CDAR2\_IG\_FDDOC\_R1\_2013APR



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

**Form Defintion Document, Release 1**

April 2013

**HL7 DSTU Ballot**

**Sponsored by:  
Structured Documents Work Group**

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# Open Issues

# 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 for form Definition document. 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 Definitoin 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 <xx> shows the entire ecosystem describing the primary use case.



## Scope

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

<to be filled in later>



## Content of the Package

The following files comprise the package:

Table 1: Content of the Package

|  |  |  |
| --- | --- | --- |
| Filename | Description | Standards Applicability |
|  |  |  |
|  |  |  |

# General, Universal Realm, 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). Each document template defined in the Consolidated CDA guide recommends use of a single preferred clinicalDocument/code. CDA R2 base Form Defintion Document is created by a remote disease management organization(DMO) patient.

## Universal Realm FormDefinition Document Header

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.32 (open)]

1. SHALL contain exactly one [1..1] realmCode **(NC:xxxxx)**.
   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 **(NC:xxxxx)**.
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] header-level templateId (**NC:xxxxx**) such that it
   1. SHALL contain exactly one [1..1] @root=”2.16.840.1.113883.10.20.32” **(NC:xxxxx).**
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 Form Definition document generated. **(NC:xxxxx).**
   2. This code SHould come from the LOINC Document Ontology where Patient Note (51855-5) is the root of the hierarchy. CDA R2 states that LOINC is the preferred vocabulary for document type specification. The Questionnaire Response Document is a universal realm document, therefore it does not mandate use of LOINC; however, LOINC is still the preferred document code vocabulary. **(NC:xxxxx).**
6. SHALL contain exactly one [1..1] title (CONF:5254).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:5256).
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: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).

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 1: UV Realm 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 Defintion 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 2: 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 at least 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 which is generated based on the Form Defition Document, does contain the information about the patient and the related constraints are defined in the Questionnaire Response Document IG.

1. SHALL contain exactly one [1..1] recordTarget (**NC:xxxxx**).
   1. Such recordTargets SHALL contain exactly one [1..1] patientRole (**NC:xxxxx**).
      1. This patientRole SHALL contain exactly one [1..1] id (**NC:xxxxx**).
         1. The value of the recordTarget/patientRole/id/@NullFlavor" SHOULD be "NI" "No Information" 2.16.840.1.113883.5.1008 NullFlavor STATIC (**NC:xxxxx**).

#### RecordTarget Example

Figure 3: UV Realm recordTarget example

<recordTarget>

<patientRole>

<id nullFlavor="NI"/>

</patientRole>

</recordTarget>

### Author

The author element represents the creator of the Form Defintion document. It is usually a healthcare institute.

1. SHALL contain at least one [1..\*] author (**NC:xxxxx**) .
   1. Such authors SHALL contain exactly one [1..1] time (**NC:xxxxx**).
   2. Such authors SHALL contain exactly one [1..1] assignedAuthor (**NC:xxxxx**).
      1. This assignedAuthor SHALL contain exactly one [1..1] id (**NC:xxxxx**).
      2. This assignedAuthor SHould contain zero or more [1..\*] addr (**NC:xxxxx**).
      3. This assignedAuthor SHould contain exactly one [1..\*] telecom
      4. This assignedAuthor **SHALL** contain exactly one [1..1] representedOrganization (**NC:xxxxx**).
      5. There SHALL be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice (**NC:xxxxx**).
      6. This assignedAuthor SHOULD contain zero or one [0..1] assignedPerson (**NC:xxxxx**).
         1. The assignedPerson, if present, SHALL contain at least one [1..\*] name (**NC:xxxxx**).
      7. This assignedAuthor SHOULD contain zero or one [0..1] assignedAuthoringDevice (**NC:xxxxx**).
         1. The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] manufacturerModelName (**NC:xxxxx**).
         2. The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] softwareName (**NC:xxxxx**).
      8. If assignedAuthor has an associated representedOrganization with 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**. (**NC:xxxxx**).

Figure 4: 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>

### Custodian

The custodian element represents the organization that is in charge of maintaining the Form Defintion 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:5519).
   1. This custodian SHALL contain exactly one [1..1] assignedCustodian (CONF:5520).
      1. This assignedCustodian SHALL contain exactly one [1..1] representedCustodianOrganization (**NC:xxxxx**).
         1. This representedCustodianOrganization SHALL contain at least one [1..\*] id (**NC:xxxxx**).
         2. This representedCustodianOrganization SHOULD contain exactly one [1..1] name (**NC:xxxxx**).
         3. This representedCustodianOrganization May contain zero or one [0..1] telecom (**NC:xxxxx**).
            1. This telecom SHOULD contain exactly one [1..1] @use(NEWCONF:xxxxx).
         4. This representedCustodianOrganization May contain zero or one [0..1] addr (NEWCONF:xxxxx).

Figure 5: 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

<Place Holder>.

# Form Definition Document-Level Template

<place holder for providing context information (Informative)>

## Form Definition Document

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.32.2.1 (open)]

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

| **Used By:** | **Contains Entries:** |
| --- | --- |
|  | Form Defintion 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 |  | **NC:xxxxx** |  |
|  | structuredBody | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | component | 1..\* | SHALL |  | **NC:xxxxx** |  |
|  | section | 1..1 | SHALL |  | **NC:xxxxx** |  |

1. SHALL conform to the Universal Realm Form Definition Document Header template
2. SHALLcontain exactly one[1..1]component(**NC:xxxxx**).
   1. **SHALL** contain exactly one [1..1] structuredBody (**NC:xxxxx**)
      1. This structuredBody SHALL contain at least one [1..\*] component (**NC:xxxxx**).
         1. Such components SHALL contain exactly one [1..1] Form Defintion Section template (templateId: 2.16.840.1.113883.10.20.32.2.1) (**NC:xxxxx**).

# Section-Level Templates

This section contains the 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 Defintion Section

[section: templateId 2.16.840.1.113883.10.20.32.2.1 (open)]

Table 6: Form Definition Section Pattern Contexts

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

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

***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 |  | **NC:xxxxx** |  |
|  | @root | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.10.20.32.2.1 |
|  | title | 1..1 | SHOULD |  | **NC:xxxxx** |  |
|  | text | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | entry | 1..\* | SHALL |  | **NC:xxxxx** |  |
|  | @typeCode | 1..1 | SHALL |  |  | DRIV |
|  | organizer | 1..1 | SHALL |  | **NC:xxxxx** |  |

1. **SHALL** contain exactly one [1..1] **templateId** (**NC:xxxxx**) such that it
   1. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.32.2.1" (**NC:xxxxx**).
2. **SHOULD** contain zero or one [1..1] **title** (**NC:xxxxx**).
3. **SHOULD** contain zero or one [1..1] **text** (**NC:xxxxx**).
4. **SHALL** contain at least one [1..\*] **entry** (**NC:xxxxx**) such that it
   1. **SHALL** contain exactly one [1..1] **@typeCode**=”DRIV”
   2. **SHALL** contain exactly one [1..1] Questions Organizer template(templateId: 2.16.840.1.113883.10.20.32.4.1) (**NC:xxxxx**).

***Figure 6: Form Definition Section example***

<seciton>

<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>

</seciton>

# Entry-Level Templates

<place holder for providing context information (Informative)>

## Questions Organizer

[organizer: templateId 2.16.840.1.113883.10.20.32.4.1 (open)]

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

| **Used By:** | **Contains Entries:** |
| --- | --- |
| Form Defintion Section (required) | Numeric Pattern  Multiple Choice 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 |  | **NC:xxxxx** | 2.16.840.1.113883.5.6 (HL7ActClass)=CLUSTER |
|  | @moodCode | | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.5.1001 (ActMood) = DEF |
|  | templateId | | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | @root | | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.10.20.32.4.1 |
|  | id | | 0..1 | SHALL |  | **NC:xxxxx** |  |
|  | code | | 1..1 | SHOULD |  | **NC:xxxxx** |  |
|  | statusCode | | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | @code | | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  | component | | 1..\* | SHALL |  | **NC:xxxxx** |  |
|  | observation | | 1..1 | SHALL |  | **NC:xxxxx** |  |

1. SHALL contain exactly one [1..1] @classCode (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (**NC:xxxxx**).
2. SHALL contain exactly one [1..1] @moodCode="DEF" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (**NC:xxxxx**).
3. SHALL contain exactly one [1..1] templateId (**NC:xxxxx**) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.1" (**NC:xxxxx**).
4. SHALL contain zero or one [0..1] id (**NC:xxxxx**).
5. SHALL contain exactly one [1..1] statusCode (**NC:xxxxx**).
   1. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (**NC:xxxxx**).
6. SHALL contain at least one [1..\*] component (**NC:xxxxx**) such that it
   1. SHALL contain at least one [1..\*] of the following templates (**NC:xxxxx**).
      1. Numeric Question Pattern template(templateID: 2.16.840.1.113883.10.20.32.4.6) (**NC:xxxxx**).
      2. Multiple Choice Question Pattern template(templateID: 2.16.840.1.113883.10.20.32.4.7) (**NC:xxxxx**).

***Figure 7: Questions Organizer Example***

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

<!-- Answers Organizer template -->

<templateId root="2.16.840.1.113883.10.20.32.4.1"/>

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

…mistake..

<statusCode code="ACTIVd"/>

<!--

Conains Continua Numeric, Multiple Choice or other defined templates

-->

<component>

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

<templateID root="2.16.840.1.113883.10.20.32.4.6"/>

...

</observation>

</component>

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

<templateID root="2.16.840.1.113883.10.20.32.4.7”/>

...

</observation>

</organizer>

## Question Media Pattern

[observationMedia: templateId 2.16.840.1.113883.10.20.32.4.2(open)]

<place holder for providing context information (Informative)>

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

| **Used By:** | **Contains Entries:** |
| --- | --- |
| Numeric Question Pattern (optional)  Multiple Choice 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 | **NC:xxxxx** | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL | CD | **NC:xxxxx** | 2.16.840.1.113883.5.1001 (ActMood) = DEF |
|  | templateId | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | @root | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.10.20.32.4.2 |
|  | value | 1..1 | SHALL |  | **NC:xxxxx** |  |

1. SHALL contain exactly one [1..1] @classCode (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (**NC:xxxxx**).
2. SHALL contain exactly one [1..1] @moodCode="DEF" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (**NC:xxxxx**).
3. SHALL contain exactly one [1..1] templateId (CONF:7126) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.2" (**NC:xxxxx**).
4. **SHALL** contain exactly one [1..1] **value** (**NC:xxxxx**)

## Question Precondition Pattern

[precondition: templateId 2.16.840.1.113883.10.20.32.4.3(open)]

<place holder for providing context information (Informative)>

***Table 12: Question Precondition Pattern Contexts***

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

***Table 13: Question Precondition Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | precondition[templateId/@root ='2.16.840.1.113883.10.20.32.4.3'] | | | | | |
|  | @typeCode | 1..1 | SHALL |  | **NC:xxxxx** | PRCN |
|  | templateID | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | @root | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.10.20.32.4.3 |
|  | criterion | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | @classCode | 1..1 | SHALL | CD | **NC:xxxxx** | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL | CD | **NC:xxxxx** | 2.16.840.1.113883.5.1001 (ActMood) = EVN.CRT |
|  | code | 1..1 | SHALL | CE | **NC:xxxxx** |  |
|  | value | 1..1 | SHALL |  | **NC:xxxxx** |  |

1. precondition SHALL contain exactly one [1..1] @typeCode=”PRCN”.
2. SHALL contain exactly one [1..1] templateId (CONF:7126) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.3" (**NC:xxxxx**).
3. **SHALL** contain exactly one [1..1] **criterion** (**NC:xxxxx**)
   1. This criterion SHALL contain exactly one [1..1] @classCode (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (**NC:xxxxx**).
   2. This criterion SHALL contain exactly one [1..1] @moodCode="EVN.CRT" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (**NC:xxxxx**).
   3. This criterion **SHALL** contain exactly one [1..1] **code** (**NC:xxxxx**).
   4. This criterion **SHALL** contain exactly one [1..1] **value** (**NC:xxxxx**).

***Figure 8: Question Criterion Pattern example***

<precondition typeCode="PRCN">

<templateId root="2.16.840.1.113883.10.20.32.4.3"/>

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

<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 2.16.840.1.113883.10.20.32.4.4 (open)]

***Table 14: Question Reference Range Pattern Contexts***

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

<place holder for providing context information (Informative)>

***Table 15: Question Reference Range Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | referenceRanage[templateId/@root ='2.16.840.1.113883.10.20.32.4.4'] | | | | | |
|  | @typeCode | 1..1 | SHALL | CD | **NC:xxxxx** | REFV |
|  | templateID | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | @root | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.10.20.32.4.4 |
|  | observationRange | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | value | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | @xsi:type | 1..1 | SHALL |  | **NC:xxxxx** | IVL\_INT |
|  | low | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | high | 1..1 | SHALL |  | **NC:xxxxx** |  |

1. The referenceRange, SHALL contain exactly one [1..1] @typeCode="REFV" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (**NC:xxxxx**).
2. SHALL contain exactly one [1..1] templateId (CONF:7126) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.4" (**NC:xxxxx**).
3. The referenceRange SHALL contain exactly one [1..1] observationRange (**NC:xxxxx**).
   1. SHALL contain exactly one [1..1] value (**NC:xxxxx**) such that it
      1. SHALL contain exactly one [1..1] @xsi:type=”IVL\_INT” (**NC:xxxxx**).
      2. SHALL contain exactly one [1..1] low (**NC:xxxxx**).
      3. SHALL contain exactly one [1..1] high (**NC:xxxxx**).

## Question Feedback Pattern

[observation: templateId 2.16.840.1.113883.10.20.32.4.5 (open)]

<place holder for providing context information (Informative)>

***Table 16: Question Feeback Pattern Contexts***

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

***Table 17: Question Feedback Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.5'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.5.1001 (ActMood) = DEF |
|  | templateId | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | @root | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.10.20.32.4.5 |
|  | precondition | 0..\* | SHOULD |  | **NC:xxxxx** |  |
|  | text | 1..1 | SHALL | ED | **NC:xxxx** |  |

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (**NC:xxxxx**).
2. **SHALL** contain exactly one [1..1] **@moodCode**="DEF" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (**NC:xxxxx**).
3. **SHALL** contain exactly one [1..1] **templateId** (**NC:xxxxx**) such that it
   1. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.32.4.5" (**NC:xxxxx**).
4. **SHOULD** contain exactly zero or more [1..1] Question Precondition Pattern template(templateId 2.16.840.1.113883.10.20.32.4.3) (**NC:xxxxx**)
5. **SHALL** contain exactly one [1..1] text (**NC:xxxxx**).

***Figure 9: Question Feedback Pattern example***

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

<templateId root="2.16.840.1.113883.10.20.32.4.5"/>

<precondition typeCode="PRCN">

<templateId root="2.16.840.1.113883.10.20.32.4.3"/>

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

<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>

</text>

Don’t take coffee just before going to bed ☺

</text>

<observation>

## Numeric Question Pattern

[observation: templateId 2.16.840.1.113883.10.20.32.4.6 (open)]

<place holder for providing context information (Informative)>

***Table 18: Numeric Question Pattern Contexts***

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

***Table 14: Numeric Question Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.6'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.5.1001 (ActMood) = DEF |
|  | templateId | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | @root | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.10.20.32.4.6 |
|  | id | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | precondition | 0..\* | SHOULD |  | **NC:xxxxx** |  |
|  | code | 1..1 | SHALL | CE | **NC:xxxxx** |  |
|  | @code | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | @codesystem | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | originalText | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | text | 0..1 | SHALL | ED | **NC:xxxx** |  |
|  | value | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | referenceRanage | 0..\* | SHOULD |  | **NC:xxxxx** |  |
|  | entryRelationship | 0..1 | SHOULD |  | **NC:xxxxx** |  |
|  | @typeCode | 1..1 | SHALL | CD | **NC:xxxxx** | REFR |
|  | observationMedia | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | entryRelationship | 0..1 | SHOULD |  | **NC:xxxxx** |  |
|  | @typeCode | 1..1 | SHALL | CD | **NC:xxxxx** | REFR |
|  | observation | 1..1 | SHALL |  | **NC:xxxxx** |  |

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (**NC:xxxxx**).
2. **SHALL** contain exactly one [1..1] **@moodCode**="DEF" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (**NC:xxxxx**).
3. **SHALL** contain exactly one [1..1] **templateId** (**NC:xxxxx**) such that it
   1. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.32.4.6" (**NC:xxxxx**).
4. **SHALL** contain exactly one [1..1] **id** (**NC:xxxxx**)
5. **SHOULD** contain exactly zero or more [1..1] Question Precondition Pattern templates (templateId 2.16.840.1.113883.10.20.32.4.3) (**NC:xxxxx**)
6. **SHALL** contain exactly one [1..1] **code** (**NC:xxxxx**).
   1. This code **SHALL** contain exactly one [1..1] @**code** (**NC:xxxxx**).
   2. This code **SHALL** contain exactly one [1..1] @**codeSystem** (**NC:xxxxx**).
   3. This code **SHALL** contain exactly one [1..1] **@originalText** (**NC:xxxxx**)
7. **MAY** contain zero or one [0..1] text (**NC:xxxxx**).
8. **SHALL** contain exactly one [1..1] **value** (**NC:xxxxx**)
9. **SHOULD** contain zero or more [0..\*] Question Reference Range Pattern template (templateId 2.16.840.1.113883.10.20.32.4.4) (**NC:xxxxx**)
10. **SHOULD** contain zero or one [0..1] entryRelationship (**NC:xxxxx**)
    1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (**NC:xxxxx**).
    2. SHALL conform to the Question Media Pattern template (templateId 2.16.840.1.113883.10.20.32.4.2) (**NC:xxxxx**)..
11. **SHOULD** contain zero or one [0..1] entryRelationship (**NC:xxxxx**)
    1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (**NC:xxxxx**).
    2. SHALL conform to the Question Feedback Pattern template (templateId 2.16.840.1.113883.10.20.32.4.5) (**NC:xxxxx**).

***Figure 10: Numeric Question Pattern example***

<entry>

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

<templateId root="2.16.840.1.113883.10.20.32.4.6"/>

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

<code code="q1" codeSystem="CONTINUA-QA-OID">

<originalText>How many hour do you sleep last night?</originalText>

</code>

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

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

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

<referenceRange typeCode="REFV">

<observationRange>

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

<low value='0'/>

<high value='24'/>

</value>

</observationRange>

</referenceRange>

<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>

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

<entryRelationship typeCode="REFR">

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

<templateId root="2.16.840.1.113883.10.20.32.4.5"/>

<precondition typeCode="PRCN">

<templateId root="2.16.840.1.113883.10.20.32.4.3"/>

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

</code>

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

<low value='2'/>

<high value='6'/>

</value>

</precondition>

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

</observation>

</entryRelationship>

</observation>

</entry>

## Multiple Choice Question Pattern

[observation: templateId 2.16.840.1.113883.10.20.32.4.7 (open)]

<place holder for providing context information (Informative)>

***Table 20: Multiple Choice Question Pattern Contexts***

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

***Table 15: Multiple Choice Question Pattern Constraints Overview***

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.7'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  | @moodCode | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.5.1001 (ActMood) = DEF |
|  | templateId | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | @root | 1..1 | SHALL |  | **NC:xxxxx** | 2.16.840.1.113883.10.20.32.4.7 |
|  | id | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | precondition | 0..\* | SHOULD |  | **NC:xxxxx** |  |
|  | code | 1..1 | SHALL | CE | **NC:xxxxx** |  |
|  | @code | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | @codesystem | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | originalText | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | text | 0..1 | SHALL | ED | **NC:xxxx** |  |
|  | value | 2..\* | SHALL |  | **NC:xxxxx** |  |
|  | @xsi:type | 1..1 | SHALL |  | **NC:xxxxx** | CE |
|  | @code | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | @codesystem | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | @displayName | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | referenceRanage | 0..\* | SHOULD |  | **NC:xxxxx** |  |
|  | entryRelationship | 0..1 | SHOULD |  | **NC:xxxxx** |  |
|  | @typeCode | 1..1 | SHALL | CD | **NC:xxxxx** | REFR |
|  | observationMedia | 1..1 | SHALL |  | **NC:xxxxx** |  |
|  | entryRelationship | 0..1 | SHOULD |  | **NC:xxxxx** |  |
|  | @typeCode | 1..1 | SHALL | CD | **NC:xxxxx** | REFR |
|  | observation | 1..1 | SHALL |  | **NC:xxxxx** |  |

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (**NC:xxxxx**).
2. **SHALL** contain exactly one [1..1] **@moodCode**="DEF" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (**NC:xxxxx**).
3. **SHALL** contain exactly one [1..1] **templateId** (**NC:xxxxx**) such that it
   1. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.32.4.7" (**NC:xxxxx**).
4. **SHALL** contain exactly one [1..1] **id** (**NC:xxxxx**)
5. **SHOULD** contain exactly zero or more [1..1] Question Precondition Pattern templates (templateId 2.16.840.1.113883.10.20.32.4.3) (**NC:xxxxx**)
6. **SHALL** contain exactly one [1..1] **code** (**NC:xxxxx**).
   1. This code **SHALL** contain exactly one [1..1] @**code** (**NC:xxxxx**).
   2. This code **SHALL** contain exactly one [1..1] @**CodeSystem** (**NC:xxxxx**).
   3. This code **SHALL** contain exactly one [1..1] **@originalText** (**NC:xxxxx**)
7. **MAY** contain zero or one [0..1] text (**NC:xxxxx**).
8. **SHALL** contain at least two or more [2..\*] **value** (**NC:xxxxx**)
   1. SHALL contain exactly one [1..1] @xsi:type="CE" (**NC:xxxxx**).
   2. This code **SHALL** contain exactly one [1..1] @**code** (**NC:xxxxx**).
   3. This code **SHALL** contain exactly one [1..1] @**CodeSystem** (**NC:xxxxx**).
9. **SHOULD** contain zero or more [0..\*] Question Reference Range Pattern template (templateId 2.16.840.1.113883.10.20.32.4.4) (**NC:xxxxx**)
10. **SHOULD** contain zero or one [0..1] entryRelationship (**NC:xxxxx**)
    1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (**NC:xxxxx**).
    2. SHALL conform to the Question Media Pattern template (templateId 2.16.840.1.113883.10.20.32.4.2) (**NC:xxxxx**).
11. **SHOULD** contain zero or one [0..1] entryRelationship (**NC:xxxxx**)
    1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (**NC:xxxxx**).
    2. SHALL conform to the Question Feedback Pattern template (templateId 2.16.840.1.113883.10.20.32.4.5) (**NC:xxxxx**)

***Figure 11: Multiple Choice Question Pattern example***

<entry>

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

<templateId root="2.16.840.1.113883.10.20.32.4.7"/>

<id extension="q2" codeSystem="CONTINUA-ID-OID">

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

<precondition typeCode="PRCN">

<templateId root="2.16.840.1.113883.10.20.32.4.3"/>

<criterion>

<code code="q1" codeSystem="CONTINUA-QA-OID">

</code>

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

<low value='2'/>

<high value='6'/>

</value>

</criterion>

</precondition>

<precondition typeCode="PRCN">

</precondition>

<code code="GUID" codeSystem="CONTINUA-QA-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"/>

<referenceRange typeCode="REFV">

<templateId root="2.16.840.1.113883.10.20.32.4.4"/>

<observationRange>

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

<low value='1'/>

<high value='3'/>

</value>

</observationRange>

</referenceRange>

<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>

<entryRelationship typeCode="REFR">

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

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

<templateId root="2.16.840.1.113883.10.20.32.4.5"/>

<precondition typeCode="PRCN">

<templateId root="'2.16.840.1.113883.10.20.32.4.3"/>

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

</code>

<value code="a2" codeSystem="CONTINUA-ANS-OID">

</precondition>

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

</observation>

</entryRelationship>

</observation>

</entry>

***Figure 12: Text Question Pattern example***

<entry>

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

<templateId root=" x.x.x.x.x.x.x.x.x.x "/>

<id extension="q2" codeSystem="CONTINUA-ID-OID">

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

<precondition typeCode="PRCN">

<templateId root="2.16.840.1.113883.10.20.32.4.3"/>

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

</code>

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

</precondition>

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

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

</code>

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

</observation>

</entry>

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** |
| --- | --- | --- |
| Form Definition Document-Level Template | document | 2.16.840.1.113883.10.20.32.1.1 |
| Section-Level Templates | document | 2.16.840.1.113883.10.20.32.2.1 |
| 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 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 |
| Numeric Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.6 |
| Multiple Choice Question Pattern | entry | 2.16.840.1.113883.10.20.32.4.7 |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

Table 14: Template Containments

| Template Title | Template Type | templateId |
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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)