medcom

HL7 Implementation Guide for CDA Release 2

Questionnaire Form Definition Document (Danish profile – DK QFDD)

Release 1.2

February 11th 2022

Revision history			
Release	**Auther**	**Date**	**Notes**
1.0	MedCom, MDM	2015-05-19	Danish profile QFDD
1.1	MedCom, MDM	2016-09-28	OID's changed to reflect MedCom OID 1.2.208.184.x.x.x To provide better search facilities in this document all pictures showing xml-code examples changed to tables with real xml code.
1.1	MedCom, MDM	2019-10-23	"Draft" fjernet.
1.1	MedCom, MDM	2020-02-17	Type error on page 31, Table 23: @code="744467-2" changed to @code="74467-2"
1.1	MedCom, MDM	2020-04-23	The numbers # of following errors and improvements refers to: https://svn.medcom.dk/svn/drafts/Standarder/HL7/PRO/PRO-infrastrukturen, diverse fund_v2.xlsx #1) Description of Information Only sections added #2) Precondition Pattern: In figure 11 precondition templateId was wrong. Changed from 2.16.840.1.113883.10.20.32.4.3 to 2.16.840.1.113883.10.20.32.4.4 #3 Copy Right Pattern Contexts on pg. 34, Table 26: Wrongly presented recursively use of Copy Right Observation. Possible ways to use Copy Right now added. #4) Numeric Question Pattern on pg. 36 & 37: Clarification of the use of Media observation and the use of feedback observation. #5) Text Question Pattern: On pg. 45, Bullet 3 templateId@root was wrong. Changed from 2.16.840.1.113883.10.20.32.4.6 to 2.16.840.1.113883.10.20.32.4.9 #6) Analog Slider Question Pattern: On pg. 46, Table 34 the header was wrong. Changed from Text Question Pattern Contexts to Analog Slider Question Pattern Contexts #7) Analog Slider Question Pattern Observation: On pg. 46, Table 35 the last zero in templateId@root=" 2.16.840.1.113883.10.20.32.4.10" appeared on the next page. Column width has now been changed. #8) Analog Slider Question Pattern Observation: On pg. 47, Bullet 4 denominator is wrongly described as a sub-element to value. Bullet 4 changed so denominator is described as an attribute. #9) Precondition Extension Pattern: On pg. 52, Bullet 5 negationInd is wrongly described as a sub-element to sdtc:precondition. Bullet 5 changed so negationInd is described as an attribute. Table of templateId's added in Appendix B: Template Ids used in QFDD.
1.1	MedCom, MDM	2020-05-06	assigningAuthorityName="MedCom" replaced by "Some Authority" "MedCom Prompt Table" replaced by "Some Table"

1.1	MedCom, SGA	2021-05-06	Minor adjustment:
			- New layout and remove empty pages
			- Add missing internal document cross-reference
			- Add reference to Narrative Block guidance
			  o QFDD content and CDA content
			- Update list of examples
			  o QFDD content

1.1	MedCom, SGA	2021-06-11	Minor adjustment:
			- Reference to DK-CDA-Header Implementation Guide v1.4, for further clarification and elaboration.
			See reference and descriptions here:
			  o QFDD content
			  o Questionaire Form Definition Document header template
			  o RecordTarget

1.2	MedCom, SGA	2022-02-11	Guideline in filling the `ClinicalDocument/id` element in Danish Profile Questionnaire Form Definition Document Header, list element 4.a

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1 INTRODUCTION

1.1 Audience

The audience for this document includes software developers and implementers of products and services that enable authoring, management, and administration of patient health questionnaires 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 Questionnaire Form Definition documents (home monitoring and patient surveys) created according to this specification.

1.2 Purpose

This document is a Danish profile of the Clinical Document Architecture (CDA) Release 2, Questionnaire Form Definition Document, Release 1.

The purpose of a Questionnaire Form Definition Document is to define health survey questions or question sets to be answered by the individual patient. Questionnaire 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 Questionnaire 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 Questionnaire Form Definition Documents may include disease management organizations, primary care physicians, health and fitness coaches, chronic condition monitors, post-acute and long-term care organizations.

1.2.1 Typical Use Case

The primary use case for the Questionnaire Form Definition Document involves the Questionnaire Form Definition author.

After creation of the Questionnaire Form Definition Document by the author, it is placed in a repository that is accessible by a disease management service. Subsequently, the disease management service will fetch the Questionnaire Form Definition Document from the repository and send it to the application hosting device based on a prescribed order or schedule.

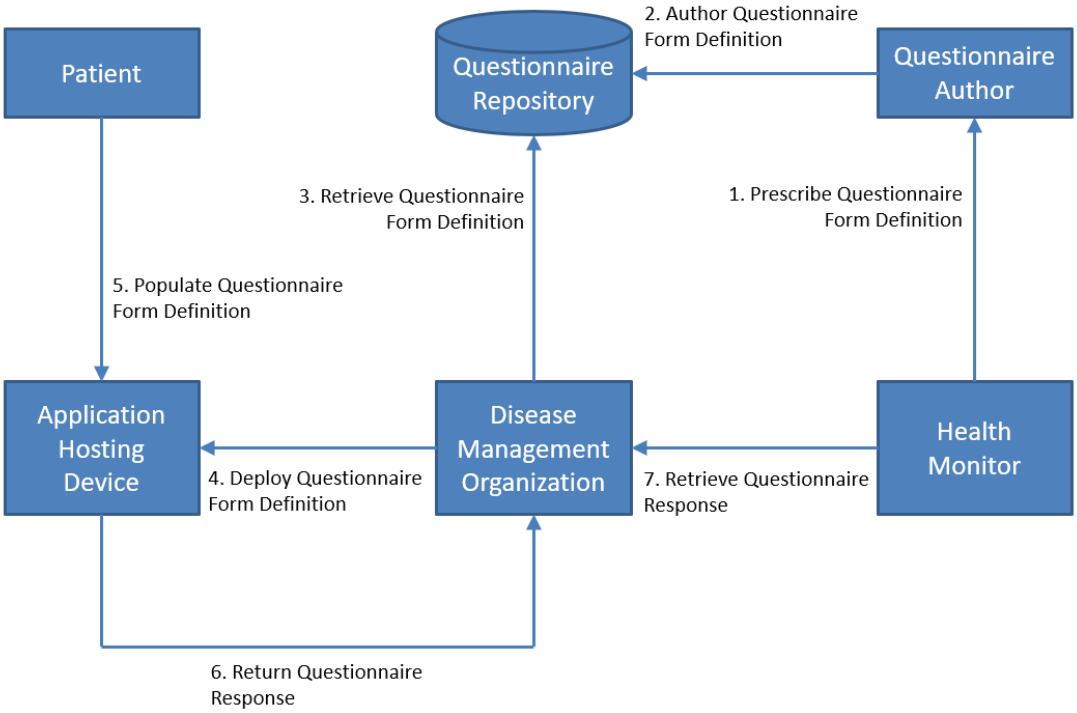

Figure 1: Typical Use Case

The application hosting device will notify the patient that a new Questionnaire Form Definition Document is available to be filled. 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. Figure 1 shows the entire ecosystem describing the typical use case.

1.3 Scope

This implementation guide is a conformance profile, as described in the "Refinement and Localization"[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]. This implementation guide does not describe every aspect of the CDA. Rather, it defines constraints on the base CDA used in Questionnaire Form Definition Document for the Danish profile.

1.4 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 document 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.

1.4.1 Keywords

The keywords **SHALL**, **SHALL NOT**, **SHOULD**, **SHOULD NOT**, **MAY**, and **NEED NOT** in this document is to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide:

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

The keyword **SHALL** allow the use of nullFlavor unless the requirement is on an attribute or the use of nullFlavor is explicitly precluded.

1.4.2 Conformance Requirements

The constraints in the original Questionnaire Form Definition Document are carried on by using the original conformance identification identifier **CONF:XX.**

If an original constraint is not used in the Danish profile the number is omitted. In most cases new constraints in the Danish profile are added by using the conformance identification identifier **CONF-DK:XX**.

All conformance requirements are numbered sequentially.

1.5 Organization of This Guide

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

- **Chapter 2:** Questionnaire 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:** Questionnaire Form Definition Document-Level Template defines the document constraints that apply to Questionnaire Form Definition Documents.
- **Chapter 4:** Section-Level Templates defines the section templates in Questionnaire Form Definition Documents.
- **Chapter 5:** Entry-Level Templates defines the entry template in Questionnaire Form Definition Documents.

1.6 Content of the Package

The following files comprise the package.

1.6.1 QFDD content

[1] http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm
[2] *HL7 Clinical Document Architecture (CDA Release 2).* http://www.hl7.org/implement/standards/cda.cfm

Files are located here: http://svn.medcom.dk/svn/releases/Standarder/HL7/PRO/QFDD/

Filename	Description	Standards Applicability
"Dokumentation" folder `DK-QFDD-v1.2.pdf`	This implementation guide	Normative
DK-CDA-Header Implementation Guide http://svn.medcom.dk/svn/releases/Standarder/HL7/CDA Header/Dokumentation/DK-CDA-Header.pdf	For further clarification and elaboration, refer to the DK-CDA-Header Implementation Guide v1.4	Normative
"Dokumentation" folder `NarrativeBlock_QFDD_-_Implementation_Guidance-vX.X.pdf`	A guidance to facilitate the development work of CDA narrative block	Informative
"Eksempler" folder `Overview_QFDD-QRD-link-resolving.xlsx`	The sample CDA XML file that includes examples of templates discussed in this guide:	Informative
"Schema" folder	Normative CDA R2 schema files to validate a Questionnaire Form Definition document instance.	Informative

Table 1: QFDD Content of the Package

1.6.2 CDA content

Filename and location	Description	Standards Applicability
`Narrative Block - Implementation Guidance.pdf` http://svn.medcom.dk/svn/releases/Standarder/HL7/NarrativeBlock/	Implementation Guidance: Narrative Block Tag.	Informative
http://svn.medcom.dk/svn/drafts/Standarder/HL7/CDA-Stylesheet/HL7_CDA/HL7_CDA_stylesheet.xsl	Stylesheet for display of CDA instances	Informative

Table 2: CDA Content of the Package

2 QUESTIONAIRE FORM DEFINITION DOCUMENT HEADER TEMPLATE

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

For further clarification and elaboration, refer to the DK-CDA-Header Implementation Guide v1.4. In case of conflicting requirements, it will be this current Implementation Guide that weighs the most.

2.1 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.

This Questionnaire Form Definition template is a Danish profile document, where LOINC is the preferred document code vocabulary.

2.2 Danish Profile Questionnaire Form Definition Document Header

`[ClinicalDocument: templateId 1.2.208.184.12.1]`

1. **SHALL** contain exactly one [1..1] `realmCode` (CONF:1).
    a. 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).
    a. This `typeId` **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.1.3"` (CONF:4).
    b. 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
    a. **SHALL** contain exactly one [1..1] `@root="2.16.208.184.12.1"` (CONF-DK:1).
4. **SHALL** contain exactly one [1..1] `id` (CONF:8).
    a. This `id` **SHALL** be a globally unique identifier for the document (CONF:9).
        i. The extension element **SHALL** be at unique version 4 UUID (CONF-DK:14)
        ii. The root element **SHALL** be a valid OID representing the responsible organization for the QFDD (CONF-DK:15)
        iii. The assigningAuthorityName element **SHALL** be the name for the responsible organization forthe QFDD (CONF-DK:16)
5. **SHALL** contain exactly one [1..1] `code` (CONF:10).
    a. This code **SHALL** specify the Questionnaire Form Definition Document (CONF-DK:2).
    b. This code **SHALL** be code = 74468-0 from (CodeSystem: LOINC `1.3.6.1.4.1.12009.10.2.5`) (CONF-DK:3).
6. **SHALL** contain exactly one [1..1] `title` (CONF:13).
7. **SHALL** contain exactly one [1..1] `sdtc:statusCode` (CONF:14).
8. This `statusCode` **SHALL** contain exactly one [1..1] `@code="NEW"` (CodeSystem: `ActStatus 2.16.840.1.113883.5.14`) (CONF:15).
9. **SHALL** contain exactly one [1..1] `effectiveTime` (CONF:16).
10. **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:17).
    a. This code **SHALL** always be set to "N" (CONF-DK:4).
11. **SHALL** contain exactly one [1..1] `languageCode`, which **SHALL** be selected from ValueSet Language `2.16.840.1.113883.1.11.11526` **DYNAMIC** (CONF:18).

Value Set: HL7 DK Confidentiality codes Code System: 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: HL7 Basic Confidentiality Kind Value Set

Value Set: Language 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	Frensh
Ar	Internet Society Language	Arabic
en_US	Internet Society Language	English, US
es-US	Internet Society Language	Spanish, US
…		

Table 4: Language Value Set

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument
   classCode="DOCCLIN"
   moodCode="EVN"
   xmlns="urn:hl7-org:v3"
   xmlns:sdtc="urn:hl7-org:sdtc"
   xmlns:voc="urn:hl7-org:v3/voc">
   <realmCode
      code="UV"/>
   <typeId
      extension="POCD_HD000040"
      root="2.16.840.1.113883.1.3"/>
   <!-- MedCom Danish QFDD-profile OID -->
   <templateId
      root="1.2.208.184.12.1"/>
   <!-- The next templateId, indicates constraints at the Questionnaere Form Definition
Document-level -->
   <templateId
      root="1.2.208.184.12.1.1.1"/>
   <id
      assigningAuthorityName="Name for the responsible organisation for the QFDD"
      extension="c8f1acf0-2e28-11e6-bdf4-0800200c9a66"
      root="1.2.208.1.1"/>
   <!-- This code is LOINC -->
   <code
      code="74468-0"
      codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC"
      displayName="Form Definition Document"/>
   <title>KOL spørgeskema</title>
   <sdtc:statusCode
      code="new"/>
   <effectiveTime
      value="20160609123030+0200"/>
   <confidentialityCode
      code="N"
      codeSystem="2.16.840.1.113883.5.25"/>
   <languageCode
      code="da-DK"/>
   <recordTarget>
      <patientRole>
         <id
            nullFlavor="NI"/>
      </patientRole>
   </recordTarget>
```

Figure 2: DK Realm Questionnaire Form Definition document header example

```
<effectiveTime value="20160609123030+0200"/>
```

Figure 3: effectiveTime with time zone example

2.2.1 RecordTarget

The following overrules the constraints specified in the DK-CDA Header Implementation Guide.

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 Questionnaire Form Definition Document Implementation Guide, the recordTarget contains “No Information”. This is indicated by using the nullFlavor="`NI`".

A Questionnaire Response Document[3], which is generated based on the Questionnaire Form Definition 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:19).
    a. Such `recordTargets` **SHALL** contain exactly one [1..1] `patientRole` (CONF:20).
        i. This `patientRole` **SHALL** contain exactly one [1..1] `id` (CONF:21).
            a. The value of the `recordTarget/patientRole/id/@NullFlavor` **SHALL** be "NI" "No Information" 2.16.840.1.113883.5.1008 NullFlavor **STATIC** (CONF:22).

```
recordTarget>
   <patientRole>
      <id nullFlavor="NI"/>
   </patientRole>
</recordTarget>
```

Figure 4: DK realm recordTarget Example

[3] HL7 Implementation Guide for CDA Release 2.0: Questionnaire Response Document. Danish Profile. DK-QRD

2.2.2 Author

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

2. **SHALL** contain at least one [1..*] `author` (CONF:23).
    a. Such `authors` **SHALL** contain exactly one [1..1] `time` (CONF:24).
    b. Such `authors` **SHALL** contain exactly one [1..1] `assignedAuthor` (CONF:25).
        i. This `assignedAuthor` **SHALL** contain exactly one [1..1] `id` (CONF:26).
        ii. This `assignedAuthor` **SHALL** contain at least one [1..*] `addr` (CONF:27).
        iii. This `assignedAuthor` **SHALL** contain at least one [1..*] `telecom` (CONF:28).
        iv. There **SHALL** be exactly one `assignedAuthor/assignedPerson` (CONF-DK:5).
        v. This `assignedAuthor` **SHOULD** contain zero or one [0..1] `assignedPerson` (CONF:30).
            a. The `assignedPerson`, if present, **SHALL** contain at least one [1..*] `name` (CONF:31).
        vi. This `assignedAuthor` **SHALL** contain exactly one [1..1] `representedOrganization` (CONF:35).
        vii. If `assignedAuthor` has an associated `representedOrganization` and no `assignedPerson`, then the value for `"ClinicalDocument/author/assignedAuthor/id/@NullFlavor"` **SHALL** be "NA" "Not applicable" `2.16.840.1.113883.5.1008` NullFlavor **STATIC** (CONF-DK:6).

```
<author
   contextControlCode="OP"
   typeCode="AUT">
   <time
      value="20160609120130+0200"/>
   <assignedAuthor
      classCode="ASSIGNED">
      <!-- This is the identfication of the organization, we don't use the personal level
identification-->
      <id
         assigningAuthorityName="SOR"
         extension="368061000016003"
         root="1.2.208.176.1.1"/>
      <addr
         use="WP">
         <streetAddressLine>Lungemedicinsk afdeling</streetAddressLine>
         <streetAddressLine>Mølleparkvej 4</streetAddressLine>
         <postalCode>9000</postalCode>
         <city>Aalborg</city>
         <country>Danmark</country>
      </addr>
      <telecom
         use="WP"
         value="tel:97664800"/>
      <assignedPerson
         classCode="PSN"
         determinerCode="INSTANCE">
         <name>
            <given>Anders</given>
            <family>Andersen</family>
         </name>
      </assignedPerson>
      <representedOrganization
         classCode="ORG"
         determinerCode="INSTANCE">
         <id
            assigningAuthorityName="SOR"
            extension="368061000016003"
            root="1.2.208.176.1.1"/>
         <name>Aalborg Universitetshospital</name>
         <telecom
            nullFlavor="NI"/>
         <addr
            use="WP">
            <streetAddressLine
               nullFlavor="NI"/>
         </addr>
      </representedOrganization>
   </assignedAuthor>
</author>
```

Figure 5: Person author example

2.2.3 Custodian

The `custodian` element represents the organization that is in charge of maintaining the Questionnaire Form Definition Document (e.g. a hospital, an ambulatory, General Practitioner). The custodian is the steward that is entrusted with the care of the document. The Questionnaire Form Definition Document has exactly one custodian.

3. **SHALL** contain exactly one [1..1] `custodian` (CONF:37).
    a. This `custodian` **SHALL** contain exactly one [1..1] `assignedCustodian` (CONF:38).
        i. This `assignedCustodian` **SHALL** contain exactly one [1..1] `representedCustodianOrganization` (CONF:39).
            1. This `representedCustodianOrganization` **SHALL** contain at least one [1..*] `id` (CONF:40).
            2. This `representedCustodianOrganization` **SHOULD** contain exactly one [1..1] `name` (CONF:41).
            3. This `representedCustodianOrganization` **SHALL** contain exactly one [1..1] `telecom` (CONF:42).
            4. This `representedCustodianOrganization` **SHALL** contain exactly one [1..1] `addr` (CONF:43).

```
<custodian
   typeCode="CST">
   <assignedCustodian
      classCode="ASSIGNED">
      <representedCustodianOrganization
         classCode="ORG"
         determinerCode="INSTANCE">
         <id
            assigningAuthorityName="SOR"
            extension="368061000016003"
            root="1.2.208.176.1.1"/>
         <name>Aalborg Universitetshospital</name>
         <telecom
            use="WP"
            value="tel:97664800"/>
         <addr
            use="WP">
            <streetAddressLine>Lungemedicinsk afdeling</streetAddressLine>
            <streetAddressLine>Mølleparkvej 4</streetAddressLine>
            <postalCode>9000</postalCode>
            <city>Aalborg</city>
            <country>Danmark</country>
         </addr>
      </representedCustodianOrganization>
   </assignedCustodian>
</custodian>
```

Figure 6: Custodian example

2.3 Rendering Header Information for Human Presentation

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

- Document title and document date
- Author of the Questionnaire Form Definition Document.
- Name of the organization who created the Questionnaire Form Definition Document along with the address, and telecommunications information
- Custodian who is managing the document, which may be the same organization as the author organization.

3 QUESTIONNAIRE FORM DEFINITION DOCUMENT-LEVEL TEMPLATE

This chapter defines the document-level template used in the Questionnaire 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.

3.1 Questionnaire Form Definition Document

`[ClinicalDocument: templateId 1.2.208.184.12.1.1.1]`

This template describes constraints that apply to the Questionnaire Form Definition Document containing set of questions.

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

Used By:	Contains Entries:
	Questionnaire Form Definition Section Copy Right Section Information Only Section

Table 5: Questionnaire Form Definition Document-Level Contexts

Name	XPath	Card	Verb	Data Type	CONF#	Fixed Value
	ClinicalDocument[templateId/@root = '1.2.208.184.12.1.1.1]					
	templateId	1..1	**SHALL**		CONF:45	
	@root	1..1	**SHALL**		CONF:46	1.2.208.184.12.1.1.1
	Component	1..1	**SHALL**		CONF:47	
	structuredBody	1..1	**SHALL**		CONF:48	
	component	1..*	**SHALL**		CONF:49	
	Section	1..1	**SHALL**		CONF:50	

Table 6: Questionnaire Form Definition Document-Level Constraint Overview

1. **SHALL** conform to the Danish Profile Questionnaire Form Definition Document Header template (`templateId: 1.2.208.184.12.1`) (CONF-DK:7).
2. **SHALL** contain exactly one [1..1] `templateId` (CONF:45) such that it
    a. **SHALL** contain exactly one [1..1] `@root="1.2.208.184.12.1.1.1"` (CONF-DK:8).
3. **SHALL** contain exactly one [1..1] `component` (CONF:47).
    a. **SHALL** contain exactly one [1..1] `structuredBody` (CONF:48).
        i. This `structuredBody` **SHALL** contain at least one [1..*] `component` (CONF:49) such that it
            1. **SHALL** contain exactly one [1..1] Questionnaire Form Definition Section template (`templateId: 2.16.840.1.113883.10.20.32.2.1`) (CONF:50).
            2. **SHALL** contain exactly one [1..1] Copy Right Section template (`templateId: 2.16.840.1.113883.10.20.32.2.2`) (CONF:51).
            3. **SHALL** contain exactly one [1..1] Information Only Section template (`templateId: 2.16.840.1.113883.10.20.32.2.1`).

4 SECTION-LEVEL TEMPLATES

This section contains section-level templates used by the Questionnaire 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)

4.1 Questionnaire Form Definition Section

`[section: templateId 2.16.840.1.113883.10.20.32.2.1]`

A Questionnaire Form Definition Document consists of sections that groups related questions. Section titles ease human-readability and navigation in the document. Section codes help with the recipient's interpretation of a 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.

Used By:	Contains Entries:
Questionnaire form definition document-level template (required)	Questions Organizer

Table 7: Questionnaire Form Definition Section Pattern Contexts

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:52	
	@root	1..1	**SHALL**		CONF:53	2.16.840.1.113883.10.20.32.2.1
	code	1..1	**SHALL**		CONF:54	74468-0
	title	0..1	**SHOULD**		CONF:55	
	text	1..1	**SHALL**		CONF:56	
	languageCode	0..1	**SHOULD**		CONF:57	
	entry	1..*	**SHALL**		CONF:58	
	@typeCode	1..1	**SHALL**		CONF:59	DRIV
	organizer	1..1	**SHALL**		CONF:60	

Table 8: Questionnaire Form Definition Section Constraint Overview

1. **SHALL** contain exactly one [1..1] `templateId` (CONF:52) such that it
    a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.2.1"` (CONF:53).
2. **SHALL** contain exactly one [1..1] `code` (CONF:54).
3. **SHOULD** contain zero or one [0..1] `title` (CONF:55).
4. **SHALL** contain exactly one [1..1] `text` (CONF:56).
    a. See NarrativeBlock_QFDD_-_Implementation_Guidance-vX.X.pdf
5. **SHOULD** contain zero or one [0..1] `languageCode` which **SHALL** be selected from ValueSet `Language 2.16.840.1.113883.1.11.11526` **DYNAMIC** (CONF:57).
6. **SHALL** contain at least one [1..*] `entry` (CONF:58) such that it
    a. **SHALL** contain exactly one [1..1] `@typeCode="DRIV"` (CONF:59)
    b. **SHALL** contain exactly one [1..1] Questions Organizer template `(templateId: 2.16.840.1.113883.10.20.32.4.1)` (CONF:60).

```
<section
   classCode="DOCSECT"
   moodCode="EVN">
   <templateId
      root="2.16.840.1.113883.10.20.32.2.1"/>
   <code
      code="74468-0"
      codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC"/>
   <title>Spørgsmål 1</title>
   <text>Hvor mange gange om dagen...</text>
   <entry
      contextConductionInd="true"
      typeCode="DRIV">
      <organizer
         classCode="BATTERY"
         moodCode="EVN">
         ...
      </organizer>
   </entry>
</section>
```

Figure 7: Questionnaire Form Definition Section example

4.2 Copy Right Section

`[section: templateId 2.16.840.1.113883.10.20.32.2.2]`

Copy Right Section is used to record copyright information related to the content of a Questionnaire Form Definition. It also contains a structured entry for recording the copyright information in machine readable form.

Note: Copy Right description may be "stamped" on any question in the questionnaire using Copy Right Pattern Observation.

Used By:	Contains Entries:
Questionnaire form definition document-level template (optional)	Copy Right Pattern Observation

Table 9: Copy Right Section Pattern Contexts

Name	XPath	Card	Verb	DataType	CONF#	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.32.2.2']					
	templateId	1..1	**SHALL**		CONF:61	
	@root	1..1	**SHALL**		CONF:62	2.16.840.1.113883.10.20.32.2.2
	Title	0..1	**SHOULD**		CONF:63	
	Text	1..1	**SHALL**		CONF:64	
	languageCode	0..1	**SHOULD**		CONF:65	
	Entry	1..*	**SHALL**		CONF:66	
	@typeCode	1..1	**SHALL**		CONF:67	DRIV
copyRightPattern	Observation	1..1	**SHALL**		CONF:68	

Table 10: Copy Right Section Constraints Overview

1. **SHALL** contain exactly one [1..1] `templateId` (CONF:61) such that it
   a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.2.2"` (CONF:62).
2. **SHOULD** contain zero or one [0..1] `title` (CONF:63).
3. **SHALL** contain exactly one [1..1] `text` (CONF:64).
4. **SHOULD** contain zero or one [0..1] `languageCode` which **SHALL** be selected from ValueSet `Language 2.16.840.1.113883.1.11.11526` **DYNAMIC** (CONF:65).
5. **SHALL** contain at least one [1..*] `entry` (CONF:66) such that it
   a. **SHALL** contain exactly one [1..1] `@typeCode="DRIV"` (CONF:67)
   b. **SHALL** contain exactly one [1..1] Copy Right Pattern Observation template (templateId: 2.16.840.1.113883.10.20.32.4.21) (CONF:68).

```
<component
   contextConductionInd="true"
   typeCode="COMP">
   <section
      classCode="DOCSECT"
      moodCode="EVN">
      <!--templateID for the Copyright Section-->
      <templateId
         root="2.16.840.1.113883.10.20.32.2.2"/>
      <title>Copyright section</title>
      <text>Copyright section</text>
      <languageCode
         code="da-DK"/>
      <entry
         contextConductionInd="true"
         typeCode="DRIV">
         <observation
            classCode="OBS"
            moodCode="EVN">
            <!--templateID for the Copyright Pattern Observation-->
            <templateId
               root="2.16.840.1.113883.10.20.32.4.21"/>
            <code
               code="COPY"
               codeSystem="2.16.840.1.113883.6.1"
               codeSystemName="LOINC"
               displayName="Code for Copyright"/>
            <value
               xsi:type="ST">Copyright tekst skrives her</value>
         </observation>
      </entry>
   </section>
</component>
```

Figure 8: Copy Right Section example

4.3 Information Only Section

`[section: templateId 2.16.840.1.113883.10.20.32.2.1 (OPEN)]`

Information Only Sections has no entry element and are used to present information to the end-user.

Information Only Sections can be placed anywhere an ordinary section can be placed. In this QFDD version it has the templateId of the Questionnaire Form Definition Section.

In the next QFDD version Information Only Sections will get its own unique templateId.

Used By:	Contains Entries:
Questionnaire form definition document-level template (optional)	Information Only Section

Table 11: Information Only Section Pattern Contexts

Name	XPath	Card	Verb	Data Type	CONF#	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.32.2.1' (OPEN)]					
	templateId	1..1	**SHALL**		CONF-DK:9	
	@root	1..1	**SHALL**		CONF-DK:10	2.16.840.1.113883.10.20.32.2.1 (OPEN)
	Title	0..1	**SHOULD**		CONF-DK:11	
	Text	1..1	**SHALL**		CONF-DK:12	
	languageCode	0..1	**SHOULD**		CONF-DK:13	

Table 12: Information Only Section Constraints Overview

1. **SHALL** contain exactly one [1..1] `templateId` (CONF-DK:9) such that it
   a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.2.1"` (CONF-DK:10).
2. **SHOULD** contain zero or one [0..1] `title` (CONF-DK:11).
3. **SHALL** contain exactly one [1..1] `text` (CONF-DK:12).
4. **SHOULD** contain zero or one [0..1] `languageCode` which **SHALL** be selected from ValueSet `Language 2.16.840.1.113883.1.11.11526` **DYNAMIC** (CONF-DK:13).

```
<component
   contextConductionInd="true"
   typeCode="COMP">
   <section
      classCode="DOCSECT"
      moodCode="EVN">
      <!--templateID for Section-->
      <templateId
         root="2.16.840.1.113883.10.20.32.2.1"/>
      <title>Title, Information Only Section</title>
      <text>
         <paragraph>
            <content styleCode="Bold">
              OM DETTE EKSEMPEL:
            </content><br/>
            Dette eksempel viser brug af
            <content styleCode="Underline">
              INFO-SEKTION
            </content>.
         </paragraph>
      </text>
      <languageCode
         code="da-DK"/>
   </section>
</component>
```

Figure 9: Information Only Section example

5 ENTRY-LEVEL TEMPLATES

This part of the guide describes the clinical statement entry templates used within the sections of the Questionnaire Form Definition 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`)
- Description and explanatory narrative.
- Required CDA acts, participants and vocabularies.
- Optional CDA acts, participants and vocabularies.

Entry-level templates also contain `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 implementation 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.

5.1 Questions Organizer

`[organizer: templateId 2.16.840.1.113883.10.20.32.4.1]`

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 "BATTERY" and is used to group entries. 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.

Used By:	Contains Entries:
Questionnaire Form Definition Section (required)	Precondition Pattern sdtc:precondition Numeric Question Pattern Observation Multiple Choice Question Pattern Observation Text Question Pattern Observation Analog Slider Question Pattern Observation Discrete Slider Question Pattern Observation

Table 13: Question Organizer Contexts

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:69	2.16.840.1.113883.5.6 (HL7ActClass)=BATTERY
	@moodCode	1..1	**SHALL**		CONF:70	2.16.840.1.113883.5.1001 (ActMood = EVN
	templateId	1..1	**SHALL**		CONF:71	
	@root	1..1	**SHALL**		CONF:72	2.16.840.1.113883.10.20.32.4.1
	Id	1..*	**SHALL**		CONF:73	
	code	0..1	**SHOUD**		CONF:74	
	statusCode	1..1	**SHALL**		CONF:75	
	@code	1..1	**SHALL**		CONF:76	2.16.840.1.113883.5.14 (ActStatus) = completed
	precondition	0..*	**MAY**		CONF:77	
	component	1..*	**SHALL**		CONF:78	
	sequenceNumber	1..1	**SHALL**		CONF:79	
question	observation	1..1	**SHALL**		CONF:80	

Table 14: Question Organizer Constraints Overview

1. **SHALL** contain exactly one [1..1] `@classCode` (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6` **STATIC**) (CONF:69).
2. **SHALL** contain exactly one [1..1] `@moodCode="EVN"` Event (CodeSystem: `ActMood 2.16.840.1.113883.5.1001` **STATIC**) (CONF:70).
3. **SHALL** contain exactly one [1..1] `templateId` (CONF:71) such that it
    a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.1"` (CONF:72).
4. **SHALL** contain at least one [1..*] `id` (CONF:73).
5. **SHOULD** contain zero or one [0..1] `code` (CONF:74).
6. **SHALL** contain exactly one [1..1] `statusCode` (CONF:75).
    a. This `statusCode` **SHALL** contain exactly one [1..1] `@code="completed"` (CodeSystem: `ActStatus 2.16.840.1.113883.5.14`) (CONF:76).
7. **MAY** contain zero or more [0..*] Precondition Pattern templates `(templateId 2.16.840.1.113883.10.20.32.4.4)` or sdtc:precondition `(templateId 2.16.840.1.113883.10.20.32.4.12)` (CONF:77).
8. **SHALL** contain at least one [1..*] `component` (CONF:78).such that it
    a. **SHALL** contain exactly one [1..1] `sequenceNumber` (CONF:79).
    b. **SHALL** contain exactly one [1..1] of the following templates (CONF:80).
        i. Numeric Question Pattern Observation template `(templateId: 2.16.840.1.113883.10.20.32.4.7)` (CONF:81).

ii. Multiple Choice Question Pattern Observation template (templateId: 2.16.840.1.113883.10.20.32.4.8) (CONF:82).
iii. Text Question Pattern Observation template (templateId: 2.16.840.1.113883.10.20.32.4.9) (CONF:83).
iv. Analog Slider Question Pattern Observation template (templateId: 2.16.840.1.113883.10.20.32.4.10) (CONF:84).
v. Discrete Slider Question Pattern Observation template (templateId: 2.16.840.1.113883.10.20.32.4.11) (CONF:85).

```
<organizer
   classCode="BATTERY"
   moodCode="EVN">
   <!-- Question Organizer template -->
   <templateId
      root="2.16.840.1.113883.10.20.32.4.1"/>
   <id
      assigningAuthorityName="Some Authority"
      extension="E01"
      root="1.2.208.N.N."/>
   <code
      code="C01"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some table"
      displayName="Some display name"/>
   <statusCode
      code="completed"/>
   <!-- Contains Continua Numeric, Multiple Choice or other defined templates -->
   <component
      contextConductionInd="true"
      typeCode="COMP">
      <sequenceNumber
         value="1"/>
      <observation
         classCode="OBS"
         moodCode="DEF"> <templateId
         root="2.16.840.1.113883.10.20.32.4.7"/>
         . . .
      </observation>
   </component>
   <component
      contextConductionInd="true"
      typeCode="COMP">
      <sequenceNumber
         value="2"/>
      <observation
         classCode="OBS"
         moodCode="DEF"> <templateId
         root="2.16.840.1.113883.10.20.32.4.8"/>
         . . .
      </observation>
   </component>

   <component
      contextConductionInd="true"
      typeCode="COMP">
      <sequenceNumber
         value="3"/>
      <observation
         classCode="OBS"
         moodCode="DEF"> <templateId
         root="2.16.840.1.113883.10.20.32.4.9"/>
         . . .
      </observation>
   </component>
</organizer>
```

Figure 10: Questions Organizer Example

5.2 Question Media Pattern

`[observationMedia: templateId 2.16.840.1.113883.10.20.32.4.2]`

In addition to the question text a question is sometimes associated with a multimedia item e.g. image. The Question Media Pattern is used to record such information which is then associated with a question represented by one of the following templates:

- Numeric Question Pattern Observation
- Multiple Choice Question Pattern Observation
- Text Question Pattern Observation
- Analog Slider Question Pattern Observation
- Discrete Slider Question Pattern Observation

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

Table 15: Question Media Pattern Contexts

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:86	2.16.840.1.113883.5.6 (HL7ActClass)=OBS
	@moodCode	1..1	**SHALL**	CD	CONF:87	2.16.840.1.113883.5.1001 (ActMood = DEF
	@ID	0..1	**SHOULD**			
	templateId	1..1	**SHALL**		CONF:88	
	@root	1..1	**SHALL**		CONF:89	2.16.840.1.113883.10.20.32.4.2
	Value	0..1	**SHALL**		CONF:90	

Table 16: Media Pattern Constraints Overview

1. **SHALL** contain exactly one [1..1] `@classCode` (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6` **STATIC**) (CONF:86).
2. **SHALL** contain exactly one [1..1] `@moodCode="DEF"` Event (CodeSystem: `ActMood 2.16.840.1.113883.5.1001` **STATIC**) (CONF:87).
3. **SHOULD** contain exactly one [0..1] `@ID`
4. **SHALL** contain exactly one [1..1] `templateId` (CONF:88) such that it
    a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.2"` (CONF:89).
5. **SHALL** contain exactly one [1..1] `value` (CONF:90).

```
<observationMedia
  ID="example.png" classCode="OBS" moodCode="DEF">
  <templateId
    root="2.16.840.1.113883.10.20.32.4.2"/>
  <value
    mediaType="image/png"
    representation="B64">
      <!-- base64 encoded image -->
      dHDM4DNY6tO+4y+jPXK5Cg6HbHoI22gMphNIbFgPkA0fnZWmNhEEGei...
  </value>
</observationMedia>
```

Figure 11: Question Media Pattern Example

```
<observationMedia
  classCode="OBS" moodCode="EVN">
  <templateId
    root="2.16.840.1.113883.10.20.32.4.2"/>
  <value
    mediaType="image/jpeg">
    <reference
      value="example"/>
  </value>
</observationMedia>
```

Figure 12: Question Media Pattern Example with reference

5.3 Criterion Pattern

`[criterion: templateId 2.16.840.1.113883.10.20.32.4.3]`

This pattern is used to express the criterion for asking a question. In the example in Figure 11 the criterion is true if answer to question “q2” is between 2 and 6.

Used By:	Contains Entries:
Precondition Pattern (required)	

Table 17: Criterion Pattern Contexts

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:91	
	@root	1..1	**SHALL**		CONF:92	2.16.840.1.113883.10.20.32.4.3
	@classCode	1..1	**SHALL**	CD	CONF:93	2.16.840.1.113883.5.6 (HL7ActClass)=OBS
	@moodCode	1..1	**SHALL**	CD	CONF:94	2.16.840.1.113883.5.1001 (ActMood = EVN.CRT
	Code	1..1	**SHALL**		CONF:95	
	Value	1..1	**SHALL**		CONF:96	

Table 18: Criterion Pattern Constraints Overview

1. **SHALL** contain exactly one [1..1] `templateId` (CONF:91) such that it
    a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.3"` (CONF:92).
2. **SHALL** contain exactly one [1..1] `@classCode` (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6` **STATIC**) (CONF:93).
3. **SHALL** contain exactly one [1..1] `@moodCode="EVN.CRT"` Event (CodeSystem: `ActMood 2.16.840.1.113883.5.1001` **STATIC**) (CONF:94).
4. **SHALL** contain exactly one [1..1] `code` (CONF:95).
5. **SHALL** contain exactly one [1..1] `value` (CONF:96).

5.4 Precondition Pattern

`[precondition: templateId 2.16.840.1.113883.10.20.32.4.4]`

The precondition class, derived from the ActRelationship class, is used along with the Criterion class to express a condition that must hold true before the activity to occur. 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 11 the criterion requires that question q2 is answered with values between 2 and 6.

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

Table 19: Precondition Pattern Contexts

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:97	PRCN
	templateId	1..1	**SHALL**		CONF:98	
	@root	1..1	**SHALL**		CONF:99	2.16.840.1.113883.10.20.32.4.4
	Criterion	1..1	**SHALL**		CONF:100	

Table 20: Precondition Pattern Constraints Overview

1. **SHALL** contain exactly one [1..1] `@typeCode="PRCN"` (CONF:97).
2. **SHALL** contain exactly one [1..1] `templateId` (CONF:98) such that it
   a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.4"` (CONF:99).
3. **SHALL** contain exactly one [1..1] Criterion Pattern template `templateId 2.16.840.1.113883.10.20.32.4.3)` (CONF:100).

```
<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="1.2.208.N.N.N"
         codeSystemName="Some Table"/>
      <value
         xsi:type="IVL_INT">
         <low
            value="2"/>
         <high
            value="6"/>
      </value>
   </criterion>
</precondition>
```

Figure 13: Precondition Pattern Example

5.5 Question Help Text Pattern Observation

[observation: templateId 2.16.840.1.113883.10.20.32.4.19]

Question Help Text Pattern Observation is used to record free text that is aimed to assist a user who answers a question. This pattern is associated with a question observation using entryRelationsip with typeCode equal to 'SUBJ'.

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

Table 21: Question Help Text Pattern Observation Contexts

Name	XPath	Card	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.19']					
	@calssCode	1..1	**SHALL**		CONF:101	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	**SHALL**		CONF:102	2.16.840.1.113882.5.1001 (ActMood) = EVN
	templateId	1..1	**SHALL**		CONF:103	
	@root	1..1	**SHALL**		CONF:104	2.16.840.1.113883.10.20.32.4.19
	Code	1..1	**SHALL**		CONF:105	
	@code	1..1	**SHALL**		CONF:106	48767-8
	@codeSystem	1..1	**SHALL**		CONF:107	2.16.840.1.113883.6.1
helpText	Value	1..1	**SHALL**		CONF:108	
	@xsi:type	1..1	**SHALL**		CONF:109	
	languageCode	0..1	**SHOULD**		CONF:110	

Table 22: Question Help Text Pattern Observation Constraints Overview

1. **SHALL** contain exactly one [1..1] `@classCode="OBS"` (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6` **STATIC**) (CONF:101).
2. **SHALL** contain exactly one [1..1] `@moodCode="EVN"` (CodeSystem: `ActMood 2.16.840.1.113883.5.1001` **STATIC**) (CONF:102).
3. **SHALL** contain exactly one [1..1] `templateId` (CONF:103) such that it
   a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.19"` (CONF:104).
4. **SHALL** contain exactly one [1..1] `code` (CONF:105)
   a. This code **SHALL** contain exactly one [1..1] `@code="48767-8"` Annotation Comment (CONF:106).
   b. This code **SHALL** contain exactly one [1..1] `(@CodeSystem:" 2.16.840.1.113883.6.1"`(CONF:107).
5. **SHALL** contain [1..1] `value` (CONF:108).
   a. **SHALL** contain [1..1] `@xsi:type="ST"` (CONF:109).
6. **SHOULD** contain zero or one [0..1] `languageCode` which **SHALL** be selected from ValueSet Language `2.16.840.1.113883.1.11.11526` **DYNAMIC** (CONF:110).

```
<observation
   classCode="OBS" moodCode="EVN">
   <!--templateID for the Question Help Text Pattern Observation-->
   <templateId
      root="2.16.840.1.113883.10.20.32.4.19"/>
   <code
      code="48767-8"
      codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC"
      displayName="Annotation Comment"/>
   <value
      language="da-DK"
      xsi:type="ST">Indtast et tal mellem 0 og 24</value>
</observation>
```

Figure 14: Questions Help Text Pattern Observation Example

5.6 Question Reference Range Pattern

`[referenceRange: templateId 2.16.840.1.113883.10.20.32.4.5]`

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 Figure 13, the value entered should be of the type 'INT' between '0' and '24'.

Used By:	Contains Entries:
Numeric Question Pattern Observation (optional)	

Table 23: Question Reference Range Pattern Contexts

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:111	REFV
	templateId	1..1	**SHALL**		CONF:112	
	@root	1..1	**SHALL**		CONF:113	2.16.840.1.113883.10.20.32.4.5
	observationRange	1..1	**SHALL**		CONF:114	
	Text	0..1	**MAY**		CONF:115	
	Value	1..1	**SHALL**		CONF:116	
	@xsi:type	1..1	**SHALL**		CONF:117	
minimumValue	Low	1..1	**SHALL**		CONF:118	
maximumValue	High	1..1	**SHALL**		CONF:119	

Table 24: Question Reference Pattern Constraints Overview

1. **SHALL** contain exactly one [1..1] `@typeCode="REFV"` (CodeSystem: `HL7ActRelationshipType 2.16.840.1.113883.5.1002`) (CONF:111).
2. **SHALL** contain exactly one [1..1] `templateId` (CONF:112) such that it
    a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.5"` (CONF:113).
3. The referenceRange **SHALL** contain exactly one [1..1] `observationRange` (CONF:114).
    a. **MAY** contain zero or one [0..1] `text` (CONF:115).
    b. **SHALL** contain exactly one [1..1] `value` (CONF:116) such that it
        i. **SHALL** contain exactly one [1..1] `@xsi:type` (CONF:117).
        ii. **SHALL** contain exactly one [1..1] `low` (CONF:118).
        iii. **SHALL** contain exactly one [1..1] `high` (CONF:119).

```
<referenceRange
   typeCode="REFV">
   <templateId
      root="2.16.840.1.113883.10.20.32.4.5"/>
   <observationRange>
      <text
         language="da-DK">Her kan skrives en tekst til reference-intervallet</text>
      <value
         xsi:type="IVL_INT">
         <low
            value="0"/>
         <high
            value="24"/>
      </value>
   </observationRange>
</referenceRange>
```

Figure 15: Questions Reference Range Pattern Example

5.7 Question Options Pattern Observation

[observation: templateId 2.16.840.1.113883.10.20.32.4.20]

Question Options Pattern Observation is used by Multiple Choice Question Pattern Observation. This is used to indicate minimum and maximum number of choices that a user should select. For Multiple Choice Question Pattern Observation where a patient can only select one of the available options, the value/high should be set to '1'. This pattern is associated with the question observation using entryRelationsip with typeCode equal to 'SUBJ'.

Used By:	Contains Entries:
Multiple Choice Question Pattern Observation (optional) Discrete Slider Question Pattern Observation (optional)	

Table 25: Question Options Pattern Contexts

Name	XPath	Card	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.20']					
	@classCode	1..1	**SHALL**		CONF:120	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	**SHALL**		CONF:121	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	**SHALL**		CONF:122	
	@root	1..1	**SHALL**		CONF:123	2.16.840.1.113883.10.20.32.4.20
	Code	1..1	**SHALL**		CONF:124	
	@code	1..1	**SHALL**		CONF:125	74467-2
	@codeSystem	1..1	**SHALL**		CONF:126	2.16.840.1.113883.6.1
	Value	1..1	**SHALL**		CONF:127	
	@xsi:type	1..1	**SHALL**		CONF:128	IVL_INT
minimumOptions	Low	1..1	**SHALL**		CONF:129	
maximumOptions	High	1..1	**SHALL**		CONF:130	

Table 26: Question Options Pattern Constraints Overview

1. **SHALL** contain exactly one [1..1] `@classCode="OBS"` (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6` **STATIC**) (CONF:120).
2. **SHALL** contain exactly one [1..1] `@moodCode="EVN"` (CodeSystem: `ActMood 2.16.840.1.113883.5.1001` **STATIC**) (CONF:121).
3. **SHALL** contain exactly one [1..1] `templateId` (CONF:122) such that it
    a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.20"` (CONF:123).
4. **SHALL** contain exactly one [1..1] **code** (CONF:124)
    a. This code **SHALL** contain exactly one [1..1] `@code="74467-2"` Number of Options (CONF:125).
    b. This code **SHALL** contain exactly one [1..1] `@CodeSystem:="2.16.840.1.113883.6.1"`(CONF:126).
5. **SHALL** contain exactly one [1..1] `value` (CONF:127).
    a. **SHALL** contain exactly one [1..1] `@xsi:type="IVL_INT"` (CONF:128).
    b. **SHALL** contain exactly one [1..1] `low` (CONF:129).
    c. **SHALL** contain exactly one [1..1] `high` (CONF:130).

```
<entryRelationship
   contextConductionInd="true" typeCode="SUBJ">
   <observation
      classCode="OBS" moodCode="EVN">
      <!--templateID for the Question Options Pattern Observation-->
      <templateId
         root="2.16.840.1.113883.10.20.32.4.20"/>
      <code
         code="74467-2"
         codeSystem="2.16.840.1.113883.6.1"
         codeSystemName="LOINC"/>
      <value xsi:type="IVL_INT">
         <!--minimum options-->
         <low value="1"/>
         <!--maximum options-->
         <high value="1"/>
      </value>
   </observation>
</entryRelationship>
```

Figure 16: Questions Options Pattern Example

5.8 Question Feedback Pattern Observation

`[observation: templateId 2.16.840.1.113883.10.20.32.4.6]`

The Question Feedback Pattern Observation 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 Precondition Pattern templates that hold the criteria for showing the feedback. In Figure 15, the feedback is given to the user if the user sleeps such that the answer to question q4 is between 2 and 6 hrs. The value element holds the feedback text to be shown to the user.

Used By:	Contains Entries:
Numeric Question Pattern Observation (optional) Multiple Choice Question Pattern Observation (optional) Analog Slider Question Pattern Observation (optional) Discrete Slider Question Pattern Observation (optional)	Precondition Pattern sdtc:precondition

Table 27: Question Feedback Pattern Contexts

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:131	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	**SHALL**		CONF:132	2.16.840.1.113883.5.1001 (ActMood) = DEF
	templateId	1..1	**SHALL**		CONF:133	
	@root	1..1	**SHALL**		CONF:134	2.16.840.1.113883.10.20.32.4.6
feedback	Code	1..1	**SHALL**		CONF:135	74466-4 (* @code?)
feedbackValue	Value	1..1	**SHALL**		CONF:136	
	languageCode	0..1	**SHOULD**		CONF:137	
logic	precondition	0..*	**SHOULD**		CONF:138	

Table 28: Question Feedback Pattern Constraints Overview

1. **SHALL** contain exactly one [1..1] `@classCode="OBS"` (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6` **STATIC**) (CONF:131).
2. **SHALL** contain exactly one [1..1] `@moodCode="DEF"` (CodeSystem: `ActMood 2.16.840.1.113883.5.1001` **STATIC**) (CONF:132).
3. **SHALL** contain exactly one [1..1] `templateId` (CONF:133) such that it
   a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.6"` (CONF:134).
4. **SHALL** contain exactly one [1..1] `code` (CONF:135).
5. **SHALL** contain exactly one [1..1] `value` (CONF:136).
6. **SHOULD** contain zero or one [0..1] `languageCode` which **SHALL** be selected from ValueSet `Language 2.16.840.1.113883.1.11.11526` **DYNAMIC** (CONF:137).
7. **SHOULD** contain zero or more [0..*] Precondition Pattern template (`templateId 2.16.840.1.113883.10.20.32.4.4`) or sdtc:precondition (`templateId 2.16.840.1.113883.10.20.32.4.12`) (CONF:138).

```
<observation
   classCode="OBS"
   moodCode="DEF">
   <!--templateID for Question Feedback Pattern-->
   <templateId
      root="2.16.840.1.113883.10.20.32.4.6"/>
   <code
      code="74466-4"
      codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC"
      displayName="Feedback to user post question response Question"/>
   <value
      xsi:type="ST">Undlad at drikke kaffe lige før du går i seng</value>
   <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="q4"
            codeSystem="1.2.208.N.N.N"
            codeSystemName="Some table"/>
         <value
            xsi:type="IVL_INT">
            <low
              value="2"/>
            <high
              value="6"/>
         </value>
      </criterion>
   </precondition>
</observation>
```

Figure 17: Questions Feedback Pattern Example

5.9 Copy Right Pattern Observation

`[observation: templateId 2.16.840.1.113883.10.20.32.4.21]`

Copy Right Pattern Observation is used to record copyright information related to the content in a Questionnaire Form Definition document. The code 'COPY' is used to indicate organization who own the intellectual property represented by a Questionnaire Form Definition document. The value element contains the actual copy right text.

Note: Copy Right Pattern Observation may be "stamped" on any question in the questionnaire through the entryRelationShip element.

Used By:	Contains Entries:
Copy Right Section (required)	

Table 29: Copy Right Pattern Observation

Name	XPath	Card	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.21']					
	@classCode	1..1	**SHALL**		CONF:139	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	**SHALL**		CONF:140	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	**SHALL**		CONF:141	
	@root	1..1	**SHALL**		CONF:142	2.16.840.1.113883.10.20.32.4.21
copyright	code	1..1	**SHALL**		CONF:143	
	@code	1..1	**SHALL**		CONF:144	COPY
	@codeSystem	1..1	**SHALL**		CONF:145	2.16.840.1.113883.5.4
copyRightText	Value	1..1	**SHALL**		CONF:146	
	@xsi:type	1..1	**SHALL**		CONF:147	ST
	languageCode	0..1	**SHOULD**		CONF:148	

Table 30: Copy Right Pattern Constraints Overview

1. **SHALL** contain exactly one [1..1] `@classCode="OBS"` (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6` **STATIC**) (CONF:139).
2. **SHALL** contain exactly one [1..1] `@moodCode="EVN"` (CodeSystem: `ActMood 2.16.840.1.113883.5.1001` **STATIC**) (CONF:140).
3. **SHALL** contain exactly one [1..1] **TEMPLATEID** (CONF:141) such that it
   a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.21"` (CONF:142).
4. **SHALL** contain exactly one [1..1] `code` (CONF:143)
   a. This code **SHALL** contain exactly one [1..1] `@code="COPY"` (CONF:144).
   b. This code **SHALL** contain exactly one [1..1] `@CodeSystem="2.16.840.1.113883.5.4"` (CONF:145).
5. **SHALL** contain [1..1] `value` (CONF:146).
   a. **SHALL** contain [1..1] `@xsi:type="ST"` (CONF:147).
6. **SHOULD** contain zero or one [0..1] `languageCode` which **SHALL** be selected from ValueSet `Language 2.16.840.1.113883.1.11.11526` **DYNAMIC** (CONF:148).

```
<observation
   classCode="OBS"
   moodCode="EVN">
   <!--templateID for the Copyright Pattern Observation-->
   <templateId
      root="2.16.840.1.113883.10.20.32.4.21"/>
   <code
      code="COPY"
      codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC"
      displayName="Code for Copyright"/>
   <value
      language="da-DK"
      xsi:type="ST">Copyright tekst skrives her</value>
</observation>
```

Figure 18: Copy Right Pattern Example

5.10 Numeric Question Pattern Observation

[observation: templateId 2.16.840.1.113883.10.20.32.4.7]

The Numeric Question Pattern Observation 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 Observation template through entryRelationship, that holds feedback to be shown to the user after answering the question.

In addition, the pattern may also be associated with the Question Media Pattern Observation template through entryRelationship.

Used By:	Contains Entries:
Questions Organizer (required) Analog Slider Question Pattern Observation (required)	Question Help Text Pattern Observation Question Media Pattern Precondition Pattern sdtc:precondition Question Reference Range Pattern Question Feedback Pattern Observation

Table 31: Numeric Question Pattern Contexts

Name	XPath	Card	Verb	DataType	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.7']					
	@classCode	1..1	**SHALL**		CONF:149	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	**SHALL**		CONF:150	2.16.840.1.113883.5.1001 (ActMood) = DEF
	templateId	1..1	**SHALL**		CONF:151	
	@root	1..1	**SHALL**		CONF:152	2.16.840.1.113883.10.20.32.4.7
question id	id	1..*	**SHALL**		CONF:153	
question	code	1..1	**SHALL**	CE	CONF:154	
	@code	1..1	**SHALL**		CONF:155	
	@codeSystem	1..1	**SHALL**		CONF:156	
	originalText	1..1	**SHALL**		CONF:157	
	languageCode	0..1	**SHOULD**		CONF:158	
	entryRelationship	0..1	**MAY**		CONF:159	
	@typeCode	1..1	**SHALL**	CD	CONF:160	SUBJ
help text	observation	1..1	**SHALL**		CONF:161	
	enryRelationship	0..1	**SHOULD**		CONF:162	
	@typeCode	1..1	**SHALL**	CD	CONF:163	REFR
associated media	observationMedia	1..1	**SHALL**		CONF:164	
	enryRelationship	0..1	**SHOULD**		CONF:164A	
	@typeCode	1..1	**SHALL**	CD	CONF:164B	REFR
question feedback	observation	1.1	**SHALL**		CONF:165	
question logic	precondition	0..*	**SHOULD**		CONF:166	
question reference range	referenceRange	0..*	**SHOULD**		CONF:167	

Table 32: Numeric Question Pattern Constraints Overview

1. **SHALL** contain exactly one [1..1] `@classCode="OBS"` (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6` **STATIC**) (CONF:149).
2. **SHALL** contain exactly one [1..1] `@moodCode="DEF"` (CodeSystem: `ActMood 2.16.840.1.113883.5.1001` **STATIC**) (CONF:150).
3. **SHALL** contain exactly one [1..1] `templateId` (CONF:151) such that it
    a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.7"` (CONF:152).
4. **SHALL** contain at least one [1..*] `id` (CONF:153).
5. **SHALL** contain exactly one [1..1] `code` (CONF:154).
    a. This `code` **SHALL** contain exactly one [1..1] `@code` (CONF:155).
    b. This `code` **SHALL** contain exactly one [1..1] `@codeSystem` (CONF:156).
    c. This `code` **SHALL** contain exactly one [1..1] `originalText` (CONF:157).
6. **SHOULD** contain zero or one [0..1] `languageCode` which **SHALL** be selected from ValueSet `Language 2.16.840.1.113883.1.11.11526` **DYNAMIC** (CONF:158).
7. **MAY** contain zero or one [0..1] `entryRelationship` (CONF:159).
    a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] `@typeCode="SUBJ"` (CodeSystem: `HL7ActRelationshipType 2.16.840.1.113883.5.1002)` (CONF:160).
    b. **SHALL** contain exactly one [1..1] Question Help Text Pattern Observation template `(templateId 2.16.840.1.113883.10.20.32.4.19)` (CONF:161).
8. **SHOULD** contain zero or one [0..1] `entryRelationship` (CONF:162).
    a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] `@typeCode="REFR"` (CodeSystem: `HL7ActRelationshipType 2.16.840.1.113883.5.1002)` (CONF:163).
    b. **SHALL** conform to the Question Media Pattern template `(templateId 2.16.840.1.113883.10.20.32.4.2)` (CONF:164).
    c. **SHOULD** contain zero or one [0..1] `entryRelationship` (CONF:164A).
    d. The entryRelationship, if present, **SHALL** contain exactly one [1..1] `@typeCode="REFR"` (CodeSystem: `HL7ActRelationshipType 2.16.840.1.113883.5.1002)` (CONF:164B).
    e. **SHALL** conform to the Question Feedback Pattern Observation template `(templateId 2.16.840.1.113883.10.20.32.4.6)` (CONF:165).
9. **SHOULD** contain zero or more [0..*] Precondition Pattern templates `(templateId 2.16.840.1.113883.10.20.32.4.4)` or sdtc:precondition `(templateId 2.16.840.1.113883.10.20.32.4.12)` (CONF:166)
10. **SHOULD** contain zero or more [0..*] Question Reference Range Pattern template `(templateId 2.16.840.1.113883.10.20.32.4.5)` (CONF:167).

```
<observation
   classCode="OBS"
   moodCode="DEF">
   <!--templateID for the Numeric Question Pattern-->
   <templateId
      root="2.16.840.1.113883.10.20.32.4.7"/>
   <id
      assigningAuthorityName="Some Authority"
      extension="ob1"
      root="1.2.208.N.N"/>
   <code
      code="q1"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some Table"
      displayName="Antal timers søvn sidste nat">
      <originalText>Hvor mange timers søvn fik du sidste nat?</originalText>
   </code>
   <entryRelationship
      contextConductionInd="true"
      typeCode="REFR">
      <observation
         classCode="OBS"
         moodCode="DEF">
         <!--templateID for the Question Feedback pattern-->
         <templateId
            root="2.16.840.1.113883.10.20.32.4.6"/>
         <code
            code="74466-4"
            codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC"
            displayName="Feedback to user post question response Question"/>
         <value
            language="da-DK"
            xsi:type="ST">Undlad at drikke kaffe lige før du går i seng</value>
         <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="q4"
                  codeSystem="1.2.208.N.N.N"
                  codeSystemName="Some table"/>
               <value
                  xsi:type="IVL_INT">
                  <low
                     value="2"/>
                  <high
                     value="6"/>
               </value>
            </criterion>
         </precondition>
      </observation>
   </entryRelationship>
   <referenceRange
      typeCode="REFV">
      <!-- templateId for the Question Reference Range Pattern-->
      <templateId
         root="2.16.840.1.113883.10.20.32.4.5"/>
      <observationRange
         classCode="OBS"
         moodCode="EVN.CRT">
         <value
            xsi:type="IVL_INT">
            <low
               value="0"/>
            <high
               value="24"/>
         </value>
      </observationRange>
   </referenceRange>
</observation>
```

Figure 19: Numeric Question Pattern Example

5.11 Multiple Choice Question Pattern Observation

`[observation: templateId 2.16.840.1.113883.10.20.32.4.8]`

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

- Precondition Pattern
- Question Help Text Pattern Observation
- Question Options Pattern Observation

In addition, this pattern may be associated with Question Options Pattern Observation which indicates the minimum and maximum number of options that must be selected by a user. In addition, this pattern may also contain Text Question Pattern Observation which is used to capture other responses of the patient depending on a selected option.

Used By:	Contains Entries:
Questions Organizer (required) Discrete Slider Question Pattern Observation (required)	Question Media Pattern Precondition Pattern sdtc:precondition Question Help Text Pattern Observation Question Options Pattern Observation Question Feedback Pattern Observation Text Question Pattern Observation

Table 33: Multiple Choice Question Pattern Observation Contexts

Name	XPath	Card	Verb	DataType	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.8']					
	@classCode	1..1	**SHALL**		CONF:168	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	**SHALL**		CONF:169	2.16.840.1.113883.5.1001 (ActMood) = DEF
	templateId	1..1	**SHALL**		CONF:170	
	@root	1..1	**SHALL**		CONF:171	2.16.840.1.113883.10.20.32.4.8
	Id	1..*	**SHALL**		CONF:172	
question	code	1..1	**SHALL**	CE	CONF:173	
	@code	1..1	**SHALL**		CONF:174	
	@codeSystem	1..1	**SHALL**		CONF:175	
	originalText	1..1	**SHALL**		CONF:176	
	languageCode	0..1	**SHOULD**		CONF:177	
answer options	value	2..*	**SHALL**		CONF:178	
	@xsi:type	1..1	**SHALL**		CONF:179	CE
	@code	1..1	**SHALL**		CONF:180	
	@codeSystem	1..1	**SHALL**		CONF:181	
	@displayName	1..1	**SHALL**		CONF:182	
	entryRelationship	0..*	**SHOULD**		CONF:183	
	@typeCode	1..1	**SHALL**	CD	CONF:184	SUBJ
help text or question options	observation	1..1	**SHALL**		CONF:185 CONF:186	
	entryRelationship	0..1	**SHOULD**		CONF:187	
	@typeCode	1..1	**SHALL**	CD	CONF:188	REFR
associatedmedia	observationMedia	1..1	**SHALL**		CONF:189	
	entryRelationship	0..*	**SHOULD**		CONF:190	
	@typeCode	1..1	**SHALL**	CD	CONF:191	REFR
question feedback	observation	1..1	**SHALL**		CONF:192	
	entryRelationship	0..1	**SHOULD**		CONF:193	
	@typeCode	1..1	**SHALL**	CD	CONF:194	REFR
associatedtext question	observation	1..1	**SHALL**		CONF:195	
question logic	precondition	0..*	**SHOULD**		CONF:196	

Table 34: Multiple Choice Question Pattern Observation Constraints Overview

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:168).
2. **SHALL** contain exactly one [1..1] **@moodCode**="DEF" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:169).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:170) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.32.4.8" (CONF:171).
4. **SHALL** contain at least one [1..*] **id** (CONF:172).
5. **SHALL** contain exactly one [1..1] **code** (CONF:173).
    a. This code **SHALL** contain exactly one [1..1] **@code** (CONF:174).
    b. This code **SHALL** contain exactly one [1..1] **@CodeSystem** (CONF:175).
    c. This code **SHALL** contain exactly one [1..1] **originalText** (CONF:176).
6. **SHOULD** contain zero or one [0..1] **languageCode** which **SHALL** be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 **DYNAMIC** (CONF:177).
7. **SHALL** contain at least two or more [2..*] **value** (CONF:178).
    a. **SHALL** contain exactly one [1..1] **@xsi:type**="CE" (CONF:179).
    b. This code **SHALL** contain exactly one [1..1] **@code** (CONF:180).
    c. This code **SHALL** contain exactly one [1..1] **@CodeSystem** (CONF:181).
    d. This code **SHALL** contain exactly one [1..1] **@displayName** (CONF:182).
8. **SHOULD** contain zero or many [0..*] entryRelationship (CONF:183) such that it.
    a. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:184).
    b. **SHALL** contain exactly one [1..1] Question Help Text Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.19) (CONF:185).
    c. **SHALL** contain exactly one [1..1] Question Options Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.20) (CONF:186).
9. **SHOULD** contain zero or one [0..1] entryRelationship (CONF:187).
    a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode**="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:188).
    b. **SHALL** conform to the Question Media Pattern template (templateId 2.16.840.1.113883.10.20.32.4.2) (CONF:189).
10. **SHOULD** contain zero or one [0..*] entryRelationship (CONF:190).
    a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode**="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:191).
    b. **SHALL** conform to the Question Feedback Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.6) (CONF:192).
11. **SHOULD** contain zero or one [0..1] entryRelationship (CONF:193).
    a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode**="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:194).
    b. **SHALL** conform to the Text Question Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.9) (CONF:195).
12. **SHOULD** contain zero or more [0..*] Precondition Pattern templates (templateId 2.16.840.1.113883.10.20.32.4.4) or sdtc:precondition (templateId 2.16.840.1.113883.10.20.32.4.12) (CONF:196).

```
<observation
   classCode="OBS"
   moodCode="DEF">
   <!--templateID for the Multiple Choice Question Pattern-->
   <templateId
      root="2.16.840.1.113883.10.20.32.4.8"/>
   <id
      assigningAuthorityName="Some Authority"
      extension="ob1"
      root="1.2.208.N.N"/>
   <code
      code="q1"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some Table"
      displayName="Konsultationsbehov">
      <originalText>Hvad er dit behov i forhold til en konsultation?</originalText>
   </code>
   <value
      code="A1"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some Table"
      displayName="Jeg ringer selv, hvis jeg har behov for en konsultation"
      xsi:type="CE"/>
   <value
      code="A2"
      codeSystem="1.2.208.N.N.N "
      codeSystemName="Some Table"
      displayName="Jeg vil gerne ringes op (telefonkonsultation)"
      xsi:type="CE"/>
   <value
      code="A3"
      codeSystem="1.2.208.N.N.N "
      codeSystemName="Some Table"
      displayName="Jeg vil gerne have en tid i ambulatoriet"
      xsi:type="CE"/>
   <entryRelationship
      contextConductionInd="true"
      typeCode="SUBJ">
      <observation
         classCode="OBS"
         moodCode="EVN">
         <!--templateID for the Question Options Pattern Observation-->
         <templateId
            root="2.16.840.1.113883.10.20.32.4.20"/>
         <code
            code="74467-2"
            codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC"/>
         <value
            xsi:type="IVL_INT">
            <!--minimum options-->
            <low
               value="1"/>
            <!--maximum options-->
            <high
               value="1"/>
         </value>
      </observation>
   </entryRelationship>
</observation>
```

Figure 20: Multiple Choice Question Pattern Observation Example 1

```
<observation
   classCode="OBS" moodCode="DEF">
   <!--templateID for the Multiple Choice Question Pattern-->
   <templateId root="2.16.840.1.113883.10.20.32.4.8"/>
   <id
      assigningAuthorityName="Some Authority"
      extension="ob8"
      root="1.2.208.N.N"/>
   <code
      code="q8"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some Table"
      displayName="Høj puls">
      <originalText>Hvad tror du er årsagen til din høje puls?</originalText>
   </code>
   <value
      code="A1"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some Table"
      displayName="Jeg havde en meget stresset dag"
      xsi:type="CE"/>
   <value
      code="A2"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some Table"
      displayName="Jeg kunne ikke tage min medicin"
      xsi:type="CE"/>
   <value
      code="A3"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some Table"
      displayName="Jeg havde trænet umiddelbart før pulsen blev målt"
      xsi:type="CE"/>
   <entryRelationship
      contextConductionInd="true"
      typeCode="SUBJ">
      <observation
         classCode="OBS"
         moodCode="EVN">
         <!--templateID for the Question Options Pattern Observation-->
         <templateId
            root="2.16.840.1.113883.10.20.32.4.20"/>
         <code
            code="74467-2"
            codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC"/>
         <value
            xsi:type="IVL_INT">
            <!--minimum options-->
            <low
               value="1"/>
            <!--maximum options-->
            <high
               value="3"/>
         </value>
      </observation>
   </entryRelationship>
   <!-- Precondition for asking this question
      Ask this question only if the answer to question q7 is A1-->
   <precondition
      typeCode="PRCN">
      <templateId
         root="2.16.840.1.113883.10.20.32.4.3"/>
      <criterion
         classCode="OBS"
         moodCode="EVN.CRT">
         <templateId
            root="2.16.840.1.113883.10.20.32.4.3"/>
         <code
            code="q7"
            codeSystem="1.2.208.N.N.N"
            codeSystemName="Some Table"> </code>
         <value
            code="A1"
            displayName="Ja"
            xsi:type="CE"/>
      </criterion>
   </precondition>
</observation>
```

Figure 21: Multiple Choice Question Pattern Observation Example 2

```
<observation
   classCode="OBS" moodCode="DEF">
   <!--templateID for the Multiple Choice Question Pattern-->
   <templateId root="2.16.840.1.113883.10.20.32.4.8"/>
   <id
      assigningAuthorityName="Some Authority"
      extension="ob9"
      root="1.2.208.N.N.N"/>
   <code
      code="q9"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some Table"
      displayName="Problem med medicin">
      <originalText>Hvor godt tåler du den receptpligtige medicin?</originalText>
   </code>
   <value
      code="B1"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some Table"
      displayName="Meget godt"
      xsi:type="CE"/>
   <value
      code="B2"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some Table"
      displayName="Godt"
      xsi:type="CE"/>
   <value
      code="B3"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some Table"
      displayName="Nogen lunde"
      xsi:type="CE"/>
   <entryRelationship
      contextConductionInd="true"
      typeCode="SUBJ">
      <observation
         classCode="OBS"
         moodCode="EVN">
         <!--templateID for the Question Options Pattern Observation-->
         <templateId
            root="2.16.840.1.113883.10.20.32.4.20"/>
         <code
            code="74467-2"
            codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC"/>
         <value
            xsi:type="IVL_INT">
            <!--minimum options-->
            <low
               value="1"/>
            <!--maximum options-->
            <high
               value="1"/>
         </value>
      </observation>
   </entryRelationship>
   <!-- Precondition for asking this question
   Ask this question only if the answer to question q7 is A1-->
   <precondition
      typeCode="PRCN">
      <templateId
         root="2.16.840.1.113883.10.20.32.4.3"/>
      <criterion
         classCode="OBS"
         moodCode="EVN.CRT">
         <templateId
            root="2.16.840.1.113883.10.20.32.4.3"/>
         <code
            code="q7"
            codeSystem="1.2.208.N.N.N"
            codeSystemName="Some Table"/>
         <value
            code="A1"
            displayName="Ja"
            xsi:type="CE"/>
      </criterion>
   </precondition>
</observation>
```

Figure 22: Multiple Choice Question Pattern Observation Example 3

5.12 Text Question Pattern Observation

[observation: templateId 2.16.840.1.113883.10.20.32.4.9]

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

Used By:	Contains Entries:
Questions Organizer (required)	Question Media Pattern Question Help Text Pattern Observation Precondition Pattern sdtc:precondition

Table 35: Text Question Pattern Contexts

Name	XPath	Card	Verb	DataType	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.9']					
	@classCode	1..1	**SHALL**		CONF:197	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	**SHALL**		CONF:198	2.16.840.1.113883.5.1001 (ActMood) = DEF
	templateId	1..1	**SHALL**		CONF:199	
	@root	1..1	**SHALL**		CONF:200	2.16.840.1.113883.10.20.32.4.9
questionId	id	1..*	**SHALL**		CONF:201	
question	code	1..1	**SHALL**	CE	CONF:202	
	@code	1..1	**SHALL**		CONF:203	
	@codeSystem	1..1	**SHALL**		CONF:204	
	originalText	1..1	**SHALL**		CONF:205	
	languageCode	0..1	**SHOULD**		CONF:206	
	entryRelationship	0..1	**MAY**		CONF:207	
	@typeCode	1..1	**SHALL**	CD	CONF:208	SUBJ
helpText	observation	1..1	**SHALL**		CONF:209	
	entryRelationship	0..1	**SHOULD**		CONF:210	
	@typeCode	1..1	**SHALL**	CD	CONF:211	REFR
associatedMedia	observationMedia	1..1	**SHALL**		CONF:212	
questionLogic	precondition	0..*	**SHOULD**		CONF:213	

Table 36: Text Question Pattern Observation Constraints Overview

1. **SHALL** contain exactly one [1..1] `@classCode="OBS"` (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6` **STATIC**) (CONF:197).
2. **SHALL** contain exactly one [1..1] `@moodCode="DEF"` (CodeSystem: `ActMood 2.16.840.1.113883.5.1001` **STATIC**) (CONF:198).
3. **SHALL** contain exactly one [1..1] **`templateId`** (CONF:199) such that it
   a) **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.6"` (CONF:200).
4. **SHALL** contain at least one [1..*] `id` (CONF:201).
5. **SHALL** contain exactly one [1..1] `code` (CONF:202).
   a) This code **SHALL** contain exactly one [1..1] `@code` (CONF:203).
   b) This code **SHALL** contain exactly one [1..1] `@codeSystem` (CONF:204).
   c) This code **SHALL** contain exactly one [1..1] `@originalText` (CONF:205).
6. **SHOULD** contain zero or one [0..1] **`languageCode`** which **SHALL** be selected from ValueSet `Language 2.16.840.1.113883.1.11.11526` **DYNAMIC** (CONF:206).
7. **MAY** contain zero or one [0..1] `entryRelationship` (CONF:207).
   a) The entryRelationship, if present, **SHALL** contain exactly one [1..1] `@typeCode="SUBJ"` (CodeSystem: `HL7ActRelationshipType 2.16.840.1.113883.5.1002`) (CONF:208).
   b) **SHALL** contain exactly one [1..1] Question Help Text Pattern Observation template `(templateId 2.16.840.1.113883.10.20.32.4.19)` (CONF:209).
8. **SHOULD** contain zero or one [0..1] `entryRelationship` (CONF:210).
   a) The entryRelationship, if present, **SHALL** contain exactly one [1..1] `@typeCode="REFR"` (CodeSystem: `HL7ActRelationshipType 2.16.840.1.113883.5.1002`) (CONF:211).
   b) **SHALL** conform to the Question Media Pattern template `(templateId 2.16.840.1.113883.10.20.32.4.2)` (CONF:212).
9. **SHOULD** contain zero or more [0..*] Precondition Pattern templates `(templateId 2.16.840.1.113883.10.20.32.4.4)` or sdtc:precondition `(templateId 2.16.840.1.113883.10.20.32.4.12)` (CONF:213).

```
<observation
   classCode="OBS"
   moodCode="DEF">
   <!--templateID for the Text Question Pattern-->
   <templateId
      root="2.16.840.1.113883.10.20.32.4.9"/>
   <id
      assigningAuthorityName="Some Authority"
      extension="ob1"
      root="1.2.208.N.N.N"/>
   <code
      code="q1"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some Table"
      displayName="Problemer ifm. Epilepsi">
      <originalText>Medfører din epilepsi (anfald/behandling) alvorlige begrænsninger for dig?
(fx sociale begrænsninger)</originalText>
   </code>
</observation>
```

Figure 23: Text Question Pattern Observation Example

5.13 Analog Slider Question Pattern Observation

`[observation: templateId 2.16.840.1.113883.10.20.32.4.10]`

The Analog Slider Question Pattern Observation is used to ask a question from the patient in the form of visual analogue scale (VAS)[4]. The Analog Slider Question Pattern Observation 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.

Used By:	Contains Entries:
Questions Organizer (required)	Numeric Question Pattern Observation

Table 37: Analog Slider Question Pattern Contexts

Name	XPath	Card	Verb	DataType	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.10']					
	templateId	1..1	**SHALL**		CONF:216	
	@root	1..1	**SHALL**		CONF:217	2.16.840.1.113883.10.20.32.4.10
	referenceRange	1..1	**SHALL**		CONF:218	
	@typeCode	1..1	**SHALL**	CD	CONF:219	REFV
	observationRange	1..1	**SHALL**		CONF:220	
	value	1..1	**SHALL**		CONF:221	
	@xsi:type	1..1	**SHALL**		CONF:222	GLIST_PQ
startOf Scale	head	1..1	**SHALL**		CONF:223	
stepSize	increment	1..1	**SHALL**		CONF:224	
endOf Scale	denominator	1..1	**SHALL**		CONF:225	

Table 38: Analog Slider Question Pattern Observation Constraints Overview

1. **SHALL** conform to the Numeric Question Pattern Observation template `(templateId 2.16.840.1.113883.10.20.32.4.7)` (CONF:214).
2. **SHALL NOT** contain Question Reference Range Pattern template `(templateId 2.16.840.1.113883.10.20.32.4.5)` (CONF:215).
3. **SHALL** contain exactly one [1..1] `templateId` (CONF:216) such that it
   a) **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.10"` (CONF:217).
4. **SHALL** contain exactly one [1..1] `referenceRange` (CONF:218).
   a) **SHALL** contain exactly one [1..1] `@typeCode="REFV"` (CodeSystem: `HL7ActRelationshipType 2.16.840.1.113883.5.1002)` (CONF:219).
   b) **SHALL** contain exactly one [1..1] `observationRange` (CONF:220).
   c) **SHALL** contain exactly one [1..1] `value` (CONF:221) such that it
      i. **SHALL** contain exactly one [1..1] `@xsi:type="GLIST_PQ"` (CONF:222).
         1. **SHALL** contain exactly one [1..1] `head` (CONF:223).
         2. **SHALL** contain exactly one [1..1] `increment` (CONF:224).
         3. **SHALL** contain exactly one [1..1] `@denominator` (CONF:225).

[4] 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)]

```
<observation
   classCode="OBS"
   moodCode="DEF">
   <!--templateID for the Numeric Question Pattern-->
   <templateId
      root="2.16.840.1.113883.10.20.32.4.7"/>
   <!--templateID for the Analog Slider Question Pattern-->
   <templateId
      root="2.16.840.1.113883.10.20.32.4.10"/>
   <id
      assigningAuthorityName="Some Authority"
      extension="ob1"
      root="1.2.208.N.N.N"/>
   <code
      code="q1"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some Table"
      displayName="Timer uden smerter pr. døgn">
      <originalText>Hvor stor en procentdel af døgnet er du smertefri?</originalText>
   </code>
   <referenceRange
      typeCode="REFV">
      <observationRange
         classCode="OBS"
         moodCode="EVN.CRT">
         <value
            denominator="100"
            xsi:type="GLIST_PQ">
            <head
               value="0"/>
            <increment
               value="1"/>
         </value>
      </observationRange>
   </referenceRange>
</observation>
```

Figure 24: Analog Slider Question Pattern Observation Example

5.14 Discrete Slider Question Pattern Observation

`[observation: templateId 2.16.840.1.113883.10.20.32.4.11]`

The Discrete Slider Question Pattern Observation is similar to the Multiple Choice Question Pattern Observation template however the user can only select one option i.e the high value in the Question Options Pattern Observation used by the Multiple Choice Question Pattern Observation template is fixed to "1". In addition the options are presented as a slider similar to Analog Slider Question Pattern Observation.

Used By:	Contains Entries:
Questions Organizer (required)	Multiple Choice Question Pattern Observation

Table 39: Discrete Slider Question Pattern Contexts

Name	XPath	Card	Verb	DataType	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.32.4.11']					
	templateId	1..1	**SHALL**		CONF:227	
	@root	1..1	**SHALL**		CONF:228	2.16.840.1.113883.10.20.32.4.11
	entryRelationship/observation/value/high/@value	1..1	**SHALL**	INT	CONF:229	1

Table 40: Discrete Slider Question Pattern Observation Constraints Overview

1. **SHALL** confirm to Multiple Choice Question Pattern Observation template `(templateId 2.16.840.1.113883.10.20.32.4.8)` (CONF:226).
2. **SHALL** contain exactly one [1..1] `templateId` (CONF:227) such that it
   a) **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.11"` (CONF:228).
3. The value of `entryRelationship/observation/value/high/@value` **SHALL** be set to "1" in the Question Options Pattern Observation template `(templateId 2.16.840.1.113883.10.20.32.4.20)` (CONF:229).

```
<observation
   classCode="OBS"
   moodCode="DEF">
   <!--templateID for the Multiple Choice Question Pattern-->
   <templateId
      root="2.16.840.1.113883.10.20.32.4.8"/>
   <!--templateID for the Discrete Slider Question Pattern-->
   <templateId
      root="2.16.840.1.113883.10.20.32.4.11"/>
   <id
      assigningAuthorityName="Some Authority"
      extension="ob2"
      root="1.2.208.N.N.N"/>
   <code
      code="q2"
      codeSystem="1.2.208.N.N.N"
      codeSystemName="Some Table"
      displayName="Smertepåvirkning ved fysisk aktivitet">
      <originalText>2. Fysisk aktivitet forværrer mine smerter</originalText>
   </code>
   <value
      code="N0"
      codeSystem="1.2.208.N.N.N"
      codeSystemName=" Some Table"
      displayName="0"
      xsi:type="CE"/>
   <value
      code="N1"
      codeSystem="1.2.208.N.N.N"
      codeSystemName=" Some Table"
      displayName="1"
      xsi:type="CE"/>
   <value
      code="N2"
      codeSystem="1.2.208.N.N.N"
      codeSystemName=" Some Table"
      displayName="2"
      xsi:type="CE"/>
   <value
      code="N3"
      codeSystem="1.2.208.N.N.N"
      codeSystemName=" Some Table"
      displayName="3"
      xsi:type="CE"/>
   <value
      code="N4"
      codeSystem="1.2.208.N.N.N"
      codeSystemName=" Some Table"
      displayName="4"
      xsi:type="CE"/>
   <entryRelationship
      contextConductionInd="true"
      typeCode="SUBJ">
      <observation
         classCode="OBS"
         moodCode="EVN">
         <!--templateID for the Question Options Pattern Observation-->
         <templateId
            root="2.16.840.1.113883.10.20.32.4.20"/>
         <code
            code="74467-2"
            codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC"/>
         <value
            xsi:type="IVL_INT">
            <!--minimum options-->
            <low
               value="0"/>
            <!--maximum options shall be "1" in case of a discrete slider-->
            <high
               value="1"/>
         </value>
      </observation>
   </entryRelationship>
</observation>
```

Figure 25: Discrete Slider Question Pattern Observation Example

6 APPENDIX A. 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 sdtc:precondition template, which is being created based on the HQMF standard.

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, nested 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 question to be asked.
AllFalse	NOR	This act is composed of subcriteria all of which must be false in order for for question to be asked.
AtLeastOneTrue	OR	This act is composed of subcriteria of which at least one must be true in order for question to be asked.
AtLeastOneFalse	NAND	This act is composed of subcriteria of which at least one must be false in order for question to be asked.
OnlyOneTrue	(see Note 1)	This act is composed of subcriteria of which exactly one must be true in order for question to be asked.
OnlyOneFalse)	(See Note 1)	This act is composed of subcriteria of which exactly one must be false in order for question to be asked.

Table 41: Logical Groupers

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.

6.1 Precondition Extension Pattern

`[sdtc:precondition: templateId 2.16.840.1.113883.10.20.32.4.12]`

1. **SHALL** contain exactly one [1..1] `@typeCode="PRCN"` (CONF:230).
2. **SHALL** contain exactly one [1..1] `templateId` (CONF:231). such that it
   a) **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.12"` (CONF:232).
3. **SHOULD** contain zero or one [0..1] `conjunctionCode` (CONF:233).
4. **SHALL** contain exactly one [1..1] Criterion Pattern template `(CONF:234)` or one of the following grouper templates (CONF:235).
   a) AllTrue Pattern template `(templateId 2.16.840.1.113883.10.20.32.4.13)` (CONF:236).
   b) AllFalse Pattern template `(templateId 2.16.840.1.113883.10.20.32.4.14)` (CONF:237).
   c) AtLeastOneTrue Pattern template `(templateId 2.16.840.1.113883.10.20.32.4.15)` (CONF:238).
   d) AtLeastOneFalse Pattern template `(templateId 2.16.840.1.113883.10.20.32.4.16)` (CONF:239).
   e) OnlyOneTrue Pattern template `(templateId 2.16.840.1.113883.10.20.32.4.17)` (CONF:240).
   f) OnlyOneFalse Pattern template `(templateId 2.16.840.1.113883.10.20.32.4.18)` (CONF:241).
5. **SHOULD** contain zero or one [0..1] `@negationInd` (CONF:242).

6.2 AllTrue Pattern

`[allTrue: templateId 2.16.840.1.113883.10.20.32.4.13]`

1. **SHALL** contain exactly one [1..1] `templateId` (CONF:243) such that it
   a) **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.13"` (CONF:244).
2. **SHALL** contain exactly one [1..1] `id` (CONF:245).
3. **SHALL** contain at least one [1..*] sdtc:precondition template `(templateId 2.16.840.1.113883.10.20.32.4.12)` (CONF:246).

6.3 AllFalse Pattern

`[allFalse: templateId 2.16.840.1.113883.10.20.32.4.14]`

1. **SHALL** contain exactly one [1..1] `templateId` (CONF:247) such that it
   a) **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.14"` (CONF:248).
2. **SHALL** contain exactly one [1..1] `id` (CONF:249).
3. **SHALL** contain at least one [1..*] sdtc:precondition template `(templateId 2.16.840.1.113883.10.20.32.4.12)` (CONF:250).

6.4 AtLeastOneTrue Pattern

`[atLeastOneTrue: templateId 2.16.840.1.113883.10.20.32.4.15]`

1. **SHALL** contain exactly one [1..1] `templateId` (CONF:251) such that it
   a) **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.15"` (CONF:252).
2. **SHALL** contain exactly one [1..1] `id` (CONF:253).
3. **SHALL** contain at least one [1..*] sdtc:precondition template `(templateId 2.16.840.1.113883.10.20.32.4.12)` (CONF:254).

6.5 AtLeastOneFalse Pattern

`[atLeastOneFalse: templateId 2.16.840.1.113883.10.20.32.4.16]`

1. **SHALL** contain exactly one [1..1] `templateId` (CONF:255) such that it
   a) **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.16"` (CONF:256).
2. **SHALL** contain exactly one [1..1] `id` (CONF:257).
3. **SHALL** contain at least one [1..*] sdtc:precondition template `(templateId 2.16.840.1.113883.10.20.32.4.12)` (CONF:258).

6.6 OnlyOneTrue Pattern

`[onlyOneTrue: templateId 2.16.840.1.113883.10.20.32.4.17]`

1. **SHALL** contain exactly one [1..1] `templateId` (CONF:259) such that it
   a) **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.17"` (CONF:260).
2. **SHALL** contain exactly one [1..1] `id` (CONF:261).
3. **SHALL** contain at least one [1..*] sdtc:precondition template `(templateId 2.16.840.1.113883.10.20.32.4.12)` (CONF:262).

6.7 OnlyOneFalse Pattern

`[onlyOneFalse: templateId 2.16.840.1.113883.10.20.32.4.18]`

1. **SHALL** contain exactly one [1..1] `templateId` (CONF:263) such that it
   a) **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.32.4.18"` (CONF:264).
2. **SHALL** contain exactly one [1..1] `id` (CONF:265).
3. **SHALL** contain at least one [1..*] sdtc:precondition template `(templateId 2.16.840.1.113883.10.20.32.4.12)` (CONF:266).

```
<observation
   classCode="OBS"
   moodCode="DEF">
   <!--templateID for the Text Question Pattern-->
   <templateId
      root="2.16.840.1.113883.10.20.32.4.9"/>
   <id
      extension="ob10"
      root="2.16.840.1.113883.3.1817.1.6"/>
   <code
      code="q10"
      codeSystem="Continua-Q-OID">
      <originalText>OK, could you please tell what is the other probable reason?</originalText>
   </code>
   <value
      xsi:type="ST"/>
   <sdtc:precondition>
      <templateId
         root="2.16.840.1.113883.10.20.32.4.12"/>
      <atLeastOneTrue>
         <templateId
            root="2.16.840.1.113883.10.20.32.4.15"/>
         <id
            extension="p1"
            root="2.16.840.1.113883.3.1817.1.6"/>
         <sdtc:precondition
            typeCode="PRCN">
            <templateId
               root="2.16.840.1.113883.10.20.32.4.12"/>
            <criterion
               classCode="OBS"
               moodCode="EVN.CRT">
               <templateId
                  root="2.16.840.1.113883.10.20.32.4.3"/>
               <code
                  code="q7"
                  codeSystem="CONTINUA-Q-OID"/>
               <value
                  code="C1"
                  codeSystem="Continua-Q-OID"
                  displayName="Yes, probably"
                  xsi:type="CE"/>
            </criterion>
         </sdtc:precondition>
         <sdtc:precondition
            typeCode="PRCN">
            <templateId
               root="2.16.840.1.113883.10.20.32.4.12"/>
            <criterion
               classCode="OBS"
               moodCode="EVN.CRT">
               <templateId
                  root="2.16.840.1.113883.10.20.32.4.3"/>
               <code
                  code="q8"
                  codeSystem="CONTINUA-Q-OID"/>
               <value
                  code="GUID5"
                  codeSystem="Continua-ANS-OID"
                  displayName="Another reason…"
                  xsi:type="CE"/>
            </criterion>
         </sdtc:precondition>
      </atLeastOneTrue>
   </sdtc:precondition>
</observation>
```

Figure 26: sdtc:precondition AtLeastOneTrue Pattern Example

7 APPENDIX B: TEMPLATE IDS USED IN QFDD

TemplateId	Description
1.2.208.184.12.1	QFDD-DK document header (root OID)
1.2.208.184.12.1.1.1	QFDD-DK document level templateId
2.16.840.1.113883.10.20.32.2.1	QFDD Section level templateId
2.16.840.1.113883.10.20.32.2.2	Copy Right section templateId
2.16.840.1.113883.10.20.32.2.1 (OPEN)	Information only section templateId
2.16.840.1.113883.10.20.32.4.1	Question organizer level templateId
2.16.840.1.113883.10.20.32.4.2	Question media templateId
2.16.840.1.113883.10.20.32.4.3	Question criterion templateId
2.16.840.1.113883.10.20.32.4.4	Precondition templateId
2.16.840.1.113883.10.20.32.4.5	Question reference range templateId
2.16.840.1.113883.10.20.32.4.6	Question feedback observation templateId
2.16.840.1.113883.10.20.32.4.7	Numeric question observation templateId
2.16.840.1.113883.10.20.32.4.8	Multiple choice question observation templateId
2.16.840.1.113883.10.20.32.4.9	Text question observation templateId
2.16.840.1.113883.10.20.32.4.10	Analog slider question observation templateId
2.16.840.1.113883.10.20.32.4.11	Discrete slider question observation templateId
2.16.840.1.113883.10.20.32.4.12	sdtc:precondition templateId
2.16.840.1.113883.10.20.32.4.13	sdtc:precondition AllTrue pattern templateId
2.16.840.1.113883.10.20.32.4.14	sdtc:precondition AllFalse pattern templateId
2.16.840.1.113883.10.20.32.4.15	sdtc:precondition AtLeastOneTrue pattern templateId
2.16.840.1.113883.10.20.32.4.16	sdtc:precondition AtLeastOneFalse pattern templateId
2.16.840.1.113883.10.20.32.4.17	sdtc:precondition OnlyOneTrue pattern templateId
2.16.840.1.113883.10.20.32.4.18	sdtc:precondition OnlyOneFalse pattern templateId
2.16.840.1.113883.10.20.32.4.19	Question help text observation templateId
2.16.840.1.113883.10.20.32.4.20	Question options observation templateId
2.16.840.1.113883.10.20.32.4.21	Copy Right observation templateId

Table 42: Template Ids used in QFDD