contain zero or one [0..1] text (CONF:9185).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:15587).
      1. The reference, if present, SHALL contain exactly one [1..1] @value (CONF:15588).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15589).
8. SHALL contain exactly one [1..1] statusCode (CONF:9049).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19112).
9. SHOULD contain zero or one [0..1] effectiveTime (CONF:9050).
   1. The effectiveTime, if present, SHALL contain exactly one [1..1] low (CONF:15603).
      1. This field represents the onset date (CONF:16882).
   2. The effectiveTime, if present, SHOULD contain zero or one [0..1] high (CONF:15604).
      1. This field represents the resolution date (CONF:16883).
   3. If the problem is known to be resolved, but the date of resolution is not known, then the high element SHALL be present, and the nullFlavor attribute SHALL be set to 'UNK'. Therefore, the existence of an high element within a problem does indicate that the problem has been resolved (CONF:16881).
10. SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHOULD be selected from ValueSet Problem Value Set 2.16.840.1.113883.3.88.12.3221.7.4 DYNAMIC (CONF:9058).
    1. This value MAY contain zero or more [0..\*] translation (CONF:16749).
       1. The translation, if present, MAY contain zero or one [0..1] @code (CodeSystem: ICD10CM 2.16.840.1.113883.6.90 STATIC) (CONF:16750).
    2. This value MAY contain zero or one [0..1] @nullFlavor (CONF:10141).
       1. If the diagnosis is unknown or the SNOMED code is unknown, @nullFlavor SHOULD be “UNK”. If the code is something other than SNOMED, @nullFlavor SHOULD be “OTH” and the other code SHOULD be placed in the translation element (CONF:10142).
11. MAY contain zero or one [0..1] entryRelationship (CONF:9059) such that it
    1. SHALL contain exactly one [1..1] @typeCode="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:9060).
    2. SHALL contain exactly one [1..1] @inversionInd="true" True (CONF:9069).
    3. SHALL contain exactly one [1..1] [Age Observation](#E_Age_Observation) (templateId:2.16.840.1.113883.10.20.22.4.31) (CONF:15590).
12. MAY contain zero or one [0..1] entryRelationship (CONF:9063) such that it
    1. SHALL contain exactly one [1..1] @typeCode="REFR" Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:9068).
    2. SHALL contain exactly one [1..1] [Problem Status](#E_Problem_Status) (templateId:2.16.840.1.113883.10.20.22.4.6) (CONF:15591).
13. MAY contain zero or one [0..1] entryRelationship (CONF:9067) such that it
    1. SHALL contain exactly one [1..1] @typeCode="REFR" Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:9064).
    2. SHALL contain exactly one [1..1] [Health Status Observation](#E_Health_Status_Observation) (templateId:2.16.840.1.113883.10.20.22.4.5) (CONF:15592).

Table 208: Problem Type

|  |  |  |
| --- | --- | --- |
| Value Set: Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 | | |
| Code | Code System | Print Name |
| 404684003 | SNOMED-CT | Finding |
| 409586006 | SNOMED-CT | Complaint |
| 282291009 | SNOMED-CT | Diagnosis |
| 64572001 | SNOMED-CT | Condition |
| 248536006 | SNOMED-CT | Finding of functional performance and activity |
| 418799008 | SNOMED-CT | Symptom |
| 55607006 | SNOMED-CT | Problem |
| 373930000 | SNOMED-CT | Cognitive function finding |

Breast Cancer Diagnosis Observation

[Observation: templateId 2.16.840.1.113883.10.20.30.3.2 (open)]

Table 209: Breast Cancer Diagnosis Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Breast Cancer Concern Act](#Breast_Cancer_Concern_Act) (required) | [Overall Stage](#E_Overall_Stage)  [Post Treatment Disease Status](#Post_Treatment_Disease_Status) |

This clinical statement represents the diagnosis of breast cancer which includes diagnosis detail and supporting observations such as breast cancer site, tumor type and cancer staging.

Notes: CONF (19288)--> Determine if a restricted Breast Cancer ProblemValue set is needed. May want to represent problems using SNOMED s.a. 408643008= Infiltrating duct carcinoma of breast (disorder)instead of using AJCC cancer diagnosis ICD-9 code as in template below.CA Registry uses value to record Histological Type or cell type of the tumor or cancer (melanoma, lymphoma, sarcoma, leukemia, etc). CodeSystem International Classification of Diseases for Oncology, Third Edition (ICD-O-3) 2.16.840.1.113883.6.43.1 DYNAMIC 2. CodeSystem International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), Appendix A-Morphology of Neoplasms) 2.16.840.1.114222.4.11.6038 DYNAMIC 3. CodeSystem International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) 2.16.840.1.113883.6.90 DYNAMIC 4. CodeSystem Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT) 2.16.840.1.113883.6.96 DYNAMIC

Table 210: Breast Cancer Diagnosis Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.2'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [19279](#C_19279) |  |
|  | @root | 1..1 | SHALL |  | [19280](#C_19280) | 2.16.840.1.113883.10.20.30.3.2 |
|  | id | 1..\* | SHALL |  | [22067](#C_22067) |  |
|  | code | 1..1 | SHALL |  | [21945](#C_21945) |  |
|  | @code | 1..1 | SHALL |  | [21946](#C_21946) | 282291009 |
|  | @codeSystem | 1..1 | SHALL |  | [24942](#C_24942) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |
|  | statusCode | 1..1 | SHALL |  | [26224](#C_26224) |  |
|  | @code | 1..1 | SHALL |  | [26225](#C_26225) | 2.16.840.1.113883.5.14 (ActStatus) = Completed |
|  | effectiveTime | 1..1 | SHALL |  | [22076](#C_22076) |  |
|  | value | 1..1 | SHALL | CD | [19287](#C_19287) |  |
|  | @code | 1..1 | SHALL | CD | [19288](#C_19288) | 2.16.840.1.113883.3.117.1.5.4.2 (AJCC ICD9CM CancerCodes) |
|  | targetSiteCode | 1..\* | SHALL |  | [21925](#C_21925) |  |
|  | @code | 1..1 | SHALL |  | [21947](#C_21947) | 2.16.840.1.113883.3.88.12.3221.8.9 (Body Site Value Set) |
|  | qualifier | 0..\* | MAY |  | [22068](#C_22068) |  |
|  | name | 1..1 | SHALL |  | [22069](#C_22069) |  |
|  | value | 1..1 | SHALL |  | [22070](#C_22070) |  |
|  | entryRelationship | 1..1 | SHALL |  | [21926](#C_21926) |  |
|  | @typeCode | 1..1 | SHALL |  | [21927](#C_21927) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SPRT |
|  | act | 1..1 | SHALL |  | [21928](#C_21928) |  |
|  | entryRelationship | 0..1 | MAY |  | [24939](#C_24939) |  |
|  | @typeCode | 1..1 | SHALL |  | [24940](#C_24940) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | observation | 1..1 | SHALL |  | [24941](#C_24941) |  |

1. Conforms to [Problem Observation](#E_Problem_Observation) template (2.16.840.1.113883.10.20.22.4.4).
2. SHALL contain exactly one [1..1] templateId (CONF:19279) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.2" (CONF:19280).
3. SHALL contain at least one [1..\*] id (CONF:22067).
4. SHALL contain exactly one [1..1] code (CONF:21945).
   1. This code SHALL contain exactly one [1..1] @code="282291009" Diagnosis (CONF:21946).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:24942).
5. SHALL contain exactly one [1..1] statusCode (CONF:26224).
   1. This statusCode SHALL contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:26225).

The presence of an effective time low indicates the problem onset date. The presence of an effective time high indicates the problem resolution date.

1. SHALL contain exactly one [1..1] effectiveTime (CONF:22076).
2. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:19287).
   1. This value SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet AJCC ICD9CM CancerCodes(temp)2.16.840.1.113883.3.117.1.5.4.2 STATIC (CONF:19288).
3. SHALL contain at least one [1..\*] targetSiteCode (CONF:21925).
   1. Such targetSiteCodes SHALL contain exactly one [1..1] @code (ValueSet: Body Site Value Set 2.16.840.1.113883.3.88.12.3221.8.9) (CONF:21947).
   2. Such targetSiteCodes MAY contain zero or more [0..\*] qualifier (CONF:22068).
      1. The qualifier, if present, SHALL contain exactly one [1..1] name (CONF:22069).
      2. The qualifier, if present, SHALL contain exactly one [1..1] value (CONF:22070).
4. SHALL contain exactly one [1..1] entryRelationship (CONF:21926) such that it
   1. SHALL contain exactly one [1..1] @typeCode="SPRT" Has support (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:21927).
   2. SHALL contain exactly one [1..1] [Overall Stage](#E_Overall_Stage) (templateId:2.16.840.1.113883.10.20.30.3.3) (CONF:21928).
5. MAY contain zero or one [0..1] entryRelationship (CONF:24939) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" Has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24940).
   2. SHALL contain exactly one [1..1] [Post Treatment Disease Status](#Post_Treatment_Disease_Status) (templateId:2.16.840.1.113883.10.20.30.3.29) (CONF:24941).

Table 211: AJCC ICD9CM CancerCodes (temp)

|  |  |  |
| --- | --- | --- |
| Value Set: AJCC ICD9CM CancerCodes (temp) 2.16.840.1.113883.3.117.1.5.4.2 | | |
| Code | Code System | Print Name |
| 174.0 | ICD9CM | Malignant Neoplasm of female breast |
| 174.1 | ICD9CM | Malignant neoplasm of central portion of female breast |
| 174.2 | ICD9CM | Malignant neoplasm of upper-inner quadrant of female breast |

Figure 67: Breast cancer diagnosis observation examples

<templateId root="2.16.840.1.113883.10.20.30.3.2"/>

<id root="4f5e6e60-e641-4e80-ac7b-cdea1029bcce"/>

<!-- SHALL diagnosis coded -->

<code code="282291009" codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT" displayName="diagnosis"/>

<statusCode code="completed"/>

<!-- Date of diagnosis -->

<effectiveTime>

<low value="20120104"/>

</effectiveTime>

<!-- SHALL value and breast cancer snomed codes -->

<value xsi:type="CD" codeSystem="2.16.840.1.113883.6.2"

codeSystemName="ICD-9" code="174.0"

displayName=" Malignant Neoplasm of female breast"/>

<!-- SHOULD -->

<targetSiteCode code="80248007"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="left breast (body structure)"/>

<!-- OVERALL STAGE-->

<entryRelationship typeCode="SPRT">

<act classCode="ACT" moodCode="EVN">

<!-- Overall stage templateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.3"/>

<code codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="254326001"

...

<!-- TNM TUMOR(T) STAGING-->

<entryRelationship typeCode="COMP">

...

<!-- TNM Node(N) STAGING -->

<entryRelationship typeCode="COMP">

<!-- TNM METASTASIS(M) STAGING -->

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<!-- TNM – Metastasis(M) STAGING TemplateID -->

...

</entryRelationship>

Cognitive Status Problem Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.73 (open)]

Table 212: Cognitive Status Problem Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Functional Status Section](#S_Functional_Status_Section) (optional) | [Assessment Scale Observation](#E_Assessment_Scale_Observation)  [Caregiver Characteristics](#E_Caregiver_Characteristics)  [Non-Medicinal Supply Activity](#E_NonMedicinal_Supply_Activity) |

A cognitive status problem observation is a clinical statement that describes a patient's cognitive condition, findings, or symptoms. Examples of cognitive problem observations are inability to recall, amnesia, dementia, and aggressive behavior.

A cognitive problem observation is a finding or medical condition. This is different from a cognitive result observation, which is a response to a question that provides insight into the patient's cognitive status, judgment, comprehension ability, or response speed.

Table 213: Cognitive Status Problem Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.73'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [14319](#C_14319) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [14320](#C_14320) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | @negationInd | 0..1 | MAY |  | [14344](#C_14344) |  |
|  | templateId | 1..1 | SHALL |  | [14346](#C_14346) |  |
|  | @root | 1..1 | SHALL |  | [14347](#C_14347) | 2.16.840.1.113883.10.20.22.4.73 |
|  | id | 1..\* | SHALL |  | [14321](#C_14321) |  |
|  | code | 1..1 | SHALL |  | [14804](#C_14804) |  |
|  | @code | 0..1 | SHOULD |  | [14805](#C_14805) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 373930000 |
|  | text | 0..1 | SHOULD |  | [14341](#C_14341) |  |
|  | reference | 0..1 | SHOULD |  | [15532](#C_15532) |  |
|  | @value | 0..1 | SHOULD |  | [15533](#C_15533) |  |
|  | statusCode | 1..1 | SHALL |  | [14323](#C_14323) |  |
|  | @code | 1..1 | SHALL |  | [19091](#C_19091) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 0..1 | SHOULD |  | [14324](#C_14324) |  |
|  | value | 1..1 | SHALL | CD | [14349](#C_14349) | 2.16.840.1.113883.3.88.12.3221.7.4 (Problem Value Set) |
|  | methodCode | 0..\* | MAY |  | [14693](#C_14693) |  |
|  | entryRelationship | 0..\* | MAY |  | [14331](#C_14331) |  |
|  | @typeCode | 1..1 | SHALL |  | [14588](#C_14588) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | supply | 1..1 | SHALL |  | [14351](#C_14351) |  |
|  | entryRelationship | 0..\* | MAY |  | [14335](#C_14335) |  |
|  | @typeCode | 1..1 | SHALL |  | [14589](#C_14589) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | observation | 1..1 | SHALL |  | [14352](#C_14352) |  |
|  | entryRelationship | 0..\* | MAY |  | [14467](#C_14467) |  |
|  | @typeCode | 1..1 | SHALL |  | [14590](#C_14590) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | observation | 1..1 | SHALL |  | [14468](#C_14468) |  |

1. Conforms to [Problem Observation](#E_Problem_Observation) template (2.16.840.1.113883.10.20.22.4.4).
2. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:14319).
3. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14320).

Use negationInd="true" to indicate that the problem was not observed.

1. MAY contain zero or one [0..1] @negationInd (CONF:14344).
2. SHALL contain exactly one [1..1] templateId (CONF:14346) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.73" (CONF:14347).
3. SHALL contain at least one [1..\*] id (CONF:14321).
4. SHALL contain exactly one [1..1] code (CONF:14804).
   1. This code SHOULD contain zero or one [0..1] @code="373930000" Cognitive function finding (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:14805).
5. SHOULD contain zero or one [0..1] text (CONF:14341).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:15532).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15533).
         1. SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15534).
6. SHALL contain exactly one [1..1] statusCode (CONF:14323).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19091).
7. SHOULD contain zero or one [0..1] effectiveTime (CONF:14324).
   1. The onset date SHALL be recorded in the low element of the effectiveTime element when known (CONF:14325).
   2. The resolution date SHALL be recorded in the high element of the effectiveTime element when known (CONF:14326).
   3. If the problem is known to be resolved, but the date of resolution is not known, then the high element SHALL be present, and the nullFlavor attribute SHALL be set to 'UNK'. Therefore, the existence of a high element within a problem does indicate that the problem has been resolved (CONF:14327).
8. SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHOULD be selected from ValueSet Problem Value Set 2.16.840.1.113883.3.88.12.3221.7.4 DYNAMIC (CONF:14349).
9. MAY contain zero or more [0..\*] methodCode (CONF:14693).
10. MAY contain zero or more [0..\*] entryRelationship (CONF:14331) such that it
    1. SHALL contain exactly one [1..1] @typeCode="REFR" refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:14588).
    2. SHALL contain exactly one [1..1] [Non-Medicinal Supply Activity](#E_NonMedicinal_Supply_Activity) (templateId:2.16.840.1.113883.10.20.22.4.50) (CONF:14351).
11. MAY contain zero or more [0..\*] entryRelationship (CONF:14335) such that it
    1. SHALL contain exactly one [1..1] @typeCode="REFR" refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:14589).
    2. SHALL contain exactly one [1..1] [Caregiver Characteristics](#E_Caregiver_Characteristics) (templateId:2.16.840.1.113883.10.20.22.4.72) (CONF:14352).
12. MAY contain zero or more [0..\*] entryRelationship (CONF:14467) such that it
    1. SHALL contain exactly one [1..1] @typeCode="COMP" has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:14590).
    2. SHALL contain exactly one [1..1] [Assessment Scale Observation](#E_Assessment_Scale_Observation) (templateId:2.16.840.1.113883.10.20.22.4.69) (CONF:14468).

Functional Status Problem Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.68 (open)]

Table 214: Functional Status Problem Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Functional Status Section](#S_Functional_Status_Section) (optional) | [Assessment Scale Observation](#E_Assessment_Scale_Observation)  [Caregiver Characteristics](#E_Caregiver_Characteristics)  [Non-Medicinal Supply Activity](#E_NonMedicinal_Supply_Activity) |

A functional status problem observation is a clinical statement that represents a patient’s functional performance and ability.

Table 215: Functional Status Problem Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.68'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [14282](#C_14282) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [14283](#C_14283) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | @negationInd | 0..1 | MAY |  | [14307](#C_14307) |  |
|  | templateId | 1..1 | SHALL |  | [14312](#C_14312) |  |
|  | @root | 1..1 | SHALL |  | [14313](#C_14313) | 2.16.840.1.113883.10.20.22.4.68 |
|  | id | 1..\* | SHALL |  | [14284](#C_14284) |  |
|  | code | 1..1 | SHALL |  | [14314](#C_14314) |  |
|  | @code | 0..1 | SHOULD |  | [14315](#C_14315) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 248536006 |
|  | text | 0..1 | SHOULD |  | [14304](#C_14304) |  |
|  | reference | 0..1 | SHOULD |  | [15552](#C_15552) |  |
|  | @value | 0..1 | SHOULD |  | [15553](#C_15553) |  |
|  | statusCode | 1..1 | SHALL |  | [14286](#C_14286) |  |
|  | @code | 1..1 | SHALL |  | [19100](#C_19100) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 0..1 | SHOULD |  | [14287](#C_14287) |  |
|  | value | 1..1 | SHALL | CD | [14291](#C_14291) | 2.16.840.1.113883.3.88.12.3221.7.4 (Problem Value Set) |
|  | @nullFlavor | 0..1 | MAY |  | [14292](#C_14292) |  |
|  | methodCode | 0..1 | MAY |  | [14316](#C_14316) |  |
|  | entryRelationship | 0..\* | MAY |  | [14294](#C_14294) |  |
|  | @typeCode | 1..1 | SHALL |  | [14584](#C_14584) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | supply | 1..1 | SHALL |  | [14317](#C_14317) |  |
|  | entryRelationship | 0..\* | MAY |  | [14298](#C_14298) |  |
|  | @typeCode | 1..1 | SHALL |  | [14586](#C_14586) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | observation | 1..1 | SHALL |  | [14318](#C_14318) |  |
|  | entryRelationship | 0..\* | MAY |  | [14463](#C_14463) |  |
|  | @typeCode | 1..1 | SHALL |  | [14587](#C_14587) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | observation | 1..1 | SHALL |  | [14464](#C_14464) |  |

1. Conforms to [Problem Observation](#E_Problem_Observation) template (2.16.840.1.113883.10.20.22.4.4).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:14282).
3. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14283).

Use negationInd="true" to indicate that the problem was not observed.

1. MAY contain zero or one [0..1] @negationInd (CONF:14307).
2. SHALL contain exactly one [1..1] templateId (CONF:14312) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.68" (CONF:14313).
3. SHALL contain at least one [1..\*] id (CONF:14284).
4. SHALL contain exactly one [1..1] code (CONF:14314).
   1. This code SHOULD contain zero or one [0..1] @code="248536006" finding of functional performance and activity (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:14315).
5. SHOULD contain zero or one [0..1] text (CONF:14304).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:15552).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15553).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15554).
6. SHALL contain exactly one [1..1] statusCode (CONF:14286).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19100).
7. SHOULD contain zero or one [0..1] effectiveTime (CONF:14287).
   1. The onset date SHALL be recorded in the low element of the effectiveTime element when known (CONF:14288).
   2. The resolution date SHALL be recorded in the high element of the effectiveTime element when known (CONF:14289).
   3. If the problem is known to be resolved, but the date of resolution is not known, then the high element SHALL be present, and the nullFlavor attribute SHALL be set to 'UNK'. Therefore, the existence of an high element within a problem does indicate that the problem has been resolved (CONF:14290).
8. SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHOULD be selected from ValueSet Problem Value Set 2.16.840.1.113883.3.88.12.3221.7.4 DYNAMIC (CONF:14291).
   1. This value MAY contain zero or one [0..1] @nullFlavor (CONF:14292).
      1. If the diagnosis is unknown or the SNOMED code is unknown, @nullFlavor SHOULD be “UNK”. If the code is something other than SNOMED, @nullFlavor SHOULD be “OTH” and the other code SHOULD be placed in the translation element (CONF:14293).
9. MAY contain zero or one [0..1] methodCode (CONF:14316).
10. MAY contain zero or more [0..\*] entryRelationship (CONF:14294) such that it
    1. SHALL contain exactly one [1..1] @typeCode="REFR" refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:14584).
    2. SHALL contain exactly one [1..1] [Non-Medicinal Supply Activity](#E_NonMedicinal_Supply_Activity) (templateId:2.16.840.1.113883.10.20.22.4.50) (CONF:14317).
11. MAY contain zero or more [0..\*] entryRelationship (CONF:14298) such that it
    1. SHALL contain exactly one [1..1] @typeCode="REFR" refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:14586).
    2. SHALL contain exactly one [1..1] [Caregiver Characteristics](#E_Caregiver_Characteristics) (templateId:2.16.840.1.113883.10.20.22.4.72) (CONF:14318).
12. MAY contain zero or more [0..\*] entryRelationship (CONF:14463) such that it
    1. SHALL contain exactly one [1..1] @typeCode="COMP" has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:14587).
    2. SHALL contain exactly one [1..1] [Assessment Scale Observation](#E_Assessment_Scale_Observation) (templateId:2.16.840.1.113883.10.20.22.4.69) (CONF:14464).

Neurotoxicity Impairment of ADLs

[Observation: templateId 2.16.840.1.113883.10.20.30.3.37 (open)]

Table 216: Neurotoxicity Impairment of ADLs Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Functional Status Section BCTPS](#Functional_Status_Section_BCTPS) (optional) |  |

This clinical statement associates neurotoxicity as the cause of a functional status observation

Table 217: Neurotoxicity Impairment of ADLs Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.37'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [26421](#C_26421) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [26422](#C_26422) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [26438](#C_26438) |  |
|  | @root | 1..1 | SHALL |  | [26439](#C_26439) | 2.16.840.1.113883.10.20.30.3.37 |
|  | entryRelationship | 1..1 | SHALL |  | [26423](#C_26423) |  |
|  | @typeCode | 1..1 | SHALL |  | [26424](#C_26424) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = CAUS |
|  | @inversionInd | 1..1 | SHALL |  | [26425](#C_26425) | true |
|  | observation | 1..1 | SHALL |  | [26426](#C_26426) |  |
|  | @classCode | 1..1 | SHALL |  | [26427](#C_26427) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [26428](#C_26428) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | id | 1..\* | SHALL |  | [26429](#C_26429) |  |
|  | code | 1..1 | SHALL |  | [26430](#C_26430) |  |
|  | @code | 1..1 | SHALL |  | [26431](#C_26431) | 2.16.840.1.113883.5.4 (ActCode) = ASSERTION |
|  | @codeSystem | 1..1 | SHALL |  | [26432](#C_26432) | 2.16.840.1.113883.5.4 |
|  | statusCode | 1..1 | SHALL |  | [26433](#C_26433) |  |
|  | @code | 1..1 | SHALL |  | [26437](#C_26437) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | value | 1..1 | SHALL | CD | [26434](#C_26434) |  |
|  | @code | 1..1 | SHALL |  | [26435](#C_26435) | 1946603 |
|  | @codeSystem | 1..1 | SHALL |  | [26436](#C_26436) | 2.16.840.1.113883.6.96 |

1. Conforms to [Functional Status Problem Observation](#E_Functional_Status_Problem_Observation) template (2.16.840.1.113883.10.20.22.4.68).
2. SHALL contain exactly one [1..1] @classCode="OBS" observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:26421).
3. SHALL contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:26422).
4. SHALL contain exactly one [1..1] templateId (CONF:26438) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.37" (CONF:26439).
5. SHALL contain exactly one [1..1] entryRelationship (CONF:26423) such that it
   1. SHALL contain exactly one [1..1] @typeCode="CAUS" has etiology for (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:26424).
   2. SHALL contain exactly one [1..1] @inversionInd="true" True (CONF:26425).
   3. SHALL contain exactly one [1..1] observation (CONF:26426).
      1. This observation SHALL contain exactly one [1..1] @classCode="OBS" observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:26427).
      2. This observation SHALL contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:26428).

This observation/id could reference the id of the detailed reaction observation in the chemo regimen or in Allergies/Adverse events section

* + 1. This observation SHALL contain at least one [1..\*] id (CONF:26429).
    2. This observation SHALL contain exactly one [1..1] code (CONF:26430).
       1. This code SHALL contain exactly one [1..1] @code="ASSERTION" Assertion (CodeSystem: ActCode 2.16.840.1.113883.5.4) (CONF:26431).
       2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.5.4" HL7ActCode (CONF:26432).
    3. This observation SHALL contain exactly one [1..1] statusCode (CONF:26433).
       1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:26437).
    4. This observation SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:26434).
       1. This value SHALL contain exactly one [1..1] @code="1946603" Neurotoxocity (CONF:26435).
       2. This value SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" SNOMED-CT (CONF:26436).

Figure 68: Neurotoxicity impairment of ADLs

<templateId root="2.16.840.1.113883.10.20.30.3.37"/>

<id root="0a2405dd-7629-40e4-abb7-8eb12432e450"/>

<code codeSystem="2.16.840.1.113883.6.96" code="248536006" displayName="finding of functional performance and activity"/>

<statusCode code="completed"/>

<effectiveTime>

<low value="20120512"/>

</effectiveTime>

<value xsi:type="CD" code="282207002"

codeSystem="2.16.840.1.113883.6.96" displayName="Difficulty initiating

walking"/>

<!-- actRelationshipTypeCode "CAUS" is "has etiology for", therefore requires

inversion Indicator -->

<entryRelationship typeCode="CAUS" inversionInd="true">

<observation classCode="OBS" moodCode="EVN">

<!-- This is could reference the id of the detailed reaction

observation in the chemo regimen or in Allergies/Adverse events

section -->

<id root="ea3d6016-7d2c-450f-aa0c-e18f1bffbbe0"/>

<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"

codeSystemName="HL7ActCode"/>

<statusCode code="completed"/>

<value xsi:type="CD" code="1946603" codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="Neurotoxocity"/>

</observation>

</entryRelationship>

Problem Status[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.6 (open)]

Table 218: Problem Status Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Problem Observation](#E_Problem_Observation) (optional) |  |

The Problem Status records whether the indicated problem is active, inactive, or resolved.

Table 219: Problem Status Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.6'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7357](#C_7357) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [7358](#C_7358) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [7359](#C_7359) |  |
|  | @root | 1..1 | SHALL |  | [10518](#C_10518) | 2.16.840.1.113883.10.20.22.4.6 |
|  | code | 1..1 | SHALL |  | [19162](#C_19162) |  |
|  | @code | 1..1 | SHALL |  | [19163](#C_19163) | 2.16.840.1.113883.6.1 (LOINC) = 33999-4 |
|  | text | 0..1 | SHOULD |  | [7362](#C_7362) |  |
|  | reference | 0..1 | SHOULD |  | [15593](#C_15593) |  |
|  | @value | 1..1 | SHALL |  | [15594](#C_15594) |  |
|  | statusCode | 1..1 | SHALL |  | [7364](#C_7364) |  |
|  | @code | 1..1 | SHALL |  | [19113](#C_19113) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | value | 1..1 | SHALL | CD | [7365](#C_7365) | 2.16.840.1.113883.3.88.12.80.68 (Problem Status Value Set) |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7357).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7358).
3. SHALL contain exactly one [1..1] templateId (CONF:7359) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.6" (CONF:10518).
4. SHALL contain exactly one [1..1] code (CONF:19162).
   1. This code SHALL contain exactly one [1..1] @code="33999-4" Status (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:19163).
5. SHOULD contain zero or one [0..1] text (CONF:7362).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:15593).
      1. The reference, if present, SHALL contain exactly one [1..1] @value (CONF:15594).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15595).
6. SHALL contain exactly one [1..1] statusCode (CONF:7364).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19113).
7. SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHALL be selected from ValueSet Problem Status Value Set 2.16.840.1.113883.3.88.12.80.68 DYNAMIC (CONF:7365).

Table 220: Problem Status Value Set

|  |  |  |
| --- | --- | --- |
| Value Set: Problem Status Value Set 2.16.840.1.113883.3.88.12.80.68 | | |
| Code | Code System | Print Name |
| 55561003 | SNOMED-CT | Active |
| 73425007 | SNOMED-CT | Iinactive |
| 413322009 | SNOMED-CT | Resolved |

Procedure Activity Act [Closed for comments; published July 2012]

[act: templateId 2.16.840.1.113883.10.20.22.4.12 (open)]

Table 221: Procedure Activity Act Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Procedures Section (entries optional)](#S_Procedures_Section_entries_optional) (optional) | [Indication](#E_Indication)  [Instructions](#E_Instructions)  [Medication Activity](#E_Medication_Activity)  [Service Delivery Location](#E_Service_Delivery_Location) |

The common notion of ""procedure"" is broader than that specified by the HL7 Version 3 Reference Information Model (RIM). Therefore procedure templates can be represented with various RIM classes: act (e.g., dressing change), observation (e.g., EEG), procedure (e.g., splenectomy).

This clinical statement represents any procedure that cannot be classified as an observation or a procedure according to the HL7 RIM. Examples of these procedures are a dressing change, teaching or feeding a patient or providing comfort measures.

Table 222: Procedure Activity Act Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | act[templateId/@root = '2.16.840.1.113883.10.20.22.4.12'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [8289](#C_8289) | 2.16.840.1.113883.5.6 (HL7ActClass) = ACT |
|  | @moodCode | 1..1 | SHALL |  | [8290](#C_8290) | 2.16.840.1.113883.11.20.9.18 (MoodCodeEvnInt) |
|  | templateId | 1..1 | SHALL |  | [8291](#C_8291) |  |
|  | @root | 1..1 | SHALL |  | [10519](#C_10519) | 2.16.840.1.113883.10.20.22.4.12 |
|  | id | 1..\* | SHALL |  | [8292](#C_8292) |  |
|  | code | 1..1 | SHALL |  | [8293](#C_8293) |  |
|  | originalText | 0..1 | SHOULD |  | [19186](#C_19186) |  |
|  | reference | 0..1 | MAY |  | [19187](#C_19187) |  |
|  | @value | 0..1 | MAY |  | [19188](#C_19188) |  |
|  | statusCode | 1..1 | SHALL |  | [8298](#C_8298) | 2.16.840.1.113883.11.20.9.22 (ProcedureAct statusCode) |
|  | effectiveTime | 0..1 | SHOULD |  | [8299](#C_8299) |  |
|  | priorityCode | 0..1 | MAY |  | [8300](#C_8300) | 2.16.840.1.113883.1.11.16866 (Act Priority Value Set) |
|  | performer | 0..\* | SHOULD |  | [8301](#C_8301) |  |
|  | assignedEntity | 1..1 | SHALL |  | [8302](#C_8302) |  |
|  | id | 1..\* | SHALL |  | [8303](#C_8303) |  |
|  | addr | 1..1 | SHALL |  | [8304](#C_8304) |  |
|  | telecom | 1..1 | SHALL |  | [8305](#C_8305) |  |
|  | representedOrganization | 0..1 | SHOULD |  | [8306](#C_8306) |  |
|  | id | 0..\* | SHOULD |  | [8307](#C_8307) |  |
|  | name | 0..\* | MAY |  | [8308](#C_8308) |  |
|  | telecom | 1..1 | SHALL |  | [8310](#C_8310) |  |
|  | addr | 1..1 | SHALL |  | [8309](#C_8309) |  |
|  | participant | 0..\* | MAY |  | [8311](#C_8311) |  |
|  | @typeCode | 1..1 | SHALL |  | [8312](#C_8312) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = LOC |
|  | participantRole | 1..1 | SHALL |  | [15599](#C_15599) |  |
|  | entryRelationship | 0..\* | MAY |  | [8314](#C_8314) |  |
|  | @typeCode | 1..1 | SHALL |  | [8315](#C_8315) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | @inversionInd | 1..1 | SHALL |  | [8316](#C_8316) | true |
|  | encounter | 1..1 | SHALL |  | [8317](#C_8317) |  |
|  | @classCode | 1..1 | SHALL |  | [8318](#C_8318) | 2.16.840.1.113883.5.6 (HL7ActClass) = ENC |
|  | @moodCode | 1..1 | SHALL |  | [8319](#C_8319) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | id | 1..1 | SHALL |  | [8320](#C_8320) |  |
|  | entryRelationship | 0..1 | MAY |  | [8322](#C_8322) |  |
|  | @typeCode | 1..1 | SHALL |  | [8323](#C_8323) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | @inversionInd | 1..1 | SHALL |  | [8324](#C_8324) | true |
|  | act | 1..1 | SHALL |  | [15600](#C_15600) |  |
|  | entryRelationship | 0..\* | MAY |  | [8326](#C_8326) |  |
|  | @typeCode | 1..1 | SHALL |  | [8327](#C_8327) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON |
|  | observation | 1..1 | SHALL |  | [15601](#C_15601) |  |
|  | entryRelationship | 0..\* | MAY |  | [8329](#C_8329) |  |
|  | @typeCode | 1..1 | SHALL |  | [8330](#C_8330) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | substanceAdministration | 1..1 | SHALL |  | [15602](#C_15602) |  |

1. SHALL contain exactly one [1..1] @classCode="ACT" Act (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8289).
2. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 STATIC 2011-04-03 (CONF:8290).
3. SHALL contain exactly one [1..1] templateId (CONF:8291) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.12" (CONF:10519).
4. SHALL contain at least one [1..\*] id (CONF:8292).
5. SHALL contain exactly one [1..1] code (CONF:8293).
   1. This code SHOULD contain zero or one [0..1] originalText (CONF:19186).
      1. The originalText, if present, MAY contain zero or one [0..1] reference (CONF:19187).
         1. The reference, if present, MAY contain zero or one [0..1] @value (CONF:19188).
            1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:19189).
   2. This code in a procedure activity act SHOULD be selected from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:19190).
6. SHALL contain exactly one [1..1] statusCode, which SHALL be selected from ValueSet ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22 DYNAMIC (CONF:8298).
7. SHOULD contain zero or one [0..1] effectiveTime (CONF:8299).
8. MAY contain zero or one [0..1] priorityCode, which SHALL be selected from ValueSet Act Priority Value Set 2.16.840.1.113883.1.11.16866 DYNAMIC (CONF:8300).
9. SHOULD contain zero or more [0..\*] performer (CONF:8301).
   1. The performer, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:8302).
      1. This assignedEntity SHALL contain at least one [1..\*] id (CONF:8303).
      2. This assignedEntity SHALL contain exactly one [1..1] addr (CONF:8304).
      3. This assignedEntity SHALL contain exactly one [1..1] telecom (CONF:8305).
      4. This assignedEntity SHOULD contain zero or one [0..1] representedOrganization (CONF:8306).
         1. The representedOrganization, if present, SHOULD contain zero or more [0..\*] id (CONF:8307).
         2. The representedOrganization, if present, MAY contain zero or more [0..\*] name (CONF:8308).
         3. The representedOrganization, if present, SHALL contain exactly one [1..1] telecom (CONF:8310).
         4. The representedOrganization, if present, SHALL contain exactly one [1..1] addr (CONF:8309).
10. MAY contain zero or more [0..\*] participant (CONF:8311).
    1. The participant, if present, SHALL contain exactly one [1..1] @typeCode="LOC" Location (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:8312).
    2. The participant, if present, SHALL contain exactly one [1..1] [Service Delivery Location](#E_Service_Delivery_Location) (templateId:2.16.840.1.113883.10.20.22.4.32) (CONF:15599).
11. MAY contain zero or more [0..\*] entryRelationship (CONF:8314).
    1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:8315).
    2. The entryRelationship, if present, SHALL contain exactly one [1..1] @inversionInd="true" true (CONF:8316).
    3. The entryRelationship, if present, SHALL contain exactly one [1..1] encounter (CONF:8317).
       1. This encounter SHALL contain exactly one [1..1] @classCode="ENC" Encounter (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8318).
       2. This encounter SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:8319).
       3. This encounter SHALL contain exactly one [1..1] id (CONF:8320).
          1. Set the encounter ID to the ID of an encounter in another section to signify they are the same encounter (CONF:16849).
12. MAY contain zero or one [0..1] entryRelationship (CONF:8322).
    1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="SUBJ" Has Subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:8323).
    2. The entryRelationship, if present, SHALL contain exactly one [1..1] @inversionInd="true" true (CONF:8324).
    3. The entryRelationship, if present, SHALL contain exactly one [1..1] [Instructions](#E_Instructions) (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:15600).
13. MAY contain zero or more [0..\*] entryRelationship (CONF:8326).
    1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:8327).
    2. The entryRelationship, if present, SHALL contain exactly one [1..1] [Indication](#E_Indication) (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:15601).
14. MAY contain zero or more [0..\*] entryRelationship (CONF:8329).
    1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:8330).
    2. The entryRelationship, if present, SHALL contain exactly one [1..1] [Medication Activity](#E_Medication_Activity) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:15602).

Table 223: MoodCodeEvnInt

|  |  |  |
| --- | --- | --- |
| Value Set: MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 | | |
| Code | Code System | Print Name |
| EVN | ActMood | Event |
| INT | ActMood | Intent |

Table 224: ProcedureAct statusCode

|  |  |  |
| --- | --- | --- |
| Value Set: ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22 | | |
| Code | Code System | Print Name |
| completed | ActStatus | Completed |
| active | ActStatus | Active |
| aborted | ActStatus | Aborted |
| cancelled | ActStatus | Cancelled |

Table 225: Act Priority Value Set

|  |  |  |
| --- | --- | --- |
| Value Set: Act Priority Value Set 2.16.840.1.113883.1.11.16866 | | |
| Code | Code System | Print Name |
| A | ActPriority | ASAP |
| CR | ActPriority | Callback results |
| CS | ActPriority | Callback for scheduling |
| CSP | ActPriority | Callback placer for scheduling |
| CSR | ActPriority | Contact recipient for scheduling |
| EL | ActPriority | Elective |
| EM | ActPriority | Emergency |
| P | ActPriority | Preoperative |
| PRN | ActPriority | As needed |
| R | ActPriority | Routine |
| RR | ActPriority | Rush reporting |
| S | ActPriority | Stat |
| T | ActPriority | Timing critical |
| UD | ActPriority | Use as directed |
| UR | ActPriority | Urgent |

Radiation Therapy Care Completed

[Act: templateId 2.16.840.1.113883.10.20.30.3.16 (open)]

Table 226: Radiation Therapy Care Completed Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Procedures Section BCTPS](#Procedures_Section_BCTPS_) (optional) | [Reasons for Radiation Therapy](#Reasons_for_Radiation_Therapy) |

This clinical statement records whether or not patient received radiation therapy. The details of the radiation therapy are not represented.

Notes: If the radiation therapy was not given, the procedure would not be present in the EHR. Consider absence of evidence equals evidence of absence.

Table 227: Radiation Therapy Care Completed Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Act[templateId/@root = '2.16.840.1.113883.10.20.30.3.16'] | | | | | |
|  | @negationInd | 1..1 | SHALL |  | [24945](#C_24945) |  |
|  | templateId | 1..1 | SHALL |  | [23179](#C_23179) |  |
|  | @root | 1..1 | SHALL |  | [23180](#C_23180) | 2.16.840.1.113883.10.20.30.3.16 |
|  | code | 1..1 | SHALL |  | [23185](#C_23185) |  |
|  | @code | 1..1 | SHALL |  | [23186](#C_23186) | 385798007 |
|  | @codeSystem | 1..1 | SHALL |  | [23445](#C_23445) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |
|  | statusCode | 1..1 | SHALL |  | [23183](#C_23183) |  |
|  | @code | 1..1 | SHALL |  | [23184](#C_23184) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 1..1 | SHALL |  | [23181](#C_23181) |  |
|  | high | 1..1 | SHALL |  | [23182](#C_23182) |  |
|  | entryRelationship | 0..1 | MAY |  | [23449](#C_23449) |  |
|  | @typeCode | 1..1 | SHALL |  | [23450](#C_23450) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON |
|  | observation | 1..1 | SHALL |  | [23451](#C_23451) |  |

1. Conforms to [Procedure Activity Act](#E_Procedure_Activity_Act) template (2.16.840.1.113883.10.20.22.4.12).

NegationInd = true indicates the patient did not complete radiation therapy and a NegationInd=false means the patient did complete radiation therapy.

1. SHALL contain exactly one [1..1] @negationInd (CONF:24945).
2. SHALL contain exactly one [1..1] templateId (CONF:23179) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.16" (CONF:23180).
3. SHALL contain exactly one [1..1] code (CONF:23185).
   1. This code SHALL contain exactly one [1..1] @code="385798007" Radiation therapy care (CONF:23186).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23445).
4. SHALL contain exactly one [1..1] statusCode (CONF:23183).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:23184).
5. SHALL contain exactly one [1..1] effectiveTime (CONF:23181).

The value for the effective time represents the date the radiation therapy is completed. If the the radiation therapy was not completed, use nullFlavor= NI for effective time high.

* 1. This effectiveTime SHALL contain exactly one [1..1] high (CONF:23182).

1. MAY contain zero or one [0..1] entryRelationship (CONF:23449) such that it
   1. SHALL contain exactly one [1..1] @typeCode="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:23450).
   2. SHALL contain exactly one [1..1] [Reasons for Radiation Therapy](#Reasons_for_Radiation_Therapy) (templateId:2.16.840.1.113883.10.20.30.3.46) (CONF:23451).

Figure 69: Radiation therapy care completed example

<templateId root="2.16.840.1.113883.10.20.30.3.16"/>

<id nullFlavor="NI"/>

<code code="385798007" codeSystem="2.16.840.1.113883.6.96"

displayName="radiation therapy care"/>

<text>Radiation Therapy Care</text>

<statusCode code="completed"/>

<!-- SHALL have an effective time HIGH.

This represents when the radiation therapy care was completed.

If the patient's radiation therapy was not completed,

then the effective time high would have a nullFlavor =NI -->

<effectiveTime>

<low value="20120809"/>

<!-- SHALL -->

<high value="20120909"/>

</effectiveTime>

<!-- REASON FOR RADIATION THERAPY -->

<entryRelationship typeCode="RSON">

<observation classCode="OBS" moodCode="EVN">

<!--Consolidated CDA Indication TemplateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.19"/>

<!-- Reason for Radiation Therapy TemplateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.46"/>

<id root="569c8703-dace-488e-ab3f-ad62d62f765d"/>

<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"

codeSystemName="HL7ActCode"/>

<statusCode code="completed"/>

<effectiveTime value="20120809"/>

<value xsi:type="CD" codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="373846009"

displayName="adjuvant - intent "/>

</observation>

</entryRelationship>

Procedure Activity Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.13 (open)]

Table 228: Procedure Activity Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Procedures Section (entries optional)](#S_Procedures_Section_entries_optional) (optional) | [Indication](#E_Indication)  [Instructions](#E_Instructions)  [Medication Activity](#E_Medication_Activity)  [Service Delivery Location](#E_Service_Delivery_Location) |

The common notion of ""procedure"" is broader than that specified by the HL7 Version 3 Reference Information Model (RIM). Therefore procedure templates can be represented with various RIM classes: act (e.g., dressing change), observation (e.g., EEG), procedure (e.g. splenectomy).

This clinical statement represents procedures that result in new information about the patient that cannot be classified as a procedure according to the HL7 RIM. Examples of these procedures are diagnostic imaging procedures, EEGs and EKGs.

Table 229: Procedure Activity Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.13'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [8282](#C_8282) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [8237](#C_8237) | 2.16.840.1.113883.11.20.9.18 (MoodCodeEvnInt) |
|  | templateId | 1..1 | SHALL |  | [8238](#C_8238) |  |
|  | @root | 1..1 | SHALL |  | [10520](#C_10520) | 2.16.840.1.113883.10.20.22.4.13 |
|  | id | 1..\* | SHALL |  | [8239](#C_8239) |  |
|  | code | 1..1 | SHALL |  | [19197](#C_19197) |  |
|  | originalText | 0..1 | SHOULD |  | [19198](#C_19198) |  |
|  | reference | 0..1 | SHOULD |  | [19199](#C_19199) |  |
|  | @value | 0..1 | SHOULD |  | [19200](#C_19200) |  |
|  | statusCode | 1..1 | SHALL |  | [8245](#C_8245) | 2.16.840.1.113883.11.20.9.22 (ProcedureAct statusCode) |
|  | effectiveTime | 0..1 | SHOULD |  | [8246](#C_8246) |  |
|  | priorityCode | 0..1 | MAY |  | [8247](#C_8247) | 2.16.840.1.113883.1.11.16866 (Act Priority Value Set) |
|  | value | 1..1 | SHALL |  | [16846](#C_16846) |  |
|  | methodCode | 0..1 | MAY | SET<CE> | [8248](#C_8248) |  |
|  | targetSiteCode | 0..\* | SHOULD |  | [8250](#C_8250) |  |
|  | @code | 1..1 | SHALL |  | [16071](#C_16071) | 2.16.840.1.113883.3.88.12.3221.8.9 (Body Site Value Set) |
|  | performer | 0..\* | SHOULD |  | [8251](#C_8251) |  |
|  | assignedEntity | 1..1 | SHALL |  | [8252](#C_8252) |  |
|  | id | 1..\* | SHALL |  | [8253](#C_8253) |  |
|  | addr | 1..1 | SHALL |  | [8254](#C_8254) |  |
|  | telecom | 1..1 | SHALL |  | [8255](#C_8255) |  |
|  | representedOrganization | 0..1 | SHOULD |  | [8256](#C_8256) |  |
|  | id | 0..\* | SHOULD |  | [8257](#C_8257) |  |
|  | name | 0..\* | MAY |  | [8258](#C_8258) |  |
|  | telecom | 1..1 | SHALL |  | [8260](#C_8260) |  |
|  | addr | 1..1 | SHALL |  | [8259](#C_8259) |  |
|  | participant | 0..\* | MAY |  | [8261](#C_8261) |  |
|  | @typeCode | 1..1 | SHALL |  | [8262](#C_8262) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = LOC |
|  | participantRole | 1..1 | SHALL |  | [15904](#C_15904) |  |
|  | entryRelationship | 0..\* | MAY |  | [8264](#C_8264) |  |
|  | @typeCode | 1..1 | SHALL |  | [8265](#C_8265) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | @inversionInd | 1..1 | SHALL |  | [8266](#C_8266) | true |
|  | encounter | 1..1 | SHALL |  | [8267](#C_8267) |  |
|  | @classCode | 1..1 | SHALL |  | [8268](#C_8268) | 2.16.840.1.113883.5.6 (HL7ActClass) = ENC |
|  | @moodCode | 1..1 | SHALL |  | [8269](#C_8269) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | id | 1..1 | SHALL |  | [8270](#C_8270) |  |
|  | entryRelationship | 0..1 | MAY |  | [8272](#C_8272) |  |
|  | @typeCode | 1..1 | SHALL |  | [8273](#C_8273) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | @inversionInd | 1..1 | SHALL |  | [8274](#C_8274) | true |
|  | act | 1..1 | SHALL |  | [15905](#C_15905) |  |
|  | entryRelationship | 0..\* | MAY |  | [8276](#C_8276) |  |
|  | @typeCode | 1..1 | SHALL |  | [8277](#C_8277) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON |
|  | observation | 1..1 | SHALL |  | [15906](#C_15906) |  |
|  | entryRelationship | 0..\* | MAY |  | [8279](#C_8279) |  |
|  | @typeCode | 1..1 | SHALL |  | [8280](#C_8280) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | substanceAdministration | 1..1 | SHALL |  | [15907](#C_15907) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8282).
2. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 STATIC 2011-04-03 (CONF:8237).
3. SHALL contain exactly one [1..1] templateId (CONF:8238) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.13" (CONF:10520).
4. SHALL contain at least one [1..\*] id (CONF:8239).
5. SHALL contain exactly one [1..1] code (CONF:19197).
   1. This code SHOULD contain zero or one [0..1] originalText (CONF:19198).
      1. The originalText, if present, SHOULD contain zero or one [0..1] reference (CONF:19199).
         1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:19200).
            1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:19201).
   2. This @code SHOULD be selected from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (CodeSystem: 2.16.840.1.113883.6.12), ICD10 PCS (CodeSystem: 2.16.840.1.113883.6.4) (CONF:19202).
6. SHALL contain exactly one [1..1] statusCode, which SHALL be selected from ValueSet ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22 DYNAMIC (CONF:8245).
7. SHOULD contain zero or one [0..1] effectiveTime (CONF:8246).
8. MAY contain zero or one [0..1] priorityCode, which SHALL be selected from ValueSet Act Priority Value Set 2.16.840.1.113883.1.11.16866 DYNAMIC (CONF:8247).
9. SHALL contain exactly one [1..1] value (CONF:16846).
10. MAY contain zero or one [0..1] methodCode (CONF:8248).
    1. MethodCode SHALL NOT conflict with the method inherent in Observation / code (CONF:8249).
11. SHOULD contain zero or more [0..\*] targetSiteCode (CONF:8250).
    1. The targetSiteCode, if present, SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet Body Site Value Set 2.16.840.1.113883.3.88.12.3221.8.9 DYNAMIC (CONF:16071).
12. SHOULD contain zero or more [0..\*] performer (CONF:8251).
    1. The performer, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:8252).
       1. This assignedEntity SHALL contain at least one [1..\*] id (CONF:8253).
       2. This assignedEntity SHALL contain exactly one [1..1] addr (CONF:8254).
       3. This assignedEntity SHALL contain exactly one [1..1] telecom (CONF:8255).
       4. This assignedEntity SHOULD contain zero or one [0..1] representedOrganization (CONF:8256).
          1. The representedOrganization, if present, SHOULD contain zero or more [0..\*] id (CONF:8257).
          2. The representedOrganization, if present, MAY contain zero or more [0..\*] name (CONF:8258).
          3. The representedOrganization, if present, SHALL contain exactly one [1..1] telecom (CONF:8260).
          4. The representedOrganization, if present, SHALL contain exactly one [1..1] addr (CONF:8259).
13. MAY contain zero or more [0..\*] participant (CONF:8261).
    1. The participant, if present, SHALL contain exactly one [1..1] @typeCode="LOC" Location (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:8262).
    2. The participant, if present, SHALL contain exactly one [1..1] [Service Delivery Location](#E_Service_Delivery_Location) (templateId:2.16.840.1.113883.10.20.22.4.32) (CONF:15904).
14. MAY contain zero or more [0..\*] entryRelationship (CONF:8264).
    1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="COMP" Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:8265).
    2. The entryRelationship, if present, SHALL contain exactly one [1..1] @inversionInd="true" true (CONF:8266).
    3. The entryRelationship, if present, SHALL contain exactly one [1..1] encounter (CONF:8267).
       1. This encounter SHALL contain exactly one [1..1] @classCode="ENC" Encounter (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:8268).
       2. This encounter SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:8269).
       3. This encounter SHALL contain exactly one [1..1] id (CONF:8270).
          1. Set encounter/id to the id of an encounter in another section to signify they are the same encounter (CONF:16847).
15. MAY contain zero or one [0..1] entryRelationship (CONF:8272) such that it
    1. SHALL contain exactly one [1..1] @typeCode="SUBJ" Has Subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:8273).
    2. SHALL contain exactly one [1..1] @inversionInd="true" true (CONF:8274).
    3. SHALL contain exactly one [1..1] [Instructions](#E_Instructions) (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:15905).
16. MAY contain zero or more [0..\*] entryRelationship (CONF:8276) such that it
    1. SHALL contain exactly one [1..1] @typeCode="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:8277).
    2. SHALL contain exactly one [1..1] [Indication](#E_Indication) (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:15906).
17. MAY contain zero or more [0..\*] entryRelationship (CONF:8279) such that it
    1. SHALL contain exactly one [1..1] @typeCode="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:8280).
    2. SHALL contain exactly one [1..1] [Medication Activity](#E_Medication_Activity) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:15907).

Table 230: MoodCodeEvnInt

|  |  |  |
| --- | --- | --- |
| Value Set: MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 | | |
| Code | Code System | Print Name |
| EVN | ActMood | Event |
| INT | ActMood | Intent |

Table 231: ProcedureAct statusCode

|  |  |  |
| --- | --- | --- |
| Value Set: ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22 | | |
| Code | Code System | Print Name |
| completed | ActStatus | Completed |
| active | ActStatus | Active |
| aborted | ActStatus | Aborted |
| cancelled | ActStatus | Cancelled |

Table 232: Act Priority Value Set

|  |  |  |
| --- | --- | --- |
| Value Set: Act Priority Value Set 2.16.840.1.113883.1.11.16866 | | |
| Code | Code System | Print Name |
| A | ActPriority | ASAP |
| CR | ActPriority | Callback results |
| CS | ActPriority | Callback for scheduling |
| CSP | ActPriority | Callback placer for scheduling |
| CSR | ActPriority | Contact recipient for scheduling |
| EL | ActPriority | Elective |
| EM | ActPriority | Emergency |
| P | ActPriority | Preoperative |
| PRN | ActPriority | As needed |
| R | ActPriority | Routine |
| RR | ActPriority | Rush reporting |
| S | ActPriority | Stat |
| T | ActPriority | Timing critical |
| UD | ActPriority | Use as directed |
| UR | ActPriority | Urgent |

Procedure Activity Procedure

[procedure: templateId 2.16.840.1.113883.10.20.22.4.14 (open)]

| Used By: | Contains Entries: |
| --- | --- |
| [Procedures Section (entries optional)](#S_Procedures_Section_entries_optional) (optional)  [Reaction Observation](#E_Reaction_Observation) (optional) | [Indication](#E_Indication)  [Instructions](#E_Instructions)  [Medication Activity](#E_Medication_Activity)  [Product Instance](#E_Product_Instance)  [Service Delivery Location](#E_Service_Delivery_Location) |

Table 233: Procedure Activity Procedure Contexts

The common notion of ""procedure"" is broader than that specified by the HL7 Version 3 Reference Information Model (RIM). Therefore procedure templates can be represented with various RIM classes: act (e.g., dressing change), observation (e.g., EEG), procedure (e.g. splenectomy).

This clinical statement represents procedures whose immediate and primary outcome (post-condition) is the alteration of the physical condition of the patient. Examples of these procedures are an appendectomy, hip replacement and a creation of a gastrostomy.

Table 234: Procedure Activity Procedure Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | procedure[templateId/@root = '2.16.840.1.113883.10.20.22.4.14'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7652](#C_7652) | 2.16.840.1.113883.5.6 (HL7ActClass) = PROC |
|  | @moodCode | 1..1 | SHALL |  | [7653](#C_7653) | 2.16.840.1.113883.11.20.9.18 (MoodCodeEvnInt) |
|  | templateId | 1..1 | SHALL |  | [7654](#C_7654) |  |
|  | @root | 1..1 | SHALL |  | [10521](#C_10521) | 2.16.840.1.113883.10.20.22.4.14 |
|  | id | 1..\* | SHALL |  | [7655](#C_7655) |  |
|  | code | 1..1 | SHALL |  | [7656](#C_7656) |  |
|  | originalText | 0..1 | SHOULD |  | [19203](#C_19203) |  |
|  | reference | 0..1 | SHOULD |  | [19204](#C_19204) |  |
|  | @value | 0..1 | SHOULD |  | [19205](#C_19205) |  |
|  | statusCode | 1..1 | SHALL |  | [7661](#C_7661) | 2.16.840.1.113883.11.20.9.22 (ProcedureAct statusCode) |
|  | effectiveTime | 0..1 | SHOULD |  | [7662](#C_7662) |  |
|  | priorityCode | 0..1 | MAY |  | [7668](#C_7668) | 2.16.840.1.113883.1.11.16866 (Act Priority Value Set) |
|  | methodCode | 0..1 | MAY | SET<CE> | [7670](#C_7670) |  |
|  | targetSiteCode | 0..\* | SHOULD |  | [7683](#C_7683) |  |
|  | @code | 1..1 | SHALL |  | [16082](#C_16082) | 2.16.840.1.113883.3.88.12.3221.8.9 (Body Site Value Set) |
|  | specimen | 0..\* | MAY |  | [7697](#C_7697) |  |
|  | specimenRole | 1..1 | SHALL |  | [7704](#C_7704) |  |
|  | id | 0..\* | SHOULD |  | [7716](#C_7716) |  |
|  | performer | 0..\* | SHOULD |  | [7718](#C_7718) |  |
|  | assignedEntity | 1..1 | SHALL |  | [7720](#C_7720) |  |
|  | id | 1..\* | SHALL |  | [7722](#C_7722) |  |
|  | addr | 1..1 | SHALL |  | [7731](#C_7731) |  |
|  | telecom | 1..1 | SHALL |  | [7732](#C_7732) |  |
|  | representedOrganization | 0..1 | SHOULD |  | [7733](#C_7733) |  |
|  | id | 0..\* | SHOULD |  | [7734](#C_7734) |  |
|  | name | 0..\* | MAY |  | [7735](#C_7735) |  |
|  | telecom | 1..1 | SHALL |  | [7737](#C_7737) |  |
|  | addr | 1..1 | SHALL |  | [7736](#C_7736) |  |
|  | participant | 0..\* | MAY |  | [7751](#C_7751) |  |
|  | @typeCode | 1..1 | SHALL |  | [7752](#C_7752) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = DEV |
|  | participantRole | 1..1 | SHALL |  | [15911](#C_15911) |  |
|  | participant | 0..\* | MAY |  | [7765](#C_7765) |  |
|  | @typeCode | 1..1 | SHALL |  | [7766](#C_7766) | 2.16.840.1.113883.5.90 (HL7ParticipationType) = LOC |
|  | participantRole | 1..1 | SHALL |  | [15912](#C_15912) |  |
|  | entryRelationship | 0..\* | MAY |  | [7768](#C_7768) |  |
|  | @typeCode | 1..1 | SHALL |  | [7769](#C_7769) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | @inversionInd | 1..1 | SHALL |  | [8009](#C_8009) | true |
|  | encounter | 1..1 | SHALL |  | [7770](#C_7770) |  |
|  | @classCode | 1..1 | SHALL |  | [7771](#C_7771) | 2.16.840.1.113883.5.6 (HL7ActClass) = ENC |
|  | @moodCode | 1..1 | SHALL |  | [7772](#C_7772) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | id | 1..1 | SHALL |  | [7773](#C_7773) |  |
|  | entryRelationship | 0..1 | MAY |  | [7775](#C_7775) |  |
|  | @typeCode | 1..1 | SHALL |  | [7776](#C_7776) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | @inversionInd | 1..1 | SHALL |  | [7777](#C_7777) | true |
|  | act | 1..1 | SHALL |  | [15913](#C_15913) |  |
|  | entryRelationship | 0..\* | MAY |  | [7779](#C_7779) |  |
|  | @typeCode | 1..1 | SHALL |  | [7780](#C_7780) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON |
|  | observation | 1..1 | SHALL |  | [15914](#C_15914) |  |
|  | entryRelationship | 0..\* | MAY |  | [7886](#C_7886) |  |
|  | @typeCode | 1..1 | SHALL |  | [7887](#C_7887) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | substanceAdministration | 1..1 | SHALL |  | [15915](#C_15915) |  |

1. SHALL contain exactly one [1..1] @classCode="PROC" Procedure (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7652).
2. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 STATIC 2011-04-03 (CONF:7653).
3. SHALL contain exactly one [1..1] templateId (CONF:7654) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.14" (CONF:10521).
4. SHALL contain at least one [1..\*] id (CONF:7655).
5. SHALL contain exactly one [1..1] code (CONF:7656).
   1. This code SHOULD contain zero or one [0..1] originalText (CONF:19203).
      1. The originalText, if present, SHOULD contain zero or one [0..1] reference (CONF:19204).
         1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:19205).
            1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:19206).
   2. This code in a procedure activity SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (CodeSystem: 2.16.840.1.113883.6.12) or ICD10 PCS (CodeSystem: 2.16.840.1.113883.6.4) (CONF:19207).
6. SHALL contain exactly one [1..1] statusCode, which SHALL be selected from ValueSet ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22 DYNAMIC (CONF:7661).
7. SHOULD contain zero or one [0..1] effectiveTime (CONF:7662).
8. MAY contain zero or one [0..1] priorityCode, which SHALL be selected from ValueSet Act Priority Value Set 2.16.840.1.113883.1.11.16866 DYNAMIC (CONF:7668).
9. MAY contain zero or one [0..1] methodCode (CONF:7670).
   1. MethodCode SHALL NOT conflict with the method inherent in Procedure / code (CONF:7890).
10. SHOULD contain zero or more [0..\*] targetSiteCode (CONF:7683).
    1. The targetSiteCode, if present, SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet Body Site Value Set 2.16.840.1.113883.3.88.12.3221.8.9 DYNAMIC (CONF:16082).
11. MAY contain zero or more [0..\*] specimen (CONF:7697).
    1. The specimen, if present, SHALL contain exactly one [1..1] specimenRole (CONF:7704).
       1. This specimenRole SHOULD contain zero or more [0..\*] id (CONF:7716).
          1. If you want to indicate that the Procedure and the Results are referring to the same specimen, the Procedure/specimen/specimenRole/id SHOULD be set to equal an Organizer/specimen/ specimenRole/id (CONF:7717).
    2. This specimen is for representing specimens obtained from a procedure (CONF:16842).
12. SHOULD contain zero or more [0..\*] performer (CONF:7718) such that it
    1. SHALL contain exactly one [1..1] assignedEntity (CONF:7720).
       1. This assignedEntity SHALL contain at least one [1..\*] id (CONF:7722).
       2. This assignedEntity SHALL contain exactly one [1..1] addr (CONF:7731).
       3. This assignedEntity SHALL contain exactly one [1..1] telecom (CONF:7732).
       4. This assignedEntity SHOULD contain zero or one [0..1] representedOrganization (CONF:7733).
          1. The representedOrganization, if present, SHOULD contain zero or more [0..\*] id (CONF:7734).
          2. The representedOrganization, if present, MAY contain zero or more [0..\*] name (CONF:7735).
          3. The representedOrganization, if present, SHALL contain exactly one [1..1] telecom (CONF:7737).
          4. The representedOrganization, if present, SHALL contain exactly one [1..1] addr (CONF:7736).
13. MAY contain zero or more [0..\*] participant (CONF:7751) such that it
    1. SHALL contain exactly one [1..1] @typeCode="DEV" Device (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7752).
    2. SHALL contain exactly one [1..1] [Product Instance](#E_Product_Instance) (templateId:2.16.840.1.113883.10.20.22.4.37) (CONF:15911).
14. MAY contain zero or more [0..\*] participant (CONF:7765) such that it
    1. SHALL contain exactly one [1..1] @typeCode="LOC" Location (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 STATIC) (CONF:7766).
    2. SHALL contain exactly one [1..1] [Service Delivery Location](#E_Service_Delivery_Location) (templateId:2.16.840.1.113883.10.20.22.4.32) (CONF:15912).
15. MAY contain zero or more [0..\*] entryRelationship (CONF:7768) such that it
    1. SHALL contain exactly one [1..1] @typeCode="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7769).
    2. SHALL contain exactly one [1..1] @inversionInd="true" true (CONF:8009).
    3. SHALL contain exactly one [1..1] encounter (CONF:7770).
       1. This encounter SHALL contain exactly one [1..1] @classCode="ENC" Encounter (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7771).
       2. This encounter SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7772).
       3. This encounter SHALL contain exactly one [1..1] id (CONF:7773).
          1. Set the encounter ID to the ID of an encounter in another section to signify they are the same encounter (CONF:16843).
16. MAY contain zero or one [0..1] entryRelationship (CONF:7775) such that it
    1. SHALL contain exactly one [1..1] @typeCode="SUBJ" Has Subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7776).
    2. SHALL contain exactly one [1..1] @inversionInd="true" true (CONF:7777).
    3. SHALL contain exactly one [1..1] [Instructions](#E_Instructions) (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:15913).
17. MAY contain zero or more [0..\*] entryRelationship (CONF:7779) such that it
    1. SHALL contain exactly one [1..1] @typeCode="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7780).
    2. SHALL contain exactly one [1..1] [Indication](#E_Indication) (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:15914).
18. MAY contain zero or more [0..\*] entryRelationship (CONF:7886) such that it
    1. SHALL contain exactly one [1..1] @typeCode="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7887).
    2. SHALL contain exactly one [1..1] [Medication Activity](#E_Medication_Activity) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:15915).

Table 235: MoodCodeEvnInt

|  |  |  |
| --- | --- | --- |
| Value Set: MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 | | |
| Code | Code System | Print Name |
| EVN | ActMood | Event |
| INT | ActMood | Intent |

Table 236: ProcedureAct statusCode

|  |  |  |
| --- | --- | --- |
| Value Set: ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22 | | |
| Code | Code System | Print Name |
| completed | ActStatus | Completed |
| active | ActStatus | Active |
| aborted | ActStatus | Aborted |
| cancelled | ActStatus | Cancelled |

Table 237: Act Priority Value Set

|  |  |  |
| --- | --- | --- |
| Value Set: Act Priority Value Set 2.16.840.1.113883.1.11.16866 | | |
| Code | Code System | Print Name |
| A | ActPriority | ASAP |
| CR | ActPriority | Callback results |
| CS | ActPriority | Callback for scheduling |
| CSP | ActPriority | Callback placer for scheduling |
| CSR | ActPriority | Contact recipient for scheduling |
| EL | ActPriority | Elective |
| EM | ActPriority | Emergency |
| P | ActPriority | Preoperative |
| PRN | ActPriority | As needed |
| R | ActPriority | Routine |
| RR | ActPriority | Rush reporting |
| S | ActPriority | Stat |
| T | ActPriority | Timing critical |
| UD | ActPriority | Use as directed |
| UR | ActPriority | Urgent |

Breast Cancer Procedures

[Procedure: templateId 2.16.840.1.113883.10.20.30.3.12 (open)]

Table 238: Breast Cancer Procedures Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Procedures Section BCTPS](#Procedures_Section_BCTPS_) (required) | [Lymph Node Sampling Result Organizer](#E_Lymph_Node_Sampling_Result_Organizer) |

This clinical statement represents procedures that are performed on a patient with breast cancer.

Notes: The "Breast Cancer Procedure" (Temp) Value Set is not yet complete. The procedures identified in the BCTPS are simply: Lumpectomy, Mastectomy, Mastectomy with immediate reconstruction, axillary dissection and sentinel node biopsy- is this unnecessarily limiting or just right for the use case? Inquire with stakeholders if breast Lymph Node biopsy results will almost always be sent in the note or only sometimes? (MAY vs SHOULD)

Table 2: Breast Cancer Procedures Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Procedure[templateId/@root = '2.16.840.1.113883.10.20.30.3.12'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [23112](#C_23112) |  |
|  | @root | 1..1 | SHALL |  | [23113](#C_23113) | 2.16.840.1.113883.10.20.30.3.12 |
|  | code | 1..1 | SHALL |  | [26725](#C_26725) | 2.16.840.1.113883.11.20.11.16 (Breast Cancer Procedures (Temp)) |
|  | statusCode | 1..1 | SHALL |  | [23128](#C_23128) |  |
|  | @code | 1..1 | SHALL |  | [23129](#C_23129) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 1..1 | SHALL |  | [23130](#C_23130) |  |
|  | methodCode | 0..1 | MAY |  | [24962](#C_24962) |  |
|  | entryRelationship | 0..1 | SHOULD |  | [23131](#C_23131) |  |
|  | organizer | 1..1 | SHALL |  | [23132](#C_23132) |  |

1. Conforms to [Procedure Activity Procedure](#E_Procedure_Activity_Procedure) template (2.16.840.1.113883.10.20.22.4.14).
2. SHALL contain exactly one [1..1] templateId (CONF:23112) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.12" (CONF:23113).
3. SHALL contain exactly one [1..1] code, which SHALL be selected from ValueSet Breast Cancer Procedures (Temp) 2.16.840.1.113883.11.20.11.16 (CONF:26725).
4. SHALL contain exactly one [1..1] statusCode (CONF:23128).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:23129).
5. SHALL contain exactly one [1..1] effectiveTime (CONF:23130).

methodCode may be used to describe the surgical method used in performing the procedure. Many Breast cancer procedure codes are pre-coordinated with the method inherent in the code. If method code is used it should not conflict with the procedureCode

1. MAY contain zero or one [0..1] methodCode (CONF:24962).
2. SHOULD contain zero or one [0..1] entryRelationship (CONF:23131).
   1. The entryRelationship, if present, SHALL contain exactly one [1..1] Lymph Node Sampling Result Organizer (templateId:2.16.840.1.113883.10.20.30.3.13) (CONF:23132).

Table 240: Breast Cancer Procedures (Temp)

|  |  |  |
| --- | --- | --- |
| Value Set: Breast Cancer Procedures (Temp) 2.16.840.1.113883.11.20.11.16 | | |
| Code | Code System | Print Name |
| 408469009 | SNOMED-CT | breast surgery |
| 79544006 | SNOMED-CT | block dissection of axillary lymph nodes |
| 396487001 | SNOMED-CT | sentinel lymph node biopsy |
| 33496007 | SNOMED-CT | breast reconstruction |
| 384723003 | SNOMED-CT | radical mastectomy |
| 172043006 | SNOMED-CT | simple mastectomy |
| 392022002 | SNOMED-CT | lumpectomy |
| 234262008 | SNOMED-CT | excision of axillary lymph node |
| … |  |  |

Figure 70: Breast cancer procedures example

<!-- BREAST CANCER PROCEDURES (example of reconstruction)-->

<entry typeCode="DRIV">

<!--SHALL contain Breast Procedures template

- the breast procedures template might only represent a procedure

and no other details or MAY/SHOULD contain biopsy info -->

<procedure classCode="PROC" moodCode="EVN">

<!-- Procedure Activity Procedure templateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.14"/>

<!-- Breast Cancer Procedures templateID-->

<templateId root="2.16.840.1.113883.10.20.30.3.12"/>

<id root="e401f340-7be2-11db-9fe1-0800200c9a66"/>

<!-- Procedure Code is bound to value set of any type of surgery

related to the breast cancer (tbd) -->

<code code="33496007" codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT" displayName="reconstruction of breast

(procedure)"/>

<text>Mammoplasty</text>

<statusCode code="completed"/>

<effectiveTime value="20121130"/>

<methodCode code="70966003" codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT" displayName="breast reconstruction with

transversus abdominis muscle flap"/>

</procedure>

</entry>

Product Instance [Closed for comments; published July 2012]

[participantRole: templateId 2.16.840.1.113883.10.20.22.4.37 (open)]

Table 242: Product Instance Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Procedure Activity Procedure](#E_Procedure_Activity_Procedure) (optional)  [Non-Medicinal Supply Activity](#E_NonMedicinal_Supply_Activity) (optional) |  |

This clinical statement represents a particular device that was placed in or used as part of a procedure or other act. This provides a record of the identifier and other details about the given product that was used. For example, it is important to have a record that indicates not just that a hip prostheses was placed in a patient but that it was a particular hip prostheses number with a unique identifier.

The FDA Amendments Act specifies the creation of a Unique Device Identification (UDI) System that requires the label of devices to bear a unique identifier that will standardize device identification and identify the device through distribution and use.

The UDI should be sent in the participantRole/id.

Table 242: Product Instance Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | participantRole[templateId/@root = '2.16.840.1.113883.10.20.22.4.37'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7900](#C_7900) | 2.16.840.1.113883.5.110 (RoleClass) = MANU |
|  | templateId | 1..1 | SHALL |  | [7901](#C_7901) |  |
|  | @root | 1..1 | SHALL |  | [10522](#C_10522) | 2.16.840.1.113883.10.20.22.4.37 |
|  | id | 1..\* | SHALL |  | [7902](#C_7902) |  |
|  | playingDevice | 1..1 | SHALL |  | [7903](#C_7903) |  |
|  | code | 0..1 | SHOULD |  | [16837](#C_16837) |  |
|  | scopingEntity | 1..1 | SHALL |  | [7905](#C_7905) |  |
|  | id | 1..\* | SHALL |  | [7908](#C_7908) |  |

1. SHALL contain exactly one [1..1] @classCode="MANU" Manufactured Product (CodeSystem: RoleClass 2.16.840.1.113883.5.110 STATIC) (CONF:7900).
2. SHALL contain exactly one [1..1] templateId (CONF:7901) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.37" (CONF:10522).
3. SHALL contain at least one [1..\*] id (CONF:7902).
4. SHALL contain exactly one [1..1] playingDevice (CONF:7903).
   1. This playingDevice SHOULD contain zero or one [0..1] code (CONF:16837).
5. SHALL contain exactly one [1..1] scopingEntity (CONF:7905).
   1. This scopingEntity SHALL contain at least one [1..\*] id (CONF:7908).

Reaction Observation[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.9 (open)]

Table 244: Reaction Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Medication Activity](#E_Medication_Activity) (optional)  [Allergy - Intolerance Observation](#E_Allergy__Intolerance_Observation) (optional)  [Substance or Device Allergy - Intolerance Observation](#E_Substance_or_Device_Allergy__Intolera) (optional) | [Medication Activity](#E_Medication_Activity)  [Procedure Activity Procedure](#E_Procedure_Activity_Procedure)  [Severity Observation](#E_Severity_Observation) |

This clinical statement represents an undesired symptom, finding, etc., due to an administered or exposed substance. A reaction can be defined with respect to its severity, and can have been treated by one or more interventions.

Table 245: Reaction Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
| Green Reaction Observation | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.9'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7325](#C_7325) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [7326](#C_7326) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [7323](#C_7323) |  |
|  | @root | 1..1 | SHALL |  | [10523](#C_10523) | 2.16.840.1.113883.10.20.22.4.9 |
|  | id | 1..1 | SHALL |  | [7329](#C_7329) |  |
|  | code | 1..1 | SHALL |  | [16851](#C_16851) |  |
| reactionFreeText | text | 0..1 | SHOULD |  | [7330](#C_7330) |  |
|  | reference | 0..1 | SHOULD |  | [15917](#C_15917) |  |
|  | @value | 0..1 | SHOULD |  | [15918](#C_15918) |  |
|  | statusCode | 1..1 | SHALL |  | [7328](#C_7328) |  |
|  | @code | 1..1 | SHALL |  | [19114](#C_19114) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 0..1 | SHOULD |  | [7332](#C_7332) |  |
|  | low | 0..1 | SHOULD |  | [7333](#C_7333) |  |
|  | high | 0..1 | SHOULD |  | [7334](#C_7334) |  |
| reactionCoded | value | 1..1 | SHALL | CD | [7335](#C_7335) | 2.16.840.1.113883.3.88.12.3221.7.4 (Problem Value Set) |
|  | entryRelationship | 0..\* | MAY |  | [7337](#C_7337) |  |
|  | @typeCode | 1..1 | SHALL |  | [7338](#C_7338) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON |
|  | @inversionInd | 1..1 | SHALL |  | [7343](#C_7343) | true |
|  | procedure | 1..1 | SHALL |  | [15920](#C_15920) |  |
|  | entryRelationship | 0..\* | MAY |  | [7340](#C_7340) |  |
|  | @typeCode | 1..1 | SHALL |  | [7341](#C_7341) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON |
|  | @inversionInd | 1..1 | SHALL |  | [7344](#C_7344) | true |
|  | substanceAdministration | 1..1 | SHALL |  | [15921](#C_15921) |  |
| severity | entryRelationship | 0..1 | SHOULD |  | [7580](#C_7580) |  |
|  | @typeCode | 1..1 | SHALL |  | [7581](#C_7581) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | @inversionInd | 1..1 | SHALL |  | [10375](#C_10375) | true |
|  | observation | 1..1 | SHALL |  | [15922](#C_15922) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7325).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7326).
3. SHALL contain exactly one [1..1] templateId (CONF:7323) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.9" (CONF:10523).
4. SHALL contain exactly one [1..1] id (CONF:7329).
5. SHALL contain exactly one [1..1] code (CONF:16851).
   1. The value set for this code element has not been specified. Implementers are allowed to use any code system, such as SNOMED CT, a locally determined code, or a nullFlavor (CONF:16852).
6. SHOULD contain zero or one [0..1] text (CONF:7330).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:15917).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15918).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15919).
7. SHALL contain exactly one [1..1] statusCode (CONF:7328).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19114).
8. SHOULD contain zero or one [0..1] effectiveTime (CONF:7332).
   1. The effectiveTime, if present, SHOULD contain zero or one [0..1] low (CONF:7333).
   2. The effectiveTime, if present, SHOULD contain zero or one [0..1] high (CONF:7334).
9. SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHALL be selected from ValueSet Problem Value Set 2.16.840.1.113883.3.88.12.3221.7.4 DYNAMIC (CONF:7335).
10. MAY contain zero or more [0..\*] entryRelationship (CONF:7337) such that it
    1. SHALL contain exactly one [1..1] @typeCode="RSON" Has reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7338).
    2. SHALL contain exactly one [1..1] @inversionInd="true" True (CONF:7343).
    3. SHALL contain exactly one [1..1] [Procedure Activity Procedure](#E_Procedure_Activity_Procedure) (templateId:2.16.840.1.113883.10.20.22.4.14) (CONF:15920).
       1. This procedure activity is intended to contain information about procedures that were performed in response to an allergy reaction (CONF:16853).
11. MAY contain zero or more [0..\*] entryRelationship (CONF:7340) such that it
    1. SHALL contain exactly one [1..1] @typeCode="RSON" Has reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7341).
    2. SHALL contain exactly one [1..1] @inversionInd="true" True (CONF:7344).
    3. SHALL contain exactly one [1..1] [Medication Activity](#E_Medication_Activity) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:15921).
       1. This medication activity is intended to contain information about medications that were administered in response to an allergy reaction (CONF:16840).
12. SHOULD contain zero or one [0..1] entryRelationship (CONF:7580) such that it
    1. SHALL contain exactly one [1..1] @typeCode="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7581).
    2. SHALL contain exactly one [1..1] @inversionInd="true" TRUE (CONF:10375).
    3. SHALL contain exactly one [1..1] [Severity Observation](#E_Severity_Observation) (templateId:2.16.840.1.113883.10.20.22.4.8) (CONF:15922).

Therapy Side Effects

[Observation: templateId 2.16.840.1.113883.10.20.30.3.42 (open)]

Table 246: Therapy Side Effects Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Chemotherapy Regimen](#E_Chemotherapy_Regimen) (optional) |  |

This clinical statement represents the side effects of a cancer treatment therapy that occurred during the patient’s treatment.

Notes: Discussion Point: We have included the whole C-CDA Allergies/Adverse events Section. The Therapy side effects could be represented there only/alternatively. We have kept this contained in the Chemotherapy Regimen template as an alternate. Value set issue: needs to define and review the complete list of codes for "Chemotherapy Side Effects" value set. (Some example codes are entered for now.)

Table 247: Therapy Side Effects Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.42'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [23941](#C_23941) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [23942](#C_23942) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [23943](#C_23943) |  |
|  | @root | 1..1 | SHALL |  | [23944](#C_23944) | 2.16.840.1.113883.10.20.30.3.42 |
|  | value | 0..1 | SHALL | CD | [23945](#C_23945) |  |
|  | @code | 1..1 | SHALL |  | [23946](#C_23946) | 2.16.840.1.113883.11.20.11.9 (Chemotherapy Side Effects) |

1. Conforms to [Reaction Observation](#E_Reaction_Observation) template (2.16.840.1.113883.10.20.22.4.9).
2. SHALL contain exactly one [1..1] @classCode="OBS" observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23941).
3. SHALL contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23942).
4. SHALL contain exactly one [1..1] templateId (CONF:23943) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.42" (CONF:23944).
5. SHALL contain zero or one [0..1] value with @xsi:type="CD" (CONF:23945).
   1. The value, if present, SHALL contain exactly one [1..1] @code (ValueSet: Chemotherapy Side Effects 2.16.840.1.113883.11.20.11.9 DYNAMIC) (CONF:23946).

Table 248: Chemotherapy Side Effects

|  |  |  |
| --- | --- | --- |
| Value Set: Chemotherapy Side Effects 2.16.840.1.113883.11.20.11.9 | | |
| Code | Code System | Print Name |
| 278040002 | SNOMED-CT | loss of hair |
| 422587007 | SNOMED-CT | nausea |
| 386033004 | SNOMED-CT | neuropathy |
| 165423001 | SNOMED-CT | red blood cell count low |
| 84229001 | SNOMED-CT | fatigue |
| 170951000 | SNOMED-CT | menopause symptoms present |

Figure 71: Therapy side effects example

<!-- Therapy Side Effects 2.16.840.1.113883.10.20.30.3.42 -->

<entryRelationship typeCode="MFST" inversionInd="true">

<!-- SHALL [1..1] Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->

<observation classCode="OBS" moodCode="EVN">

<!-- C-CDA Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->

<templateId root="2.16.840.1.113883.10.20.22.4.9"/>

<!-- therapy side effects observation 2.16.840.1.113883.10.20.30.3.42 –

->

<templateId root="2.16.840.1.113883.10.20.30.3.42"/>

<id root="eac7fa14-c31e-4577-ba62-a021c4481bff"/>

<code nullFlavor="NA"/>

<statusCode code="completed"/>

<effectiveTime>

<low nullFlavor="NI"/>

</effectiveTime>

<value xsi:type="CD" code="56317004"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"

displayName="alopecia"/>

</observation>

</entryRelationship>

<!-- 2nd instance of actual reaction (toxicities) occurred during the therapy –

->

<entryRelationship typeCode="MFST" inversionInd="true">

<!-- SHALL [1..1] Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->

<observation classCode="OBS" moodCode="EVN">

<!-- C-CDA Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->

<templateId root="2.16.840.1.113883.10.20.22.4.9"/>

<!-- therapy side effects observation 2.16.840.1.113883.10.20.30.3.42 –

->

<templateId root="2.16.840.1.113883.10.20.30.3.42"/>

<id root="7abbe099-ed3e-444b-8cd1-db7093aa94e4"/>

<code nullFlavor="NA"/>

<statusCode code="completed"/>

<effectiveTime>

<low nullFlavor="NI"/>

</effectiveTime>

<value xsi:type="CD" code="16932000"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"

displayName="nausea and vomiting"/>

</observation>

</entryRelationship>

<!-- MAY [0..\*] instructions (possible side effects of the therapy -->

<!-- Possible Side Effects 2.16.840.1.113883.10.20.30.3.35 -->

<entryRelationship typeCode="SUBJ">

<!-- Instructions template requires intent mood -->

<act classCode="ACT" moodCode="INT">

<!-- C-CDA Instructions Template -->

<templateId root="2.16.840.1.113883.10.20.22.4.20"/>

<!-- Possible Side Effects Template -->

<templateId root="2.16.840.1.113883.10.20.30.3.35"/>

<code code="396080005"

displayName="medication side effects education"

codeSystem="2.16.840.1.113883.6.96"

...

Result Observation[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.2 (open)]

Table 249: Result Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Result Organizer](#E_Result_Organizer) (required) |  |

This clinical statement represents details of a lab, radiology, or other study performed on a patient.

The result observation includes a statusCode to allow recording the status of an observation. If a Result Observation is not completed, the Result Organizer must include corresponding statusCode. “Pending” results (e.g., a test has been run but results have not been reported yet) should be represented as “active” ActStatus.

Table 250: Result Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.2'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7130](#C_7130) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [7131](#C_7131) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [7136](#C_7136) |  |
|  | @root | 1..1 | SHALL |  | [9138](#C_9138) | 2.16.840.1.113883.10.20.22.4.2 |
|  | id | 1..\* | SHALL |  | [7137](#C_7137) |  |
|  | code | 1..1 | SHALL |  | [7133](#C_7133) |  |
|  | text | 0..1 | SHOULD |  | [7138](#C_7138) |  |
|  | reference | 0..1 | SHOULD |  | [15924](#C_15924) |  |
|  | @value | 0..1 | SHOULD |  | [15925](#C_15925) |  |
|  | statusCode | 1..1 | SHALL |  | [7134](#C_7134) |  |
|  | @code | 1..1 | SHALL |  | [14849](#C_14849) | 2.16.840.1.113883.11.20.9.39 (Result Status) |
|  | effectiveTime | 1..1 | SHALL |  | [7140](#C_7140) |  |
|  | value | 1..1 | SHALL |  | [7143](#C_7143) |  |
|  | interpretationCode | 0..\* | SHOULD |  | [7147](#C_7147) |  |
|  | methodCode | 0..1 | MAY | SET<CE> | [7148](#C_7148) |  |
|  | targetSiteCode | 0..1 | MAY | SET<CD> | [7153](#C_7153) |  |
|  | author | 0..1 | MAY |  | [7149](#C_7149) |  |
|  | referenceRange | 0..\* | SHOULD |  | [7150](#C_7150) |  |
|  | observationRange | 1..1 | SHALL |  | [7151](#C_7151) |  |
|  | code | 0..0 | SHALL NOT |  | [7152](#C_7152) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7130).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7131).
3. SHALL contain exactly one [1..1] templateId (CONF:7136) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.2" (CONF:9138).
4. SHALL contain at least one [1..\*] id (CONF:7137).
5. SHALL contain exactly one [1..1] code (CONF:7133).
   1. SHOULD be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:19211).
   2. Laboratory results SHOULD be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or other constrained terminology named by the US Department of Health and Human Services Office of National Coordinator or other federal agency. Local and/or regional codes for laboratory results are allowed. The Local and/or regional codes SHOULD be sent in the translation element. See the Local code example figure (CONF:19212).
6. SHOULD contain zero or one [0..1] text (CONF:7138).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:15924).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15925).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15926).
7. SHALL contain exactly one [1..1] statusCode (CONF:7134).
   1. This statusCode SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 STATIC (CONF:14849).
8. SHALL contain exactly one [1..1] effectiveTime (CONF:7140).
   1. Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards) (CONF:16838).
9. SHALL contain exactly one [1..1] value (CONF:7143).
10. SHOULD contain zero or more [0..\*] interpretationCode (CONF:7147).
11. MAY contain zero or one [0..1] methodCode (CONF:7148).
12. MAY contain zero or one [0..1] targetSiteCode (CONF:7153).
13. MAY contain zero or one [0..1] author (CONF:7149).
14. SHOULD contain zero or more [0..\*] referenceRange (CONF:7150).
    1. The referenceRange, if present, SHALL contain exactly one [1..1] observationRange (CONF:7151).
       1. This observationRange SHALL NOT contain [0..0] code (CONF:7152).

Table 251: Result Status

|  |  |  |
| --- | --- | --- |
| Value Set: Result Status 2.16.840.1.113883.11.20.9.39 | | |
| Code | Code System | Print Name |
| aborted | ActStatus | aborted |
| active | ActStatus | active |
| cancelled | ActStatus | cancelled |
| completed | ActStatus | completed |
| held | ActStatus | held |
| suspended | ActStatus | suspended |

Cardiac Function Observation

[Observation: templateId 2.16.840.1.113883.10.20.30.3.21 (open)]

Table 252: Cardiac Function Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Results Section BCTPS](#Results_Section_BCTPS) (required) |  |

This clinical statement represents results from cardiac function tests. An effectiveTime is required and is used to infer whether a test was done prior to or after a treatment such as chemotherapy.

Notes: Design Note: code element - ValueSet for Cardiac Function Tests (Temp) (2.16.840.1.113883.11.20.11.5) TBD

Table 253: Cardiac Function Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.21'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [23497](#C_23497) |  |
|  | @root | 1..1 | SHALL |  | [26226](#C_26226) | 2.16.840.1.113883.10.20.30.3.21 |
|  | code | 1..1 | SHALL |  | [23500](#C_23500) | 2.16.840.1.113883.11.20.11.5 (Cardiac Function Tests (Temp)) |
|  | statusCode | 1..1 | SHALL |  | [23501](#C_23501) |  |
|  | @code | 1..1 | SHALL |  | [23502](#C_23502) | 2.16.840.1.113883.5.14 (ActStatus) = Completed |
|  | value | 1..1 | SHALL | PQ | [23504](#C_23504) |  |

1. Conforms to [Result Observation](#E_Result_Observation) template (2.16.840.1.113883.10.20.22.4.2).
2. SHALL contain exactly one [1..1] templateId (CONF:23497) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.21" (CONF:26226).
3. SHALL contain exactly one [1..1] code, which SHALL be selected from ValueSet Cardiac Function Tests (Temp) 2.16.840.1.113883.11.20.11.5 (CONF:23500).
4. SHALL contain exactly one [1..1] statusCode (CONF:23501).
   1. This statusCode SHALL contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23502).
5. SHALL contain exactly one [1..1] value with @xsi:type="PQ" (CONF:23504).

Table 254: Cardiac Function Tests (Temp)

|  |  |  |
| --- | --- | --- |
| Value Set: Cardiac Function Tests (Temp) 2.16.840.1.113883.11.20.11.5 | | |
| Code | Code System | Print Name |
| 70822001 | SNOMED-CT | cardiac ejection fraction |
| 40701008 | SNOMED-CT | echocardiography |
| 404221001 | SNOMED-CT | multiple gated acquisition scanning (MUGA) |

Figure 72: Cardiac function observation example

<entry>

<!-- consolidated CDA Result Observation templateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.2"/>

<!-- Cardiac Function Observation templateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.21"/>

<observation classCode="OBS" moodCode="EVN">

<code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT"

code="404221001" displayName="multiple gated acquisition

scanning"/>

<statusCode code="completed"/>

<!-- Consolidated CDA Result Observation requires effective time -->

<effectiveTime value="201203231430"/>

<value xsi:type="PQ" value="76" unit="[%]"/>

</observation>

</entry>

<entry>

<!-- consolidated CDA Result Observation templateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.2"/>

<!-- Cardiac Function Observation templateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.21"/>

<observation classCode="OBS" moodCode="EVN">

<code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT"

code="404221001" displayName="multiple gated acquisition

scanning"/>

<statusCode code="completed"/>

<!-- Consolidated CDA Result Observation requires effective time -->

<effectiveTime value="201207041430"/>

<value xsi:type="PQ" value="39" unit="[%]"/>

</observation>

</entry>

<entry>

<!-- consolidated CDA Result Observation templateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.2"/>

<!-- Cardiac Function Observation templateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.21"/>

<observation classCode="OBS" moodCode="EVN" negationInd="false">

<code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT"

code="70822001" displayName="cardiac ejection fraction"/>

<statusCode code="completed"/>

<!-- Consolidated CDA Result Observation requires effective time -->

<effectiveTime value="201211041430"/>

<value xsi:type="PQ" value="30" unit="[%]"/>

</observation>

</entry>

Cognitive Status Result Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.74 (open)]

Table 255: Cognitive Status Result Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Functional Status Section](#S_Functional_Status_Section) (optional)  [Cognitive Status Result Organizer](#E_Cognitive_Status_Result_Organizer) (required) | [Assessment Scale Observation](#E_Assessment_Scale_Observation)  [Caregiver Characteristics](#E_Caregiver_Characteristics)  [Non-Medicinal Supply Activity](#E_NonMedicinal_Supply_Activity) |

This clinical statement contains details of an evaluation or assessment of a patient’s cognitive status. The evaluation may include assessment of a patient's mood, memory, and ability to make decisions. The statement, if present, will include supporting caregivers, non-medical devices, and the time period for which the evaluation and assessment were performed.

This is different from a cognitive status problem observation, which is a clinical statement that describes a patient's cognitive condition, findings, or symptoms. Examples of cognitive problem observations are inability to recall, amnesia, dementia, and aggressive behavior.

Table 256: Cognitive Status Result Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.74'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [14249](#C_14249) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [14250](#C_14250) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [14255](#C_14255) |  |
|  | @root | 1..1 | SHALL |  | [14256](#C_14256) | 2.16.840.1.113883.10.20.22.4.74 |
|  | id | 1..\* | SHALL |  | [14257](#C_14257) |  |
|  | code | 1..1 | SHALL |  | [14591](#C_14591) |  |
|  | @code | 0..1 | SHOULD |  | [14592](#C_14592) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 373930000 |
|  | text | 0..1 | SHOULD |  | [14258](#C_14258) |  |
|  | reference | 0..1 | SHOULD |  | [15549](#C_15549) |  |
|  | @value | 0..1 | SHOULD |  | [15550](#C_15550) |  |
|  | statusCode | 1..1 | SHALL |  | [14254](#C_14254) |  |
|  | @code | 1..1 | SHALL |  | [19092](#C_19092) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 1..1 | SHALL |  | [14261](#C_14261) |  |
|  | value | 1..1 | SHALL |  | [14263](#C_14263) |  |
|  | interpretationCode | 0..\* | SHOULD |  | [14264](#C_14264) |  |
|  | methodCode | 0..1 | MAY | SET<CE> | [14265](#C_14265) |  |
|  | targetSiteCode | 0..1 | MAY | SET<CD> | [14270](#C_14270) |  |
|  | author | 0..1 | MAY |  | [14266](#C_14266) |  |
|  | entryRelationship | 0..\* | MAY |  | [14272](#C_14272) |  |
|  | @typeCode | 1..1 | SHALL |  | [14593](#C_14593) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | supply | 1..1 | SHALL |  | [14273](#C_14273) |  |
|  | entryRelationship | 0..\* | MAY |  | [14276](#C_14276) |  |
|  | @typeCode | 1..1 | SHALL |  | [14594](#C_14594) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | observation | 1..1 | SHALL |  | [14277](#C_14277) |  |
|  | entryRelationship | 0..\* | MAY |  | [14469](#C_14469) |  |
|  | @typeCode | 1..1 | SHALL |  | [14595](#C_14595) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
|  | observation | 1..1 | SHALL |  | [14470](#C_14470) |  |
|  | referenceRange | 0..\* | SHOULD |  | [14267](#C_14267) |  |
|  | observationRange | 1..1 | SHALL |  | [14268](#C_14268) |  |
|  | code | 0..0 | SHALL NOT |  | [14269](#C_14269) |  |

1. Conforms to [Result Observation](#E_Result_Observation) template (2.16.840.1.113883.10.20.22.4.2).
2. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:14249).
3. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14250).
4. SHALL contain exactly one [1..1] templateId (CONF:14255) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.74" (CONF:14256).
5. SHALL contain at least one [1..\*] id (CONF:14257).
6. SHALL contain exactly one [1..1] code (CONF:14591).
   1. This code SHOULD contain zero or one [0..1] @code="373930000" Cognitive function finding (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:14592).
7. SHOULD contain zero or one [0..1] text (CONF:14258).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:15549).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15550).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15551).
8. SHALL contain exactly one [1..1] statusCode (CONF:14254).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19092).

Represents clinically effective time of the measurement, which may be the time the measurement was performed (e.g., a BP measurement), or may be the time the sample was taken (and measured some time afterwards).

1. SHALL contain exactly one [1..1] effectiveTime (CONF:14261).
2. SHALL contain exactly one [1..1] value (CONF:14263).
   1. If xsi:type=“CD”, SHOULD contain a code from SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:14271).
3. SHOULD contain zero or more [0..\*] interpretationCode (CONF:14264).
4. MAY contain zero or one [0..1] methodCode (CONF:14265).
5. MAY contain zero or one [0..1] targetSiteCode (CONF:14270).
6. MAY contain zero or one [0..1] author (CONF:14266).
7. MAY contain zero or more [0..\*] entryRelationship (CONF:14272) such that it
   1. SHALL contain exactly one [1..1] @typeCode="REFR" refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:14593).
   2. SHALL contain exactly one [1..1] [Non-Medicinal Supply Activity](#E_NonMedicinal_Supply_Activity) (templateId:2.16.840.1.113883.10.20.22.4.50) (CONF:14273).
8. MAY contain zero or more [0..\*] entryRelationship (CONF:14276) such that it
   1. SHALL contain exactly one [1..1] @typeCode="REFR" refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:14594).
   2. SHALL contain exactly one [1..1] [Caregiver Characteristics](#E_Caregiver_Characteristics) (templateId:2.16.840.1.113883.10.20.22.4.72) (CONF:14277).
9. MAY contain zero or more [0..\*] entryRelationship (CONF:14469) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:14595).
   2. SHALL contain exactly one [1..1] [Assessment Scale Observation](#E_Assessment_Scale_Observation) (templateId:2.16.840.1.113883.10.20.22.4.69) (CONF:14470).
10. SHOULD contain zero or more [0..\*] referenceRange (CONF:14267).
    1. The referenceRange, if present, SHALL contain exactly one [1..1] observationRange (CONF:14268).
       1. This observationRange SHALL NOT contain [0..0] code (CONF:14269).

Estrogen Receptor Status

[Observation: templateId 2.16.840.1.113883.10.20.30.3.19 (open)]

Table 257: Estrogen Receptor Status Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Receptor Status Organizer](#E_Receptor_Status_Organizer) (required) |  |

This clinical statement represents the estrogen receptor status results.

Table 258: Estrogen Receptor Status Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.19'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [23461](#C_23461) |  |
|  | @root | 1..1 | SHALL |  | [23462](#C_23462) | 2.16.840.1.113883.10.20.30.3.19 |
|  | code | 1..1 | SHALL |  | [23463](#C_23463) |  |
|  | @code | 1..1 | SHALL |  | [23464](#C_23464) | 16112-5 |
|  | @codeSystem | 1..1 | SHALL |  | [23465](#C_23465) | 2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
|  | statusCode | 1..1 | SHALL |  | [23466](#C_23466) |  |
|  | @code | 1..1 | SHALL |  | [23467](#C_23467) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | value | 1..1 | SHALL | CD | [23565](#C_23565) |  |
|  | @code | 1..1 | SHALL |  | [23566](#C_23566) | 2.16.840.1.113883.11.20.11.2 (Estrogen Recepetor Status (temp)) |

1. Conforms to [Result Observation](#E_Result_Observation) template (2.16.840.1.113883.10.20.22.4.2).
2. SHALL contain exactly one [1..1] templateId (CONF:23461) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.19" (CONF:23462).
3. SHALL contain exactly one [1..1] code (CONF:23463).
   1. This code SHALL contain exactly one [1..1] @code="16112-5" Estrogen Receptor [interpretation] in Tissue (CONF:23464).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:23465).
4. SHALL contain exactly one [1..1] statusCode (CONF:23466).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:23467).
5. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:23565).
   1. This value SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet Estrogen and Progesterone Recepetor Status (temp) 2.16.840.1.113883.11.20.11.2 (CONF:23566).

Table 259: Estrogen Recepetor Status (temp)

|  |  |  |
| --- | --- | --- |
| Value Set: Estrogen Recepetor Status (temp) 2.16.840.1.113883.11.20.11.2 | | |
| Code | Code System | Print Name |
| 260385009 | SNOMED-CT | Negative |
| 10828004 | SNOMED-CT | Positive |

Figure 73: Estrogen receptor status example

<observation classCode="OBS" moodCode="EVN">

<!-- consolidated CDA Result Observation templateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.2"/>

<!-- Estrogen Receptor Status templateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.19"/>

<id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>

<code code="16112-5"

displayName="Estrogen Receptor [interpretation] in Tissue"

codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>

<text> ER status </text>

<statusCode code="completed"/>

<effectiveTime value="201203231430"/>

<!-- Need to specify ER Status ValueSet -->

<value xsi:type="CD" code="10828004"

codeSystem="2.16.840.1.113883.6.96" displayName="positive"/>

</observation>

Functional Status Result Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.67 (open)]

Table 260: Functional Status Result Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Functional Status Section](#S_Functional_Status_Section) (optional)  [Functional Status Result Organizer](#E_Functional_Status_Result_Organizer) (required) | [Assessment Scale Observation](#E_Assessment_Scale_Observation)  [Caregiver Characteristics](#E_Caregiver_Characteristics)  [Non-Medicinal Supply Activity](#E_NonMedicinal_Supply_Activity) |

This clinical statement represents details of an evaluation or assessment of a patient's functional status. The evaluation may include assessment of a patient's language, vision, hearing, activities of daily living, behavior, general function, mobility, and self-care status. The statement, if present, will include supporting caregivers, non-medical devices, and the time period for which the evaluation and assessment were performed.

Table 261: Functional Status Result Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.67'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [13905](#C_13905) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [13906](#C_13906) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [13889](#C_13889) |  |
|  | @root | 1..1 | SHALL |  | [13890](#C_13890) | 2.16.840.1.113883.10.20.22.4.67 |
|  | id | 1..\* | SHALL |  | [13907](#C_13907) |  |
|  | code | 1..1 | SHALL |  | [13908](#C_13908) | 2.16.840.1.113883.6.1 (LOINC) |
|  | @code | 0..1 | SHALL |  | [26448](#C_26448) | 2.16.840.1.113883.6.1 (LOINC) |
|  | text | 0..1 | SHOULD |  | [13926](#C_13926) |  |
|  | reference | 0..1 | SHOULD |  | [13927](#C_13927) |  |
|  | statusCode | 1..1 | SHALL |  | [13929](#C_13929) |  |
|  | @code | 1..1 | SHALL |  | [19101](#C_19101) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 1..1 | SHALL |  | [13930](#C_13930) |  |
|  | value | 1..1 | SHALL |  | [13932](#C_13932) |  |
|  | interpretationCode | 0..\* | SHOULD |  | [13933](#C_13933) |  |
|  | methodCode | 0..1 | MAY |  | [13934](#C_13934) |  |
|  | targetSiteCode | 0..1 | MAY |  | [13935](#C_13935) |  |
|  | author | 0..1 | MAY |  | [13936](#C_13936) |  |
|  | entryRelationship | 0..1 | MAY |  | [13892](#C_13892) |  |
|  | @typeCode | 1..1 | SHALL |  | [14596](#C_14596) | REFR |
|  | supply | 1..1 | SHALL |  | [14218](#C_14218) |  |
|  | entryRelationship | 0..1 | MAY |  | [13895](#C_13895) |  |
|  | @typeCode | 1..1 | SHALL |  | [14597](#C_14597) | REFR |
|  | observation | 1..1 | SHALL |  | [13897](#C_13897) |  |
|  | entryRelationship | 0..1 | MAY |  | [14465](#C_14465) |  |
|  | @typeCode | 1..1 | SHALL |  | [14598](#C_14598) | COMP |
|  | observation | 1..1 | SHALL |  | [14466](#C_14466) |  |
|  | referenceRange | 0..\* | SHOULD |  | [13937](#C_13937) |  |
|  | observationRange | 1..1 | SHALL |  | [13938](#C_13938) |  |

1. Conforms to [Result Observation](#E_Result_Observation) template (2.16.840.1.113883.10.20.22.4.2).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:13905).
3. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:13906).
4. SHALL contain exactly one [1..1] templateId (CONF:13889) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.67" (CONF:13890).
5. SHALL contain at least one [1..\*] id (CONF:13907).
6. SHALL contain exactly one [1..1] code (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:13908).
   1. This code SHALL contain zero or one [0..1] @code, which SHOULD be selected from CodeSystem LOINC (2.16.840.1.113883.6.1) STATIC (CONF:26448).
7. SHOULD contain zero or one [0..1] text (CONF:13926).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:13927).
      1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:13928).
8. SHALL contain exactly one [1..1] statusCode (CONF:13929).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19101).

Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards)

1. SHALL contain exactly one [1..1] effectiveTime (CONF:13930).
2. SHALL contain exactly one [1..1] value (CONF:13932).
   1. If xsi:type=“CD”, SHOULD contain a code from SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:14234).
3. SHOULD contain zero or more [0..\*] interpretationCode (CONF:13933).
4. MAY contain zero or one [0..1] methodCode (CONF:13934).
5. MAY contain zero or one [0..1] targetSiteCode (CONF:13935).
6. MAY contain zero or one [0..1] author (CONF:13936).
7. MAY contain zero or one [0..1] entryRelationship (CONF:13892) such that it
   1. SHALL contain exactly one [1..1] @typeCode="REFR" refers to (CONF:14596).
   2. SHALL contain exactly one [1..1] [Non-Medicinal Supply Activity](#E_NonMedicinal_Supply_Activity) (templateId:2.16.840.1.113883.10.20.22.4.50) (CONF:14218).
8. MAY contain zero or one [0..1] entryRelationship (CONF:13895) such that it
   1. SHALL contain exactly one [1..1] @typeCode="REFR" refers to (CONF:14597).
   2. SHALL contain exactly one [1..1] [Caregiver Characteristics](#E_Caregiver_Characteristics) (templateId:2.16.840.1.113883.10.20.22.4.72) (CONF:13897).
9. MAY contain zero or one [0..1] entryRelationship (CONF:14465) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" has component (CONF:14598).
   2. SHALL contain exactly one [1..1] [Assessment Scale Observation](#E_Assessment_Scale_Observation) (templateId:2.16.840.1.113883.10.20.22.4.69) (CONF:14466).
10. SHOULD contain zero or more [0..\*] referenceRange (CONF:13937).
    1. The referenceRange, if present, SHALL contain exactly one [1..1] observationRange (CONF:13938).
       1. This observationRange SHALL NOT contain [0..0] code (CONF:13939).

HER2 Receptor Status

[Observation: templateId 2.16.840.1.113883.10.20.30.3.38 (open)]

Table 262: HER2 Receptor Status Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Receptor Status Organizer](#E_Receptor_Status_Organizer) (required) |  |

This clinical statement represents the human epidermal growth factor (HER2) status. The HER2 result level may help determine the type of drug to treat the breast cancer and predicts a patient's response to HER2 directed therapy. Also prognostric of overall survival.

Notes: Design step: Value Set pending for ValueSet HER2 Receptor Status 2.16.840.1.113883.11.20.11.4

Table 263: HER2 Receptor Status Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.38'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [23525](#C_23525) |  |
|  | @root | 1..1 | SHALL |  | [23526](#C_23526) | 2.16.840.1.113883.10.20.30.3.19 |
|  | code | 1..1 | SHALL |  | [23527](#C_23527) |  |
|  | @code | 1..1 | SHALL |  | [23528](#C_23528) | 48676-1 |
|  | @codeSystem | 1..1 | SHALL |  | [23529](#C_23529) | 2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
|  | statusCode | 1..1 | SHALL |  | [23530](#C_23530) |  |
|  | @code | 1..1 | SHALL |  | [23531](#C_23531) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | value | 1..1 | SHALL | CD | [23563](#C_23563) |  |
|  | @code | 1..1 | SHALL |  | [23564](#C_23564) | 2.16.840.1.113883.11.20.11.4 (HER2 Receptor Status) |

1. Conforms to [Result Observation](#E_Result_Observation) template (2.16.840.1.113883.10.20.22.4.2).
2. SHALL contain exactly one [1..1] templateId (CONF:23525) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.19" (CONF:23526).
3. SHALL contain exactly one [1..1] code (CONF:23527).
   1. This code SHALL contain exactly one [1..1] @code="48676-1" HER2 [interpretation] in Tissue (CONF:23528).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:23529).
4. SHALL contain exactly one [1..1] statusCode (CONF:23530).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23531).
5. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:23563).
   1. This value SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet HER2 Receptor Status 2.16.840.1.113883.11.20.11.4 (CONF:23564).

Table 264: HER2 Receptor Status

|  |  |  |
| --- | --- | --- |
| Value Set: HER2 Receptor Status 2.16.840.1.113883.11.20.11.4 | | |
| Code | Code System | Print Name |
| 260385009 | SNOMED-CT | Negative |
| 10828004 | SNOMED-CT | Positive |

Figure 74: HER2 receptor status example

<observation classCode="OBS" moodCode="EVN">

<!-- consolidated CDA Result Observation templateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.2"/>

<!-- HER2 Receptor Status -->

<templateId root="2.16.840.1.113883.10.20.30.3.38"/>

<id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>

<code code="48676-1"

displayName="HER2 [interpretation] in tissue"

codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>

<text> HER2 status </text>

<statusCode code="completed"/>

<effectiveTime value="201203231430"/>

<!-- Need to specify HER2 Receptor Status ValueSet -->

<value xsi:type="CD" code="10828004"

codeSystem="2.16.840.1.113883.6.96" displayName="positive"/>

</observation>

Number of Lymph Nodes Positive

[Observation: templateId 2.16.840.1.113883.10.20.30.3.15 (open)]

Table 265: Number of Lymph Nodes Positive Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Lymph Node Sampling Result Organizer](#E_Lymph_Node_Sampling_Result_Organizer) (optional) |  |

This clinical statement represents of the number of lymph node that are positive for cancer.

Table 266: Number of Lymph Nodes Positive Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.15'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [22175](#C_22175) |  |
|  | @root | 1..1 | SHALL |  | [22176](#C_22176) | 2.16.840.1.113883.10.20.30.3.15 |
|  | code | 1..1 | SHALL |  | [22177](#C_22177) |  |
|  | @code | 1..1 | SHALL |  | [22178](#C_22178) | 44622-9 |
|  | @codeSystem | 1..1 | SHALL |  | [23442](#C_23442) | 2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
|  | value | 1..1 | SHALL | INT | [22179](#C_22179) |  |

1. Conforms to [Result Observation](#E_Result_Observation) template (2.16.840.1.113883.10.20.22.4.2).
2. SHALL contain exactly one [1..1] templateId (CONF:22175) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.15" (CONF:22176).
3. SHALL contain exactly one [1..1] code (CONF:22177).
   1. This code SHALL contain exactly one [1..1] @code="44622-9" Regional lymph nodes containing metastases (CONF:22178).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:23442).
4. SHALL contain exactly one [1..1] value with @xsi:type="INT" (CONF:22179).

Figure 75: Number of lymph nodes positive example

<!-- SHOULD number of Lymph Nodes Positive -->

<observation classCode="OBS" moodCode="EVN">

     <!-- Result observation templateID -->

     <templateId

root="2.16.840.1.113883.10.20.22.4.2"/>

     <!-- Number of lymph nodes positive templateID -->

     <templateId root="2.16.840.1.113883.10.20.30.3.15"/>

     <id root="df9133b3-1adb-11e0-ac64-0800200c9a66"/>

     <code codeSystem="2.16.840.1.113883.6.1"

         codeSystemName="LOINC" code="44622-9"

         displayName="Regional lymph nodes containing metastases"/>

     <statusCode code="completed"/>

     <effectiveTime value="200003231430"/>

     <value xsi:type="INT" value="3"/>

     <interpretationCode code="A"

         codeSystem="2.16.840.1.113883.5.83"/>

</observation>

Number of Lymph Nodes Removed and Examined

[Observation: templateId 2.16.840.1.113883.10.20.30.3.14 (open)]

Table 267: Number of Lymph Nodes Removed and Examined Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Lymph Node Sampling Result Organizer](#E_Lymph_Node_Sampling_Result_Organizer) (optional) |  |

This clinical statement represents the number of lymph nodes examined.

Table 268: Number of Lymph Nodes Removed and Examined Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.14'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [22180](#C_22180) |  |
|  | @root | 1..1 | SHALL |  | [22181](#C_22181) | 2.16.840.1.113883.10.20.30.3.14 |
|  | code | 1..1 | SHALL |  | [22182](#C_22182) |  |
|  | @code | 1..1 | SHALL |  | [22183](#C_22183) | 44621-1 |
|  | @codeSystem | 1..1 | SHALL |  | [23443](#C_23443) | 2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
|  | value | 1..1 | SHALL | INT | [22184](#C_22184) |  |

1. Conforms to [Result Observation](#E_Result_Observation) template (2.16.840.1.113883.10.20.22.4.2).
2. SHALL contain exactly one [1..1] templateId (CONF:22180) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.14" (CONF:22181).
3. SHALL contain exactly one [1..1] code (CONF:22182).
   1. This code SHALL contain exactly one [1..1] @code="44621-1" Regional lymph nodes identified (CONF:22183).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:23443).
4. SHALL contain exactly one [1..1] value with @xsi:type="INT" (CONF:22184).

Figure 76: Number of lymph nodes removed and examined example

<!-- Number of lymph nodes removed and examined templateiId -->

<templateId root="2.16.840.1.113883.10.20.30.3.14"/>

<id root="df9133b2-1adb-11e0-ac64-0800200c9a66"/>

<code codeSystem="2.16.840.1.113883.6.1" code="44621-1"

codeSystemName="LOINC"

displayName="Regional lymph nodes identified"/>

<statusCode code="completed"/>

<effectiveTime value="201203231430"/>

<value xsi:type="INT" value="6"/>

</observation>

Oncotype DX Score

[Observation: templateId 2.16.840.1.113883.10.20.30.3.18 (open)]

Table 269: Oncotype DX Score Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Receptor Status Organizer](#E_Receptor_Status_Organizer) (required) |  |

This clinical statement records the score of the oncotype diagnosis test which is a genomic test to determine the expression of the gene 21 panel. The test results assist providers in formulating a treatment plan and therapy for the patient. The score is recorded in the value as an integer.

Notes: Design note: The Oncotype Dx Score is a test performed by Genomic Health in their CLIA certified Lab. There is no LOINC code to represent this test. Another name for the test is "21gene RT -PCR Test".

Table 270: Oncotype DX Score Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.18'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [23193](#C_23193) |  |
|  | @root | 1..1 | SHALL |  | [23194](#C_23194) | 2.16.840.1.113883.10.20.30.3.18 |
|  | code | 1..1 | SHALL |  | [23196](#C_23196) |  |
|  | @code | 1..1 | SHALL |  | [23197](#C_23197) | 56780-0 |
|  | @codeSystem | 1..1 | SHALL |  | [23494](#C_23494) | 2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
|  | statusCode | 1..1 | SHALL |  | [23198](#C_23198) |  |
|  | @code | 1..1 | SHALL |  | [23199](#C_23199) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | value | 1..1 | SHALL | INT | [23201](#C_23201) |  |

1. Conforms to [Result Observation](#E_Result_Observation) template (2.16.840.1.113883.10.20.22.4.2).
2. SHALL contain exactly one [1..1] templateId (CONF:23193) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.18" (CONF:23194).
3. SHALL contain exactly one [1..1] code (CONF:23196).
   1. This code SHALL contain exactly one [1..1] @code="56780-0" CYP21A2 gene mutations tested for in Blood or Tissue by Molecular genetics method Nominal (CONF:23197).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:23494).
4. SHALL contain exactly one [1..1] statusCode (CONF:23198).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:23199).
5. SHALL contain exactly one [1..1] value with @xsi:type="INT" (CONF:23201).

Figure 77: Oncotype DX score example

<!-- Oncotype DX Score templateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.18"/>

<id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>

<!-- Temporary code to represent either ONCOTYPE DX or 21gene RT-PCR test. -->

<code code="56780-0"

displayName="CYP21A2 gene mutations tested for in Blood or Tissue by Molecular genetics method Nominal"

codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>

<text> ONCOTYPE DX </text>

<statusCode code="completed"/>

<effectiveTime value="201203231430"/>

<value xsi:type="INT" value="9"/>

Progesterone Receptor Status

[Observation: templateId 2.16.840.1.113883.10.20.30.3.20 (open)]

Table 271: Progesterone Receptor Status Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Receptor Status Organizer](#E_Receptor_Status_Organizer) (required) |  |

This clinical statement represents the progesterone receptor status results.

Notes: Is the description for the value set accurate?

Table 272: Progesterone Receptor Status Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.20'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [23470](#C_23470) |  |
|  | @root | 1..1 | SHALL |  | [23471](#C_23471) | 2.16.840.1.113883.10.20.30.3.20 |
|  | code | 1..1 | SHALL |  | [23472](#C_23472) |  |
|  | @code | 1..1 | SHALL |  | [23473](#C_23473) | 16113-3 |
|  | @codeSystem | 1..1 | SHALL |  | [23474](#C_23474) | 2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
|  | statusCode | 1..1 | SHALL |  | [23475](#C_23475) |  |
|  | @code | 1..1 | SHALL |  | [23476](#C_23476) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | value | 1..1 | SHALL | CD | [23567](#C_23567) |  |
|  | @code | 1..1 | SHALL |  | [23568](#C_23568) | 2.16.840.1.113883.11.20.11.3 (Progesterone Receptor Status (temp)) |

1. Conforms to [Result Observation](#E_Result_Observation) template (2.16.840.1.113883.10.20.22.4.2).
2. SHALL contain exactly one [1..1] templateId (CONF:23470) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.20" (CONF:23471).
3. SHALL contain exactly one [1..1] code (CONF:23472).
   1. This code SHALL contain exactly one [1..1] @code="16113-3" Progesterone Receptor [interpretation] in Tissue (CONF:23473).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:23474).
4. SHALL contain exactly one [1..1] statusCode (CONF:23475).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:23476).
5. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:23567).
   1. This value SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet Estrogen and Progesterone Recepetor Status (temp) 2.16.840.1.113883.11.20.11.2 (CONF:23568).

Table 273: Progesterone Receptor Status (temp)

|  |  |  |
| --- | --- | --- |
| Value Set: Estrogen and Progesterone Recepetor Status (temp) 2.16.840.1.113883.11.20.11.2 | | |
| Code | Code System | Print Name |
| 260385009 | SNOMED-CT | Negative |
| 10828004 | SNOMED-CT | Positive |
| 261665006 | SNOMED-CT | Unknown |

Figure 78: Progesterone receptor status

<templateId root="2.16.840.1.113883.10.20.30.3.20"/>

<id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>

<code code="16113-3"

displayName=" Progesterone Receptor [interpretation] in Tissue"

codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>

<text> PR status </text>

<statusCode code="completed"/>

<effectiveTime value="201203231430"/>

<!-- Need to specify PR Status ValueSet -->

<value xsi:type="CD" code="10828004"

codeSystem="2.16.840.1.113883.6.96"

displayName="positive"/>

Result Organizer [Closed for comments; published July 2012]

[organizer: templateId 2.16.840.1.113883.10.20.22.4.1 (open)]

Table 274: Result Organizer Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Results Section (entries optional)](#S_Results_Section_entries_optional) (optional) | [Result Observation](#E_Result_Observation) |

This clinical statement identifies set of result observations. It contains information applicable to all of the contained result observations. Result type codes categorize a result into one of several commonly accepted values (e.g., “Hematology”, “Chemistry”, “Nuclear Medicine”). These values are often implicit in the Organizer/code (e.g., an Organizer/code of “complete blood count” implies a ResultTypeCode of “Hematology”). This template requires Organizer/code to include a ResultTypeCode either directly or as a translation of a code from some other code system.

An appropriate nullFlavor can be used when the organizer/code or organizer/id is unknown.

If any Result Observation within the organizer has a statusCode of ‘active’, the Result Organizer must also have as statusCode of ‘active.

Table 275: Result Organizer Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | organizer[templateId/@root = '2.16.840.1.113883.10.20.22.4.1'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7121](#C_7121) | 2.16.840.1.113883.5.6 (HL7ActClass) |
|  | @moodCode | 1..1 | SHALL |  | [7122](#C_7122) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [7126](#C_7126) |  |
|  | @root | 1..1 | SHALL |  | [9134](#C_9134) | 2.16.840.1.113883.10.20.22.4.1 |
|  | id | 1..\* | SHALL |  | [7127](#C_7127) |  |
|  | code | 1..1 | SHALL |  | [7128](#C_7128) |  |
|  | statusCode | 1..1 | SHALL |  | [7123](#C_7123) |  |
|  | @code | 1..1 | SHALL |  | [14848](#C_14848) | 2.16.840.1.113883.11.20.9.39 (Result Status) |
|  | component | 1..\* | SHALL |  | [7124](#C_7124) |  |
|  | observation | 1..1 | SHALL |  | [14850](#C_14850) |  |

1. SHALL contain exactly one [1..1] @classCode (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7121).
   1. SHOULD contain zero or one [0..1] @classCode="CLUSTER" Cluster (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) OR SHOULD contain zero or one [0..1] @classCode="BATTERY" Battery (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7165).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7122).
3. SHALL contain exactly one [1..1] templateId (CONF:7126) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.1" (CONF:9134).
4. SHALL contain at least one [1..\*] id (CONF:7127).
5. SHALL contain exactly one [1..1] code (CONF:7128).
   1. SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12) (CONF:19218).
   2. Laboratory results SHOULD be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or other constrained terminology named by the US Department of Health and Human Services Office of National Coordinator or other federal agency. Local and/or regional codes for laboratory results SHOULD also be allowed (CONF:19219).
6. SHALL contain exactly one [1..1] statusCode (CONF:7123).
   1. This statusCode SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 STATIC (CONF:14848).
7. SHALL contain at least one [1..\*] component (CONF:7124) such that it
   1. SHALL contain exactly one [1..1] [Result Observation](#E_Result_Observation) (templateId:2.16.840.1.113883.10.20.22.4.2) (CONF:14850).

Table 276: Result Status

|  |  |  |
| --- | --- | --- |
| Value Set: Result Status 2.16.840.1.113883.11.20.9.39 | | |
| Code | Code System | Print Name |
| aborted | ActStatus | aborted |
| active | ActStatus | active |
| cancelled | ActStatus | cancelled |
| completed | ActStatus | completed |
| held | ActStatus | held |
| suspended | ActStatus | suspended |

Cognitive Status Result Organizer [Closed for comments; published July 2012]

[organizer: templateId 2.16.840.1.113883.10.20.22.4.75 (open)]

Table 277: Cognitive Status Result Organizer Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Functional Status Section](#S_Functional_Status_Section) (optional) | [Cognitive Status Result Observation](#E_Cognitive_Status_Result_Observation) |

This clinical statement identifies a set of cognitive status result observations. It contains information applicable to all of the contained cognitive status result observations. A result organizer may be used to group questions in a Patient Health Questionnaire (PHQ).

An appropriate nullFlavor can be used when the organizer/code or organizer/id is unknown.

Table 278: Cognitive Status Result Organizer Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | organizer[templateId/@root = '2.16.840.1.113883.10.20.22.4.75'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [14369](#C_14369) | 2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER |
|  | @moodCode | 1..1 | SHALL |  | [14371](#C_14371) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [14375](#C_14375) |  |
|  | @root | 1..1 | SHALL |  | [14376](#C_14376) | 2.16.840.1.113883.10.20.22.4.75 |
|  | id | 1..\* | SHALL |  | [14377](#C_14377) |  |
|  | code | 1..1 | SHALL |  | [14378](#C_14378) |  |
|  | @code | 0..1 | SHOULD |  | [14697](#C_14697) |  |
|  | statusCode | 1..1 | SHALL |  | [14372](#C_14372) |  |
|  | @code | 1..1 | SHALL |  | [19093](#C_19093) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | component | 1..\* | SHALL |  | [14373](#C_14373) |  |
|  | observation | 1..1 | SHALL |  | [14381](#C_14381) |  |

1. Conforms to [Result Organizer](#E_Result_Organizer) template (2.16.840.1.113883.10.20.22.4.1).
2. SHALL contain exactly one [1..1] @classCode="CLUSTER", which SHALL be selected from CodeSystem HL7ActClass (2.16.840.1.113883.5.6) STATIC (CONF:14369).
3. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14371).
4. SHALL contain exactly one [1..1] templateId (CONF:14375) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.75" (CONF:14376).
5. SHALL contain at least one [1..\*] id (CONF:14377).
6. SHALL contain exactly one [1..1] code (CONF:14378).
   1. This code SHOULD contain zero or one [0..1] @code (CONF:14697).
      1. Should be selected from ICF (codeSystem 2.16.840.1.113883.6.254) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96) (CONF:14698).
7. SHALL contain exactly one [1..1] statusCode (CONF:14372).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19093).
8. SHALL contain at least one [1..\*] component (CONF:14373) such that it
   1. SHALL contain exactly one [1..1] [Cognitive Status Result Observation](#E_Cognitive_Status_Result_Observation) (templateId:2.16.840.1.113883.10.20.22.4.74) (CONF:14381).

Functional Status Result Organizer [Closed for comments; published July 2012]

[organizer: templateId 2.16.840.1.113883.10.20.22.4.66 (open)]

Table 279: Functional Status Result Organizer Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Functional Status Section](#S_Functional_Status_Section) (optional) | [Functional Status Result Observation](#E_Functional_Status_Result_Observation) |

This clinical statement identifies a set of functional status result observations. It contains information applicable to all of the contained functional status result observations. A functional status organizer may group self-care observations related to a patient's ability to feed, bathe, and dress.

An appropriate nullFlavor can be used when the organizer/code or organizer/id is unknown.

Table 280: Functional Status Result Organizer Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | organizer[templateId/@root = '2.16.840.1.113883.10.20.22.4.66'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [14355](#C_14355) | 2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER |
|  | @moodCode | 1..1 | SHALL |  | [14357](#C_14357) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [14361](#C_14361) |  |
|  | @root | 1..1 | SHALL |  | [14362](#C_14362) | 2.16.840.1.113883.10.20.22.4.66 |
|  | id | 1..\* | SHALL |  | [14363](#C_14363) |  |
|  | code | 1..1 | SHALL |  | [14364](#C_14364) |  |
|  | @code | 0..1 | SHOULD |  | [14747](#C_14747) |  |
|  | statusCode | 1..1 | SHALL |  | [14358](#C_14358) |  |
|  | @code | 1..1 | SHALL |  | [19102](#C_19102) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | component | 1..\* | SHALL |  | [14359](#C_14359) |  |
|  | observation | 1..1 | SHALL |  | [14368](#C_14368) |  |

1. Conforms to [Result Organizer](#E_Result_Organizer) template (2.16.840.1.113883.10.20.22.4.1).
2. SHALL contain exactly one [1..1] @classCode="CLUSTER", which SHALL be selected from CodeSystem HL7ActClass (2.16.840.1.113883.5.6) STATIC (CONF:14355).
3. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:14357).
4. SHALL contain exactly one [1..1] templateId (CONF:14361) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.66" (CONF:14362).
5. SHALL contain at least one [1..\*] id (CONF:14363).
6. SHALL contain exactly one [1..1] code (CONF:14364).
   1. This code SHOULD contain zero or one [0..1] @code (CONF:14747).
      1. SHOULD be selected from ICF (codeSystem 2.16.840.1.113883.6.254) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96) (CONF:14748).
7. SHALL contain exactly one [1..1] statusCode (CONF:14358).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19102).
8. SHALL contain at least one [1..\*] component (CONF:14359) such that it
   1. SHALL contain exactly one [1..1] [Functional Status Result Observation](#E_Functional_Status_Result_Observation) (templateId:2.16.840.1.113883.10.20.22.4.67) (CONF:14368).

Lymph Node Sampling Result Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.30.3.13 (open)]

Table 281: Lymph Node Sampling Result Organizer Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Breast Cancer Procedures](#E_Breast_Cancer_Procedures) (optional) | [Number of Lymph Nodes Positive](#E_Number_of_Lymph_Nodes_Positive)  [Number of Lymph Nodes Removed and Examined](#E_Number_of_Lymph_Nodes_Removed_and_Exa) |

This clinical statement represents the lymph nodes that were removed and examined and the number of those that were positive for pathology. This representation may include a reference to the full pathology report or details about each pathology finding.

Notes: Design note: Code may not need to be specified. Most appropriate as Battery or a Cluster? Are these tests often ordered all at one time? Pending right now as a cluster of related labs but may change. Bob review needed for URL reference Sample specimen: Is there more than one specimen taken?

Table 282: Lymph Node Sampling Result Organizer Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Organizer[templateId/@root = '2.16.840.1.113883.10.20.30.3.13'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [23314](#C_23314) | 2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER |
|  | templateId | 1..1 | SHALL |  | [23315](#C_23315) |  |
|  | @root | 1..1 | SHALL |  | [23316](#C_23316) | 2.16.840.1.113883.10.20.30.3.13 |
|  | code | 1..1 | SHALL |  | [23324](#C_23324) |  |
|  | @code | 1..1 | SHALL |  | [23325](#C_23325) | 178292004 |
|  | @codeSystem | 1..1 | SHALL |  | [23326](#C_23326) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |
|  | statusCode | 1..1 | SHALL |  | [23327](#C_23327) |  |
|  | @code | 1..1 | SHALL |  | [23328](#C_23328) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 1..1 | SHALL |  | [23330](#C_23330) |  |
|  | specimen | 1..\* | SHALL |  | [23331](#C_23331) |  |
|  | specimenRole | 1..1 | SHALL |  | [23332](#C_23332) |  |
|  | id | 1..1 | SHALL |  | [23333](#C_23333) |  |
|  | specimenPlayingEntity | 0..1 | SHOULD |  | [23334](#C_23334) |  |
|  | code | 1..1 | SHALL |  | [23335](#C_23335) |  |
|  | @codeSystem | 1..1 | SHALL |  | [23336](#C_23336) | 2.16.840.1.113883.6.96 (SNOMED-CT) |
|  | reference | 0..\* | MAY |  | [23337](#C_23337) |  |
|  | @typeCode | 1..1 | SHALL |  | [24948](#C_24948) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  | externalDocument | 1..1 | SHALL |  | [24949](#C_24949) |  |
|  | id | 1..\* | SHALL |  | [24950](#C_24950) |  |
|  | code | 0..1 | MAY |  | [24957](#C_24957) |  |
|  | @code | 1..1 | SHALL |  | [24958](#C_24958) | 34122-2 |
|  | @codeSystem | 1..1 | SHALL |  | [24959](#C_24959) | 2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
|  | text | 0..1 | MAY |  | [24951](#C_24951) |  |
|  | @mediaType | 1..1 | SHALL |  | [24952](#C_24952) |  |
|  | reference | 0..1 | MAY |  | [24953](#C_24953) |  |
|  | @value | 1..1 | SHALL |  | [24968](#C_24968) |  |
|  | component | 0..1 | SHOULD |  | [23318](#C_23318) |  |
|  | observation | 1..1 | SHALL |  | [23320](#C_23320) |  |
|  | component | 0..1 | SHOULD |  | [23321](#C_23321) |  |
|  | observation | 1..1 | SHALL |  | [23323](#C_23323) |  |

1. Conforms to [Result Organizer](#E_Result_Organizer) template (2.16.840.1.113883.10.20.22.4.1).
2. SHALL contain exactly one [1..1] @classCode="CLUSTER" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23314).
3. SHALL contain exactly one [1..1] templateId (CONF:23315) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.13" (CONF:23316).
4. SHALL contain exactly one [1..1] code (CONF:23324).
   1. This code SHALL contain exactly one [1..1] @code="178292004" Lymph node sampling (CONF:23325).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23326).
5. SHALL contain exactly one [1..1] statusCode (CONF:23327).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:23328).
6. SHALL contain exactly one [1..1] effectiveTime (CONF:23330).
7. SHALL contain at least one [1..\*] specimen (CONF:23331).
   1. Such specimens SHALL contain exactly one [1..1] specimenRole (CONF:23332).
      1. This specimenRole SHALL contain exactly one [1..1] id (CONF:23333).
      2. This specimenRole SHOULD contain zero or one [0..1] specimenPlayingEntity (CONF:23334).
         1. The specimenPlayingEntity, if present, SHALL contain exactly one [1..1] code (CONF:23335).
            1. This code SHALL contain exactly one [1..1] @codeSystem (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23336).

A reference may be made to additional information in a pathology report.

1. MAY contain zero or more [0..\*] reference (CONF:23337).
   1. The reference, if present, SHALL contain exactly one [1..1] @typeCode="REFR" Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24948).
   2. The reference, if present, SHALL contain exactly one [1..1] externalDocument (CONF:24949).
      1. This externalDocument SHALL contain at least one [1..\*] id (CONF:24950).

The code represents the type of document. Either a code and/or text description would be used to describe the external document.

* + 1. This externalDocument MAY contain zero or one [0..1] code (CONF:24957).
       1. The code, if present, SHALL contain exactly one [1..1] @code="34122-2" Pathology Note (CONF:24958).
       2. The code, if present, SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" LOINC (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:24959).
    2. This externalDocument MAY contain zero or one [0..1] text (CONF:24951).
       1. The text, if present, SHALL contain exactly one [1..1] @mediaType (CONF:24952).
       2. The text, if present, MAY contain zero or one [0..1] reference (CONF:24953).
          1. The reference, if present, SHALL contain exactly one [1..1] @value (CONF:24968).

1. SHOULD contain zero or one [0..1] component (CONF:23318) such that it
   1. SHALL contain exactly one [1..1] [Number of Lymph Nodes Removed and Examined](#E_Number_of_Lymph_Nodes_Removed_and_Exa) (templateId:2.16.840.1.113883.10.20.30.3.14) (CONF:23320).
2. SHOULD contain zero or one [0..1] component (CONF:23321) such that it
   1. SHALL contain exactly one [1..1] [Number of Lymph Nodes Positive](#E_Number_of_Lymph_Nodes_Positive) (templateId:2.16.840.1.113883.10.20.30.3.15) (CONF:23323).

Figure 79: Lymph node sampling result organizer example

<templateId root="2.16.840.1.113883.10.20.30.3.13"/>

<!-- Same ID as the diagnosis ID (perhaps)-->

<id root="7d5a02b0-67a4-11db-bd13-0800200c9a66"/>

<code codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="178292004"

displayName="Lymph node sampling"/>

<statusCode code="completed"/>

<effectiveTime value="200003231430"/>

<specimen>

<specimenRole>

<id root="df9133b1-1adb-11e0-ac64-0800200c9a66"/>

<specimenPlayingEntity>

<!-- Specimen type -->

<code codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="397436009"

displayName="(a)specimen obtained by lymphadenectomy"/>

</specimenPlayingEntity>

</specimenRole>

</specimen>

<!-- MAY contain [0..\*] external reference to the full pathology report (not

seperate template)-->

<!-- @typeCode could also be XCRPT, so may not need to be constrained in IG -->

<reference typeCode="REFR">

<externalDocument classCode="DOCCLIN" moodCode="EVN">

<!-- SHALL ID -->

<id root="10021d19-5b29-4771-bce4-236109943dd4"/>

<code code="34122-2" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC" displayName="Pathology Note"/>

<text mediaType="Pathology/pdf">

<reference

value="Pathology Note.10021d19-5b29-4771-bce4-236109943dd4.pdf"/>

</text>

</externalDocument>

</reference>

<!-- NUMBER OF LYMPH NODES REMOVED AND EXAMINED -->

<component>

<!-- SHOULD Number of lymph nodes removed and examined -->

<observation classCode="OBS" moodCode="EVN">

<!-- Result observation templateId -->

<templateId root="2.16.840.1.113883.10.20.22.4.2"

assigningAuthorityName="HL7 C-CDA"/>

<!-- Number of lymph nodes removed and examined templateiId -->

<templateId root="2.16.840.1.113883.10.20.30.3.14"/>

...

<!-- NUMBER OF LYMPH NODES POSITIVE -->

<component>

<!-- SHOULD number of Lymph Nodes Positive -->

<observation classCode="OBS" moodCode="EVN">

<!-- Result observation templateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.2"

assigningAuthorityName="HL7 C-CDA"/>

...

Receptor Status Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.30.3.17 (open)]

Table 283: Receptor Status Organizer Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Results Section BCTPS](#Results_Section_BCTPS) (required) | [Estrogen Receptor Status](#Estrogen_Receptor_Status)  [HER2 Receptor Status](#HER2_Receptor_Status_)  [Oncotype DX Score](#Oncotype_DX_Score)  [Progesterone Receptor Status](#E_Progesterone_Receptor_Status) |

This clinical statement represents a group of labs that are used to predict a patient's response to therapy.

Table 284: Receptor Status Organizer Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Organizer[templateId/@root = '2.16.840.1.113883.10.20.30.3.17'] | | | | | |
|  | templateId | 1..1 | SHALL |  | [23479](#C_23479) |  |
|  | @root | 1..1 | SHALL |  | [23480](#C_23480) | 2.16.840.1.113883.10.20.30.3.17 |
|  | code | 1..1 | SHALL |  | [23481](#C_23481) |  |
|  | @code | 1..1 | SHALL |  | [23482](#C_23482) | 246113000 |
|  | @codeSystem | 1..1 | SHALL |  | [23483](#C_23483) | 2.16.840.1.113883.6.96 (SNOMED-CT) |
|  | statusCode | 1..1 | SHALL |  | [23484](#C_23484) |  |
|  | @code | 1..1 | SHALL |  | [23485](#C_23485) | 2.16.840.1.113883.5.14 (ActStatus) = Completed |
|  | component | 1..1 | SHALL |  | [23488](#C_23488) |  |
|  | observation | 1..1 | SHALL |  | [23489](#C_23489) |  |
|  | component | 1..1 | SHALL |  | [23490](#C_23490) |  |
|  | observation | 1..1 | SHALL |  | [23491](#C_23491) |  |
|  | component | 1..1 | SHALL |  | [23492](#C_23492) |  |
|  | observation | 1..1 | SHALL |  | [23496](#C_23496) |  |
|  | component | 1..1 | SHALL |  | [23493](#C_23493) |  |
|  | observation | 1..1 | SHALL |  | [23536](#C_23536) |  |

1. Conforms to [Result Organizer](#E_Result_Organizer) template (2.16.840.1.113883.10.20.22.4.1).
2. SHALL contain exactly one [1..1] templateId (CONF:23479) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.17" (CONF:23480).
3. SHALL contain exactly one [1..1] code (CONF:23481).
   1. This code SHALL contain exactly one [1..1] @code="246113000" Receptor Status (CONF:23482).
   2. This code SHALL contain exactly one [1..1] @codeSystem (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23483).
4. SHALL contain exactly one [1..1] statusCode (CONF:23484).
   1. This statusCode SHALL contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:23485).
5. SHALL contain exactly one [1..1] component (CONF:23488) such that it
   1. SHALL contain exactly one [1..1] [Estrogen Receptor Status](#Estrogen_Receptor_Status) (templateId:2.16.840.1.113883.10.20.30.3.19) (CONF:23489).
6. SHALL contain exactly one [1..1] component (CONF:23490) such that it
   1. SHALL contain exactly one [1..1] [Progesterone Receptor Status](#E_Progesterone_Receptor_Status) (templateId:2.16.840.1.113883.10.20.30.3.20) (CONF:23491).
7. SHALL contain exactly one [1..1] component (CONF:23492) such that it
   1. SHALL contain exactly one [1..1] [Oncotype DX Score](#Oncotype_DX_Score) (templateId:2.16.840.1.113883.10.20.30.3.18) (CONF:23496).
8. SHALL contain exactly one [1..1] component (CONF:23493) such that it
   1. SHALL contain exactly one [1..1] [HER2 Receptor Status](#HER2_Receptor_Status_) (templateId:2.16.840.1.113883.10.20.30.3.38) (CONF:23536).

Figure 80: Receptor status organizer example

<organizer classCode="CLUSTER" moodCode="EVN">

<!-- Result Organizer templateID from Consolidated CDA -->

<templateId root="2.16.840.1.113883.10.20.22.4.1"/>

<!-- Receptor status Organizer template ID -->

<templateId root="2.16.840.1.113883.10.20.30.3.17"/>

<id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>

<code code="246113000" displayName="Receptor Status"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>

<statusCode code="completed"/>

<!-- ONCOTYPE DX SCORE -->

<component>

<observation classCode="OBS" moodCode="EVN">

<!-- consolidated CDA Result Observation templateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.2"/>

<!-- Oncotype DX Score templateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.18"/>

<id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>

...

<!-- ESTROGEN RECEPTOR STATUS -->

<component>

<observation classCode="OBS" moodCode="EVN">

<!-- consolidated CDA Result Observation templateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.2"/>

<!-- Estrogen Receptor Status templateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.19"/>

<id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>

...

<!-- PROGESTERONE RECEPTOR STATUS -->

<component>

<observation classCode="OBS" moodCode="EVN">

<!-- consolidated CDA Result Observation templateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.2"/>

<!-- Progesterone Receptor Status templateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.20"/>

<id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>

...

<!-- HER2 RECEPTOR STATUS -->

<component>

<observation classCode="OBS" moodCode="EVN">

<!-- consolidated CDA Result Observation templateID -->

<templateId root="2.16.840.1.113883.10.20.22.4.2"/>

<!-- HER2 Receptor Status -->

<templateId root="2.16.840.1.113883.10.20.30.3.38"/>

<id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>

<code code="48676-1"

displayName="HER2 [interpretation] in tissue"

codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>

<text> HER2 status </text>

<statusCode code="completed"/>

<effectiveTime value="201203231430"/>

<value xsi:type="CD" code="10828004"

codeSystem="2.16.840.1.113883.6.96" displayName="positive"/>

...

Service Delivery Location [Closed for comments; published July 2012]

[participantRole: templateId 2.16.840.1.113883.10.20.22.4.32 (open)]

Table 285: Service Delivery Location Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Procedure Activity Procedure](#E_Procedure_Activity_Procedure) (optional)  [Procedure Activity Act](#E_Procedure_Activity_Act) (optional)  [Procedure Activity Observation](#E_Procedure_Activity_Observation) (optional)  [Encounter Activities](#E_Encounter_Activities) (optional) |  |

This clinical statement represents the location of a service event where an act, observation or procedure took place.

Table 286: Service Delivery Location Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | participantRole[templateId/@root = '2.16.840.1.113883.10.20.22.4.32'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7758](#C_7758) | 2.16.840.1.113883.5.111 (RoleCode) = SDLOC |
|  | templateId | 1..1 | SHALL |  | [7635](#C_7635) |  |
|  | @root | 1..1 | SHALL |  | [10524](#C_10524) | 2.16.840.1.113883.10.20.22.4.32 |
|  | code | 1..1 | SHALL |  | [16850](#C_16850) | 2.16.840.1.113883.1.11.20275 (HealthcareServiceLocation) |
|  | addr | 0..\* | SHOULD |  | [7760](#C_7760) |  |
|  | telecom | 0..\* | SHOULD |  | [7761](#C_7761) |  |
|  | playingEntity | 0..1 | MAY |  | [7762](#C_7762) |  |
|  | @classCode | 1..1 | SHALL |  | [7763](#C_7763) | 2.16.840.1.113883.5.41 (EntityClass) = PLC |
|  | name | 0..1 | MAY |  | [16037](#C_16037) |  |

1. SHALL contain exactly one [1..1] @classCode="SDLOC" (CodeSystem: RoleCode 2.16.840.1.113883.5.111 STATIC) (CONF:7758).
2. SHALL contain exactly one [1..1] templateId (CONF:7635) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.32" (CONF:10524).
3. SHALL contain exactly one [1..1] code, which SHALL be selected from ValueSet HealthcareServiceLocation 2.16.840.1.113883.1.11.20275 STATIC (CONF:16850).
4. SHOULD contain zero or more [0..\*] addr (CONF:7760).
5. SHOULD contain zero or more [0..\*] telecom (CONF:7761).
6. MAY contain zero or one [0..1] playingEntity (CONF:7762).
   1. The playingEntity, if present, SHALL contain exactly one [1..1] @classCode="PLC" (CodeSystem: EntityClass 2.16.840.1.113883.5.41 STATIC) (CONF:7763).
   2. The playingEntity, if present, MAY contain zero or one [0..1] name (CONF:16037).

Severity Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.8 (open)]

Table 287: Severity Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Reaction Observation](#E_Reaction_Observation) (optional)  [Allergy - Intolerance Observation](#E_Allergy__Intolerance_Observation) (optional)  [Substance or Device Allergy - Intolerance Observation](#E_Substance_or_Device_Allergy__Intolera) (required) |  |

This clinical statement represents the gravity of the problem, such as allergy or reaction, in terms of its actual or potential impact on the patient. The Severity Observation can be associated with an Allergy Observation, Reaction Observation or both. When the Severity Observation is associated directly with an Allergy it characterizes the Allergy. When the Severity Observation is associated with a Reaction Observation it characterizes a Reaction. A person may manifest many symptoms in a reaction to a single substance, and each reaction to the substance can be represented. However, each reaction observation can have only one severity observation associated with it. For example, someone may have a rash reaction observation as well as an itching reaction observation, but each can have only one level of severity.

Table 288: Severity Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
| Green Severity Observation | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.8'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7345](#C_7345) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [7346](#C_7346) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [7347](#C_7347) |  |
|  | @root | 1..1 | SHALL |  | [10525](#C_10525) | 2.16.840.1.113883.10.20.22.4.8 |
|  | code | 1..1 | SHALL |  | [19168](#C_19168) |  |
|  | @code | 1..1 | SHALL |  | [19169](#C_19169) | 2.16.840.1.113883.5.4 (ActCode) = SEV |
| severityFreeText | text | 0..1 | SHOULD |  | [7350](#C_7350) |  |
|  | reference | 0..1 | SHOULD |  | [15928](#C_15928) |  |
|  | @value | 0..1 | SHOULD |  | [15929](#C_15929) |  |
|  | statusCode | 1..1 | SHALL |  | [7352](#C_7352) |  |
|  | @code | 1..1 | SHALL |  | [19115](#C_19115) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
| severityCoded | value | 1..1 | SHALL | CD | [7356](#C_7356) | 2.16.840.1.113883.3.88.12.3221.6.8 (Problem Severity) |
|  | interpretationCode | 0..\* | SHOULD |  | [9117](#C_9117) |  |
|  | @code | 0..1 | SHOULD |  | [16038](#C_16038) | 2.16.840.1.113883.1.11.78 (Observation Interpretation (HL7)) |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7345).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7346).
3. SHALL contain exactly one [1..1] templateId (CONF:7347) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.8" (CONF:10525).
4. SHALL contain exactly one [1..1] code (CONF:19168).
   1. This code SHALL contain exactly one [1..1] @code="SEV" (CodeSystem: ActCode 2.16.840.1.113883.5.4 STATIC) (CONF:19169).
5. SHOULD contain zero or one [0..1] text (CONF:7350).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:15928).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15929).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15930).
6. SHALL contain exactly one [1..1] statusCode (CONF:7352).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19115).
7. SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHALL be selected from ValueSet Problem Severity 2.16.840.1.113883.3.88.12.3221.6.8 DYNAMIC (CONF:7356).
8. SHOULD contain zero or more [0..\*] interpretationCode (CONF:9117).
   1. The interpretationCode, if present, SHOULD contain zero or one [0..1] @code, which SHOULD be selected from ValueSet Observation Interpretation (HL7) 2.16.840.1.113883.1.11.78 DYNAMIC (CONF:16038).

Table 289: Problem Severity

|  |  |  |
| --- | --- | --- |
| Value Set: Problem Severity 2.16.840.1.113883.3.88.12.3221.6.8 | | |
| Code | Code System | Print Name |
| 255604002 | SNOMED-CT | Mild (qualifier value) |
| 371923003 | SNOMED-CT | Mild to moderate (qualifier value) |
| 6736007 | SNOMED-CT | Moderate (severity modifier) (qualifier value) |
| 371924009 | SNOMED-CT | Moderate to severe (qualifier value) |
| 24484000 | SNOMED-CT | Severe (severity modifier) (qualifier value) |
| 399166001 | SNOMED-CT | Fatal (qualifier value) |

Table 290: Observation Interpretation (HL7)

|  |  |  |
| --- | --- | --- |
| Value Set: Observation Interpretation (HL7) 2.16.840.1.113883.1.11.78 | | |
| Code | Code System | Print Name |
| A | HITSP-CS-83 | Abnormal |
| B | HITSP-CS-83 | better |
| Carrier | HITSP-CS-83 | Carrier |
| D | HITSP-CS-83 | decreased |
| HX | HITSP-CS-83 | above high threshold |
| I | HITSP-CS-83 | intermediate |
| IND | HITSP-CS-83 | Indeterminate |
| LX | HITSP-CS-83 | below low threshold |
| MS | HITSP-CS-83 | moderately susceptible |
| N | HITSP-CS-83 | Normal |
| NEG | HITSP-CS-83 | Negative |
| POS | HITSP-CS-83 | Positive |
| R | HITSP-CS-83 | resistent |
| S | HITSP-CS-83 | susceptible |
| U | HITSP-CS-83 | increased |
| VS | HITSP-CS-83 | Very susceptible |
| W | HITSP-CS-83 | worse |

Substance or Device Allergy - Intolerance Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.24.3.90 (open)]

Table 291: Substance or Device Allergy - Intolerance Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
|  | [Allergy Status Observation](#E_Allergy_Status_Observation)  [Reaction Observation](#E_Reaction_Observation)  [Severity Observation](#E_Severity_Observation) |

This clinical statement represents that an allergy or adverse reaction to a substance or device exists or does not exist. The agent that is the cause of the allergy or adverse reaction is represented as a participant in the observation.

Table 292: Substance or Device Allergy - Intolerance Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.24.3.90'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [16303](#C_16303) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [16304](#C_16304) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [16305](#C_16305) |  |
|  | @root | 1..1 | SHALL |  | [16306](#C_16306) | 2.16.840.1.113883.10.20.24.3.90 |
|  | id | 1..\* | SHALL |  | [16307](#C_16307) |  |
|  | code | 1..1 | SHALL |  | [16345](#C_16345) |  |
|  | @code | 1..1 | SHALL |  | [16346](#C_16346) | 2.16.840.1.113883.5.4 (ActCode) = ASSERTION |
|  | statusCode | 1..1 | SHALL |  | [16308](#C_16308) |  |
|  | @code | 1..1 | SHALL |  | [26354](#C_26354) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 1..1 | SHALL |  | [16309](#C_16309) |  |
|  | value | 1..1 | SHALL | CD | [16312](#C_16312) |  |
|  | @code | 1..1 | SHALL | CS | [16317](#C_16317) | 2.16.840.1.113883.3.88.12.3221.6.2 (Allergy/Adverse Event Type Value Set) |
|  | participant | 0..\* | SHOULD |  | [16318](#C_16318) |  |
|  | @typeCode | 1..1 | SHALL |  | [16319](#C_16319) | 2.16.840.1.113883.5.90 (HL7ParticipationType) = CSM |
|  | participantRole | 1..1 | SHALL |  | [16320](#C_16320) |  |
|  | @classCode | 1..1 | SHALL |  | [16321](#C_16321) | 2.16.840.1.113883.5.110 (RoleClass) = MANU |
|  | playingEntity | 1..1 | SHALL |  | [16322](#C_16322) |  |
|  | @classCode | 1..1 | SHALL |  | [16323](#C_16323) | 2.16.840.1.113883.5.41 (EntityClass) = MMAT |
|  | code | 1..1 | SHALL |  | [16324](#C_16324) |  |
|  | originalText | 0..1 | SHOULD |  | [16326](#C_16326) |  |
|  | reference | 0..1 | SHOULD |  | [16327](#C_16327) |  |
|  | @value | 0..1 | SHOULD |  | [16328](#C_16328) |  |
|  | translation | 0..\* | MAY | SET<PQR> | [16330](#C_16330) |  |
|  | entryRelationship | 0..1 | MAY |  | [16333](#C_16333) |  |
|  | @typeCode | 1..1 | SHALL |  | [16335](#C_16335) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | @inversionInd | 1..1 | SHALL |  | [16334](#C_16334) | true |
|  | observation | 1..1 | SHALL |  | [16336](#C_16336) |  |
|  | entryRelationship | 0..\* | SHOULD |  | [16337](#C_16337) |  |
|  | @typeCode | 1..1 | SHALL |  | [16339](#C_16339) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = MFST |
|  | @inversionInd | 1..1 | SHALL |  | [16338](#C_16338) | true |
|  | observation | 1..1 | SHALL |  | [16340](#C_16340) |  |
|  | entryRelationship | 1..1 | SHALL |  | [16341](#C_16341) |  |
|  | @typeCode | 1..1 | SHALL |  | [16342](#C_16342) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | @inversionInd | 1..1 | SHALL |  | [16343](#C_16343) | true |
|  | observation | 1..1 | SHALL |  | [16344](#C_16344) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:16303).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:16304).
3. SHALL contain exactly one [1..1] templateId (CONF:16305) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.24.3.90" (CONF:16306).
4. SHALL contain at least one [1..\*] id (CONF:16307).
5. SHALL contain exactly one [1..1] code (CONF:16345).
   1. This code SHALL contain exactly one [1..1] @code="ASSERTION" Assertion (CodeSystem: ActCode 2.16.840.1.113883.5.4 STATIC) (CONF:16346).
6. SHALL contain exactly one [1..1] statusCode (CONF:16308).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:26354).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:16309).
8. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:16312).
   1. This value SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet Allergy/Adverse Event Type Value Set 2.16.840.1.113883.3.88.12.3221.6.2 DYNAMIC (CONF:16317).
9. SHOULD contain zero or more [0..\*] participant (CONF:16318).
   1. The participant, if present, SHALL contain exactly one [1..1] @typeCode="CSM" Consumable (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 STATIC) (CONF:16319).
   2. The participant, if present, SHALL contain exactly one [1..1] participantRole (CONF:16320).
      1. This participantRole SHALL contain exactly one [1..1] @classCode="MANU" Manufactured Product (CodeSystem: RoleClass 2.16.840.1.113883.5.110 STATIC) (CONF:16321).
      2. This participantRole SHALL contain exactly one [1..1] playingEntity (CONF:16322).
         1. This playingEntity SHALL contain exactly one [1..1] @classCode="MMAT" Manufactured Material (CodeSystem: EntityClass 2.16.840.1.113883.5.41 STATIC) (CONF:16323).
         2. This playingEntity SHALL contain exactly one [1..1] code (CONF:16324).
            1. This code SHOULD contain zero or one [0..1] originalText (CONF:16326).

The originalText, if present, SHOULD contain zero or one [0..1] reference (CONF:16327).

The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:16328).

This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:16329).

* + - * 1. This code MAY contain zero or more [0..\*] translation (CONF:16330).
        2. In an allergy to a specific medication the code SHALL be selected from the ValueSet 2.16.840.1.113883.3.88.12.80.16 Medication Brand Name DYNAMIC or the ValueSet 2.16.840.1.113883.3.88.12.80.17 Medication Clinical Drug DYNAMIC (CONF:16325).
        3. In an allergy to a class of medications the code SHALL be selected from the ValueSet 2.16.840.1.113883.3.88.12.80.18 Medication Drug Class DYNAMIC (CONF:16331).
        4. In an allergy to a food or other substance the code SHALL be selected from the ValueSet 2.16.840.1.113883.3.88.12.80.20 Ingredient Name DYNAMIC (CONF:16332).

1. MAY contain zero or one [0..1] entryRelationship (CONF:16333) such that it
   1. SHALL contain exactly one [1..1] @typeCode="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:16335).
   2. SHALL contain exactly one [1..1] @inversionInd="true" True (CONF:16334).
   3. SHALL contain exactly one [1..1] [Allergy Status Observation](#E_Allergy_Status_Observation) (templateId:2.16.840.1.113883.10.20.22.4.28) (CONF:16336).
2. SHOULD contain zero or more [0..\*] entryRelationship (CONF:16337) such that it
   1. SHALL contain exactly one [1..1] @typeCode="MFST" Is Manifestation of (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:16339).
   2. SHALL contain exactly one [1..1] @inversionInd="true" True (CONF:16338).
   3. SHALL contain exactly one [1..1] [Reaction Observation](#E_Reaction_Observation) (templateId:2.16.840.1.113883.10.20.22.4.9) (CONF:16340).
3. SHALL contain exactly one [1..1] entryRelationship (CONF:16341) such that it
   1. SHALL contain exactly one [1..1] @typeCode="SUBJ" Has Subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:16342).
   2. SHALL contain exactly one [1..1] @inversionInd="true" True (CONF:16343).
   3. SHALL contain exactly one [1..1] [Severity Observation](#E_Severity_Observation) (templateId:2.16.840.1.113883.10.20.22.4.8) (CONF:16344).

Table 293: Allergy/Adverse Event Type Value Set

|  |  |  |
| --- | --- | --- |
| Value Set: Allergy/Adverse Event Type Value Set 2.16.840.1.113883.3.88.12.3221.6.2 | | |
| Code | Code System | Print Name |
| 419199007 | SNOMED-CT | Allergy to substance (disorder) |
| 416098002 | SNOMED-CT | Drug allergy (disorder) |
| 59037007 | SNOMED-CT | Drug intolerance (disorder) |
| 414285001 | SNOMED-CT | Food allergy (disorder) |
| 235719002 | SNOMED-CT | Food intolerance (disorder) |
| 420134006 | SNOMED-CT | Propensity to adverse reactions (disorder) |
| 419511003 | SNOMED-CT | Propensity to adverse reactions to drug (disorder) |
| 418471000 | SNOMED-CT | Propensity to adverse reactions to food (disorder) |
| 418038007 | SNOMED-CT | Propensity to adverse reactions to substance (disorder) |

Allergy - Intolerance Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.7 (open)]

Table 294: Allergy - Intolerance Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Allergy Problem Act](#E_Allergy_Problem_Act) (required) | [Allergy Status Observation](#E_Allergy_Status_Observation)  [Reaction Observation](#E_Reaction_Observation)  [Severity Observation](#E_Severity_Observation) |

This clinical statement represents that an allergy or adverse reaction exists or does not exist. The agent that is the cause of the allergy or adverse reaction is represented as a manufactured material participant playing entity in the allergy observation. While the agent is often implicit in the alert observation (e.g. ""allergy to penicillin""), it should also be asserted explicitly as an entity. The manufactured material participant is used to represent natural and non-natural occurring substances.

NOTE: The agent responsible for an allergy or adverse reaction is not always a manufactured material (for example, food allergies), nor is it necessarily consumed. The following constraints reflect limitations in the base CDA R2 specification, and should be used to represent any type of responsible agent.

Table 295: Allergy - Intolerance Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
| Green Allergy Observation | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.7'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7379](#C_7379) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [7380](#C_7380) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [7381](#C_7381) |  |
|  | @root | 1..1 | SHALL |  | [10488](#C_10488) | 2.16.840.1.113883.10.20.22.4.7 |
|  | id | 1..\* | SHALL |  | [7382](#C_7382) |  |
|  | code | 1..1 | SHALL |  | [15947](#C_15947) |  |
|  | @code | 1..1 | SHALL |  | [15948](#C_15948) | 2.16.840.1.113883.5.4 (ActCode) = ASSERTION |
|  | statusCode | 1..1 | SHALL |  | [19084](#C_19084) |  |
|  | @code | 1..1 | SHALL |  | [19085](#C_19085) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
| adverseEventDate | effectiveTime | 1..1 | SHALL |  | [7387](#C_7387) |  |
|  | value | 1..1 | SHALL | CD | [7390](#C_7390) |  |
|  | originalText | 0..1 | SHOULD |  | [7422](#C_7422) |  |
|  | reference | 0..1 | MAY |  | [15949](#C_15949) |  |
|  | @value | 0..1 | SHOULD |  | [15950](#C_15950) |  |
| adverseEventType | @code | 1..1 | SHALL |  | [9139](#C_9139) | 2.16.840.1.113883.3.88.12.3221.6.2 (Allergy/Adverse Event Type Value Set) |
| product | participant | 0..1 | SHOULD |  | [7402](#C_7402) |  |
|  | @typeCode | 1..1 | SHALL |  | [7403](#C_7403) | 2.16.840.1.113883.5.90 (HL7ParticipationType) = CSM |
| productDetail | participantRole | 1..1 | SHALL |  | [7404](#C_7404) |  |
|  | @classCode | 1..1 | SHALL |  | [7405](#C_7405) | 2.16.840.1.113883.5.110 (RoleClass) = MANU |
|  | playingEntity | 1..1 | SHALL |  | [7406](#C_7406) |  |
|  | @classCode | 1..1 | SHALL |  | [7407](#C_7407) | 2.16.840.1.113883.5.41 (EntityClass) = MMAT |
| productCoded | code | 1..1 | SHALL |  | [7419](#C_7419) |  |
| productFreeText | originalText | 0..1 | SHOULD |  | [7424](#C_7424) |  |
|  | reference | 0..1 | SHOULD |  | [7425](#C_7425) |  |
|  | @value | 0..1 | SHOULD |  | [15952](#C_15952) |  |
|  | translation | 0..\* | MAY | SET<PQR> | [7431](#C_7431) |  |
|  | entryRelationship | 0..1 | MAY |  | [7440](#C_7440) |  |
|  | @typeCode | 1..1 | SHALL |  | [7906](#C_7906) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | @inversionInd | 1..1 | SHALL |  | [7446](#C_7446) | true |
|  | observation | 1..1 | SHALL |  | [15954](#C_15954) |  |
| reaction | entryRelationship | 0..\* | SHOULD |  | [7447](#C_7447) |  |
|  | @typeCode | 1..1 | SHALL |  | [7907](#C_7907) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = MFST |
|  | @inversionInd | 1..1 | SHALL |  | [7449](#C_7449) | true |
|  | observation | 1..1 | SHALL |  | [15955](#C_15955) |  |
| severity | entryRelationship | 0..1 | SHOULD |  | [9961](#C_9961) |  |
|  | @typeCode | 1..1 | SHALL |  | [9962](#C_9962) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ |
|  | @inversionInd | 1..1 | SHALL |  | [9964](#C_9964) | true |
|  | observation | 1..1 | SHALL |  | [15956](#C_15956) |  |

1. Conforms to [Substance or Device Allergy - Intolerance Observation](#E_Substance_or_Device_Allergy__Intolera) template (2.16.840.1.113883.10.20.24.3.90).
2. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7379).
3. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7380).
4. SHALL contain exactly one [1..1] templateId (CONF:7381) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.7" (CONF:10488).
5. SHALL contain at least one [1..\*] id (CONF:7382).
6. SHALL contain exactly one [1..1] code (CONF:15947).
   1. This code SHALL contain exactly one [1..1] @code="ASSERTION" Assertion (CodeSystem: ActCode 2.16.840.1.113883.5.4 STATIC) (CONF:15948).
7. SHALL contain exactly one [1..1] statusCode (CONF:19084).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19085).
8. SHALL contain exactly one [1..1] effectiveTime (CONF:7387).
   1. If it is unknown when the allergy began, this effectiveTime SHALL contain low/@nullFLavor="UNK" (CONF:9103).
   2. If the allergy is no longer a concern, this effectiveTime MAY contain zero or one [0..1] high (CONF:10082).
9. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:7390).
   1. This value SHOULD contain zero or one [0..1] originalText (CONF:7422).
      1. The originalText, if present, MAY contain zero or one [0..1] reference (CONF:15949).
         1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15950).
            1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15951).
   2. This value SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet Allergy/Adverse Event Type Value Set 2.16.840.1.113883.3.88.12.3221.6.2 DYNAMIC (CONF:9139).
10. SHOULD contain zero or one [0..1] participant (CONF:7402) such that it
    1. SHALL contain exactly one [1..1] @typeCode="CSM" Consumable (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 STATIC) (CONF:7403).
    2. SHALL contain exactly one [1..1] participantRole (CONF:7404).
       1. This participantRole SHALL contain exactly one [1..1] @classCode="MANU" Manufactured Product (CodeSystem: RoleClass 2.16.840.1.113883.5.110 STATIC) (CONF:7405).
       2. This participantRole SHALL contain exactly one [1..1] playingEntity (CONF:7406).
          1. This playingEntity SHALL contain exactly one [1..1] @classCode="MMAT" Manufactured Material (CodeSystem: EntityClass 2.16.840.1.113883.5.41 STATIC) (CONF:7407).
          2. This playingEntity SHALL contain exactly one [1..1] code (CONF:7419).
             1. This code SHOULD contain zero or one [0..1] originalText (CONF:7424).

The originalText, if present, SHOULD contain zero or one [0..1] reference (CONF:7425).

The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15952).

This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15953).

* + - * 1. This code MAY contain zero or more [0..\*] translation (CONF:7431).
        2. In an allergy to a specific medication the code SHALL be selected from the ValueSet 2.16.840.1.113883.3.88.12.80.16 Medication Brand Name DYNAMIC or the ValueSet 2.16.840.1.113883.3.88.12.80.17 Medication Clinical Drug DYNAMIC (CONF:7421).
        3. In an allergy to a class of medications the code SHALL be selected from the ValueSet 2.16.840.1.113883.3.88.12.80.18 Medication Drug Class DYNAMIC (CONF:10083).
        4. In an allergy to a food or other substance the code SHALL be selected from the ValueSet 2.16.840.1.113883.3.88.12.80.20 Ingredient Name DYNAMIC (CONF:10084).

1. MAY contain zero or one [0..1] entryRelationship (CONF:7440) such that it
   1. SHALL contain exactly one [1..1] @typeCode="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7906).
   2. SHALL contain exactly one [1..1] @inversionInd="true" True (CONF:7446).
   3. SHALL contain exactly one [1..1] [Allergy Status Observation](#E_Allergy_Status_Observation) (templateId:2.16.840.1.113883.10.20.22.4.28) (CONF:15954).
2. SHOULD contain zero or more [0..\*] entryRelationship (CONF:7447) such that it
   1. SHALL contain exactly one [1..1] @typeCode="MFST" Is Manifestation of (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:7907).
   2. SHALL contain exactly one [1..1] @inversionInd="true" True (CONF:7449).
   3. SHALL contain exactly one [1..1] [Reaction Observation](#E_Reaction_Observation) (templateId:2.16.840.1.113883.10.20.22.4.9) (CONF:15955).
3. SHOULD contain zero or one [0..1] entryRelationship (CONF:9961) such that it
   1. SHALL contain exactly one [1..1] @typeCode="SUBJ" Has Subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:9962).
   2. SHALL contain exactly one [1..1] @inversionInd="true" True (CONF:9964).
   3. SHALL contain exactly one [1..1] [Severity Observation](#E_Severity_Observation) (templateId:2.16.840.1.113883.10.20.22.4.8) (CONF:15956).

Table 296: Allergy/Adverse Event Type Value Set

|  |  |  |
| --- | --- | --- |
| Value Set: Allergy/Adverse Event Type Value Set 2.16.840.1.113883.3.88.12.3221.6.2 | | |
| Code | Code System | Print Name |
| 419199007 | SNOMED-CT | Allergy to substance (disorder) |
| 416098002 | SNOMED-CT | Drug allergy (disorder) |
| 59037007 | SNOMED-CT | Drug intolerance (disorder) |
| 414285001 | SNOMED-CT | Food allergy (disorder) |
| 235719002 | SNOMED-CT | Food intolerance (disorder) |
| 420134006 | SNOMED-CT | Propensity to adverse reactions (disorder) |
| 419511003 | SNOMED-CT | Propensity to adverse reactions to drug (disorder) |
| 418471000 | SNOMED-CT | Propensity to adverse reactions to food (disorder) |
| 418038007 | SNOMED-CT | Propensity to adverse reactions to substance (disorder) |

TNM Metastasis Staging

[Observation: templateId 2.16.840.1.113883.10.20.30.3.8 (open)]

Table 297: TNM Metastasis Staging Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Overall Stage](#E_Overall_Stage) (required) |  |

This clinical statement represents the AJCC staging of metastasis.

Notes: Design Note: Node Staging (temp) (2.16.840.1.113883.11.20.11.14) is a place holder for ValueSet.

Table 298: TNM Metastasis Staging Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.8'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [21872](#C_21872) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [21873](#C_21873) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [21874](#C_21874) |  |
|  | @root | 1..1 | SHALL |  | [21875](#C_21875) | 2.16.840.1.113883.10.20.30.3.8 |
|  | id | 1..\* | SHALL |  | [22073](#C_22073) |  |
|  | code | 1..1 | SHALL |  | [21877](#C_21877) |  |
|  | @code | 1..1 | SHALL | CD | [21878](#C_21878) | 277208005 |
|  | @codeSystem | 1..1 | SHALL |  | [23440](#C_23440) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |
|  | statusCode | 1..1 | SHALL |  | [22047](#C_22047) |  |
|  | @code | 1..1 | SHALL |  | [22048](#C_22048) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 1..1 | SHALL |  | [22080](#C_22080) |  |
|  | value | 1..1 | SHALL | CD | [22049](#C_22049) |  |
|  | @code | 1..1 | SHALL |  | [22051](#C_22051) | 2.16.840.1.113883.11.20.11.15 (TNM Metastasis Staging) |
|  | methodCode | 1..1 | SHALL |  | [24933](#C_24933) |  |
|  | @code | 1..1 | SHALL |  | [24934](#C_24934) | 443830009 |
|  | @codeSystem | 1..1 | SHALL |  | [24935](#C_24935) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:21872).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:21873).
3. SHALL contain exactly one [1..1] templateId (CONF:21874) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.8" (CONF:21875).
4. SHALL contain at least one [1..\*] id (CONF:22073).
5. SHALL contain exactly one [1..1] code (CONF:21877).
   1. This code SHALL contain exactly one [1..1] @code="277208005" M - Metastasis stages (CONF:21878).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23440).
6. SHALL contain exactly one [1..1] statusCode (CONF:22047).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:22048).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:22080).
8. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:22049).
   1. This value SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet TNM Metastasis Staging 2.16.840.1.113883.11.20.11.15 (CONF:22051).
9. SHALL contain exactly one [1..1] methodCode (CONF:24933).
   1. This methodCode SHALL contain exactly one [1..1] @code="443830009" American Joint Commission on Cancer,Cancer Staging Manual,7th edition neoplasm staging system (CONF:24934).
   2. This methodCode SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:24935).

Table 299: TNM Metastasis Staging

|  |  |  |
| --- | --- | --- |
| Value Set: TNM Metastasis Staging 2.16.840.1.113883.11.20.11.15 | | |
| Code | Code System | Print Name |
| 30893008 | SNOMED-CT | M0 |
| 55440008 | SNOMED-CT | M1 |
| 370029008 | SNOMED-CT | M1 |
| 370030003 | SNOMED-CT | M1 |
| 370031004 | SNOMED-CT | M1 |
| 370032006 | SNOMED-CT | M1 |
| 261927002 | SNOMED-CT | M1 |
| 370035008 | SNOMED-CT | M1 |
| 370036009 | SNOMED-CT | M1 |
| 370037000 | SNOMED-CT | M1 |
| 370038005 | SNOMED-CT | M1 |
| 370034007 | SNOMED-CT | M1 |
| 370033001 | SNOMED-CT | M1 |
| 261928007 | SNOMED-CT | M1 |
| 370039002 | SNOMED-CT | M1 |
| 370040000 | SNOMED-CT | M1 |
| 370041001 | SNOMED-CT | M1 |
| 370042008 | SNOMED-CT | M1 |
| 370043003 | SNOMED-CT | M1 |
| 370044009 | SNOMED-CT | M1 |
| 261929004 | SNOMED-CT | M1 |
| 370045005 | SNOMED-CT | M1 |
| 27167007 | SNOMED-CT | MX |

Figure 81: TNM metastatis staging

<!-- TNM - Metastasis (M) STAGING TemplateID -->

<templateId root="2.16.840.1.113883.10.20.30.3.8"/>

<code codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="277208005"

displayName="M - Metastasis stages"/>

<statusCode code="completed"/>

<!-- SHALL be bound to a value set AJCC set of values -->

<value xsi:type="CD"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="55440008"

displayName="M1 category"/>

<!-- SHALL method code -->

<methodCode code="443830009"

displayName="American Joint Commission on Cancer,

Cancer Staging Manual,

7th edition neoplasm staging system"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT"/>

TNM Node Staging

[Observation: templateId 2.16.840.1.113883.10.20.30.3.7 (open)]

Table 300: TNM Node Staging Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Overall Stage](#E_Overall_Stage) (required) |  |

This clinical statement template represents the AJCC staging of lymph node involvement.

Notes: Design Note: Node Staging2.16.840.1.113883.11.20.11.14 ValueSet in Observation value is a place holder.

Table 301: TNM Node Staging Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.7'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [21846](#C_21846) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [21847](#C_21847) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [21848](#C_21848) |  |
|  | @root | 1..1 | SHALL |  | [21849](#C_21849) | 2.16.840.1.113883.10.20.30.3.7 |
|  | id | 1..\* | SHALL |  | [22072](#C_22072) |  |
|  | code | 1..1 | SHALL |  | [21851](#C_21851) |  |
|  | @code | 1..1 | SHALL |  | [21852](#C_21852) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 371494008 |
|  | @codeSystem | 1..1 | SHALL |  | [23438](#C_23438) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |
|  | statusCode | 1..1 | SHALL |  | [22043](#C_22043) |  |
|  | @code | 1..1 | SHALL |  | [22044](#C_22044) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 1..1 | SHALL |  | [22079](#C_22079) |  |
|  | value | 1..1 | SHALL | CD | [22045](#C_22045) |  |
|  | @code | 1..1 | SHALL | CD | [22046](#C_22046) | 2.16.840.1.113883.11.20.11.14 (TNM Node Staging) |
|  | methodCode | 1..1 | SHALL |  | [24936](#C_24936) |  |
|  | @code | 1..1 | SHALL |  | [24937](#C_24937) | 443830009 |
|  | @codeSystem | 1..1 | SHALL |  | [24938](#C_24938) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:21846).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:21847).
3. SHALL contain exactly one [1..1] templateId (CONF:21848) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.7" (CONF:21849).
4. SHALL contain at least one [1..\*] id (CONF:22072).
5. SHALL contain exactly one [1..1] code (CONF:21851).
   1. This code SHALL contain exactly one [1..1] @code="371494008" stage of regional lymph node involvement by tumor (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:21852).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23438).
6. SHALL contain exactly one [1..1] statusCode (CONF:22043).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:22044).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:22079).
8. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:22045).
   1. This value SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet TNM Node Staging 2.16.840.1.113883.11.20.11.14 (CONF:22046).
9. SHALL contain exactly one [1..1] methodCode (CONF:24936).
   1. This methodCode SHALL contain exactly one [1..1] @code="443830009" American Joint Commission on Cancer,Cancer Staging Manual,7th edition neoplasm staging system (CONF:24937).
   2. This methodCode SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:24938).

Figure 82: TNM node staging example

<!-- TNM - Node (N) STAGING TemplateID-->

<templateId root="2.16.840.1.113883.10.20.30.3.7"/>

<code codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="371494008"

displayName="stage of regional lymph node involvement by tumor"/>

<statusCode code="completed"/>

<!-- SHALL be bound to a value set AJCC set of values -->

<value xsi:type="CD"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="53623008"

displayName="N1 category"/>

<!-- SHALL method code -->

<methodCode code="443830009"

displayName="American Joint Commission on Cancer,

Cancer Staging Manual,

7th edition neoplasm staging system"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT"/>

TNM Tumor Staging

[Observation: templateId 2.16.840.1.113883.10.20.30.3.5 (open)]

Table 302: TNM Tumor Staging Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Overall Stage](#E_Overall_Stage) (required) |  |

This clinical statement template represents the AJCC staging of the tumor.

Notes: Design Note: Need to define high level tumor stage for temp value set Tumor Stage 2.16.840.1.113883.11.20.11.13.

Table 303: TNM Tumor Staging Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.5'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [21822](#C_21822) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [21823](#C_21823) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [19350](#C_19350) |  |
|  | @root | 1..1 | SHALL |  | [19351](#C_19351) | 2.16.840.1.113883.10.20.30.3.5 |
|  | id | 1..\* | SHALL |  | [22071](#C_22071) |  |
|  | code | 1..1 | SHALL |  | [21825](#C_21825) |  |
|  | @code | 1..1 | SHALL |  | [21826](#C_21826) | 371508000 |
|  | @codeSystem | 1..1 | SHALL |  | [23436](#C_23436) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |
|  | statusCode | 1..1 | SHALL |  | [22052](#C_22052) |  |
|  | @code | 1..1 | SHALL |  | [22053](#C_22053) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 1..1 | SHALL |  | [22078](#C_22078) |  |
|  | value | 1..1 | SHALL | CD | [22054](#C_22054) |  |
|  | @code | 1..1 | SHALL |  | [22055](#C_22055) | 2.16.840.1.113883.11.20.11.13 (TNM Tumor Staging) |
|  | methodCode | 1..1 | SHALL |  | [24930](#C_24930) |  |
|  | @code | 1..1 | SHALL |  | [24931](#C_24931) | 443830009 |
|  | @codeSystem | 1..1 | SHALL |  | [24932](#C_24932) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96 |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:21822).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:21823).
3. SHALL contain exactly one [1..1] templateId (CONF:19350) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.5" (CONF:19351).
4. SHALL contain at least one [1..\*] id (CONF:22071).
5. SHALL contain exactly one [1..1] code (CONF:21825).
   1. This code SHALL contain exactly one [1..1] @code="371508000" Tumor Stage (CONF:21826).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23436).
6. SHALL contain exactly one [1..1] statusCode (CONF:22052).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:22053).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:22078).
8. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:22054).
   1. This value SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet TNM Tumor Staging 2.16.840.1.113883.11.20.11.13 (CONF:22055).
9. SHALL contain exactly one [1..1] methodCode (CONF:24930).
   1. This methodCode SHALL contain exactly one [1..1] @code="443830009" American Joint Commission on Cancer,Cancer Staging Manual,7th edition neoplasm staging system (CONF:24931).
   2. This methodCode SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:24932).

Table 304: TNM Tumor Staging

|  |  |  |
| --- | --- | --- |
| Value Set: TNM Tumor Staging 2.16.840.1.113883.11.20.11.13 | | |
| Code | Code System | Print Name |
| 23351008 | SNOMED-CT | T1 |
| 369895002 | SNOMED-CT | T1 |
| 369897005 | SNOMED-CT | T1 |
| 369898000 | SNOMED-CT | T1 |
| 369899008 | SNOMED-CT | T1 |
| 67673008 | SNOMED-CT | T2 |
| 369900003 | SNOMED-CT | T2 |
| 261651009 | SNOMED-CT | T2 |
| 261652002 | SNOMED-CT | T2 |
| 261653007 | SNOMED-CT | T2 |
| 14410001 | SNOMED-CT | T3 |
| 369901004 | SNOMED-CT | T3 |
| 261654001 | SNOMED-CT | T3 |
| 261655000 | SNOMED-CT | T3 |
| 261656004 | SNOMED-CT | T3 |
| 261657008 | SNOMED-CT | T3 |
| 261658003 | SNOMED-CT | T3 |
| 65565005 | SNOMED-CT | T4 |
| 369902006 | SNOMED-CT | T4 |
| 369903001 | SNOMED-CT | T4 |
| 369905008 | SNOMED-CT | T4 |
| 369906009 | SNOMED-CT | T4 |
| 373190002 | SNOMED-CT | T4 |
| 445110009 | SNOMED-CT | T4 |
| 261659006 | SNOMED-CT | T4 |
| 261660001 | SNOMED-CT | T4 |
| 261661002 | SNOMED-CT | T4 |
| 261662009 | SNOMED-CT | T4 |
| 67101007 | SNOMED-CT | TX |

Figure 83: TNM tumor staging example

<!-- TNM - Tumor (T) STAGING templateID-->

<templateId root="2.16.840.1.113883.10.20.30.3.5"/>

<code codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="371508000"

displayName="Tumor stage"/>

<statusCode code="completed"/>

<!-- SHALL be bound to a valueset AJCC set of values -->

<value xsi:type="CD"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT" code="67673008"

displayName="T2 category"/>

<!-- SHALL method code -->

<methodCode code="443830009"

displayName="American Joint Commission on Cancer,

Cancer Staging Manual,

7th edition neoplasm staging system"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED-CT"/>

Vital Sign Observation[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.27 (open)]

Table 305: Vital Sign Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Vital Signs Organizer](#E_Vital_Signs_Organizer) (required) |  |

Vital signs are represented as are other results, with additional vocabulary constraints.

Table 306: Vital Sign Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.27'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7297](#C_7297) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [7298](#C_7298) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [7299](#C_7299) |  |
|  | @root | 1..1 | SHALL |  | [10527](#C_10527) | 2.16.840.1.113883.10.20.22.4.27 |
|  | id | 1..\* | SHALL |  | [7300](#C_7300) |  |
|  | code | 1..1 | SHALL |  | [7301](#C_7301) | 2.16.840.1.113883.3.88.12.80.62 (Vital Sign Result Value Set) |
|  | text | 0..1 | SHOULD |  | [7302](#C_7302) |  |
|  | reference | 0..1 | SHOULD |  | [15943](#C_15943) |  |
|  | @value | 0..1 | SHOULD |  | [15944](#C_15944) |  |
|  | statusCode | 1..1 | SHALL |  | [7303](#C_7303) |  |
|  | @code | 1..1 | SHALL |  | [19119](#C_19119) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 1..1 | SHALL |  | [7304](#C_7304) |  |
|  | value | 1..1 | SHALL | PQ | [7305](#C_7305) |  |
|  | interpretationCode | 0..1 | MAY |  | [7307](#C_7307) |  |
|  | methodCode | 0..1 | MAY | SET<CE> | [7308](#C_7308) |  |
|  | targetSiteCode | 0..1 | MAY | SET<CD> | [7309](#C_7309) |  |
|  | author | 0..1 | MAY |  | [7310](#C_7310) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7297).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7298).
3. SHALL contain exactly one [1..1] templateId (CONF:7299) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.27" (CONF:10527).
4. SHALL contain at least one [1..\*] id (CONF:7300).
5. SHALL contain exactly one [1..1] code, which SHOULD be selected from ValueSet Vital Sign Result Value Set 2.16.840.1.113883.3.88.12.80.62 DYNAMIC (CONF:7301).
6. SHOULD contain zero or one [0..1] text (CONF:7302).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:15943).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:15944).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15945).
7. SHALL contain exactly one [1..1] statusCode (CONF:7303).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19119).
8. SHALL contain exactly one [1..1] effectiveTime (CONF:7304).
9. SHALL contain exactly one [1..1] value with @xsi:type="PQ" (CONF:7305).
10. MAY contain zero or one [0..1] interpretationCode (CONF:7307).
11. MAY contain zero or one [0..1] methodCode (CONF:7308).
12. MAY contain zero or one [0..1] targetSiteCode (CONF:7309).
13. MAY contain zero or one [0..1] author (CONF:7310).

Table 307: Vital Sign Result Value Set

|  |  |  |
| --- | --- | --- |
| Value Set: Vital Sign Result Value Set 2.16.840.1.113883.3.88.12.80.62 | | |
| Code | Code System | Print Name |
| 8310-5 | LOINC | Body Temperature |
| 8462-4 | LOINC | BP Diastolic |
| 8480-6 | LOINC | BP Systolic |
| 8287-5 | LOINC | Head Circumference |
| 8867-4 | LOINC | Heart Rate |
| 8302-2 | LOINC | Height |
| 8306-3 | LOINC | Height (Lying) |
| 2710-2 | LOINC | O2 % BldC Oximetry |
| 9279-1 | LOINC | Respiratory Rate |
| 3141-9 | LOINC | Weight Measured |

Body Height

[Observation: templateId 2.16.840.1.113883.10.20.30.3.26 (open)]

Table 308: Body Height Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Vital Signs Organizer BCTPS](#E_Vital_Signs_Organizer_BCTPS) (required) |  |

This clinical statement represents the number that describes the vertical distance of an individual. The [in/cm] = Unified Code for Units of Measure symbols represent a determinate amount or quantity used as the standard of measurement.

Table 309: Body Height Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.26'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [24107](#C_24107) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [24108](#C_24108) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [24862](#C_24862) |  |
|  | @root | 1..1 | SHALL |  | [24863](#C_24863) | 2.16.840.1.113883.10.20.30.3.26 |
|  | code | 1..1 | SHALL |  | [24113](#C_24113) |  |
|  | @code | 1..1 | SHALL |  | [24114](#C_24114) | 8302-2 |
|  | @codeSystem | 1..1 | SHALL |  | [24129](#C_24129) | 2.16.840.1.113883.6.1 |
|  | value | 1..1 | SHALL | PQ | [24124](#C_24124) |  |
|  | @unit | 1..1 | SHALL |  | [24126](#C_24126) | 2.16.840.1.113883.11.20.11.18 (Unit Of Body Height) |

1. Conforms to [Vital Sign Observation](#E_Vital_Sign_Observation) template (2.16.840.1.113883.10.20.22.4.27).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:24107).
3. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:24108).
4. SHALL contain exactly one [1..1] templateId (CONF:24862) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.26" (CONF:24863).
5. SHALL contain exactly one [1..1] code (CONF:24113).
   1. This code SHALL contain exactly one [1..1] @code="8302-2" Body height (CONF:24114).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" LOINC (CONF:24129).
6. SHALL contain exactly one [1..1] value with @xsi:type="PQ" (CONF:24124).
   1. This value SHALL contain exactly one [1..1] @unit, which SHALL be selected from ValueSet Unit Of Body Height 2.16.840.1.113883.11.20.11.18 (CONF:24126).

Table 310: Unit Of Body Height

|  |  |  |
| --- | --- | --- |
| Value Set: Unit Of Body Height 2.16.840.1.113883.11.20.11.18 | | |
| Code | Code System | Print Name |
| cm | UCUM | cm |
| [in\_i] | UCUM | in |

Figure 84: Body height example

<templateId root="2.16.840.1.113883.10.20.30.3.26"/>

<id root="c6f88321-67ad-11db-bd13-0800200c9a66"/>

<!-- SHALL @code and single value binding -->

<code code="8302-2" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC" displayName="Height"/>

<text>

<reference value="#height1"/>

</text>

<statusCode code="completed"/>

<effectiveTime value="20120407"/>

<!-- SHALL with unit (not value) constained to ucum valueset of cm/inches -->

<value xsi:type="PQ" value="152.4" unit="cm"/>

<interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>

Body Surface Area

[Observation: templateId 2.16.840.1.113883.10.20.30.3.28 (open)]

Table 311: Body Surface Area Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Vital Signs Organizer BCTPS](#E_Vital_Signs_Organizer_BCTPS) (required) |  |

The calculated numerical quantity that represents the 2-dimensional extent of the body surface relating height to weight.

Table 312: Body Surface Area Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.28'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [24864](#C_24864) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [24865](#C_24865) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [24868](#C_24868) |  |
|  | @root | 1..1 | SHALL |  | [24869](#C_24869) | 2.16.840.1.113883.10.20.30.3.28 |
|  | code | 1..1 | SHALL |  | [24872](#C_24872) |  |
|  | @code | 1..1 | SHALL |  | [24873](#C_24873) | 3140-1 |
|  | @codeSystem | 1..1 | SHALL |  | [25999](#C_25999) | 2.16.840.1.113883.6.1 |
|  | value | 1..1 | SHALL | PQ | [24883](#C_24883) |  |
|  | @unit | 1..1 | SHALL |  | [24885](#C_24885) | 2.16.840.1.113883.6.8 (UCUM) = m2 |

1. Conforms to [Vital Sign Observation](#E_Vital_Sign_Observation) template (2.16.840.1.113883.10.20.22.4.27).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:24864).
3. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:24865).
4. SHALL contain exactly one [1..1] templateId (CONF:24868) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.28" (CONF:24869).
5. SHALL contain exactly one [1..1] code (CONF:24872).
   1. This code SHALL contain exactly one [1..1] @code="3140-1" BSA (Body Surface Area) (CONF:24873).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" LOINC (CONF:25999).
6. SHALL contain exactly one [1..1] value with @xsi:type="PQ" (CONF:24883).
   1. This value SHALL contain exactly one [1..1] @unit="m2" (CodeSystem: UCUM 2.16.840.1.113883.6.8 STATIC) (CONF:24885).

Figure 85: Body surface area example

<templateId root="2.16.840.1.113883.10.20.30.3.28"/>

<id root="c6f88321-67ad-11db-bd13-0800200c9a66"/>

<!-- SHALL @code and single value binding -->

<code code="3140-1" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC" displayName="BSA (Body Surface Area)"/>

<text>

<reference value="#BSA1"/>

</text>

<statusCode code="completed"/>

<effectiveTime value="20120407"/>

<!-- SHALL with unit (not value) constained to ucum code m2 -->

<value xsi:type="PQ" value="1.31" unit="m2"/>

<interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>

Body Weight

[Observation: templateId 2.16.840.1.113883.10.20.30.3.27 (open)]

Table 313: Body Weight Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Vital Signs Organizer BCTPS](#E_Vital_Signs_Organizer_BCTPS) (required) |  |

The number that describes the vertical force exerted by the mass of an individual as a result of gravity. The [lb/kg] = Unified Code for Units of Measure symbols that represent a determinate amount or quantity used as the standard of measurement for the vertical force exerted by the mass of an individual as a result of gravity.

Table 314: Body Weight Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.27'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [23521](#C_23521) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | [23522](#C_23522) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [24860](#C_24860) |  |
|  | @root | 1..1 | SHALL |  | [24861](#C_24861) | 2.16.840.1.113883.10.20.30.3.27 |
|  | code | 1..1 | SHALL |  | [23547](#C_23547) |  |
|  | @code | 1..1 | SHALL |  | [23548](#C_23548) | 3141-9 |
|  | @codeSystem | 1..1 | SHALL |  | [24947](#C_24947) | 2.16.840.1.113883.6.1 |
|  | value | 1..1 | SHALL | PQ | [23558](#C_23558) |  |
|  | @unit | 1..1 | SHALL |  | [23560](#C_23560) | 2.16.840.1.113883.11.20.11.17 (Unit Of Body Weight) |

1. Conforms to [Vital Sign Observation](#E_Vital_Sign_Observation) template (2.16.840.1.113883.10.20.22.4.27).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23521).
3. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23522).
4. SHALL contain exactly one [1..1] templateId (CONF:24860) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.27" (CONF:24861).
5. SHALL contain exactly one [1..1] code (CONF:23547).
   1. This code SHALL contain exactly one [1..1] @code="3141-9" Body weight Measured (CONF:23548).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" LOINC (CONF:24947).
6. SHALL contain exactly one [1..1] value with @xsi:type="PQ" (CONF:23558).
   1. This value SHALL contain exactly one [1..1] @unit, which SHALL be selected from ValueSet Unit Of Body Weight 2.16.840.1.113883.11.20.11.17 DYNAMIC (CONF:23560).

Table 315: Unit Of Body Weight

|  |  |  |
| --- | --- | --- |
| Value Set: Unit Of Body Weight 2.16.840.1.113883.11.20.11.17 | | |
| Code | Code System | Print Name |
| kg | UCUM | kg |
| [lb\_av] | UCUM | lb |

Figure 86: Body weight example

<templateId root="2.16.840.1.113883.10.20.30.3.27"/>

<id root="0dec5daa-7095-41d1-be80-75bd58dff2fb"/>

<!-- SHALL @code and single value binding -->

<code code="3141-9" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC" displayName="Weight Measured"/>

<text>

<reference value="#weight1"/>

</text>

<statusCode code="completed"/>

<effectiveTime value="20120407"/>

<!-- SHALL with unit (not value) constained to ucum valueset of kg/pounds -->

<value xsi:type="PQ" value="45" unit="kg"/>

<interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"

/>

Vital Signs Organizer [Closed for comments; published July 2012]

[organizer: templateId 2.16.840.1.113883.10.20.22.4.26 (open)]

Table 316: Vital Signs Organizer Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Vital Signs Section (entries optional)](#S_Vital_Signs_Section_entries_optional) (optional) | [Vital Sign Observation](#E_Vital_Sign_Observation) |

The Vital Signs Organizer groups vital signs, which is similar to the Result Organizer, but with further constraints.

An appropriate nullFlavor can be used when the organizer/code or organizer/id is unknown.

Table 317: Vital Signs Organizer Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | organizer[templateId/@root = '2.16.840.1.113883.10.20.22.4.26'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [7279](#C_7279) | 2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER |
|  | @moodCode | 1..1 | SHALL |  | [7280](#C_7280) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [7281](#C_7281) |  |
|  | @root | 1..1 | SHALL |  | [10528](#C_10528) | 2.16.840.1.113883.10.20.22.4.26 |
|  | id | 1..\* | SHALL |  | [7282](#C_7282) |  |
|  | code | 1..1 | SHALL |  | [19176](#C_19176) |  |
|  | @code | 1..1 | SHALL |  | [19177](#C_19177) | 2.16.840.1.113883.6.96 (SNOMED-CT) = 46680005 |
|  | statusCode | 1..1 | SHALL |  | [7284](#C_7284) |  |
|  | @code | 1..1 | SHALL |  | [19120](#C_19120) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | effectiveTime | 1..1 | SHALL |  | [7288](#C_7288) |  |
|  | component | 1..\* | SHALL |  | [7285](#C_7285) |  |
|  | observation | 1..1 | SHALL |  | [15946](#C_15946) |  |

1. SHALL contain exactly one [1..1] @classCode="CLUSTER" CLUSTER (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:7279).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:7280).
3. SHALL contain exactly one [1..1] templateId (CONF:7281) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.26" (CONF:10528).
4. SHALL contain at least one [1..\*] id (CONF:7282).
5. SHALL contain exactly one [1..1] code (CONF:19176).
   1. This code SHALL contain exactly one [1..1] @code="46680005" Vital signs (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:19177).
6. SHALL contain exactly one [1..1] statusCode (CONF:7284).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19120).

The effectiveTime represents clinically effective time of the measurement, which is most likely when the measurement was performed (e.g., a BP measurement).

1. SHALL contain exactly one [1..1] effectiveTime (CONF:7288).
2. SHALL contain at least one [1..\*] component (CONF:7285) such that it
   1. SHALL contain exactly one [1..1] [Vital Sign Observation](#E_Vital_Sign_Observation) (templateId:2.16.840.1.113883.10.20.22.4.27) (CONF:15946).

Vital Signs Organizer BCTPS

[organizer: templateId 2.16.840.1.113883.10.20.30.3.25 (open)]

Table 318: Vital Signs Organizer BCTPS Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Vital Signs Section BCTPS](#Vital_Signs_Section_BCTPS) (required) | [Body Height](#Body_Height)  [Body Surface Area](#E_Body_Surface_Area)  [Body Weight](#E_Body_Weight) |

This clinical statement represents a vital signs organizer that conforms to the C-CDA Vital Signs Organizer; this is required with vital signs observation entries. This vital signs organizer contains height, weight, and body surface area entries.

Table 319: Vital Signs Organizer BCTPS Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | organizer[templateId/@root = '2.16.840.1.113883.10.20.30.3.25'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | [24889](#C_24889) | 2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER |
|  | @moodCode | 1..1 | SHALL |  | [24890](#C_24890) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | [24893](#C_24893) |  |
|  | @root | 1..1 | SHALL |  | [24894](#C_24894) | 2.16.840.1.113883.10.20.30.3.25 |
|  | code | 1..1 | SHALL |  | [24896](#C_24896) |  |
|  | @code | 1..1 | SHALL |  | [24897](#C_24897) | 46680005 |
|  | @codeSystem | 1..1 | SHALL |  | [26000](#C_26000) | 2.16.840.1.113883.6.96 |
|  | component | 1..1 | SHALL |  | [24901](#C_24901) |  |
|  | observation | 1..1 | SHALL |  | [24902](#C_24902) |  |
|  | component | 1..1 | SHALL |  | [24903](#C_24903) |  |
|  | observation | 1..1 | SHALL |  | [24904](#C_24904) |  |
|  | component | 1..1 | SHALL |  | [24905](#C_24905) |  |
|  | observation | 1..1 | SHALL |  | [26001](#C_26001) |  |

1. Conforms to [Vital Signs Organizer](#E_Vital_Signs_Organizer) template (2.16.840.1.113883.10.20.22.4.26).
2. SHALL contain exactly one [1..1] @classCode="CLUSTER" CLUSTER (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:24889).
3. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:24890).
4. SHALL contain exactly one [1..1] templateId (CONF:24893) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.25" (CONF:24894).
5. SHALL contain exactly one [1..1] code (CONF:24896).
   1. This code SHALL contain exactly one [1..1] @code="46680005" vital signs (CONF:24897).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" SNOMED CT (CONF:26000).
6. SHALL contain exactly one [1..1] component (CONF:24901) such that it
   1. SHALL contain exactly one [1..1] [Body Height](#Body_Height) (templateId:2.16.840.1.113883.10.20.30.3.26) (CONF:24902).
7. SHALL contain exactly one [1..1] component (CONF:24903) such that it
   1. SHALL contain exactly one [1..1] [Body Weight](#E_Body_Weight) (templateId:2.16.840.1.113883.10.20.30.3.27) (CONF:24904).
8. SHALL contain exactly one [1..1] component (CONF:24905) such that it
   1. SHALL contain exactly one [1..1] [Body Surface Area](#E_Body_Surface_Area) (templateId:2.16.840.1.113883.10.20.30.3.28) (CONF:26001).

Figure 87: Vital Signs Organizer BCTPS example

<templateId root="2.16.840.1.113883.10.20.30.3.25"/>

<id root="16f81685-cb5b-470b-9823-fca324968479"/>

<code code="46680005" codeSystem="2.16.840.1.113883.6.96"

displayName="Vital Signs" codeSystemName="SNOMED CT">

<originalText>Vital Signs</originalText>

</code>

<statusCode code="completed"/>

<effectiveTime value="20120407"/>

<component>

<!-- BODY HEIGHT in cm -->

<observation classCode="OBS" moodCode="EVN">

<!-- Vital signs Observation template from Consolidation

templateID-->

<templateId root="2.16.840.1.113883.10.20.22.4.27"/>

<!-- Body Height template -->

...

<component>

<!-- BODY WEIGHT -->

<observation classCode="OBS" moodCode="EVN">

<!-- Vital signs Observation template from Consolidation

templateID-->

<templateId root="2.16.840.1.113883.10.20.22.4.27"/>

<!-- Body weight templateID-->

<templateId root="2.16.840.1.113883.10.20.30.3.27"/>

<id root="0dec5daa-7095-41d1-be80-75bd58dff2fb"/>

...

<!-- BODY SURFACE AREA -->

<observation classCode="OBS" moodCode="EVN">

<!-- Vital signs Observation template from Consolidation

templateID-->

<templateId root="2.16.840.1.113883.10.20.22.4.27"/>

<!-- Body Weight templateID-->

<templateId root="2.16.840.1.113883.10.20.30.3.28"/>

<id root="c6f88321-67ad-11db-bd13-0800200c9a66"/>

<!-- SHALL @code and single value binding -->

<code code="3140-1" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC" displayName="BSA (Body Surface Area)"/>

<text>

<reference value="#BSA1"/>

</text>

<statusCode code="completed"/>

<effectiveTime value="20120407"/>

<!-- SHALL with unit (not value) constained to ucum code m2 -->

<value xsi:type="PQ" value="1.31" unit="m2"/>

<interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"

/>

</observation>

</component>

</organizer>

# References

* *HL7 Clinical Document Architecture (CDA Release 2)*. <http://www.hl7.org/implement/standards/cda.cfm>
* *HL7 Clinical Document Architecture (CDA) Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries* Release 1 August 2012 (add link)
* *HL7 Clinical Genomics Work Group The Family History Standard – Implementation Guide (US Realm)* December 2012 (add link)
* *HL7 Version 3 Interoperability Standards,* Normative Edition 2010. [http://www.hl7.org/memonly/downloads/v3edition.cfm](http://www.hl7.org/memonly/downloads/v3edition.cfm#V32010) (must be an HL7 member)
* *HL7 Version 3 Publishing Facilitator's Guide* <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm>
* Add Remaining…

1. Acronyms and Abbreviations

BCTPS Breast Cancer Treatment Plan Summary

CCR Continuity of Care Record

CDA Clinical Document Architecture

CDC Centers for Disease Control and Prevention

CRS Care Record Summary

DSTU Draft Standard for Trial Use

EHR Electronic Health Record

EMR Electronic Medical Record

HER2 Human Epidermal Growth Factor

HL7 Health Level Seven

IG Implementation Guide

LOINC Logical Observation Identifiers Names and Codes

NHSN National Healthcare Safety Network

OID Object identifier

PHIN VADS Public Health Information Network Vocabulary Access and Distribution System

R2 Release 2

RIM Reference Information Model

RMIM Refined Message Information Model

SDWG Structured Documents Working Group

SNOMED CT Systematized Nomenclature of Medicine, Clinical Terms

TNM Tumor Nodal Metastasis

XML Extensible Mark-up Language

1. Template IDs Used in this Guide

This appendix lists all templateIds used in this guide in [alphabetical order](#T_Alpha_List_Of_TemplateIds) and in [containment order](#T_Template_Containment).

Table 320: Template List

| Template Title | Template Type | templateId |
| --- | --- | --- |
| [Clinical Oncology Treatment Plan and Summary](#D_Clinical_Oncology_Treatment_Plan_and_) | document | 2.16.840.1.113883.10.20.30.1.1 |
| [US Realm Header](#D_US_Realm_Header) | document | 2.16.840.1.113883.10.20.22.1.1 |
| [Allergies Section (entries optional)](#S_Allergies_Section_entries_optional) | section | 2.16.840.1.113883.10.20.22.2.6 |
| [Encounters Section (entries optional)](#S_Encounters_Section_entries_optional) | section | 2.16.840.1.113883.10.20.22.2.22 |
| [Encounters Section BCTPS](#Encounters_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.9 |
| [Family History Section](#S_Family_History_Section) | section | 2.16.840.1.113883.10.20.22.2.15 |
| [Family History Section BCTPS](#Family_History_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.3 |
| [Functional Status Section](#S_Functional_Status_Section) | section | 2.16.840.1.113883.10.20.22.2.14 |
| [Functional Status Section BCTPS](#Functional_Status_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.8 |
| [Medications Section (entries optional)](#S_Medications_Section_entries_optional) | section | 2.16.840.1.113883.10.20.22.2.1 |
| [Medications Section BCTPS](#S_Medications_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.7 |
| [Plan of Care Section](#S_Plan_of_Care_Section) | section | 2.16.840.1.113883.10.20.22.2.10 |
| [Plan of Care Section BCTPS](#S_Plan_of_Care_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.6 |
| [Problem Section (entries optional)](#S_Problem_Section_entries_optional) | section | 2.16.840.1.113883.10.20.22.2.5 |
| [Problem Section BCTPS](#S_Problem_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.1 |
| [Procedures Section (entries optional)](#S_Procedures_Section_entries_optional) | section | 2.16.840.1.113883.10.20.22.2.7 |
| [Procedures Section BCTPS](#Procedures_Section_BCTPS_) | section | 2.16.840.1.113883.10.20.30.2.4 |
| [Results Section (entries optional)](#S_Results_Section_entries_optional) | section | 2.16.840.1.113883.10.20.22.2.3 |
| [Results Section BCTPS](#Results_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.2 |
| [Vital Signs Section (entries optional)](#S_Vital_Signs_Section_entries_optional) | section | 2.16.840.1.113883.10.20.22.2.4 |
| [Vital Signs Section BCTPS](#Vital_Signs_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.5 |
| [Age Observation](#E_Age_Observation) | entry | 2.16.840.1.113883.10.20.22.4.31 |
| [Allergy - Intolerance Observation](#E_Allergy__Intolerance_Observation) | entry | 2.16.840.1.113883.10.20.22.4.7 |
| [Allergy Problem Act](#E_Allergy_Problem_Act) | entry | 2.16.840.1.113883.10.20.22.4.30 |
| [Allergy Status Observation](#E_Allergy_Status_Observation) | entry | 2.16.840.1.113883.10.20.22.4.28 |
| [Anthracycline Medication Activity](#Anthracycline_Medication_Activity) | entry | 2.16.840.1.113883.10.20.30.3.24 |
| [Anthracycline Medication Information](#Anthracycline_Medication_Information) | entry | 2.16.840.1.113883.10.20.30.3.33 |
| [Assessment Scale Observation](#E_Assessment_Scale_Observation) | entry | 2.16.840.1.113883.10.20.22.4.69 |
| [Assessment Scale Supporting Observation](#E_Assessment_Scale_Supporting_Observati) | entry | 2.16.840.1.113883.10.20.22.4.86 |
| [Body Height](#Body_Height) | entry | 2.16.840.1.113883.10.20.30.3.26 |
| [Body Surface Area](#E_Body_Surface_Area) | entry | 2.16.840.1.113883.10.20.30.3.28 |
| [Body Weight](#E_Body_Weight) | entry | 2.16.840.1.113883.10.20.30.3.27 |
| [Breast Cancer Concern Act](#Breast_Cancer_Concern_Act) | entry | 2.16.840.1.113883.10.20.30.3.6 |
| [Breast Cancer Diagnosis Observation](#E_Breast_Cancer_Diagnosis_Observation) | entry | 2.16.840.1.113883.10.20.30.3.2 |
| [Breast Cancer Procedures](#E_Breast_Cancer_Procedures) | entry | 2.16.840.1.113883.10.20.30.3.12 |
| [Cardiac Function Observation](#Cardiac_Function_Observation) | entry | 2.16.840.1.113883.10.20.30.3.21 |
| [Caregiver Characteristics](#E_Caregiver_Characteristics) | entry | 2.16.840.1.113883.10.20.22.4.72 |
| [Chemotherapy Dose Reduction](#Chemotherapy_Dose_Reduction) | entry | 2.16.840.1.113883.10.20.30.3.39 |
| [Chemotherapy Medication Activity](#E_Chemotherapy_Medication_Activity) | entry | 2.16.840.1.113883.10.20.30.3.44 |
| [Chemotherapy Regimen](#E_Chemotherapy_Regimen) | entry | 2.16.840.1.113883.10.20.30.3.1 |
| [Chemotherapy Regimen Plans](#E_Chemotherapy_Regimen_Plans) | entry | 2.16.840.1.113883.10.20.30.3.30 |
| [Clinical Drug Trial](#Clinical_Drug_Trial) | entry | 2.16.840.1.113883.10.20.30.3.4 |
| [Cognitive Status Problem Observation](#E_Cognitive_Status_Problem_Observation) | entry | 2.16.840.1.113883.10.20.22.4.73 |
| [Cognitive Status Result Observation](#E_Cognitive_Status_Result_Observation) | entry | 2.16.840.1.113883.10.20.22.4.74 |
| [Cognitive Status Result Organizer](#E_Cognitive_Status_Result_Organizer) | entry | 2.16.840.1.113883.10.20.22.4.75 |
| [Drug Therapy Discontinued](#Drug_Therapy_Discontinued) | entry | 2.16.840.1.113883.10.20.30.3.43 |
| [Drug Vehicle](#E_Drug_Vehicle) | entry | 2.16.840.1.113883.10.20.22.4.24 |
| [Encounter Activities](#E_Encounter_Activities) | entry | 2.16.840.1.113883.10.20.22.4.49 |
| [Encounter Diagnosis](#E_Encounter_Diagnosis) | entry | 2.16.840.1.113883.10.20.22.4.80 |
| [Endocrine Medication Activity](#Endocrine_Medication_Activity) | entry | 2.16.840.1.113883.10.20.30.3.23 |
| [Endocrine Medication Information](#E_Endocrine_Medication_Information) | entry | 2.16.840.1.113883.10.20.30.3.22 |
| [Estrogen Receptor Status](#Estrogen_Receptor_Status) | entry | 2.16.840.1.113883.10.20.30.3.19 |
| [Family History Death Observation](#E_Family_History_Death_Observation) | entry | 2.16.840.1.113883.10.20.22.4.47 |
| [Family History Observation](#E_Family_History_Observation) | entry | 2.16.840.1.113883.10.20.22.4.46 |
| [Family History of Cancer None](#Family_History_of_Cancer_None) | entry | 2.16.840.1.113883.10.20.30.3.11 |
| [Family History Organizer](#E_Family_History_Organizer) | entry | 2.16.840.1.113883.10.20.22.4.45 |
| [Family History Pedigree](#E_Family_History_Pedigree) | entry | 2.16.840.1.113883.10.20.30.3.48 |
| [Functional Status Problem Observation](#E_Functional_Status_Problem_Observation) | entry | 2.16.840.1.113883.10.20.22.4.68 |
| [Functional Status Result Observation](#E_Functional_Status_Result_Observation) | entry | 2.16.840.1.113883.10.20.22.4.67 |
| [Functional Status Result Organizer](#E_Functional_Status_Result_Organizer) | entry | 2.16.840.1.113883.10.20.22.4.66 |
| [Health Status Observation](#E_Health_Status_Observation) | entry | 2.16.840.1.113883.10.20.22.4.5 |
| [HER2 Receptor Status](#HER2_Receptor_Status_) | entry | 2.16.840.1.113883.10.20.30.3.38 |
| [Highest Pressure Ulcer Stage](#E_Highest_Pressure_Ulcer_Stage) | entry | 2.16.840.1.113883.10.20.22.4.77 |
| [Hospitalization for Toxicity](#Hospitalization_for_Toxicity) | entry | 2.16.840.1.113883.10.20.30.3.36 |
| [Immunization Medication Information](#E_Immunization_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.54 |
| [Indication](#E_Indication) | entry | 2.16.840.1.113883.10.20.22.4.19 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Last menstrual period](#E_Last_menstrual_period) | entry | 2.16.840.1.113883.10.20.30.3.34 |
| [Lymph Node Sampling Result Organizer](#E_Lymph_Node_Sampling_Result_Organizer) | entry | 2.16.840.1.113883.10.20.30.3.13 |
| [Medication Activity](#E_Medication_Activity) | entry | 2.16.840.1.113883.10.20.22.4.16 |
| [Medication Dispense](#E_Medication_Dispense) | entry | 2.16.840.1.113883.10.20.22.4.18 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Medication Supply Order](#E_Medication_Supply_Order) | entry | 2.16.840.1.113883.10.20.22.4.17 |
| [Neurotoxicity Impairment of ADLs](#Neurotoxicity_Impairment_of_ADLs) | entry | 2.16.840.1.113883.10.20.30.3.37 |
| [Non-Medicinal Supply Activity](#E_NonMedicinal_Supply_Activity) | entry | 2.16.840.1.113883.10.20.22.4.50 |
| [Number of Lymph Nodes Positive](#E_Number_of_Lymph_Nodes_Positive) | entry | 2.16.840.1.113883.10.20.30.3.15 |
| [Number of Lymph Nodes Removed and Examined](#E_Number_of_Lymph_Nodes_Removed_and_Exa) | entry | 2.16.840.1.113883.10.20.30.3.14 |
| [Number of Pressure Ulcers Observation](#E_Number_of_Pressure_Ulcers_Observation) | entry | 2.16.840.1.113883.10.20.22.4.76 |
| [Oncotype DX Score](#Oncotype_DX_Score) | entry | 2.16.840.1.113883.10.20.30.3.18 |
| [Overall Stage](#E_Overall_Stage) | entry | 2.16.840.1.113883.10.20.30.3.3 |
| [Plan of Care Activity Act](#E_Plan_of_Care_Activity_Act) | entry | 2.16.840.1.113883.10.20.22.4.39 |
| [Plan of Care Activity Encounter](#E_Plan_of_Care_Activity_Encounter) | entry | 2.16.840.1.113883.10.20.22.4.40 |
| [Plan of Care Activity Observation](#E_Plan_of_Care_Activity_Observation) | entry | 2.16.840.1.113883.10.20.22.4.44 |
| [Plan of Care Activity Procedure](#E_Plan_of_Care_Activity_Procedure) | entry | 2.16.840.1.113883.10.20.22.4.41 |
| [Plan of Care Activity Reconstruction Procedure](#E_Plan_of_Care_Activity_Reconstruction_) | entry | 2.16.840.1.113883.10.20.30.3.31 |
| [Plan of Care Activity Substance Administration](#E_Plan_of_Care_Activity_Substance_Admini) | entry | 2.16.840.1.113883.10.20.22.4.42 |
| [Plan of Care Activity Supply](#E_Plan_of_Care_Activity_Supply) | entry | 2.16.840.1.113883.10.20.22.4.43 |
| [Plan of Care Radiation Activity](#E_Plan_of_Care_Radiation_Activity) | entry | 2.16.840.1.113883.10.20.30.3.32 |
| [Possible Side Effects](#Possible_Side_Effects) | entry | 2.16.840.1.113883.10.20.30.3.35 |
| [Post Treatment Disease Status](#Post_Treatment_Disease_Status) | entry | 2.16.840.1.113883.10.20.30.3.29 |
| [Precondition for Substance Administration](#E_Precondition_for_Substance_Administrat) | entry | 2.16.840.1.113883.10.20.22.4.25 |
| [Pressure Ulcer Observation](#E_Pressure_Ulcer_Observation_) | entry | 2.16.840.1.113883.10.20.22.4.70 |
| [Problem Concern Act (Condition)](#E_Problem_Concern_Act_Condition) | entry | 2.16.840.1.113883.10.20.22.4.3 |
| [Problem Observation](#E_Problem_Observation) | entry | 2.16.840.1.113883.10.20.22.4.4 |
| [Problem Status](#E_Problem_Status) | entry | 2.16.840.1.113883.10.20.22.4.6 |
| [Procedure Activity Act](#E_Procedure_Activity_Act) | entry | 2.16.840.1.113883.10.20.22.4.12 |
| [Procedure Activity Observation](#E_Procedure_Activity_Observation) | entry | 2.16.840.1.113883.10.20.22.4.13 |
| [Procedure Activity Procedure](#E_Procedure_Activity_Procedure) | entry | 2.16.840.1.113883.10.20.22.4.14 |
| [Product Instance](#E_Product_Instance) | entry | 2.16.840.1.113883.10.20.22.4.37 |
| [Progesterone Receptor Status](#E_Progesterone_Receptor_Status) | entry | 2.16.840.1.113883.10.20.30.3.20 |
| [Radiation Therapy Care Completed](#Radiation_Therapy_Care_Completed) | entry | 2.16.840.1.113883.10.20.30.3.16 |
| [Reaction Observation](#E_Reaction_Observation) | entry | 2.16.840.1.113883.10.20.22.4.9 |
| [Reasons for Radiation Therapy](#Reasons_for_Radiation_Therapy) | entry | 2.16.840.1.113883.10.20.30.3.46 |
| [Receptor Status Organizer](#E_Receptor_Status_Organizer) | entry | 2.16.840.1.113883.10.20.30.3.17 |
| [Result Observation](#E_Result_Observation) | entry | 2.16.840.1.113883.10.20.22.4.2 |
| [Result Organizer](#E_Result_Organizer) | entry | 2.16.840.1.113883.10.20.22.4.1 |
| [Service Delivery Location](#E_Service_Delivery_Location) | entry | 2.16.840.1.113883.10.20.22.4.32 |
| [Severity Observation](#E_Severity_Observation) | entry | 2.16.840.1.113883.10.20.22.4.8 |
| [Substance or Device Allergy - Intolerance Observation](#E_Substance_or_Device_Allergy__Intolera) | entry | 2.16.840.1.113883.10.20.24.3.90 |
| [Therapy Side Effects](#Therapy_Side_Effects) | entry | 2.16.840.1.113883.10.20.30.3.42 |
| [TNM Metastasis Staging](#E_TNM_Metastasis_Staging) | entry | 2.16.840.1.113883.10.20.30.3.8 |
| [TNM Node Staging](#E_TNM_Node_Staging) | entry | 2.16.840.1.113883.10.20.30.3.7 |
| [TNM Tumor Staging](#E_TNM_Tumor_Staging_) | entry | 2.16.840.1.113883.10.20.30.3.5 |
| [Trastuzumab Medication Activity](#Trastuzumab_Medication_Activity) | entry | 2.16.840.1.113883.10.20.30.3.40 |
| [Trastuzumab Medication Information](#E_Trastuzumab_Medication_Information) | entry | 2.16.840.1.113883.10.20.30.3.41 |
| [Vital Sign Observation](#E_Vital_Sign_Observation) | entry | 2.16.840.1.113883.10.20.22.4.27 |
| [Vital Signs Organizer](#E_Vital_Signs_Organizer) | entry | 2.16.840.1.113883.10.20.22.4.26 |
| [Vital Signs Organizer BCTPS](#E_Vital_Signs_Organizer_BCTPS) | entry | 2.16.840.1.113883.10.20.30.3.25 |

Table 321: Template Containments

| Template Title | Template Type | templateId |
| --- | --- | --- |
| [Clinical Oncology Treatment Plan and Summary](#D_Clinical_Oncology_Treatment_Plan_and_) | document | 2.16.840.1.113883.10.20.30.1.1 |
| [Allergies Section (entries optional)](#S_Allergies_Section_entries_optional) | section | 2.16.840.1.113883.10.20.22.2.6 |
| [Allergy Problem Act](#E_Allergy_Problem_Act) | entry | 2.16.840.1.113883.10.20.22.4.30 |
| [Allergy - Intolerance Observation](#E_Allergy__Intolerance_Observation) | entry | 2.16.840.1.113883.10.20.22.4.7 |
| [Allergy Status Observation](#E_Allergy_Status_Observation) | entry | 2.16.840.1.113883.10.20.22.4.28 |
| [Reaction Observation](#E_Reaction_Observation) | entry | 2.16.840.1.113883.10.20.22.4.9 |
| [Medication Activity](#E_Medication_Activity) | entry | 2.16.840.1.113883.10.20.22.4.16 |
| [Drug Vehicle](#E_Drug_Vehicle) | entry | 2.16.840.1.113883.10.20.22.4.24 |
| [Indication](#E_Indication) | entry | 2.16.840.1.113883.10.20.22.4.19 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Medication Dispense](#E_Medication_Dispense) | entry | 2.16.840.1.113883.10.20.22.4.18 |
| [Immunization Medication Information](#E_Immunization_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.54 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Medication Supply Order](#E_Medication_Supply_Order) | entry | 2.16.840.1.113883.10.20.22.4.17 |
| [Immunization Medication Information](#E_Immunization_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.54 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Medication Supply Order](#E_Medication_Supply_Order) | entry | 2.16.840.1.113883.10.20.22.4.17 |
| [Immunization Medication Information](#E_Immunization_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.54 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Precondition for Substance Administration](#E_Precondition_for_Substance_Administrat) | entry | 2.16.840.1.113883.10.20.22.4.25 |
| [Procedure Activity Procedure](#E_Procedure_Activity_Procedure) | entry | 2.16.840.1.113883.10.20.22.4.14 |
| [Indication](#E_Indication) | entry | 2.16.840.1.113883.10.20.22.4.19 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Medication Activity](#E_Medication_Activity) | entry | 2.16.840.1.113883.10.20.22.4.16 |
| [Drug Vehicle](#E_Drug_Vehicle) | entry | 2.16.840.1.113883.10.20.22.4.24 |
| [Indication](#E_Indication) | entry | 2.16.840.1.113883.10.20.22.4.19 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Medication Dispense](#E_Medication_Dispense) | entry | 2.16.840.1.113883.10.20.22.4.18 |
| [Immunization Medication Information](#E_Immunization_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.54 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Medication Supply Order](#E_Medication_Supply_Order) | entry | 2.16.840.1.113883.10.20.22.4.17 |
| [Immunization Medication Information](#E_Immunization_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.54 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Medication Supply Order](#E_Medication_Supply_Order) | entry | 2.16.840.1.113883.10.20.22.4.17 |
| [Immunization Medication Information](#E_Immunization_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.54 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Precondition for Substance Administration](#E_Precondition_for_Substance_Administrat) | entry | 2.16.840.1.113883.10.20.22.4.25 |
| [Product Instance](#E_Product_Instance) | entry | 2.16.840.1.113883.10.20.22.4.37 |
| [Service Delivery Location](#E_Service_Delivery_Location) | entry | 2.16.840.1.113883.10.20.22.4.32 |
| [Severity Observation](#E_Severity_Observation) | entry | 2.16.840.1.113883.10.20.22.4.8 |
| [Severity Observation](#E_Severity_Observation) | entry | 2.16.840.1.113883.10.20.22.4.8 |
| [Encounters Section BCTPS](#Encounters_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.9 |
| [Hospitalization for Toxicity](#Hospitalization_for_Toxicity) | entry | 2.16.840.1.113883.10.20.30.3.36 |
| [Indication](#E_Indication) | entry | 2.16.840.1.113883.10.20.22.4.19 |
| [Family History Section BCTPS](#Family_History_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.3 |
| [Family History of Cancer None](#Family_History_of_Cancer_None) | entry | 2.16.840.1.113883.10.20.30.3.11 |
| [Family History Organizer](#E_Family_History_Organizer) | entry | 2.16.840.1.113883.10.20.22.4.45 |
| [Family History Observation](#E_Family_History_Observation) | entry | 2.16.840.1.113883.10.20.22.4.46 |
| [Age Observation](#E_Age_Observation) | entry | 2.16.840.1.113883.10.20.22.4.31 |
| [Family History Death Observation](#E_Family_History_Death_Observation) | entry | 2.16.840.1.113883.10.20.22.4.47 |
| [Family History Pedigree](#E_Family_History_Pedigree) | entry | 2.16.840.1.113883.10.20.30.3.48 |
| [Functional Status Section BCTPS](#Functional_Status_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.8 |
| [Neurotoxicity Impairment of ADLs](#Neurotoxicity_Impairment_of_ADLs) | entry | 2.16.840.1.113883.10.20.30.3.37 |
| [Medications Section BCTPS](#S_Medications_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.7 |
| [Anthracycline Medication Activity](#Anthracycline_Medication_Activity) | entry | 2.16.840.1.113883.10.20.30.3.24 |
| [Anthracycline Medication Information](#Anthracycline_Medication_Information) | entry | 2.16.840.1.113883.10.20.30.3.33 |
| [Chemotherapy Dose Reduction](#Chemotherapy_Dose_Reduction) | entry | 2.16.840.1.113883.10.20.30.3.39 |
| [Chemotherapy Regimen](#E_Chemotherapy_Regimen) | entry | 2.16.840.1.113883.10.20.30.3.1 |
| [Chemotherapy Medication Activity](#E_Chemotherapy_Medication_Activity) | entry | 2.16.840.1.113883.10.20.30.3.44 |
| [Chemotherapy Dose Reduction](#Chemotherapy_Dose_Reduction) | entry | 2.16.840.1.113883.10.20.30.3.39 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Clinical Drug Trial](#Clinical_Drug_Trial) | entry | 2.16.840.1.113883.10.20.30.3.4 |
| [Drug Therapy Discontinued](#Drug_Therapy_Discontinued) | entry | 2.16.840.1.113883.10.20.30.3.43 |
| [Possible Side Effects](#Possible_Side_Effects) | entry | 2.16.840.1.113883.10.20.30.3.35 |
| [Therapy Side Effects](#Therapy_Side_Effects) | entry | 2.16.840.1.113883.10.20.30.3.42 |
| [Endocrine Medication Activity](#Endocrine_Medication_Activity) | entry | 2.16.840.1.113883.10.20.30.3.23 |
| [Endocrine Medication Information](#E_Endocrine_Medication_Information) | entry | 2.16.840.1.113883.10.20.30.3.22 |
| [Trastuzumab Medication Activity](#Trastuzumab_Medication_Activity) | entry | 2.16.840.1.113883.10.20.30.3.40 |
| [Trastuzumab Medication Information](#E_Trastuzumab_Medication_Information) | entry | 2.16.840.1.113883.10.20.30.3.41 |
| [Plan of Care Section BCTPS](#S_Plan_of_Care_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.6 |
| [Chemotherapy Regimen Plans](#E_Chemotherapy_Regimen_Plans) | entry | 2.16.840.1.113883.10.20.30.3.30 |
| [Chemotherapy Medication Activity](#E_Chemotherapy_Medication_Activity) | entry | 2.16.840.1.113883.10.20.30.3.44 |
| [Chemotherapy Dose Reduction](#Chemotherapy_Dose_Reduction) | entry | 2.16.840.1.113883.10.20.30.3.39 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Clinical Drug Trial](#Clinical_Drug_Trial) | entry | 2.16.840.1.113883.10.20.30.3.4 |
| [Possible Side Effects](#Possible_Side_Effects) | entry | 2.16.840.1.113883.10.20.30.3.35 |
| [Plan of Care Activity Reconstruction Procedure](#E_Plan_of_Care_Activity_Reconstruction_) | entry | 2.16.840.1.113883.10.20.30.3.31 |
| [Plan of Care Radiation Activity](#E_Plan_of_Care_Radiation_Activity) | entry | 2.16.840.1.113883.10.20.30.3.32 |
| [Problem Section BCTPS](#S_Problem_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.1 |
| [Breast Cancer Concern Act](#Breast_Cancer_Concern_Act) | entry | 2.16.840.1.113883.10.20.30.3.6 |
| [Breast Cancer Diagnosis Observation](#E_Breast_Cancer_Diagnosis_Observation) | entry | 2.16.840.1.113883.10.20.30.3.2 |
| [Overall Stage](#E_Overall_Stage) | entry | 2.16.840.1.113883.10.20.30.3.3 |
| [TNM Metastasis Staging](#E_TNM_Metastasis_Staging) | entry | 2.16.840.1.113883.10.20.30.3.8 |
| [TNM Node Staging](#E_TNM_Node_Staging) | entry | 2.16.840.1.113883.10.20.30.3.7 |
| [TNM Tumor Staging](#E_TNM_Tumor_Staging_) | entry | 2.16.840.1.113883.10.20.30.3.5 |
| [Post Treatment Disease Status](#Post_Treatment_Disease_Status) | entry | 2.16.840.1.113883.10.20.30.3.29 |
| [Last menstrual period](#E_Last_menstrual_period) | entry | 2.16.840.1.113883.10.20.30.3.34 |
| [Procedures Section BCTPS](#Procedures_Section_BCTPS_) | section | 2.16.840.1.113883.10.20.30.2.4 |
| [Breast Cancer Procedures](#E_Breast_Cancer_Procedures) | entry | 2.16.840.1.113883.10.20.30.3.12 |
| [Lymph Node Sampling Result Organizer](#E_Lymph_Node_Sampling_Result_Organizer) | entry | 2.16.840.1.113883.10.20.30.3.13 |
| [Number of Lymph Nodes Positive](#E_Number_of_Lymph_Nodes_Positive) | entry | 2.16.840.1.113883.10.20.30.3.15 |
| [Number of Lymph Nodes Removed and Examined](#E_Number_of_Lymph_Nodes_Removed_and_Exa) | entry | 2.16.840.1.113883.10.20.30.3.14 |
| [Radiation Therapy Care Completed](#Radiation_Therapy_Care_Completed) | entry | 2.16.840.1.113883.10.20.30.3.16 |
| [Reasons for Radiation Therapy](#Reasons_for_Radiation_Therapy) | entry | 2.16.840.1.113883.10.20.30.3.46 |
| [Results Section BCTPS](#Results_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.2 |
| [Cardiac Function Observation](#Cardiac_Function_Observation) | entry | 2.16.840.1.113883.10.20.30.3.21 |
| [Receptor Status Organizer](#E_Receptor_Status_Organizer) | entry | 2.16.840.1.113883.10.20.30.3.17 |
| [Estrogen Receptor Status](#Estrogen_Receptor_Status) | entry | 2.16.840.1.113883.10.20.30.3.19 |
| [HER2 Receptor Status](#HER2_Receptor_Status_) | entry | 2.16.840.1.113883.10.20.30.3.38 |
| [Oncotype DX Score](#Oncotype_DX_Score) | entry | 2.16.840.1.113883.10.20.30.3.18 |
| [Progesterone Receptor Status](#E_Progesterone_Receptor_Status) | entry | 2.16.840.1.113883.10.20.30.3.20 |
| [Vital Signs Section BCTPS](#Vital_Signs_Section_BCTPS) | section | 2.16.840.1.113883.10.20.30.2.5 |
| [Vital Signs Organizer BCTPS](#E_Vital_Signs_Organizer_BCTPS) | entry | 2.16.840.1.113883.10.20.30.3.25 |
| [Body Height](#Body_Height) | entry | 2.16.840.1.113883.10.20.30.3.26 |
| [Body Surface Area](#E_Body_Surface_Area) | entry | 2.16.840.1.113883.10.20.30.3.28 |
| [Body Weight](#E_Body_Weight) | entry | 2.16.840.1.113883.10.20.30.3.27 |
| [US Realm Header](#D_US_Realm_Header) | document | 2.16.840.1.113883.10.20.22.1.1 |
| [Substance or Device Allergy - Intolerance Observation](#E_Substance_or_Device_Allergy__Intolera) | entry | 2.16.840.1.113883.10.20.24.3.90 |
| [Allergy Status Observation](#E_Allergy_Status_Observation) | entry | 2.16.840.1.113883.10.20.22.4.28 |
| [Reaction Observation](#E_Reaction_Observation) | entry | 2.16.840.1.113883.10.20.22.4.9 |
| [Medication Activity](#E_Medication_Activity) | entry | 2.16.840.1.113883.10.20.22.4.16 |
| [Drug Vehicle](#E_Drug_Vehicle) | entry | 2.16.840.1.113883.10.20.22.4.24 |
| [Indication](#E_Indication) | entry | 2.16.840.1.113883.10.20.22.4.19 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Medication Dispense](#E_Medication_Dispense) | entry | 2.16.840.1.113883.10.20.22.4.18 |
| [Immunization Medication Information](#E_Immunization_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.54 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Medication Supply Order](#E_Medication_Supply_Order) | entry | 2.16.840.1.113883.10.20.22.4.17 |
| [Immunization Medication Information](#E_Immunization_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.54 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Medication Supply Order](#E_Medication_Supply_Order) | entry | 2.16.840.1.113883.10.20.22.4.17 |
| [Immunization Medication Information](#E_Immunization_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.54 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Precondition for Substance Administration](#E_Precondition_for_Substance_Administrat) | entry | 2.16.840.1.113883.10.20.22.4.25 |
| [Procedure Activity Procedure](#E_Procedure_Activity_Procedure) | entry | 2.16.840.1.113883.10.20.22.4.14 |
| [Indication](#E_Indication) | entry | 2.16.840.1.113883.10.20.22.4.19 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Medication Activity](#E_Medication_Activity) | entry | 2.16.840.1.113883.10.20.22.4.16 |
| [Drug Vehicle](#E_Drug_Vehicle) | entry | 2.16.840.1.113883.10.20.22.4.24 |
| [Indication](#E_Indication) | entry | 2.16.840.1.113883.10.20.22.4.19 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Medication Dispense](#E_Medication_Dispense) | entry | 2.16.840.1.113883.10.20.22.4.18 |
| [Immunization Medication Information](#E_Immunization_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.54 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Medication Supply Order](#E_Medication_Supply_Order) | entry | 2.16.840.1.113883.10.20.22.4.17 |
| [Immunization Medication Information](#E_Immunization_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.54 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Medication Supply Order](#E_Medication_Supply_Order) | entry | 2.16.840.1.113883.10.20.22.4.17 |
| [Immunization Medication Information](#E_Immunization_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.54 |
| [Instructions](#E_Instructions) | entry | 2.16.840.1.113883.10.20.22.4.20 |
| [Medication Information](#E_Medication_Information) | entry | 2.16.840.1.113883.10.20.22.4.23 |
| [Precondition for Substance Administration](#E_Precondition_for_Substance_Administrat) | entry | 2.16.840.1.113883.10.20.22.4.25 |
| [Product Instance](#E_Product_Instance) | entry | 2.16.840.1.113883.10.20.22.4.37 |
| [Service Delivery Location](#E_Service_Delivery_Location) | entry | 2.16.840.1.113883.10.20.22.4.32 |
| [Severity Observation](#E_Severity_Observation) | entry | 2.16.840.1.113883.10.20.22.4.8 |
| [Severity Observation](#E_Severity_Observation) | entry | 2.16.840.1.113883.10.20.22.4.8 |

1. Summary of Vocabularies (Non-normative)

For the user’s convenience, this table summarizes the vocabularies (code systems) used in this guide.

Table 322: List of Vocabularies

|  |  |
| --- | --- |
| Root OIDs | |
| codeSystem | codeSystemName |
| 2.16.840.1.113883.5.25 | HL7 Confidentiality Code |
| 2.16.840.1.113883.5.4 | HL7 actCode |
| 2.16.840.1.113883.5.83 | HL7 Observation Interpretation |
| 2.16.840.1.113883.6.259 | HL7 HealthcareServiceLocation |
| 2.16.840.1.113883.12.162 | HL7 RouteOfAdministration |
| 2.16.840.1.113883.6.1 | LOINC® |
| 2.16.840.1.113883.6.88 | RxNorm |
| 2.16.840.1.113883.6.96 | SNOMED CT |
| 2.16.840.1.113883.6.104 | ICD-9-CM Procedure |
| 2.16.840.1.113883.6.59 | CVX |
| 2.16.840.1.113883.6.243 | PHVS\_Occupation\_CDC |
| 2.16.840.1.113883.6.101 | NUCCProviderCodes |

1. MIME Multipart/Related Messages

The following text is taken from the Claims Attachments Implementation Guide (AIS00000) in Section 2.4 <http://www.hl7.org/documentcenter/public/wg/ca/CDAR2AIS0000R030_ImplementationGuideDraft.pdf>. For up-to-date guidance, refer to the latest edition of that specification.

MIME Multipart/Related Messages

An attachment is comprised of the CDA document, including any supporting files necessary to render the attested content of the document. Two Internet request for comments (RFCs) are needed to properly construct the mime multipart message. When supporting files are needed, the collection of information shall be organized using a MIME multipart/related package constructed according to RFC 2557. Within the MIME package, supporting files must be encoded using Base-64. RFC-4648 should be used when encoding the contents of the MIME package using Base-64. Finally, RFC-2392 may be used to reference other content that appears in the same X12 transaction to use the same content to answer multiple questions for a single claim. Internet RFCs can be downloaded from the RFC editor page at <http://www.rfc-editor.org>.

RFC-2557 MIME Encapsulation of Aggregate Documents, Such as HTML (MHTML)

This RFC describes how to construct a MIME multipart/related package, and how URLs are resolved within content items of that package. RFC-2557 can be obtained at: <http://www.rfc-editor.org/rfc/rfc2557.txt>

A MIME multipart/related package is made up of individual content items. Each content item has a MIME header identifying the item. Each content item is delimited from other content items using a string of application specified text. In addition, there must be an ending boundary. The actual content is recorded between these delimiter strings using a BASE-64 encoding of the content item. There is also a MIME header for the entire package.

The first content item of a multipart/related message supporting attachments is the CDA document, containing the header and structured or non-structured body. Subsequent content items included in this package will contain additional content that appears within the body of the document. The CDA document will reference these additional content items by their URLs.

Referencing Supporting Files in Multipart/Related Messages

Because the CDA document and its supporting files may have already existed in a clinical information system, references may already exist within the CDA document to URLs that are not accessible outside of the clinical information system that created the document. When the CDA document is sent via attachments, these URLs may no longer be accessible by the receiving information system. Therefore, each content item that is referenced by a URL within the CDA document must be included as a content item in the MIME package. Each content item may specify the URL by which it is known using the Content-Location header. The receiver of this MIME package shall translate URL references according the RFC-2557. This will ensure resolution of the original URL to the correct content item within the MIME package. Thus, URL references contained within an original document need not be rewritten when the CDA package is transmitted. Instead, these URLs are simply supplied as the value of the Content-Location header in the MIME package.

This capability allows for the same content item to be referred to more than once in a MIME multipart/related package without requiring the content item to be supplied twice. However, it does not allow a separate MIME multipart/related package to contain references to information sent in a previously recorded package.

Referencing Documents from Other Multiparts within the Same X12 Transactions

RFC-2392 is used when referencing content across MIME package boundaries, but still contained within the same X12 transaction (ST to SE). This can occur when the same document answers multiple questions for a single claim. Each component of a MIME package may be assigned a content identifier using the Content-ID header for the content item. For example, this header would appear as:

Content-ID: <07EE4DAC-76C4-4a98-967E-F6EF9667DED1>

This content identifier is a unique identifier for the content item, which means it must never be used to refer to any other content item. RFC-2392 defines the cid: URL scheme (http: and ftp: are two other URL schemes). This URL scheme allows for references by the Content-ID header to be resolved. The URL for the content item identified above would be:

cid:07EE4DAC-76C4-4a98-967E-F6EF9667DED1

Receivers of the MIME multipart message must be able to resolve a cid: URL to the content item that it identifies. Senders must ensure that they only refer to items that have already been transmitted to the receiver by their cid: URL. Thus, this implementation guide prohibits forward URL references using the cid: URL scheme.

Content items shall not be referenced across X12 transactions using the cid: URL scheme. For example, if the payer previously requested information using a 277, and the provider returned that information in a MIME multipart/related package in a 275, and then the payer requested additional information in another 277, the provider may not refer to the content item previously returned in the prior 275 transaction.

1. <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm> [↑](#footnote-ref-1)
2. <http://www.hl7.org/implement/standards/cda.cfm> [↑](#footnote-ref-2)
3. <http://www.cdc.gov/phin/library/guides/Implementation_Guide_for_Ambulatory_Healthcare_Provider_Reporting_to_Central_Cancer_Registries_August_2012.pdf> (accessed 11/14/2012) [↑](#footnote-ref-3)
4. <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7> [↑](#footnote-ref-4)
5. <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm> [↑](#footnote-ref-5)
6. <http://wiki.hl7.org/index.php?title=Consolidated_CDA_Templates_Errata> [↑](#footnote-ref-6)
7. <http://wiki.hl7.org/index.php?title=Consolidated_CDA_Templates_Suggested_Enhancements> [↑](#footnote-ref-7)
8. http://trifolia.lantanagroup.com [↑](#footnote-ref-8)
9. <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm> [↑](#footnote-ref-9)
10. <http://www.hl7.org/memonly/downloads/v3edition.cfm#V32010> (must be a member to view) [↑](#footnote-ref-10)
11. *HL7 Clinical Document Architecture (CDA Release 2)* <http://www.hl7.org/implement/standards/cda.cfm> [↑](#footnote-ref-11)
12. *HL7 Clinical Document Architecture (CDA Release 2)*. http://www.hl7.org/implement/standards/cda.cfm [↑](#footnote-ref-12)
13. <http://www.w3.org/TR/xpath/> [↑](#footnote-ref-13)
14. From CDA Normative Web edition: 4.2.1.7 ClinicalDocument.setId - Represents an identifier that is common across all document revisions and “Document Identification, Revisions, and Addenda” under 4.2.3.1 ParentDocument [↑](#footnote-ref-14)
15. From CDA Normative Web edition: 4.2.1.8 ClinicalDocument.versionNumber An integer value used to version successive replacement documents [↑](#footnote-ref-15)