CDAR2\_IG\_FDDOC\_R1\_2013APR



**HL7 Implementation Guide for CDA® Release 2.0:**

**Form Definition Document, Release 1**

April 2013

**HL7 DSTU Ballot**

**Sponsored by:  
Structured Documents Work Group**

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# Introduction

## Audience

The audience for this document includes software developers and implementers of products and services that enable authoring, management, and administration of patient health surveys and their responses. This includes public and private disease management organizations as well as local, regional, and national health information exchange networks that wish to create and/or process Form Definition documents (patient surveys) created according to this specification.

## Purpose

Patient-centred outcomes monitoring, is increasingly needed to improve the cost effectiveness and quality of health services.

This document describes constraints on the Clinical Document Architecture (CDA) Release 2 (R2) header and body elements of Form Definition documents. The purpose of a Form Definition document is to capture the health survey questions or question sets to be administered to a patient. Form Definition documents enable the definition of questions for surveying the patient’s perceptions on their health and the impact that any treatments or adjustments to lifestyle have had on their quality of life. The Form Definition documents may carry a variety of clinical and non-clinical questions and branching logic in order to present the patient with a dynamic health survey for assessing health status including, but not limited to, the patient’s functional, cognitive, and physiological characteristics. Authors of the Form Definition documents may include disease management organizations, primary care physicians, health and fitness coaches, chronic condition monitors, post-acute and long-term care.

Typical Use Case

The primary use case for the Form Definition document involves the Form Definition author, which may be a human or a device or software system. After creation of the Form Definition document, it is placced in a repository that is accessible by a disease management service. The disease management service will then send the Form Definition to the application hosting device based on a prediscribed order or schedule. The application hosting device will in turn signal to the patient that a new Form Definition document is available and it will create a questionnaire specific for the particular patient. The Questionnaire Response document is created as the patient fills out the questionnaire and is sent back to the disease monitoring station where it is ready for review by a human or computer monitor. Figure 1 shows the entire ecosystem describing the primary use case.

## Scope

Figure 1: Typical Use Case

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) This implementation guide does not describe every aspect of CDA. Rather, it defines constraints on the base CDA used in Form Definition in the Universal Realm. Additional optional CDA elements, not included here, can be included and the result will be compliant with the specifications in this guide.

## Approach

Overall, the approach taken here is consistent with balloted implementation guides (IGs) for CDA. These publications view the ultimate implementation specification as a series of layered constraints. CDA itself is a set of constraints on the Health Level Seven (HL7) Reference Information Model (RIM). 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.

## Organization of This Guide

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

Chapter 2: Form Definition document Header Template describes constraints that apply to the header for all Universal Realm documents within the scope of this implementation guide.

Chapter 3: Form Definition Document-Level Template defines the document constraints that apply to Form Definition Documents.

Chapter 4: Section-Level Templates defines the section templates in Form Definition Documents.

Chapter 5: Entry-Level Templates defines the entry template in Form Definition Documents.

## Content of the Package

The following files comprise the package:

Table 1: Content of the Package

|  |  |  |
| --- | --- | --- |
| Filename | Description | Standards Applicability |
| CDAR2\_IG\_FDDOC\_R1\_2013APR | This implemenation guide. | Normative |
| FDSample-26032013.xml | The sample CDA XML file that includes examples of templates discussed in this guide. | informative |

# Form Definition document Header Template

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

## Document Type Codes

CDA R2 states that LOINC is the preferred vocabulary for document type codes. The document type code specifies the type of document being exchanged (e.g., History and Physical). The use of a single clinicalDocument/code is preferred for a CDA document template. Form Definition template is a universal realm document, therefore it does not mandate use of LOINC; however, LOINC is still the preferred document code vocabulary.

## Universal Realm Form Definition Document Header

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.32 (open)]

1. SHALL contain exactly one [1..1] realmCode (CONF: 1).
   1. This realmCode SHOULD be selected from HL7 ValueSet BindingRealm[2.16.840.1.113883.1.11.20355] from codesystem hl7Realm [2.16.840.1.113883.5.1124] STATIC 2010-11-11 (CONF: 2).
2. SHALL contain exactly one [1..1] typeId (CONF: 3).
   1. This typeId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.1.3" (CONF: 4).
   2. This typeId SHALL contain exactly one [1..1] @extension="POCD\_HD000040" (CONF: 5).
3. SHALL contain exactly one [1..1] header-level templateId (CONF: 6) such that it
   1. SHALL contain exactly one [1..1] @root=”2.16.840.1.113883.10.20.32” (CONF: 7).
4. SHALL contain exactly one [1..1] id (CONF: 8).
   1. This id SHALL be a globally unique identifier for the document (CONF: 9).
5. SHALL contain exactly one [1..1] code (CONF: 10).
   1. This code SHALL specify the Form Definition document generated (CONF: 11).
   2. This code SHould be a code from the LOINC Document Ontology which indicates a Form Definition document containing questions to be asked from the user. CDA R2 states that LOINC is the preferred vocabulary for document type specification. Form Definition template is a universal realm document, therefore it does not mandate use of LOINC; however, LOINC is still the preferred document code vocabulary (CONF: 12).
6. SHALL contain exactly one [1..1] title (CONF: 13).
7. SHALL contain exactly one [1..1] effectiveTime (CONF: 14).
8. SHALL contain exactly one [1..1] confidentialityCode, which SHALL be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC 2010-04-21 (CONF: 15).
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: 16).

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 2: UV Realm Form Definition document header example

<realmCode code="UV"/>

<typeId root="2.16.840.1.113883.1.3" extension="POCD\_HD000040"/>

<!-- General Form Definition Header Template -->

<templateId root="2.16.840.1.113883.10.20.32"/>

<!-- \*\*\* 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="2.16.840.1.113883.10.20.32.1.1"/>

<id extension="999" root="2.16.840.1.113883.19"/>

<!— code should be LOINC, but could come from a different code system -->

<code codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC" code="x.x.x.x"

displayName="Form Definition Document"/>

<title>Patient Questionnaire/Survey Document</title>

<effectiveTime value="20121126145000-0500"/>

<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>

<languageCode code="en-US"/>

Figure 3: 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="20121126145000-0500"/>

<!-- November 26, 2012, 2:50PM, 5 hours behind UTC -->

### RecordTarget

The recordTarget records the patient whose health information is described by the clinical document. Each recordTarget must contain exactly one patientRole element. In the context of the Form Definition Document Implementation guide, the recordTarget contains “No Information”. This is indicated by using the nullFlavor="NI". Questionnaire Response Document [\href{reference to the questionnaire response document}], which is generated based on the Form Defition Document, does contain the information about the patient. The related constraints are defined in the Questionnaire Response document IG.

1. SHALL contain exactly one [1..1] recordTarget (CONF: 17).
   1. Such recordTargets SHALL contain exactly one [1..1] patientRole (CONF: 18).
      1. This patientRole SHALL contain exactly one [1..1] id (CONF: 19).
         1. The value of the recordTarget/patientRole/id/@NullFlavor" SHALL be "NI" "No Information" 2.16.840.1.113883.5.1008 NullFlavor STATIC (CONF: 20).

Figure 4: UV Realm recordTarget Example

<recordTarget>

<patientRole>

<id nullFlavor="NI"/>

</patientRole>

</recordTarget>

### Author

The author element represents the creator of the Form Definition Document. It is usually a healthcare organization. In this case the author represents the healthcare organization that creates the Form Definition Document that is to be used to survey the patient.

1. SHALL contain at least one [1..\*] author (CONF: 21).
   1. Such authors SHALL contain exactly one [1..1] time (CONF: 22).
   2. Such authors SHALL contain exactly one [1..1] assignedAuthor (CONF: 23).
      1. This assignedAuthor SHALL contain exactly one [1..1] id (CONF: 24).
      2. This assignedAuthor SHould contain zero or one [0..1] addr (CONF: 25).
      3. This assignedAuthor SHould contain zero or one [0..1] telecom
      4. This assignedAuthor **SHALL** contain exactly one [1..1] representedOrganization (CONF: 26).
      5. There SHALL be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice (CONF: 27).
      6. This assignedAuthor SHOULD contain zero or one [0..1] assignedPerson (CONF: 28).
         1. The assignedPerson, if present, SHALL contain at least one [1..\*] name (CONF: 29).
      7. This assignedAuthor SHOULD contain zero or one [0..1] assignedAuthoringDevice (CONF: 30).
         1. The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] manufacturerModelName (CONF: 31).
         2. The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] softwareName (CONF: 32).
      8. If assignedAuthor has an associated representedOrganization and no assignedPerson or assignedAuthoringDevice, then the value for "ClinicalDocument/author/assignedAuthor/id/@NullFlavor" **SHALL** be "NA" "Not applicable" 2.16.840.1.113883.5.1008 NullFlavor **STATIC** (CONF: 33).

Figure 5: Person author example

<author>

<time value="200910011200"/>

<assignedAuthor>

<addr use="HP">

<streetAddressLine>2222 Home Street</streetAddressLine>

<city>Boston</city>

<state>MA</state>

<postalCode>02368</postalCode>

<country>US</country>

</addr>

<telecom value="tel:(555)555-2004" use="HP"/>

<assignedPerson>

<name>

<given>Adam</given>

<family>Everyman</family>

</name>

</assignedPerson>

</assignedAuthor>

<representedOrganization>

<name>NIST Healthcare Testing Laboratory</name>

<telecom nullFlavor="NI"/>

<addr nullFlavor="NI"/>

</representedOrganization>

</author>

Figure 6: Device author example

<author>

<time value="20121126145000-0500"/>

<assignedAuthor>

<id extension="777.11" root="2.16.840.1.113883.19"/>

<addr nullFlavor="NA"/>

<telecom nullFlavor="NA"/>

<assignedAuthoringDevice>

<manufacturerModelName>ACME PHR</manufacturerModelName>

<softwareName>MyPHR v1.0</softwareName>

</assignedAuthoringDevice>

<representedOrganization>

<id extension="999" root="1.2.3.4.5.6.7.8.9.12345"/>

<name>ACME PHR Solutions,Inc.</name>

<telecom use="WP" value="tel:123-123-12345"/>

<addr>

<streetAddressLine>4 Future Way</streetAddressLine>

<city>Provenance</city>

<state>RI</state>

<postalCode>02919</postalCode>

</addr>

</representedOrganization>

</assignedAuthor>

</author>

### Custodian

The custodian element represents the organization that is in charge of maintaining the Form Definition document (e.g. disease management organization (DMO)). The custodian is the steward that is entrusted with the care of the document. The Form Definition Document has exactly one custodian.

1. SHALL contain exactly one [1..1] custodian (CONF: 34).
   1. This custodian SHALL contain exactly one [1..1] assignedCustodian (CONF: 35).
      1. This assignedCustodian SHALL contain exactly one [1..1] representedCustodianOrganization (CONF: 36).
         1. This representedCustodianOrganization SHALL contain at least one [1..\*] id (CONF: 37).
         2. This representedCustodianOrganization SHOULD contain exactly one [1..1] name (CONF: 38).
         3. This representedCustodianOrganization May contain zero or one [0..1] telecom (CONF: 39).
            1. This telecom SHOULD contain exactly one [1..1] @use (CONF: 40).
         4. This representedCustodianOrganization May contain zero or one [0..1] addr (CONF: 41).

Figure 7: Custodian examples

<custodian>

<assignedCustodian>

<representedCustodianOrganization>

<id/>

<name>NIST Healthcare Testing Laboratory</name>

<telecom value="tel:(555)555-1212" use="WP"/>

<addr use="WP"/>

<streetAddressLine>123 Boylston Street</streetAddressLine>

<city>Blue Hill</city>

<state>MA</state>

<postalCode>02368</postalCode>

<country>USA</country>

<addr use="WP"/>

</representedCustodianOrganization>

</assignedCustodian>

</custodian>

## Rendering Header Information for Human Presentation

Good practice would recommend that the following information be present whenever the Form Definition document is viewed:

* Document title and document dates
* Author of the Form Definition document.
* Name of the organization who created the Form Definition document along with the address, and telecommunications information
* Custodian who is managing such documents, which may be the same organization as the Authored organization.

# Form Definition Document-Level Template

This chapter defines the document-level template used in the Form Definition Document containing a set of questions to be asked from the patient. Document-level templates describe the purpose and rules for constructing a conforming CDA document for its use case. Document templates include constraints on the CDA header and contain section-level templates which, in turn contain entry-level templates. Form Definition Document template is a universal template, hence contains the minimum constraints. Base CDA constraints are not repeated if not further constrained.

## Form Definition Document

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.32.2.1 (open)]

This template describes constraints that apply to the Form Definition Document containing set of questions. Document templates include constraints on the CDA header and identify contained section-level templates.

This document-level template contains the following information:

* Description and explanatory narrative.
* Template metadata (e.g., templateId, etc.)
* Header constraints
* The required section-level template

***Table 4: Form Definition Document-Level Contexts***

| **Used By:** | **Contains Entries:** |
| --- | --- |
|  | Form Definition Section |

Table 5: Form Definition Document-Level Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | ClinicalDocument[templateId/@root = '2.16.840.1.113883.10.20.32.2.1'] | | | | | |
|  | component | 1..1 | SHALL |  | <CONF:43> |  |
|  | structuredBody | 1..1 | SHALL |  | <CONF:44> |  |
|  | component | 1..\* | SHALL |  | CONF:45 |  |
|  | section | 1..1 | SHALL |  | [CONF:4](CONF:45)6 |  |

1. SHALL conform to the Universal Realm Form Definition Document Header template (CONF: 42).
2. SHALLcontain exactly one[1..1]component(CONF: 43).
   1. **SHALL** contain exactly one [1..1] structuredBody (CONF: 44).
      1. This structuredBody SHALL contain at least one [1..\*] component (CONF: 45).
         1. Such components SHALL contain exactly one [1..1] Form Definition Section template (templateId: 2.16.840.1.113883.10.20.32.2.1) (CONF: 46).

# Section-Level Templates

This section contains section-level templates used by the Form Definition document in this Implementation Guide. Section-level templates are always included in a document.

Each section-level template contains the following:

* Template metadata (e.g., templateId, etc.)
* Description
* Section code
* Section title
* Entry-level template names and Ids for referenced templates (required and optional)

## Form Definition Section

[section: templateId 2.16.840.1.113883.10.20.32.2.1 (open)]

A Form Definition document consists of sections that groups related questions. Section titles ease human-readability and navigation in the document. Section codes may help with the recipient’s interpretation of each section. A section template defined by this implementation guide requires the use of at least one structured entry, where a structured entry contains the question that is intended for a patient to answer.

Table 6: Form Definition Section Pattern Contexts

| Used By: | Contains Entries: |
| --- | --- |
| Form Definition Document-Level Template (required) | Questions Organizer |

***Table 7: Form Definition Section Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | section[templateId/@root = '2.16.840.1.113883.10.20.32.2.1'] | | | | | |
|  | templateId | 1..1 | SHALL |  | CONF:47 |  |
|  | @root | 1..1 | SHALL |  | <CONF:48> | 2.16.840.1.113883.10.20.32.2.1 |
|  | title | 1..1 | SHOULD |  | CONF:49 |  |
|  | text | 1..1 | SHALL |  | CONF:50 |  |
|  | languageCode | 0..1 | SHOULD |  | CONF:51 |  |
|  | entry | 1..\* | SHALL |  | CONF:52 |  |
|  | @typeCode | 1..1 | SHALL |  | CONF:53 | DRIV |
|  | organizer | 1..1 | SHALL |  | CONF:54 |  |

1. **SHALL** contain exactly one [1..1] **templateId** (CONF: 47) such that it
   1. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.32.2.1" (CONF: 48).
2. **SHOULD** contain zero or one [0..1] **title** (CONF: 49).
3. **SHALL** contain exactly one [1..1] **text** (CONF: 50).
4. SHOULD contain zero or one [1..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC (CONF: 51).
5. **SHALL** contain at least one [1..\*] **entry** (CONF: 52) such that it
   1. **SHALL** contain exactly one [1..1] **@typeCode**=”DRIV” (CONF: 53)
   2. **SHALL** contain exactly one [1..1] Questions Organizer template(templateId: 2.16.840.1.113883.10.20.32.4.1) (CONF: 54).

***Figure 8: Form Definition Section example***

<section>

<templateId root="2.16.840.1.113883.10.20.32.2.1"/>

<title>Form Definition Document</title>

<text>

...

</text>

<entry typeCode="DRIV">

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

...

</organizer>

</entry>

</section>

# Entry-Level Templates

This part of the guide describes the clinical statement entry templates used within the sections of the Questionnaire Response document. Entry templates contain constraints that are required for conformance.

Each entry-level template description contains the following information:

* Key template metadata (e.g., templateId, etc.)
* Description and explanatory narrative.
* Required CDA acts, participants and vocabularies.
* Optional CDA acts, participants and vocabularies.

Entry-level templates may also describe an id element, which is an identifier for that entry. This id may be referenced within the document, or by the system receiving the document. The id assigned must be globally unique. In this implemenation guide, the entry level templates (except the Questions Organizer template) are used in the “DEFINITION” mood i.e. moodCode=“DEF”, which shows the act of obtaining patient response to a question.

## Questions Organizer

[organizer: templateId 2.16.840.1.113883.10.20.32.4.1 (open)]

This template can be used to create groupings of other entries (or templates) that share a common context e.g. questions related to a specific health domain or topic. The organizer/@classCode is equal to “CLUSTER” and is used to group entries into a compound statement. The organizer/code could be used to indicate questions related to a specific health domain e.g. nutrition or mental status. The sequenceNumber is used to indicate the relative order of the organizer/component which contains question represented by the generic observation class.

***Table 8: Questions Organizer Contexts***

| **Used By:** | **Contains Entries:** |
| --- | --- |
| Form Definition Section (required) | Precondition Pattern  Numeric Question Pattern  Multiple Choice Question Pattern  Text Question Pattern  Analog Slider Question Pattern  Discrete Slider Question Pattern |

***Table 9: Questions Organizer Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | organizer[templateId/@root = '2.16.840.1.113883.10.20.32.4.1'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | <CONF:55> | 2.16.840.1.113883.5.6 (HL7ActClass)=CLUSTER |
|  | @moodCode | 1..1 | SHALL |  | <CONF:56> | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  | templateId | 1..1 | SHALL |  | <CONF:57> |  |
|  | @root | 1..1 | SHALL |  | <CONF:58> | 2.16.840.1.113883.10.20.32.4.1 |
|  | id | 1..1 | SHALL |  | CONF:59 |  |
|  | code | 0..1 | SHOULD |  | CONF:60 |  |
|  | statusCode | 1..1 | SHALL |  | CONF:61 |  |
|  | @code | 1..1 | SHALL |  | CONF:62 | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | precondition | 0..\* | MAY |  | CONF:63 |  |
|  | component | 1..\* | SHALL |  | CONF:64 |  |
|  | sequenceNumber | 1..1 | SHALL |  | CONF:65 |  |
|  | observation | 1..1 | SHALL |  | CONF:66 |  |

1. SHALL contain exactly one [1..1] @classCode (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF: 55).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF: 56).
3. SHALL contain exactly one [1..1] templateId (CONF: 57) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.1" (CONF: 58).
4. SHALL contain exactly one [0..1] id (CONF: 59).
5. **SHOULD** contain zero or one [0..1] code (CONF: 60).
6. SHALL contain exactly one [1..1] statusCode (CONF: 61).
   1. This statusCode **SHALL** contain exactly one [1..1] **@code**="COMPLETED" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF: 62).
7. **MAY** contain zero or more [0..\*] Precondition Pattern templates (templateId 2.16.840.1.113883.10.20.32.4.4) (CONF: 63).
8. SHALL contain at least one [1..\*] component (CONF: 64).such that it
   1. SHALL contain exactly one [1..1] squenceNumber (CONF: 65).
   2. SHALL contain at least one [1..\*] of the following templates (CONF: 66).
      1. Numeric Question Pattern template(templateId: 2.16.840.1.113883.10.20.32.4.7) (CONF: 67).
      2. Multiple Choice Question Pattern template(templateId: 2.16.840.1.113883.10.20.32.4.8) (CONF: 68).
      3. Text Question Pattern template(templateId: 2.16.840.1.113883.10.20.32.4.9) (CONF: 69).
      4. Analog Slider Question Pattern template(templateId: 2.16.840.1.113883.10.20.32.4.10) (CONF: 70).
      5. Discrete Slider Question Pattern template(templateId: 2.16.840.1.113883.10.20.32.4.11) (CONF: 71).

***Figure 9: Questions Organizer Example***

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

<!-- Questions Organizer template -->

<templateId root="2.16.840.1.113883.10.20.32.4.1"/>

<id extension="01" root="CONTINUA-ID-OID">

<code code="O1" codeSystem="CONTINUA-ORGANIZER-OID" displayName="Questions related fitness"/>

<statusCode code="COMPLETED"/>

<!--

Conains Numeric, Multiple Choice or other defined templates for questions

-->

<component>

<sequenceNumber value=”1">

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

<templateId root="2.16.840.1.113883.10.20.32.4.7"/>

...

</observation>

</component>

<component>

<sequenceNumber value=”2">

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

<templateId root="2.16.840.1.113883.10.20.32.4.8”/>

...

</observation>

</component>

<component>

<sequenceNumber value=”3">

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

<templateId root="2.16.840.1.113883.10.20.32.4.10”/>

...

</observation>

</component>

</organizer>

## Question Media Pattern

[observationMedia: templateId 2.16.840.1.113883.10.20.32.4.2(open)]

The Question Media Pattern is used to associate media with a question represented by one of the following templates:

* Numeric Question Pattern
* Multiple Choice Question Pattern
* Text Question Pattern
* Analog Slider Question Pattern
* Discrete Slider Question Pattern

***Table 10: Question Media Pattern Contexts***

| **Used By:** | **Contains Entries:** |
| --- | --- |
| Numeric Question Pattern (optional)  Multiple Choice Question Pattern (optional)  Text Question Pattern (optional)  Analog Slider Question Pattern (optional)  Discrete Slider Question Pattern (optional) |  |

***Table 11: Media Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | observationMedia[templateId/@root ='2.16.840.1.113883.10.20.32.4.2'] | | | | | |
|  | @classCode | 1..1 | SHALL | CD | CONF:72 | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL | CD | CONF:73 | 2.16.840.1.113883.5.1001 (ActMood) = DEF |
|  | templateId | 1..1 | SHALL |  | CONF:74 |  |
|  | @root | 1..1 | SHALL |  | CONF:75 | 2.16.840.1.113883.10.20.32.4.2 |
|  | value | 1..1 | SHALL |  | CONF:76 |  |

1. SHALL contain exactly one [1..1] @classCode (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF: 72).
2. SHALL contain exactly one [1..1] @moodCode="DEF" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF: 73).
3. SHALL contain exactly one [1..1] templateId (CONF: 74) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.2" (CONF: 75).
4. **SHALL** contain exactly one [1..1] **value** (CONF: 76).

## Criterion Pattern

[criterion: templateId 2.16.840.1.113883.10.20.32.4.3(open)]

This pattern is used to express the criterion for asking a question. In the example in Figure 10 the criterion requires that question 2 is answered with values between 2 and 6.

***Table 12: Criterion Pattern Contexts***

| **Used By:** | **Contains Entries:** |
| --- | --- |
| Precondition Pattern (required) |  |

***Table 13: Criterion Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | criterion[templateId/@root ='2.16.840.1.113883.10.20.32.4.3'] | | | | | |
|  | templateID | 1..1 | SHALL |  | <CONF:77> |  |
|  | @root | 1..1 | SHALL |  | CONF:78 | 2.16.840.1.113883.10.20.32.4.3 |
|  | @classCode | 1..1 | SHALL | CD | CONF:79 | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL | CD | CONF:80 | 2.16.840.1.113883.5.1001 (ActMood) = EVN.CRT |
|  | code | 1..1 | SHALL | CE | CONF:81 |  |
|  | value | 1..1 | SHALL |  | CONF:82 |  |

1. SHALL contain exactly one [1..1] templateId (CONF: 77) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.3" (CONF: 78).
2. SHALL contain exactly one [1..1] @classCode (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF: 79).
3. SHALL contain exactly one [1..1] @moodCode="EVN.CRT" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF: 80).
4. **SHALL** contain exactly one [1..1] **code** (CONF: 81).
5. **SHALL** contain exactly one [1..1] **value** (CONF: 82).

## Precondition Pattern

[precondition: templateId 2.16.840.1.113883.10.20.32.4.4(open)]

The precondition class, derived from the ActRelationship class, is used along with the Criterion class to express a condition that must hold true before some other activity occurs. Each entry level template that represents a question may be associated with zero or more Precondition Patterns which determines whether a question should be asked or not. A question is asked only if all preconditions hold true (a.k.a AllTrue). In the example in Figure 10 the criterion requires that question 2 is answered with values between 2 and 6.

***Table 14: Precondition Pattern Contexts***

| **Used By:** | **Contains Entries:** |
| --- | --- |
| Numeric Question Pattern (optional)  Multiple Choice Question Pattern (optional)  Text Question Pattern (optional)  Analog Slider Question Pattern (optional)  Discrete Slider Question Pattern (optional) | Criterion Pattern |

***Table 15: Precondition Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | precondition[templateId/@root ='2.16.840.1.113883.10.20.32.4.4'] | | | | | |
|  | @typeCode | 1..1 | SHALL |  | <CONF:83> | PRCN |
|  | templateID | 1..1 | SHALL |  | <CONF:84> |  |
|  | @root | 1..1 | SHALL |  | CONF:85 | 2.16.840.1.113883.10.20.32.4.4 |
|  | criterion | 1..1 | SHALL |  | CONF:86 |  |

1. SHALL contain exactly one [1..1] @typeCode=”PRCN” (CONF: 83).
2. SHALL contain exactly one [1..1] templateId (CONF: 84) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.4" (CONF: 85).
3. **SHALL** contain exactly one [1..1] Criterion Pattern template templateId 2.16.840.1.113883.10.20.32.4.3) (CONF: 86).

***Figure 10: Precondition Pattern example***

<precondition typeCode="PRCN">

<templateId root="2.16.840.1.113883.10.20.32.4.4"/>

<criterion classCode="OBS" moodCode="EVN.CRT" >

<templateId root="2.16.840.1.113883.10.20.32.4.3"/>

<code code="q2" codeSystem="CONTINUA-ID-OID">

</code>

<!—answer to question q2 is between 2 and 6 -->

<value xsi:type="IVL\_INT">

<low value="2"/>

<high value="6"/>

</value>

</criterion>

</precondition>

## Question Reference Range Pattern

[referenceRange: templateId 2.16.840.1.113883.10.20.32.4.5 (open)]

The Question Reference Range Pattern is used to hold lower and upper boundaries for the expected question response in the context of this implementation guide. For example, in case of Multiple Choice Question Pattern this indicates the minimum and maximum number of choices that a user can select. For Multiple Choice Question Pattern where the patient can only select only one of the available options, the referenceRange high values should be set to ‘1’.

***Table 16: Question Reference Range Pattern Contexts***

| **Used By:** | **Contains Entries:** |
| --- | --- |
| Numeric Question Pattern (optional)  Multiple Choice Question Pattern (optional)  Discrete Slider Question Pattern (optional) |  |

***Table 17: Question Reference Range Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | referenceRange[templateId/@root ='2.16.840.1.113883.10.20.32.4.5'] | | | | | |
|  | @typeCode | 1..1 | SHALL | CD | CONF:87 | REFV |
|  | templateId | 1..1 | SHALL |  | <CONF:88> |  |
|  | @root | 1..1 | SHALL |  | CONF:89 | 2.16.840.1.113883.10.20.32.4.5 |
|  | observationRange | 1..1 | SHALL |  | CONF:90 |  |
|  | text | 0..1 | MAY |  | <CONF:91> |  |
|  | value | 1..1 | SHALL |  | <CONF:92> |  |
|  | @xsi:type | 1..1 | SHALL |  | <CONF:93> |  |
|  | low | 1..1 | SHALL |  | <CONF:94> |  |
|  | high | 1..1 | SHALL |  | <CONF:95> |  |
|  | interpretationCode | 0..1 | SHOULD |  | CONF:96 |  |

1. SHALL contain exactly one [1..1] @typeCode="REFV" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF: 87).
2. SHALL contain exactly one [1..1] templateId (CONF: 88) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.5" (CONF: 89).
3. The referenceRange SHALL contain exactly one [1..1] observationRange (CONF: 90).
   1. MAY contain zero or one [0..1] text (CONF: 91).
   2. SHALL contain exactly one [1..1] value (CONF: 92) such that it
      1. SHALL contain exactly one [1..1] @xsi:type=”IVL\_INT” (CONF: 93).
      2. SHALL contain exactly one [1..1] low (CONF: 94).
      3. SHALL contain exactly one [1..1] high (CONF: 95).
   3. SHOULD contain zero or one [0..1] interpretationCode (CONF: 96).

***Figure 11: Question Reference Range Pattern example***

<referenceRange typeCode="REFV">

<templateId root="2.16.840.1.113883.10.20.32.4.5"/>

<observationRange>

<value xsi:type="IVL\_INT">

<low value='0'>

<high value='24'>

<value>

</observationRange>

</referenceRange>

## Question Feedback Pattern

[observation: templateId 2.16.840.1.113883.10.20.32.4.6 (open)]

The Question Feedback Pattern is a generic observation class used to provide the feedback to the patient upon answering the question. This pattern may be associated with zero or more Question Precondition Pattern templates that hold the criteria for showing the feedback. In Figure 12, the feedback is given to the user if the user sleeps such that the answer to question 2 is between 2 and 6 hrs. The text element holds the feedback text to be shown to the user.

***Table 18: Question Feeback Pattern Contexts***

| **Used By:** | **Contains Entries:** |
| --- | --- |
| Numeric Question Pattern (optional)  Multiple Choice Question Pattern (optional)  Analog Slider Question Pattern (optional)  Discrete Slider Question Pattern (optional) | Precondition Pattern |

***Table 19: Question Feedback Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.6'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | CONF:97 | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | <CONF:98> | 2.16.840.1.113883.5.1001 (ActMood) = DEF |
|  | templateId | 1..1 | SHALL |  | <CONF:99> |  |
|  | @root | 1..1 | SHALL |  | CONF:100 | 2.16.840.1.113883.10.20.32.4.5 |
|  | precondition | 0..\* | SHOULD |  | <CONF:101> |  |
|  | text | 1..1 | SHALL | ED | CONF:102 |  |
|  | languageCode | 0..1 | SHOULD |  | [CONF:10](CONF:101)3 |  |

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF: 97).
2. **SHALL** contain exactly one [1..1] **@moodCode**="DEF" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF: 98).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF: 99) such that it
   1. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.32.4.6" (CONF: 100).
4. **SHALL** contain at least one [1..\*] Precondition Pattern template(templateId 2.16.840.1.113883.10.20.32.4.4) (CONF: 101).
5. **SHALL** contain exactly one [1..1] text (CONF: 102).
6. SHOULD contain zero or one [1..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC (CONF: 103).

***Figure 12: Question Feedback Pattern Example***

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

<templateId root="2.16.840.1.113883.10.20.32.4.6"/>

<precondition typeCode="PRCN">

<templateId root="2.16.840.1.113883.10.20.32.4.4"/>

<criterion classCode="OBS" moodCode="EVN.CRT" >

<templateId root="2.16.840.1.113883.10.20.32.4.3"/>

<code code="q2" codeSystem="CONTINUA-ID-OID"/>

<!—answer to question q2 is between 2 and 6 -->

<value xsi:type="IVL\_INT" >

<low value="2"/>

<high value="6"/>

</value>

</criterion>

</precondition>

</text>

Don’t take coffee just before going to bed ☺

</text>

<observation>

## Numeric Question Pattern

[observation: templateId 2.16.840.1.113883.10.20.32.4.7 (open)]

The Numeric Question Pattern is used to construct the question instance where the expected response is a number of the following data types

1. INT

2. REAL

3. TS

This pattern may be associated with zero or more Precondition Pattern templates which hold the criteria for asking this question. Question Reference Range Pattern template may also be associated with this pattern indicating the expected range of observation.value (i.e. answer to the question). In addition, the pattern may be associated with the Question Feedback Pattern template through entryRelationship that holds text feedback to be shown to the user after answering the question.

***Table 20: Numeric Question Pattern Contexts***

| **Used By:** | **Contains Entries:** |
| --- | --- |
| Questions Organizer (required)  Analog Slider Question Pattern (required) | Question Media Pattern  Precondition Pattern  Question Reference Range Pattern  Question Feedback Pattern |

***Table 21: Numeric Question Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.7'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | <CONF:104> | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | <CONF:105> | 2.16.840.1.113883.5.1001 (ActMood) = DEF |
|  | templateId | 1..1 | SHALL |  | CONF:106 |  |
|  | @root | 1..1 | SHALL |  | CONF:107 | 2.16.840.1.113883.10.20.32.4.7 |
|  | id | 1..1 | SHALL |  | <CONF:108> |  |
|  | code | 1..1 | SHALL | CE | <CONF:109> |  |
|  | @code | 1..1 | SHALL |  | <CONF:110> |  |
|  | @codesystem | 1..1 | SHALL |  | <CONF:111> |  |
|  | originalText | 1..1 | SHALL |  | [CONF:11](CONF:113)2 |  |
|  | text | 0..1 | MAY | ED | <CONF:113> |  |
|  | languageCode | 0..1 | SHOULD |  | <CONF:114> |  |
|  | value | 1..1 | SHALL |  | <CONF:115> |  |
|  | entryRelationship | 0..1 | SHOULD |  | <CONF:116> |  |
|  | @typeCode | 1..1 | SHALL | CD | <CONF:117> | REFR |
|  | observationMedia | 1..1 | SHALL |  | CONF:118 |  |
|  | entryRelationship | 0..1 | SHOULD |  | <CONF:119> |  |
|  | @typeCode | 1..1 | SHALL | CD | <CONF:120> | REFR |
|  | observation | 1..1 | SHALL |  | <CONF:121> |  |
|  | precondition | 0..\* | SHOULD |  | <CONF:122> |  |
|  | referenceRange | 0..\* | SHOULD |  | [CONF:1](CONF:117)23 |  |

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF: 104).
2. **SHALL** contain exactly one [1..1] **@moodCode**="DEF" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF: 105).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF: 106) such that it
   1. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.32.4.7" (CONF: 107).
4. **SHALL** contain exactly one [1..1] **id** (CONF: 108).
5. **SHALL** contain exactly one [1..1] **code** (CONF: 109).
   1. This code **SHALL** contain exactly one [1..1] @**code** (CONF: 110).
   2. This code **SHALL** contain exactly one [1..1] @**codeSystem** (CONF: 111).
   3. This code **SHALL** contain exactly one [1..1] **@originalText** (CONF: 112).
6. **MAY** contain zero or one [0..1] text (CONF: 113).
7. SHOULD contain zero or one [1..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC (CONF: 114).
8. **SHALL** contain exactly one [1..1] **value** (CONF: 115).
9. **SHOULD** contain zero or one [0..1] entryRelationship (CONF: 116).
   1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF: 117).
   2. SHALL conform to the Question Media Pattern template (templateId 2.16.840.1.113883.10.20.32.4.2) (CONF: 118).
10. **SHOULD** contain zero or one [0..1] entryRelationship (CONF: 119).
    1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF: 120).
    2. SHALL conform to the Question Feedback Pattern template (templateId 2.16.840.1.113883.10.20.32.4.6) (CONF: 121).
11. **SHOULD** contain zero or more [0..\*] Precondition Pattern templates (templateId 2.16.840.1.113883.10.20.32.4.4) (CONF: 122).
12. **SHOULD** contain zero or more [0..\*] Question Reference Range Pattern template (templateId 2.16.840.1.113883.10.20.32.4.5) (CONF: 123).

***Figure 13: Numeric Question Pattern example***

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

<templateId root="2.16.840.1.113883.10.20.32.4.7"/>

<id extension="q1" root="CONTINUA-ID-OID">

<code code="GUID\_1" codeSystem="CONTINUA-Q-OID">

<originalText>How many hours did you sleep last night?</originalText>

</code>

<text>Please enter only one value</text>

<value xsi:type="INT" value=””/>

<entryRelationship typeCode="REFR">

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

<templateId root="2.16.840.1.113883.10.20.32.4.2"/>

<value mediaType="image/jpeg">

<reference value="URL"/>

</value>

</observationMedia>

</entryRelationship>

<!— Feedback to the user based on his/her answer.-->

<entryRelationship typeCode="REFR">

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

<templateId root="2.16.840.1.113883.10.20.32.4.6"/>

<precondition typeCode="PRCN">

<templateId root="2.16.840.1.113883.10.20.32.4.4"/>

<criterion classCode="OBS" moodCode="EVN.CRT" >

<templateId root="2.16.840.1.113883.10.20.32.4.3"/>

<code code="GUID\_1" codeSystem="CONTINUA-ID-OID"/>

<value xsi:type="IVL\_INT">

<low value='2'/>

<high value='6'/>

</value>

</criterion>

</precondition>

<text>Don’t take coffee just before going to bed☺</text>

</observation>

</entryRelationship>

<!— the expected value should be between 0 and 24.-->

<referenceRange typeCode="REFV">

<templateId root="2.16.840.1.113883.10.20.32.4.5"/>

<observationRange>

<value xsi:type="IVL\_INT">

<low value='0'/>

<high value='24'/>

</value>

</observationRange>

</referenceRange>

</observation>

## Multiple Choice Question Pattern

[observation: templateId 2.16.840.1.113883.10.20.32.4.8 (open)]

The Multiple Choice Question Pattern is used to construct the multiple choice question instance. Similar to Numeric Question Pattern template, this pattern may be also associated with the following templates:

* Precondition Pattern
* Question Reference Range Pattern
* Question Feedback Pattern

Question Reference Range Pattern indicates the minimum and maximim number of options that must be selected by a user. In addition, this pattern may also contain Text Question Pattern which is used to capture other responses of the patient if patient selects the the other option.

***Table 22: Multiple Choice Question Pattern Contexts***

| **Used By:** | **Contains Entries:** |
| --- | --- |
| Questions Organizer (required)  Discrete Slider Question Pattern (required) | Question Media Pattern  Precondition Pattern  Question Reference Range Pattern  Question Feedback Pattern  Text Question Pattern |

***Table 23: Multiple Choice Question Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.8'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | CONF:124 | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | <CONF:125> | 2.16.840.1.113883.5.1001 (ActMood) = DEF |
|  | templateId | 1..1 | SHALL |  | <CONF:126> |  |
|  | @root | 1..1 | SHALL |  | CONF:127 | 2.16.840.1.113883.10.20.32.4.8 |
|  | id | 1..1 | SHALL |  | CONF:128 |  |
|  | code | 1..1 | SHALL | CE | <CONF:129> |  |
|  | @code | 1..1 | SHALL |  | <CONF:130> |  |
|  | @codesystem | 1..1 | SHALL |  | <CONF:131> |  |
|  | originalText | 1..1 | SHALL |  | <CONF:132> |  |
|  | text | 0..1 | SHALL | ED | <CONF:133> |  |
|  | languageCode | 0..1 | SHOULD |  | CONF:134 |  |
|  | value | 2..\* | SHALL |  | <CONF:135> |  |
|  | @xsi:type | 1..1 | SHALL |  | <CONF:136> | CE |
|  | @code | 1..1 | SHALL |  | <CONF:137> |  |
|  | @codesystem | 1..1 | SHALL |  | <CONF:138> |  |
|  | @displayName | 1..1 | SHALL |  | <CONF:139> |  |
|  | entryRelationship | 0..1 | SHOULD |  | <CONF:140> |  |
|  | @typeCode | 1..1 | SHALL | CD | <CONF:141> | REFR |
|  | observationMedia | 1..1 | SHALL |  | <CONF:142> |  |
|  | entryRelationship | 0..1 | SHOULD |  | <CONF:143> |  |
|  | @typeCode | 1..1 | SHALL | CD | <CONF:144> | REFR |
|  | observation | 1..1 | SHALL |  | <CONF:145> |  |
|  | entryRelationship | 0..1 | SHOULD |  | [CONF:14](CONF:145)6 |  |
|  | @typeCode | 1..1 | SHALL | CD | <CONF:147> | REFR |
|  | observation | 1..1 | SHALL |  | CONF:148 |  |
|  | precondition | 0..\* | SHOULD |  | <CONF:149> |  |
|  | referenceRange | 0..\* | SHOULD |  | CONF:150 |  |

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF: 124).
2. **SHALL** contain exactly one [1..1] **@moodCode**="DEF" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF: 125).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF: 126) such that it
   1. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.32.4.8" (CONF: 127).
4. **SHALL** contain exactly one [1..1] **id** (CONF: 128).
5. **SHALL** contain exactly one [1..1] **code** (CONF: 129).
   1. This code **SHALL** contain exactly one [1..1] @**code** (CONF: 130).
   2. This code **SHALL** contain exactly one [1..1] @**CodeSystem** (CONF: 131).
   3. This code **SHALL** contain exactly one [1..1] **@originalText** (CONF: 132).
6. **MAY** contain zero or one [0..1] text (CONF: 133).
7. SHOULD contain zero or one [1..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC (CONF: 134).
8. **SHALL** contain at least two or more [2..\*] **value** (CONF: 135).
   1. SHALL contain exactly one [1..1] @xsi:type="CE" (CONF: 136).
   2. This code **SHALL** contain exactly one [1..1] @**code** (CONF: 137).
   3. This code **SHALL** contain exactly one [1..1] @**CodeSystem** (CONF: 138).
   4. This code **SHALL** contain exactly one [1..1] @**displayName** (CONF: 139).
9. **SHOULD** contain zero or one [0..1] entryRelationship (CONF: 140).
   1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF: 141).
   2. SHALL conform to the Question Media Pattern template (templateId 2.16.840.1.113883.10.20.32.4.2) (CONF: 142).
10. **SHOULD** contain zero or one [0..1] entryRelationship (CONF: 143).`
    1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF: 144).
    2. SHALL conform to the Question Feedback Pattern template (templateId 2.16.840.1.113883.10.20.32.4.6) (CONF: 145).
11. **SHOULD** contain zero or one [0..1] entryRelationship (CONF: 146).
    1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF: 147).
    2. SHALL conform to the Text Question Pattern template (templateId 2.16.840.1.113883.10.20.32.4.9) (CONF: 148).
12. **SHOULD** contain zero or more [0..\*] Precondition Pattern templates (templateId 2.16.840.1.113883.10.20.32.4.4) (CONF: 149).
13. **SHOULD** contain zero or more [0..\*] Question Reference Range Pattern template (templateId 2.16.840.1.113883.10.20.32.4.5) (CONF: 150).

***Figure 14: Multiple Choice Question Pattern example***

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

<templateId root="2.16.840.1.113883.10.20.32.4.8"/>

<id extension="q2" root="CONTINUA-ID-OID"/>

<code code="GUID" codeSystem="CONTINUA-Q-OID">

<originalText>Compared to last week how would you rate your health status in general?</originalText>

</code>

<text>you may select upto three options</text>

<value xsi:type="CE" code="A1" codeSystem="CONTINUA-ANS-OID”, displayName="The same as last week"/>

<value xsi:type="CE" code="A2" codeSystem="CONTINUA-ANS-OID”, displayName="Better than last week"/>

<value xsi:type="CE" code="A3" codeSystem="CONTINUA-ANS-OID”, displayName="Worse than last week"/>

<value xsi:type="CE" code="A4" codeSystem="CONTINUA-ANS-OID”, displayName="other"/>

<entryRelationship typeCode="REFR">

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

<templateId root="2.16.840.1.113883.10.20.32.4.2"/>

<value mediaType="image/jpeg">

<reference value="smileyface.jpg or URL"/>

</value>

</observationMedia>

</entryRelationship>

<!— criterion for asking this question.This depends on answer to previous question-->

<precondition typeCode="PRCN">

<templateId root="2.16.840.1.113883.10.20.32.4.4"/>

<criterion>

<templateId root="2.16.840.1.113883.10.20.32.4.3"/>

<code code="q1" codeSystem="CONTINUA-ID-OID"/>

<value xsi:type="IVL\_INT">

<low value='2'/>

<high value='6'/>

</value>

</criterion>

</precondition>

<referenceRange typeCode="REFV">

<templateId root="2.16.840.1.113883.10.20.32.4.5"/>

<observationRange>

<value xsi:type="IVL\_INT">

<low value='1'/>

<high value='3'/>

</value>

</observationRange>

</referenceRange>

<entryRelationship typeCode="REFR">

<!— Feedback to the user based on his/her answer to the current question-->

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

<templateId root="2.16.840.1.113883.10.20.32.4.6"/>

<text>Please try to sleep more ☺</text>

<precondition typeCode="PRCN">

<templateId root="'2.16.840.1.113883.10.20.32.4.4"/>

<criterion>

<templateId root="2.16.840.1.113883.10.20.32.4.3"/>

<code code="q2" codeSystem="CONTINUA-ID-OID"/>

<value code="a4" codeSystem="CONTINUA-ANS-OID"/>

</criterion>

</precondition>

</observation>

</entryRelationship>

</observation>

## Text Question Pattern

[observation: templateId 2.16.840.1.113883.10.20.32.4.9 (open)]

The Text Question Pattern is used to create an instance of the question where the expected answer is free text data type. Similar to Numeric Question Pattern and Multiple Choice Question Pattern templates, this pattern may also be associated with zero or more Precondition Pattern templates that hold the criteria for asking the question.

***Table 22: Text Question Pattern Contexts***

| **Used By:** | **Contains Entries:** |
| --- | --- |
| Questions Organizer (required) | Question Media Pattern  Precondition Pattern |

***Table 23: Text Question Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.9'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | <CONF:1>51 | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | CONF:152 | 2.16.840.1.113883.5.1001 (ActMood) = DEF |
|  | templateId | 1..1 | SHALL |  | CONF:153 |  |
|  | @root | 1..1 | SHALL |  | <CONF:1>54 | 2.16.840.1.113883.10.20.32.4.9 |
|  | id | 1..1 | SHALL |  | <CONF:155> |  |
|  | code | 1..1 | SHALL | CE | <CONF:156> |  |
|  | @code | 1..1 | SHALL |  | <CONF:157> |  |
|  | @codesystem | 1..1 | SHALL |  | <CONF:158> |  |
|  | originalText | 1..1 | SHALL |  | <CONF:159> |  |
|  | text | 0..1 | MAY | ED | <CONF:160> |  |
|  | languageCode | 0..1 | SHOULD |  | <CONF:161> |  |
|  | value | 1..1 | SHALL |  | <CONF:162> |  |
|  | entryRelationship | 0..1 | SHOULD |  | <CONF:163> |  |
|  | @typeCode | 1..1 | SHALL | CD | <CONF:164> | REFR |
|  | observationMedia | 1..1 | SHALL |  | <CONF:165> |  |
|  | precondition | 0..\* | SHOULD |  | [CONF:1](CONF:156)66 |  |

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF: 151).
2. **SHALL** contain exactly one [1..1] **@moodCode**="DEF" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF: 152).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF: 153) such that it
   1. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.32.4.6" (CONF: 154).
4. **SHALL** contain exactly one [1..1] **id** (CONF: 155).
5. **SHALL** contain exactly one [1..1] **code** (CONF: 156).
   1. This code **SHALL** contain exactly one [1..1] @**code** (CONF: 157).
   2. This code **SHALL** contain exactly one [1..1] @**codeSystem** (CONF: 158).
   3. This code **SHALL** contain exactly one [1..1] **@originalText** (CONF: 159).
6. **MAY** contain zero or one [0..1] text (CONF: 160).
7. SHOULD contain zero or one [1..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC (CONF: 161).
8. **SHALL** contain exactly one [1..1] **value** (CONF: 162).
9. **SHOULD** contain zero or one [0..1] entryRelationship (CONF: 163).
   1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF: 164).
   2. SHALL conform to the Question Media Pattern template (templateId 2.16.840.1.113883.10.20.32.4.2) (CONF: 165).
10. **SHOULD** contain zero or more [0..\*] Precondition Pattern templates (templateId 2.16.840.1.113883.10.20.32.4.4) (CONF: 166).

***Figure 15: Text Question Pattern example***

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

<templateId root="2.16.840.1.113883.10.20.32.4.9"/>

<id extension="q2" root="CONTINUA-ID-OID"/>

<code code="q3" codeSystem="CONTINUA-Q-OID">

<originalText>Why do you feel worse?</originalText>

</code>

<value xsi:type="ST"></value>

<!— criterion for asking this question. This depends on the answer to the question 2- Multiple Choice Question-->

<precondition typeCode="PRCN">

<templateId root="2.16.840.1.113883.10.20.32.4.4"/>

<criterion>

<templateId root="2.16.840.1.113883.10.20.32.4.3"/>

<code code="q2" codeSystem="CONTINUA-Q-OID"/>

<value code="a3" codeSystem="CONTINUA-ANS-OID"/>

<criterion>

</precondition>

</observation>

## Analog Slider Question Pattern

[observation: templateId 2.16.840.1.113883.10.20.32.4.10 (open)]

The Analog Slider Question Pattern is used to ask a question from the patient in the form of visual analogue scale (VAS)[[3]](#footnote-3). The Analog Slider Question Pattern is used to create an instance that carries the information necessary to construct VAS. The continuum range is indicated by the referenceRange/observationRange construct where the data type of the value/@xsi:type=“GLIST\_PQ”. The head (or starting point) of the scale is indicated by value/head, the step size is indicated by value/increment and the tail (or the end) of the scale is indicated by value/denominator.

***Table 18: Analog Slider Question Pattern Contexts***

| **Used By:** | **Contains Entries:** |
| --- | --- |
| Questions Organizer (required) | Numeric Question Pattern |

***Table 14: Analog Slider Question Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.10'] | | | | | |
|  | templateId | 1..1 | SHALL |  | CONF:169 |  |
|  | @root | 1..1 | SHALL |  | CONF:170 | 2.16.840.1.113883.10.20.32.4.10 |
|  | referenceRange | 1..1 | SHALL |  | CONF:171 |  |
|  | @typeCode | 1..1 | SHALL | CD | CONF:172 | REFV |
|  | observationRange | 1..1 | SHALL |  | CONF:173 |  |
|  | value | 1..1 | SHALL |  | CONF:174 |  |
|  | @xsi:type | 1..1 | SHALL |  | CONF:175 | GLIST\_PQ |
|  | head | 1..1 | SHALL |  | CONF:176 |  |
|  | increment | 1..1 | SHALL |  | CONF:177 |  |
|  | denominator | 1..1 | SHALL |  | <CONF:178> |  |
|  | interpretationCode | 1..1 | SHOULD |  | CONF:179 |  |

1. **SHALL** conform to the Numeric Question Pattern template (templateId 2.16.840.1.113883.10.20.32.4.7) (CONF: 167).
2. **SHALL NOT** contain Question Reference Range Pattern template (templateId 2.16.840.1.113883.10.20.32.4.5) (CONF: 168).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF: 169) such that it
   1. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.32.4.10" (CONF: 170).
4. **SHALL** contain exactly one [1..1] referenceRange (CONF: 171).
   1. SHALL contain exactly one [1..1] @typeCode="REFV" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF: 172).
   2. SHALL contain exactly one [1..1] observationRange (CONF: 173).
      1. SHALL contain exactly one [1..1] value (CONF: 174) such that it
         1. SHALL contain exactly one [1..1] @xsi:type=”GLIST\_PQ” (CONF: 175).
         2. SHALL contain exactly one [1..1] head (CONF: 176).
         3. SHALL contain exactly one [1..1] increment (CONF: 177).
         4. SHALL contain exactly one [1..1] denominator (CONF: 178).
      2. SHOULD contain zero or one [0..1] interpretationCode (CONF: 179).

***Figure 16: Analog Slider Question Pattern example***

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

<templateId root="2.16.840.1.113883.10.20.32.4.7"/>

<templateId root="2.16.840.1.113883.10.20.32.4.10"/>

<id extension="q4" root="CONTINUA-ID-OID"/>

<code code="q4" codeSystem="CONTINUA-Q-OID">

<originalText> what is the percentage of time that you are pain free?</originalText>

</code>

<text>…</text>

<value xsi:type="INT" value=””/>

<!— the expected value should be between 0 and 100.-->

<referenceRange typeCode="REFV">

<observationRange>

<value xsi:type="GLIST\_PQ" denominator=”100”>

<head value='0'/>

<increment value='1'/>

</value>

</observationRange>

</referenceRange>

## Discrete Slider Question Pattern

[observation: templateId 2.16.840.1.113883.10.20.32.4.11 (open)]

The Discrete Slider Question Pattern is similar to the Multiple Choice Question Pattern template however the user can only select one option i.e the observationRange/high/@value is fixed to “1”. In addition the options are presented as a slider similar to Analog Slider Question Pattern.

***Table 26: Discrete Slider Question Pattern Contexts***

| **Used By:** | **Contains Entries:** |
| --- | --- |
| Questions Organizer (required) | Multiple Choice Question Pattern |

***Table 27: Discrete Slider Question Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.11'] | | | | | |
|  | templateId | 1..1 | SHALL |  | CONF:181 |  |
|  | @root | 1..1 | SHALL |  | CONF:182 | 2.16.840.1.113883.10.20.32.4.11 |
|  | referenceRange/observationRange/value/high/@value | 1..1 | SHALL | INT | CONF:183 | 1 |

1. **SHALL** confirm to Multiple Choice Question Pattern template (templateId 2.16.840.1.113883.10.20.32.4.8) (CONF: 180).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF: 181) such that it
   1. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.32.4.11" (CONF: 182).
3. **SHALL** contain exactly one [1..1] referenceRange/observationRange/value/high/@value=”1” (CONF: 183).

***Figure 17: Discrete Slider Question Pattern example***

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

<templateId root="2.16.840.1.113883.10.20.32.4.8"/>

<templateId root="2.16.840.1.113883.10.20.32.4.11"/>

<id extension="q5" root="CONTINUA-ID-OID"/>

<code code="GUID" codeSystem="CONTINUA-Q-OID">

<originalText>Compared to last week how would you rate your health status in general?</originalText>

</code>

<value xsi:type="CE" code="A1" codeSystem="CONTINUA-ANS-OID”, displayName="The same as last week"/>

<value xsi:type="CE" code="A2" codeSystem="CONTINUA-ANS-OID”, displayName="Better than last week"/>

<value xsi:type="CE" code="A3" codeSystem="CONTINUA-ANS-OID”, displayName="Worse than last week"/>

<referenceRange typeCode="REFV">

<templateId root="2.16.840.1.113883.10.20.32.4.5"/>

<observationRange>

<value xsi:type="IVL\_INT">

<low value='0'/>

<high value='1'/>

</value>

</observationRange>

</referenceRange>

</observation>

1. Template IDs Used in This Guide

This appendix lists all templateIds used in this guide in [alphabetical order](#Alphabetical_List_of_Templates) and in [containment order](#Template_Containments).

***Table 13: Alphabetical*** ***List of Templates by Type***

| **Template Title** | **Template Type** | **templateId** |
| --- | --- | --- |
| Analog Slider Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.10 |
| Criterion Pattern | entry | 2.16.840.1.113883.10.20.32.4.3 |
| Discrete Slider Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.11 |
| Form Definition Document-Level Template | document | 2.16.840.1.113883.10.20.32.1.1 |
| Multiple Choice Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.8 |
| Numeric Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.7 |
| Precondition Pattern | entry | 2.16.840.1.113883.10.20.32.4.4 |
| Questions Organizer | entry | 2.16.840.1.113883.10.20.32.4.1 |
| Question Media Pattern | entry | 2.16.840.1.113883.10.20.32.4.2 |
| Question Reference Range Pattern | entry | 2.16.840.1.113883.10.20.32.4.5 |
| Question Feedback Pattern | entry | 2.16.840.1.113883.10.20.32.4.6 |
| Form Definition Section | section | 2.16.840.1.113883.10.20.32.2.1 |
| Text Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.9 |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

Table 14: Template Containments

| Template Title | Template Type | templateId |
| --- | --- | --- |
| Form Definition Document-Level Template | document | 2.16.840.1.113883.10.20.32.1.1 |
| Form Definition Section | section | 2.16.840.1.113883.10.20.32.2.1 |
| Questions Organizer | entry | 2.16.840.1.113883.10.20.32.4.1 |
| Precondition Pattern | entry | 2.16.840.1.113883.10.20.32.4.4 |
| Criterion Pattern | entry | 2.16.840.1.113883.10.20.32.4.3 |
| Numeric Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.6 |
| Question Media Pattern | entry | 2.16.840.1.113883.10.20.32.4.2 |
| Precondition Pattern | entry | 2.16.840.1.113883.10.20.32.4.4 |
| Question Reference Range Pattern | entry | 2.16.840.1.113883.10.20.32.4.4 |
| Question Feedback Pattern | entry | 2.16.840.1.113883.10.20.32.4.5 |
| Multiple Choice Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.7 |
| Question Media Pattern | entry | 2.16.840.1.113883.10.20.32.4.2 |
| Precondition Pattern | entry | 2.16.840.1.113883.10.20.32.4.3 |
| Question Reference Range Pattern | entry | 2.16.840.1.113883.10.20.32.4.4 |
| Question Feedback Pattern | entry | 2.16.840.1.113883.10.20.32.4.5 |
| Text Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.8 |
| Text Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.8 |
| Question Media Pattern | entry | 2.16.840.1.113883.10.20.32.4.2 |
| Precondition Pattern | entry | 2.16.840.1.113883.10.20.32.4.3 |
| Analog Slider Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.9 |
| Numeric Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.6 |
| Discrete Slider Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.10 |
| Multiple Choice Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.7 |

1. extensions to CDA R2

Where there is a need to communicate information for which there is no suitable representation in CDA R2, extensions to CDA R2 have been developed. This section serves to summarize the extensions and provide implementation guidance. Using the Precondition Pattern template based on the CDA R2, one can only realize AllTrue logic i.e. every precondition must be true for the act to be performed (i.e question to be asked from from the patient). In order to realize the AllTrue and other types of logics (i.e. AllFalse, AtLeastOneTrue, AtLeastOneFalse, OnlyOneTrue and OnlyOneFalse), one can use the Precondition Extension Pattern template, which is being created based on the HQMF standard. Since this template is created based on an extension to CDA R2, it has not been listed in the Table 13 and Table 14 which only contains the templates that are based on the CDA R2.

Extensions created for this guide include:

* sdtc:precondition- The precondition extension allows grouping of multiple preconditions through logical grouper(s). this further consists of the following elements and attributes
  + precondition.conjunctionCode

The conjunction code is fixed to the appropriate value for each grouper to ensure that the grouper generates the appropriate logical connective.

* + precondition.Grouper

A precondition can contain additional groupers to perform complicated Boolean logic.

* + precondition.crtierion

A precondition can contain criteria for performing an act.

* + Precondition.negationInd

The negation indicator is fixed to the appropriate value for each grouper to ensure that the grouper generates the appropriate logical connective.

* + precondition.typeCode

The type code is fixed to “PRCN” (precondition).

* Grouper Attributes
  + Grouper.classCode

The class code is fixed to “GROUPER” (Grouper)

* + Grouper.moodCode

The mood code is fixed to “EVN” (event)

* + Grouper.id

A unique identifier for this grouper expression.

* + Grouper Relationships
    - Grouper.precondition

Each grouper connects to the criteria that it groups with a precondition relationship. The precondition relationships vary in their definitions to ensure that the grouper computes the appropriate logic described by the name of the grouper.

* Logical Groupers

Preconditions can be grouped together in AND/OR/XOR expressions using grouper acts. These groupers allow only one kind of precondition to enforce the logic described by the name of the grouper. Groupers can combine other groupers or individual criteria to allow for more complex Boolean logic to be computed.

|  |  |  |
| --- | --- | --- |
| **Grouper Class Name** | **Boolean Expression Equivalent** | **Description** |
| * AllTrue | AND | This act is composed of subcriteria all of which must be true in order for the item being counted to appear in the measure. |
| * AllFalse | NOR | This act is composed of subcriteria all of which must be false in order for the item being counted to appear in the measure. |
| * AtLeastOneTrue | OR | This act is composed of subcriteria of which at least one must be true in order for the item being counted to appear in the measure. |
| * AtLeastOneFalse | NAND | This act is composed of subcriteria of which at least one must be false in order for the item being counted to appear in the measure. |
| * OnlyOneTrue | (see Note 1) | This act is composed of subcriteria of which exactly one must be true in order for the item being counted to appear in the measure. |
| * OnlyOneFalse | (see Note 1) | This act is composed of subcriteria of which exactly one must be false in order for the item being counted to appear in the measure. |

Note 1: OnlyOneTrue and OnlyOneFalse represent the positive and negative forms of the HL7 Exclusive OR operation (XOR), which is defined as “One and only one of the XOR conditions must be true (false).” The generalization of this over more than two operands does not follow typical conventions in Boolean logic.

To resolve issues that need to be addressed by extension, the developers of this guide chose to approach extensions as follows:

* An extension is a collection of element or attribute declarations and rules for their application to the CDA Release 2.0.
* A single namespace for all extension elements or attributes that may be used by this guide will be defined.
* The namespace for extensions created by the HL7 Structured Documents Working Group (formerly Stuctured Documents Technical Committee) shall be urn:hl7-org:sdtc.
* This namespace shall be used as the namespace for any extension elements or attributes that are defined by this implementation guide.
* Each extension element shall use the same HL7 vocabularies and data types used by CDA Release 2.0.
* Each extension element shall use the same conventions for order and naming as is used by the current HL7 tooling.
* An extension element shall appear in the XML where the expected RIM element of the same name would have appeared had that element not been otherwise constrained from appearing in the CDA XML schema.

1. ***Precondition Extension Pattern***

[precondition: templateId 2.16.840.1.113883.10.20.32.4.12(open)]

1. SHALL contain exactly one [1..1] @typeCode=”PRCN” (CONF: 184).
2. SHALL contain exactly one [1..1] templateId (CONF: 185). such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.12" (CONF: 186).
3. SHALL contain exactly one [1..1] Criterion Pattern template (CONF: 187).or one of the following grouper templates (CONF: 188).
   1. AllTrue Pattern template (templateId 2.16.840.1.113883.10.20.32.4.13) (CONF: 189).
   2. AllFalse Pattern template (templateId 2.16.840.1.113883.10.20.32.4.14) (CONF: 190).
   3. AtLeastOneTrue Pattern template (templateId 2.16.840.1.113883.10.20.32.4.15) (CONF: 191).
   4. AtLeastOneFalse Pattern template (templateId 2.16.840.1.113883.10.20.32.4.16) (CONF: 192).
   5. OnlyOneTrue Pattern template (templateId 2.16.840.1.113883.10.20.32.4.17) (CONF: 193).
   6. OnlyOneFalse Pattern template (templateId 2.16.840.1.113883.10.20.32.4.18) (CONF: 194).
4. ***AllTrue Pattern***

[precondition: templateId 2.16.840.1.113883.10.20.32.4.13(open)]

1. SHALL contain exactly one [1..1] templateId (CONF: 195) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.12" (CONF: 196).
2. **SHALL** contain exactly one [1..1] **id** (CONF: 197).
3. **SHALL** contain exactly one [1..1] P**recondition Extension Pattern** template (templateId 2.16.840.1.113883.10.20.32.4.12) (CONF: 198).
4. ***AllFalse Pattern***

[precondition: templateId 2.16.840.1.113883.10.20.32.4.14(open)]

1. SHALL contain exactly one [1..1] templateId (CONF: 199) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.14" (CONF: 200).
2. **SHALL** contain exactly one [1..1] **id** (CONF: 201).
3. **SHALL** contain exactly one [1..1] P**recondition Extension Pattern** template (templateId 2.16.840.1.113883.10.20.32.4.12) (CONF: 202).
4. ***AtLeastOneTrue Pattern***

[precondition: templateId 2.16.840.1.113883.10.20.32.4.15(open)]

1. SHALL contain exactly one [1..1] templateId (CONF: 203) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.15" (CONF: 204).
2. **SHALL** contain exactly one [1..1] **id** (CONF: 205).
3. **SHALL** contain exactly one [1..1] P**recondition Extension Pattern** template (templateId 2.16.840.1.113883.10.20.32.4.12) (CONF: 206).
4. ***AtLeastOneFalse Pattern***

[precondition: templateId 2.16.840.1.113883.10.20.32.4.16(open)]

1. SHALL contain exactly one [1..1] templateId (CONF: 207) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.16" (CONF: 208).
2. **SHALL** contain exactly one [1..1] **id** (CONF: 209).
3. **SHALL** contain exactly one [1..1] P**recondition Extension Pattern** template (templateId 2.16.840.1.113883.10.20.32.4.12) (CONF: 210).
4. ***OnlyOneTrue Pattern***

[precondition: templateId 2.16.840.1.113883.10.20.32.4.17(open)]

1. SHALL contain exactly one [1..1] templateId (CONF: 211) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.12" (CONF: 212).
2. **SHALL** contain exactly one [1..1] **id** (CONF: 213).
3. **SHALL** contain exactly one [1..1] P**recondition Extension Pattern** template (templateId 2.16.840.1.113883.10.20.32.4.12) (CONF: 214).
4. ***OnlyOneFalse Pattern***

[precondition: templateId 2.16.840.1.113883.10.20.32.4.18(open)]

1. SHALL contain exactly one [1..1] templateId (CONF: 215) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.18" (CONF: 216).
2. **SHALL** contain exactly one [1..1] **id** (CONF: 217).
3. **SHALL** contain exactly one [1..1] P**recondition Extension Pattern** template (templateId 2.16.840.1.113883.10.20.32.4.12) (CONF: 218).

1. <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm> [↑](#footnote-ref-1)
2. *HL7 Clinical Document Architecture (CDA Release 2).* <http://www.hl7.org/implement/standards/cda.cfm> [↑](#footnote-ref-2)
3. VAS is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. For example, the amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain. From the patient's perspective this spectrum appears continuous- their pain does not take discrete jumps, as a categorization of none, mild, moderate and severe would suggest. It was to capture this idea of an underlying continuum that the VAS was devised [D. Gould et al. “Information Point: Visual Analog Scale (VAS)”, Available at <http://www.cebp.nl/vault_public/filesystem/?ID=1478> (Accessed on 17-March-2013)] [↑](#footnote-ref-3)