

**HL7 Implementation Guide for CDA Release 2**  
**Questionnaire Response Document**  
**(Danish profile – DK QRD)**

**Release 1.3**  
**February 11<sup>th</sup> 2022**

Revision history			
Release	Author	Date	Notes
1.0	MedCom, MDM	2015-05-19	Danish profile. Questionnaire Response Document
1.1	MedCom, MDM	2016-11-10	<p>The use of references to external documents added.</p> <p>To provide better search facilities in this document all pictures showing xml-code examples changed to tables with real xml code.</p>
1.1	MedCom, MDM	2016-11-13	URL reference added to Valid XDS Reference Types
1.2	MedCom, MDM	2017-11-08	<p>To be consistent with XDS Metadata for Document Sharing, Danish profile, version 0.95 the following elements are added to the CDA header part of this document:</p> <p>documentationOf.serviceEvent.effectiveTime which shall contain the time interval used when a person answered the questionnaire.</p> <p>documentationOf.serviceEvent.code which shall contain the questionnaire type.</p>
1.2	MedCom, MDM	2018-08-10	Changed documentationOf to InFulfillmentOf on page 21, bullet 16.
1.2	MedCom, MDM	2019-10-23	“Draft” removed
1.2	MedCom, MDM	2020-05-06	<p>All errors found in <a href="https://svn.medcom.dk/svn/drafts/Standarder/HL7/PRO/PRO-infrastrukturen_diverse_fund_v2.xlsx">https://svn.medcom.dk/svn/drafts/Standarder/HL7/PRO/PRO-infrastrukturen_diverse_fund_v2.xlsx</a> has been corrected</p> <p>Description of Information Only sections added.</p> <p>Table of templateId's added in <a href="#">Appendix A: Template Ids used in QRD</a></p> <p>“MedCom Prompt Table” replaced by “Some Table”</p>
1.2	MedCom, MDM	2020-05-11	Missing mandatory id in organizer example added
1.2	MedCom, SGA	2021-05-06	<p>Minor adjustment:</p> <ul style="list-style-type: none"> <li>- New layout and remove empty pages</li> <li>- In <a href="#">Multiple Choice Response Pattern Observation</a> is the cardinality for selectedAnswerOptions corrected from [1..*] to [0...*]</li> <li>- Add missing internal document cross-reference</li> <li>- Add reference to Narrative Block guidance <ul style="list-style-type: none"> <li>o <a href="#">QRD content</a> and <a href="#">CDA content</a></li> </ul> </li> <li>- Update list of examples <ul style="list-style-type: none"> <li>o <a href="#">QRD content</a></li> </ul> </li> </ul>
1.3	MedCom, SGA	2022-02-11	<p>Change in the specification of using reference to link the QRD and the QFDD.</p> <ul style="list-style-type: none"> <li>- New method for the reference element: <ul style="list-style-type: none"> <li>o <a href="#">Numeric Response Pattern Observation</a></li> <li>o <a href="#">Multiple Choice Response Pattern Observation</a></li> <li>o <a href="#">Text Response Pattern Observation</a></li> <li>o <a href="#">Analog Slider Response Pattern Observation</a></li> <li>o <a href="#">Discrete Slider Response Pattern Observation</a></li> </ul> </li> <li>- Section <a href="#">5.9 External References</a></li> </ul>

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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 Response 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 Response Document, Release 1.

The purpose of a Questionnaire Response document is to capture the health survey answers or answer sets to questions that have been administered to a patient. Questionnaire Response documents enable the capture of responses 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 Response documents may carry a variety of clinical and non-clinical responses in order to convey back to the healthcare organization the results of a patient questionnaire prescribed according to the Form Definition document<sup>1</sup>. Authors of the Questionnaire Response documents may include the patients who are under the care of disease management organizations, primary care physicians, health and fitness coaches, chronic condition monitors, and post-acute and long-term care providers or their agents.

---

<sup>1</sup> HL7 Implementation Guide for CDA Release 2.0. Questionnaire Form Definition Document (Danish Profile – DK-QFDD). Release 1.1, September 28<sup>th</sup> 2016.

### 1.2.1 Typical Use Case

The primary use case for the Questionnaire Response document starts with the authoring of the survey based on the Form Definition document. It involves the Form Definition author, which may be a human or a device or software system acting on the behalf of a human. After creation of the Form Definition document, 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. The application hosting device will in turn signal to the patient that a new Form Definition document is available, and it will create a questionnaire specific for the particular patient.

The Questionnaire Response document is created as the patient fills out the questionnaire and is sent back to the disease monitoring station where it is ready for review by a human or computer monitor. Figure 1 shows the primary typical use case for the entire ecosystem.

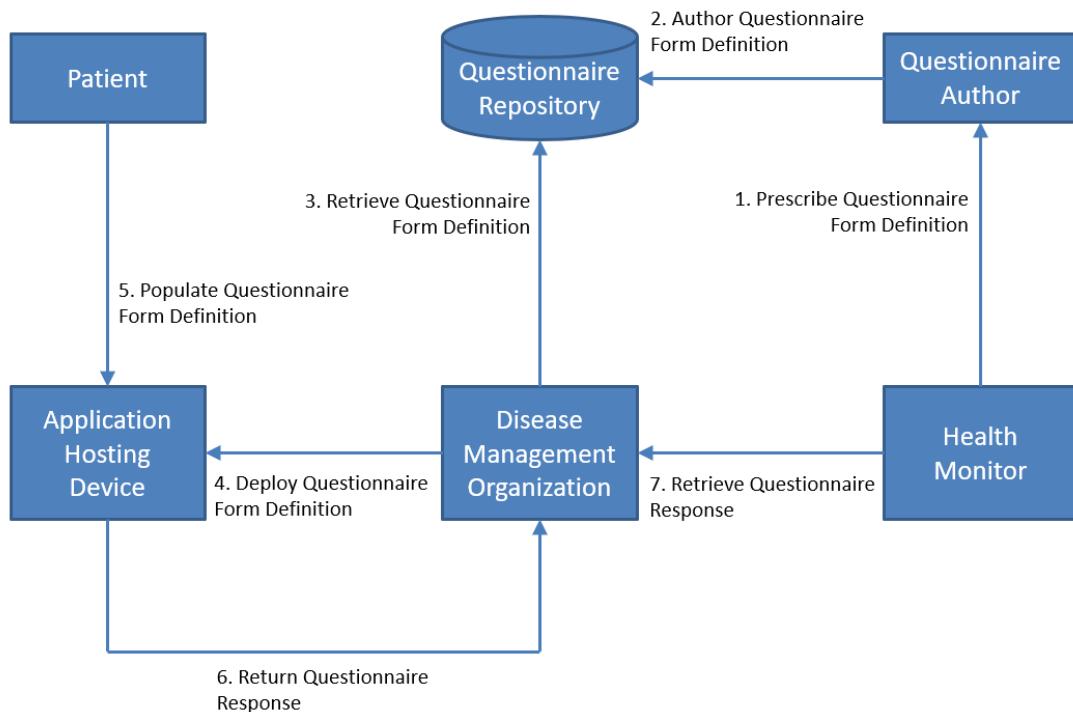


Figure 1: Typical Use Case

### 1.3 Scope

This implementation guide is a conformance profile, as described in the “Refinement and Localization”<sup>2</sup> section of the HL7 Version 3 Interoperability Standards. The base standard for this implementation guide is the HL7 Clinical Document Architecture, Release 2.0<sup>3</sup>. This implementation guide does not describe every aspect of the CDA. Rather, it defines constraints on the base CDA used in Questionnaire Response 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.

<sup>2</sup> <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm>

<sup>3</sup> HL7 Clinical Document Architecture (CDA Release 2). <http://www.hl7.org/implement/standards/cda.cfm>

#### 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 Response CDA document. The main chapters are:

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

## 1.6 Content of the Package

The following files comprise the package.

### 1.6.1 QRD content

Files are located here: <http://svn.medcom.dk/svn/releases/standarder/HL7/PRO/QRD>

Filename	Description	Standards Applicability
"Dokumentation" folder DK-QRD-v1.3.pdf	This implementation guide	Normative
"Dokumentation" folder DK-QFDD-v1.2.pdf	Specification for: <ul style="list-style-type: none"><li>• Copy Right Section</li><li>• Question Help Text Pattern Observation</li><li>• Question Options Pattern Observation</li></ul>	Normative
"Dokumentation" folder NarrativeBlock_QRD_- _Implementation_Guidance-vX.X.pdf	A guidance to facilitate the development work of CDA narrative block	Informative
"Eksempler" folder QRD_Example_1.0_Numeric_Question.xml QRD_Example_1.1_Numeric_Question_- _Graphics.xml QRD_Example_2.0_Multiple_Choise_Qu estion.xml QRD_Example_2.1_Multiple_Choise_Qu estion_-_Grouped.xml QRD_Example_3.0_Text_Question.xml QRD_Example_3.1.1_Text_Question_- _Associated_Text_Question.xml QRD_Example_3.1.2_Text_Question_- _Associated_Text_Question.xml QRD_Example_4.0_Analog_Slider_Ques tion.xml QRD_Example_4.1_Analog_Slider_Ques tion_-_Question_Feedback_Pattern Observation.xml QRD_Example_5.0_Discrete_Slider_Qu estion.xml	The sample CDA XML file that includes examples of templates discussed in this guide: <ul style="list-style-type: none"><li>• Example 1.0: Numeric Question</li><li>• Example 1.1: Numeric Question (Graphics)</li><li>• Example 2.0: Multiple Choice Question</li><li>• Example 2.1: Multiple Choice Question (Grouped)</li><li>• Example 3.0: Text Question</li><li>• Example 3.1.1: Text Question (Associated Text Question)</li><li>• Example 3.1.2: Text Question (Associated Text Question)</li><li>• Example 4.0: Analog Slider Question</li><li>• Example 4.1: Analog Slider Question (Question Feedback Pattern Observation)</li><li>• Example 5.0: Discrete Slider Question</li></ul>	Informative
"Schema" folder	Normative CDA R2 schema files to validate a Questionnaire Form Definition document instance.	Informative

Table 1: QRD Content of the Package

## 1.6.2 CDA content

Filename and location	Description	Standards Applicability
Narrative Block - Implementation Guidance.pdf <a href="http://svn.medcom.dk/svn/releases/Standarder/HL7/NarrativeBlock/">http://svn.medcom.dk/svn/releases/Standarder/HL7/NarrativeBlock/</a>	Implementation Guidance: Narrative Block Tag.	Normative
<a href="http://svn.medcom.dk/svn/drafts/Standarder/HL7/CDA-Stylesheet/HL7_CDA/HL7_CDA_stylesheet.xsl">http://svn.medcom.dk/svn/drafts/Standarder/HL7/CDA-Stylesheet/HL7_CDA/HL7_CDA_stylesheet.xsl</a>	Stylesheet for display of CDA instances	Normative
<a href="https://svn.medcom.dk/svn/releases/Standarder/HL7/PRO/QRD/Dokumentation/QFDD-QRD-link-resolving-v1.0.pdf">https://svn.medcom.dk/svn/releases/Standarder/HL7/PRO/QRD/Dokumentation/QFDD-QRD-link-resolving-v1.0.pdf</a>	<b>Link resolving between QFDD and QRD</b> The document describes how to link between a questionnaire response (QRD) and the associated questionnaire definition (QFDD)	Normative

*Table 2: CDA Content of the Package*

## 2 QUESTIONNAIRE RESPONSE 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.

### 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 Response Document is a Danish profile document, where LOINC is the preferred document code vocabulary.

### 2.2 Danish Profile Questionnaire Form Definition Document Header

[ClinicalDocument: templateId 1.2.208.184.13.1]

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-DK:1) such that it
  - a. This templateId **SHALL** contain exactly one [1..1] @root="1.2.208.184.13.1" (CONF-DK:2).
4. **SHALL** contain exactly one [1..1] id (CONF:9).
  - a. This id **SHALL** be a globally unique identifier for the document (CONF:10).
5. **SHALL** contain exactly one [1..1] code (CONF:11).
  - a. This code **SHALL** specify the Questionnaire Response Document generated by patient in response to a Questionnaire Form Definition document containing a specific measure (CONF-DK:2).
  - b. This code **SHALL** be a code from the LOINC Document Ontology which indicates a Questionnaire Response document containing responses to questions asked from the patient. (CONF-DK:3).
6. **SHALL** contain exactly one [1..1] title (CONF:14).
7. **SHALL** contain exactly one [1..1] effectiveTime (CONF:15).
8. **SHALL** contain exactly one [1..1] confidentialityCode, which **SHALL** be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 **STATIC** (CONF:16).
  - a. This code **SHALL** always be set to "N" (CONF-DK:4).
9. **SHALL** contain exactly one [1..1] languageCode, which **SHALL** be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 **DYNAMIC** (CONF:17).

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 <a href="http://www.ietf.org/rfc/rfc4646.txt">http://www.ietf.org/rfc/rfc4646.txt</a>	
<b>Code</b>	<b>Code System</b>	<b>Print name</b>
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="DOCLIN"
  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 Questionnaire Form Definition Document-level -->
  <templateId
    root="1.2.208.184.12.1.1.1"/>
  <id
    assigningAuthorityName="Some Authority"
    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"/>

```

Figure 2: DK Realm Questionnaire Form Definition document header example

```
<effectiveTime value="20161209123030+0100"/>
```

Figure 3: effectiveTime with time zone example

## 2.2.1 RecordTarget

The `recordTarget` records the patient whose health information (in the context of this IG, patient responses to a set of questions (or patient reported outcome measure) asked through the Questionnaire Form Definition Document) is described by the clinical document; each `recordTarget` must contain at least one `patientRole` element.

10. **SHALL** contain exactly one [1..1] `recordTarget` (CONF:18).
  - a. Such `recordTargets` **SHALL** contain exactly one [1..1] `patientRole` (CONF:19).
    - i. This `patientRole` **SHALL** contain exactly one [1..1] `id` (CONF-DK: 5).
    - ii. This `patientRole` **SHALL** contain exactly one [1..1] `addr` (CONF:21).
    - iii. This `patientRole` **SHALL** contain at least one [1..1] `telecom` (CONF:22).
    - iv. This `patientRole` **SHALL** contain exactly one [1..1] `patient` (CONF:23).
      1. This `patient` **SHALL** contain exactly one [1..1] `name` (CONF:24).
      2. This `patient` **SHALL** contain exactly one [1..1] `administrativeGenderCode` (CONF:25).
      3. This `patient` **SHALL** contain exactly one [1..1] `birthTime` (CONF:25).
        - a. **SHALL** be precise to year (CONF:27).
        - b. **SHALL** be precise to month (CONF-DK: 6).
        - c. **SHALL** be precise to day (CONF-DK: 7).
        - d. hhMMSS and offset from UTC **SHALL** be set to "000000+0000" (CONF-DK: 8).

```
<recordTarget  
    contextControlCode="OP"  
    typeCode="RCT">  
    <patientRole  
        classCode="PAT">  
        <id  
            assigningAuthorityName="CPR"  
            extension="2512489996"  
            root="1.2.208.176.1.2"/>  
        <addr  
            use="H">  
            <streetAddressLine>Skovvejen 12</streetAddressLine>  
            <streetAddressLine>Landet</streetAddressLine>  
            <postalCode>5700</postalCode>  
            <city>Svendborg</city>  
            <country>Danmark</country>  
        </addr>  
        <telecom  
            use="H"  
            value="tel:65123456"/>  
        <telecom  
            use="WP"  
            value="mailto:nab@udkantsdanmark.dk"/>  
        <patient  
            classCode="PSN"  
            determinerCode="INSTANCE">  
            <name>  
                <given>Nancy</given>  
                <given>Ann</given>  
                <family>Berggren</family>  
            </name>  
            <administrativeGenderCode  
                code="F"  
                codeSystem="2.16.840.1.113883.5.1"  
                codeSystemName="HL7"/>  
            <birthTime  
                value="19481225000000+0000"/>  
        </patient>  
    </patientRole>  
</recordTarget>
```

Figure 4: DK realm Questionnaire Response recordTarget example

## 2.2.2 Author

The `author` element represents the creator of the clinical document. In the context of this IG (the Questionnaire Response Document), the author is usually the patient who answers questions.

11. **SHALL** contain at least one [1..\*] `author` (CONF:29).
  - a. Such authors **SHALL** contain exactly one [1..1] `time` (CONF:30).
  - b. Such authors **SHALL** contain exactly one [1..1] `assignedAuthor` (CONF:31).
    - i. This `assignedAuthor` **SHALL** contain exactly one [1..1] `id` (CONF:32) such that it
    - ii. This `assignedAuthor` **SHALL** contain at least one [1..\*] `addr` (CONF:36)
    - iii. This `assignedAuthor` **SHALL** contain at least one [1..\*] `telecom` (CONF:37).
    - iv. There **SHALL** be exactly one `assignedAuthor/assignedPerson` (CONF-DK: 9).
    - v. This `assignedAuthor` **SHOULD** contain zero or one [0..1] `assignedPerson` (CONF:39).
      1. The `assignedPerson`, if present, **SHALL** contain at least one [1..\*] `name` (CONF:40).
    - vi. 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: 10).

```
<author
  contextControlCode="OP"
  typeCode="AUT">
  <time
    value="20150513134510+0100"/>
  <assignedAuthor
    classCode="ASSIGNED">
    <id
      assigningAuthorityName="CPR"
      extension="2512489996"
      root="1.2.208.176.1.2"/>
    <!-- The PAN IG includes conformance constraints on the code element.
        This author/assignedAuthor/code/@code must be a code from one of
        two value sets:
        PersonalRelationshipRoleType or ResponsibleParty. Both of these
        value sets include codes from the HL7 RoleCode Code System.-->
    <code
      code="SELF"
      codeSystem="2.16.840.1.113883.5.111"
      codeSystemName="HL7 Role code"
      displayName="Self"/>
    <addr
      use="H">
      <streetAddressLine>Skovvejen 12</streetAddressLine>
      <streetAddressLine>Landet</streetAddressLine>
      <postalCode>5700</postalCode>
      <city>Svendborg</city>
      <country>Danmark</country>
    </addr>
    <telecom
      use="H"
      value="tel:65123456"/>
    <telecom
      use="WP"
      value="mailto:nab@udkantsdanmark.dk"/>
    <assignedPerson
      classCode="PSN"
      determinerCode="INSTANCE">
      <name>
        <given>Nancy</given>
        <given>Ann</given>
        <family>Berggren</family>
      </name>
    </assignedPerson>
  </assignedAuthor>
</author>
```

Figure 5: Person author example

### 2.2.3 DataEnterer

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

12. **MAY** contain zero or one [0..1] `dataEnterer` (CONF:45).
  - a. Such `dataEnterer`, if present, **SHALL** contain exactly one [1..1] `assignedEntity` (CONF:46).
    - i. This `assignedEntity` **SHALL** contain exactly one [1..1] `id` (CONF:47)
    - ii. This `assignedEntity` **SHALL** contain exactly one [1..1] `addr` (CONF:48)
    - iii. This `assignedEntity` **SHALL** contain exactly one [1..1] `telecom` (CONF:49)
    - iv. This `assignedEntity` **SHALL** contain exactly one [1..1] `assignedPerson` (CONF:50)
      1. This `assignedPerson` **SHALL** contain exactly one [1..1] `name` (CONF:51)
    - v. This `assignedEntity` **MAY** contain zero or one [0..1] code to encode the relationship of the person to the `recordTarget` (CONF:52)

```
<dataEnterer
  typeCode="ENT">
  <assignedEntity
    classCode="ASSIGNED">
    <id
      assigningAuthorityName="CPR"
      extension="2512484996"
      root="1.2.208.176.1.2"/>
    <addr
      use="H">
      <streetAddressLine>Byvej 12</streetAddressLine>
      <streetAddressLine>Svinget</streetAddressLine>
      <postalCode>5000</postalCode>
      <city>Odense C</city>
      <country>Danmark</country>
    </addr>
    <telecom
      use="H"
      value="tel:65123456"/>
    <telecom
      use="WP"
      value="mailto:aeb@udkantsdanmark.dk"/>
    <assignedPerson
      classCode="PSN"
      determinerCode="INSTANCE">
      <name>
        <given>Adam</given>
        <given>Everyman</given>
        <family>Berggren</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</dataEnterer>
```

Figure 6: `dataEnterer Example`

## **2.2.4 Informant**

The `informant` element is not used in this profile.

## 2.2.5 Custodian

The `custodian` element represents the organization that is in charge of maintaining the document (e.g. a remote disease management organization (DMO)). The custodian is the steward that is entrusted with the use and management of the document. Every CDA document has exactly one custodian.

13. **SHALL** contain exactly one [1..1] custodian (CONF:60).
  - a. This custodian **SHALL** contain exactly one [1..1] assignedCustodian (CONF:61).
    - i. This assignedCustodian **SHALL** contain exactly one [1..1] representedCustodianOrganization which may be the person when the document is not maintained by an organization (CONF:62).
      1. This representedCustodianOrganization **SHALL** contain at least one [1..\*] id (CONF:63).
      2. This representedCustodianOrganization **SHALL** contain exactly one [1..1] name (CONF:64).
      3. This representedCustodianOrganization **SHALL** contain exactly one [1..1] telecom (CONF:65).
        - a. This telecom **SHOULD** contain exactly one [1..1] @use (CONF:66).
      4. This representedCustodianOrganization **SHALL** contain exactly one [1..1] addr (CONF:67).

```
<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 7: Custodian example

## 2.2.6 InformationRecipient

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

14. **MAY** contain zero or more [0..\*] informationRecipient (CONF:68).
  - a. The informationRecipient **SHALL** contain exactly one [1..1] intendedRecipient (CONF:69).
    - i. This intendedRecipient **SHOULD** contain atleast one [1..\*] id (CONF:70).
    - ii. This intendedRecipient **MAY** contain zero or one [0..1] informationRecipient (CONF:71).
      1. The informationRecipient, if present, **SHALL** contain at least one [1..1] name (CONF:72).
    - iii. This intendedRecipient **MAY** contain zero or one [0..1] receivedOrganisation (CONF:73).
      1. The receivedOrganisation, if present, **SHALL** contain at least one [1..1] name (CONF:74).

```
<!-- Primary Care physician (PCP) as recipient -->
<informationRecipient
  typeCode="PRCP">
  <intendedRecipient
    classCode="ASSIGNED">
      <!-- The physician's number (Ydernummer). -->
      <id
        assigningAuthorityName="Region Midtjylland"
        extension="624799"
        root="1.2.208.176.1.4"/>
      <telecom
        use="WP"
        value="tel:99331800"/>
      <informationRecipient
        classCode="PSN"
        determinerCode="INSTANCE">
        <name>
          <prefix>Uddannelsesamanuensis</prefix>
          <given>Hans</given>
          <family>Jensen</family>
        </name>
      </informationRecipient>
      <receivedOrganization
        classCode="ORG"
        determinerCode="INSTANCE">
        <!-- Organization (SOR-ID) -->
        <id
          assigningAuthorityName="SOR"
          extension="478791000016005"
          root="1.2.208.176.1.1"/>
        <name>Lægerne Sløjfen</name>
        <telecom
          use="WP"
          value="tel:99331800"/>
        <addr
          use="WP">
          <streetAddressLine>Fyrkildevej 7, 1</streetAddressLine>
          <postalCode>9220</postalCode>
          <city>Aalborg Øst</city>
          <country>Danmark</country>
        </addr>
      </receivedOrganization>
    </intendedRecipient>
  </informationRecipient>
```

Figure 8: informationRecipient example

## **2.2.7 LegalAuthenticator**

The `legalAuthenticator` element is not used in this profile.

## **2.2.8 Authenticator**

The authenticator element is not used in this profile.

## 2.2.9 Participant (Support)

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

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

15. **MAY** contain zero or more [0..\*] `participant` (CONF:98).
  - a. The `participant`, if present, **MAY** contain zero or one [0..1] `time` (CONF:99).
  - b. Such `participant`(s), if present, **SHALL** have an `associatedPerson` or `scopingOrganization` element under `participant/associatedEntity` (CONF:100).
  - c. Unless otherwise specified by the document specific header constraints, when `participant/@typeCode` is IND, `associatedEntity/@classCode` **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.33 INDRoleclassCodes **STATIC** 2011-09-30 (CONF:101).

Value Set: INDRoleclassCodes 2.16.840.1.113883.11.20.9.33 STATIC 2011-09-30		
Code System(s): RoleClass 2.16.840.1.113883.5.110		
Code	Code System	Print name
PRS	RoleClass	personal relationship
NOK	RoleClass	next of kin
CAREGIVER	RoleClass	Caregiver
AGNT	RoleClass	Agent
GUAR	RoleClass	Guarantor
ECON	RoleClass	emergency contact

Table 5: IND Role classCode Value Set

```
<participant
  typeCode="IND">
  <associatedEntity
    classCode="NOK">
    <addr
      use="H">
      <streetAddressLine>Vestergade 17</streetAddressLine>
      <postalCode>9220</postalCode>
      <city>Aalborg Øst</city>
      <country>Danmark</country>
    </addr>
    <telecom
      use="H"
      value="tel:23122312"/>
    <associatedPerson
      classCode="PSN">
      <name>
        <prefix>Forvalter</prefix>
        <given>Martha</given>
        <family>Berggren</family>
      </name>
    </associatedPerson>
  </associatedEntity>
</participant>
```

Figure 9: Participant Example for a Supporting Person

## 2.2.10 InFulfillmentOf

The `inFulfillmentOf` element represents orders that are fulfilled by this Questionnaire Response document. For example, in the Continua eco-system, a remote DMO creates a task for the patient to fill-in the Questionnaire which is represented according to the Questionnaire Form Definition Document Implementation Guide. Reference to such task is stored in the `id` field of the Questionnaire Response Document. Such ids may represent a globally unique identifier for the task object.

16. **MAY** contain zero or more [0..\*] `inFulfillmentOf` (CONF:102).
  - a. The `inFulfillmentOf`, if present, **SHALL** contain exactly one [1..1] `order` (CONF:103).
    - i. This `order` **SHALL** contain at least one [1..\*] `id` (CONF:104).

## 2.2.11 DocumentationOf

The documentationOf element is used to hold eventCodeList entries which are converted to metadata used to search for documents in the Danish XDS infrastructure. Further information on metadata in the document [http://svn.medcom.dk/svn/drafts/Standarder/IHE/DK\\_profil\\_metadata/Metadata-v096.pdf](http://svn.medcom.dk/svn/drafts/Standarder/IHE/DK_profil_metadata/Metadata-v096.pdf)

The necessary metadata is the period of time over which the questionnaire is answered and a code for the questionnaire type.

The first occurrence of documentationOf shall only contain the start and end time of the period over which the questionnaire was answered.

The second occurrence of documentationOf shall only contain the code of the questionnaire type.

17. **SHALL** contain exactly two [2..2] documentationOf (CONF-DK:21).
  - a. The first documentationOf **SHALL** contain exactly one [1..1] serviceEvent.
    - i. This serviceEvent **SHALL** contain exactly one [1..1] effectiveTime/low element such that it
      1. **SHALL** contain exactly one [1..1] @value holding the time when the person began answering the questionnaire (CONF-DK:22).
    - ii. This serviceEvent **SHALL** contain exactly one [1..1] effectiveTime/high element such that it
      1. **SHALL** contain exactly one [1..1] @value holding the time when the person completed the questionnaire. It is allowed to use an appropriate nullFlavor (CONF-DK:23).
  - b. The second documentationOf **SHALL** contain exactly one [1..1] serviceEvent.
    - i. This serviceEvent **SHALL** contain exactly one [1..1] code element such that it
      1. **SHALL** have exactly one [1..1] @code holding the questionnaire type code (CONF-DK:24)
      2. **SHALL** have exactly one [1..1] @codeSystem holding the OID of the questionnaire type code codesystem (CONF-DK:25)
      3. **SHALL** have exactly one [1..1] @displayName holding the description of the questionnaire type (CONF-DK:25)
      4. **SHALL** have exactly one [1..1] @codeSystemName holding the name of the questionnaire type code codesystem (CONF-DK:27)

```
<documentationOf
  typeCode="DOC">
  <serviceEvent
    classCode="MPROT"
    moodCode="EVN">
    <effectiveTime>
      <low
        value="20171108103010+0100"/>
      <high
        nullFlavor="NI"/>
    </effectiveTime>
  </serviceEvent>
</documentationOf>

<documentationOf
  typeCode="DOC">
  <serviceEvent
    classCode="MPROT"
    moodCode="EVN">
    <code
      code="KCCQ-12"
      codeSystem="1.2.208.999.9.9"
      codeSystemName="PRO Spørgeskematyper"
      displayName="Kansas City Cardiomyopathy Questionnaire"/>
  </serviceEvent>
</documentationOf>
```

Figure 10: DocumentationOf example of Period of time and QRD Type

## 2.3 Rendering Header Information for Human Presentation

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

- Document title and document dates
- Names of all persons along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Names of selected organizations along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Date of birth for recordTarget

### 3 QUESTIONNAIRE RESPONSE DOCUMENT-LEVEL TEMPLATE

This chapter defines document-level template used in the Questionnaire Response Document containing set of question responses answered by 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. Questionnaire Response Document template is a universal template, hence contains the minimum constraints. Base CDA constraints are not repeated if not further constrained.

For the patient generated Questionnaire Response Document, the header conforms to the DK Patient Generated Document Header template. For the clinicians generated responses in DK Realm, this Implementation Guide requires conformance to DK General Header template.

#### 3.1 Questionnaire Response Document

[ClinicalDocument: templateId 1.2.208.184.13.1.1.1]

This template describes constraints that apply to the Questionnaire Response 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:
	<a href="#">Questionnaire Response Section</a> <a href="#">Copy Right Section</a> <a href="#">Information Only Section</a>

*Table 6: Questionnaire Request Document Contexts*

Name	XPath	Card	Verb	Data Type	CONF#	Fixed Value
	ClinicalDocument[templateId/@root = '1.2.208.184.13.1.1.1']					
templateId		1..1	<b>SHALL</b>			
@root		1..1	<b>SHALL</b>			1.2.208.184.13.1.1.1
Component		1..1	<b>SHALL</b>		CONF:114	
structuredBody		1..1	<b>SHALL</b>		CONF:115	
component		1..*	<b>SHALL</b>		CONF:116	
Section		1..1	<b>SHALL</b>		CONF:117	

*Table 7: Questionnaire Response Document Constraints Overview*

1. **SHALL** conform to the Danish Profile Questionnaire Response Document Header template (templateId: 1.2.208.184.13) (CONF-DK: 11).
2. Patient generated Questionnaire Response Document in DK Realm **SHOULD** conform to the DK Realm Generated Document Header template (templateId: 1.2.208.184.13.1.1.1) (CONF-DK: 12).
3. **SHALL** contain exactly one [1..1] templateId (CONF:112) such that it
  - a. **SHALL** contain exactly one [1..1] @root="1.2.208.184.13.1.1.1" (CONF:113).
4. **SHALL** contain exactly one [1..1] component (CONF:114).
  - a. **SHALL** contain exactly one [1..1] structuredBody (CONF:115).
    - i. This structuredBody **SHALL** contain at least one [1..\*] component (CONF:116) such that it
      1. **SHALL** contain exactly one [1..1] [Questionnaire Response Section](#) template (templateId: 2.16.840.1.113883.10.20.33.2.1) (CONF:117).
      2. **SHALL** contain exactly one [1..1] [Copy Right Section](#) template (templateId: 2.16.840.1.113883.10.20.32.2.2) (CONF:118).
      3. **SHALL** contain exactly one [1..1] [Information Only Section](#) template (templateId: 2.16.840.1.113883.10.20.33.2.1).

## 4 SECTION-LEVEL TEMPLATES

This section contains section-level templates used by the Questionnaire Response 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 Response Section

[section: templateId 2.16.840.1.113883.10.20.33.2.1]

A Questionnaire Response Document consists of sections that groups related question responses. Section title ease human-readability and navigation in the document. Section code 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, which contains patient response to a question.

Used By:	Contains Entries:
<a href="#">Questionnaire Response document-level template (required)</a>	<a href="#">Response Organizer</a>

Table 8: Questionnaire Response Section Pattern Contexts

Name	XPath	Card	Verb	Data Type	CONF#	Fixed Value
section[templateId/@root = '2.16.840.1.113883.10.20.33.2.1']						
templateId	1..1	<b>SHALL</b>		CONF:119		
@root	1..1	<b>SHALL</b>		CONF:120	2.16.840.1.113883.10.20.33.2.1	
code	1..1	<b>SHALL</b>		CONF:121	74465-6	
title	0..1	<b>SHOULD</b>		CONF:122		
text	1..1	<b>SHALL</b>		CONF:123		
languageCode	0..1	<b>SHOULD</b>		CONF:124		
entry	1..*	<b>SHALL</b>		CONF:125		
@typeCode	1..1	<b>SHALL</b>		CONF:126	DRIV	
organizer	1..1	<b>SHALL</b>		CONF:127		

Table 9: Questionnaire Request Section Constraint Overview

1. **SHALL** contain exactly one [1..1] templateId (CONF:119) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.2.1" (CONF:120).
2. **SHALL** contain exactly one [1..1] code (CONF:121).
3. **SHOULD** contain zero or one [0..1] title (CONF:122).
4. **SHALL** contain exactly one [1..1] text (CONF:123).
  - a. See [NarrativeBlock\\_QRD - 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:124).
6. **SHALL** contain at least one [1..\*] entry (CONF:125) such that it
  - a. **SHALL** contain exactly one [1..1] @typeCode="DRIV" (CONF:126)
  - b. **SHALL** contain exactly one [1..1] [Response Organizer](#) template (templateId: 2.16.840.1.113883.10.20.33.4.1) (CONF:127).

```

<section
  classCode="DOCSECT"
  moodCode="EVN">
  <templateId
    root="2.16.840.1.113883.10.20.33.2.1"/>
  <code
    code="74465-6"
    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 11: Questionnaire Request Section example

## 4.2 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 QRD version it has the templateId of the Questionnaire Form Definition Section (QFDD).

In the next QFDD version Information Only Sections will get its own unique templateId, which will be used in the next version of QRD as well.

Used By:	Contains Entries:
<a href="#">Questionnaire Response document-level template</a> (optional)	Information Only Section don't contain any entries

Table 10: 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	<b>SHALL</b>			CONF-DK:9	
@root	1..1	<b>SHALL</b>			CONF-DK:10	2.16.840.1.113883.10.20.32.2.1 (OPEN)
Title	0..1	<b>SHOULD</b>			CONF-DK:11	
Text	1..1	<b>SHALL</b>			CONF-DK:12	
languageCode	0..1	<b>SHOULD</b>			CONF-DK:13	

Table 11: 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 12: 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.

## 5.1 Response Organizer

[organizer: templateId 2.16.840.1.113883.10.20.33.4.1]

This template can be used to create groupings of other entries (or templates) that share a common context e.g. question responses 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 response represented by the generic observation class.

Used By:	Contains Entries:
<a href="#">Questionnaire Response Section (required)</a>	<a href="#">Numeric Response Pattern Observation</a> <a href="#">Multiple Choice Response Pattern Observation</a> <a href="#">Text Response Pattern Observation</a> <a href="#">Analog Slider Response Pattern Observation</a> <a href="#">Discrete Slider Response Pattern Observation</a>

*Table 12: Response Organizer Contexts*

Name	XPath	Card	Verb	Data Type	CONF#	Fixed Value
	organizer[templateId/@root = '2.16.840.1.113883.10.20.33.4.1']					
	@classCode	1..1	<b>SHALL</b>		CONF:128	2.16.840.1.113883.5.6 (HL7ActClass)=BATTERY
	@moodCode	1..1	<b>SHALL</b>		CONF:129	2.16.840.1.113883.5.1001 (ActMood = EVN)
	templateId	1..1	<b>SHALL</b>		CONF:130	
	@root	1..1	<b>SHALL</b>		CONF:131	2.16.840.1.113883.10.20.33.4.1
	id	1..*	<b>SHALL</b>		CONF:132	
	code	0..1	<b>SHOULD</b>		CONF:133	
	statusCode	1..1	<b>SHALL</b>		CONF:134	
	@code	1..1	<b>SHALL</b>		CONF:135	2.16.840.1.113883.5.14 (ActStatus) = completed
	component	1..*	<b>MAY</b>		CONF:136	
	sequenceNumber	1..1	<b>SHALL</b>		CONF:137	
	observation	1..1	<b>SHALL</b>		CONF:138	

*Table 13: Response Organizer Constraints Overview*

1. **SHALL** contain exactly one [1..1] @classCode="BATTERY" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:128).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:129).
3. **SHALL** contain exactly one [1..1] templateId (CONF:130) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.1" (CONF:131).
4. **SHALL** contain at least one [1..\*] id (CONF:132).
5. **SHOULD** contain zero or one [0..1] code (CONF:133).
6. **SHALL** contain exactly one [1..1] statusCode (CONF:134).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:135).
7. **SHALL** contain at least one [1..\*] component (CONF:136) such that it
  - a. **SHALL** contain exactly one [1..1] squenceNumber (CONF:137).
    - i. **SHALL** contain exactly one [1..1] of the following templates (CONF:138)
      - [Numeric Response Pattern Observation](#) template (templateId: 2.16.840.1.113883.10.20.33.4.4) (CONF:139).
      - [Multiple Choice Response Pattern Observation](#) template (templateId: 2.16.840.1.113883.10.20.33.4.5) (CONF:140).
      - [Text Response Pattern Observation](#) template (templateId: 2.16.840.1.113883.10.20.33.4.6) (CONF:141).
      - [Analog Slider Response Pattern Observation](#) (templateId: 2.16.840.1.113883.10.20.33.4.7) (CONF:142).
      - v. [Discrete Slider Response Pattern Observation](#) template (templateId: 2.16.840.1.113883.10.20.33.4.8) (CONF:143).

```

<organizer
  classCode="BATTERY"
  moodCode="EVN">
  <!-- Answers Organizer templateId -->
  <templateId
    root="2.16.840.1.113883.10.20.33.4.1"/>
  <id
    extension="7f6020a5-4b91-4e28-b3b7-c477b655403f"
    root="1.2.208.184"/>
  <statusCode
    code="completed"/>
  <!-- Contains response to numeric, multiple choice, text, analog or discrete slider question
  templates defined in the Questionnaire Form Definition Document IG -->
  <component
    contextConductionInd="true"
    typeCode="COMP">
    <sequenceNumber
      value="1"/>
    <!-- The following observation contains the response(s) -->
    <observation
      classCode="OBS"
      moodCode="EVN">
      <!--templateID for the Numeric Response Pattern-->
      <templateId
        root="2.16.840.1.113883.10.20.33.4.4"/>
      .
      .
      </observation>
    </component>
    <component
      contextConductionInd="true"
      typeCode="COMP">
      <sequenceNumber
        value="2"/>
      <observation
        classCode="OBS"
        moodCode="EVN">
        <!--templateID for the Multiple Choice Response Pattern-->
        <templateId
          root="2.16.840.1.113883.10.20.33.4.5"/>
      .
      .
      </observation>
    </component>
    <component
      contextConductionInd="true"
      typeCode="COMP">
      <sequenceNumber
        value="3"/>
      <observation
        classCode="OBS"
        moodCode="EVN">
        <!--templateID for the Text Response Pattern-->
        <templateId
          root="2.16.840.1.113883.10.20.33.4.6"/>
      .
      .
      </observation>
    </component>
    <component
      contextConductionInd="true"
      typeCode="COMP">
      <sequenceNumber
        value="4"/>
      <observation
        classCode="OBS"
        moodCode="EVN">
        <!--templateID for the Discrete Slider Response Pattern-->
        <templateId
          root="2.16.840.1.113883.10.20.33.4.8"/>
      .
      .
      </observation>
    </component>
  </organizer>

```

**Figure 13: Response Organizer Example**

## 5.2 Response Media Pattern

[observationMedia: templateId 2.16.840.1.113883.10.20.33.4.2]

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

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

The media was part of the question presented to the user.

Used By:	Contains Entries:
<a href="#">Numeric Response Pattern Observation</a> (optional) <a href="#">Multiple Choice Response Pattern Observation</a> (optional) <a href="#">Text Response Pattern Observation</a> (optional) <a href="#">Analog Slider Response Pattern Observation</a> (optional) <a href="#">Discrete Slider Response Pattern Observation</a> (optional)	

Table 14: Response Media Pattern Contexts

Name	XPath	Card	Verb	Data Type	CONF#	Fixed Value
	observationMedia[templateId/@root ='2.16.840.1.113883.10.20.33.4.2']					
	@classCode	1..1	<b>SHALL</b>	CD	CONF:144	2.16.840.1.113883.5.6 (HL7ActClass)=OBS
	@moodCode	1..1	<b>SHALL</b>	CD	CONF:145	2.16.840.1.113883.5.1001 (ActMood) = EVN
	@ID	0..1	<b>SHOULD</b>			
	templateId	1..1	<b>SHALL</b>		CONF:146	
	@root	1..1	<b>SHALL</b>		CONF:147	2.16.840.1.113883.10.20.33.4.2
	Value	0..1	<b>SHALL</b>		CONF:148	

Table 15: Media Pattern Constraints Overview

1. **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:144).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:145).
3. **SHOULD** contain exactly one [0..1] @ID
4. **SHALL** contain exactly one [1..1] templateId (CONF:146) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.2" (CONF:147).
5. **SHALL** contain exactly one [1..1] value (CONF:148).
- 6.

```
<observationMedia
  ID="example.png" classCode="OBS" moodCode="DEF">
  <templateId
    root="2.16.840.1.113883.10.20.33.4.2"/>
  <value
    mediaType="image/png" representation="B64">
      <!-- base64 encoded image -->
      dHDM4DNY6tO+4y+jPXK5Cg6HbHoI22gMphNIbFgPkA0fnZWmNhEEGei...
    </value>
</observationMedia>
```

Figure 14: Response Media Pattern Example

```
<observationMedia
  classCode="OBS" moodCode="EVN">
  <templateId
    root="2.16.840.1.113883.10.20.33.4.2"/>
  <value
    mediaType="image/jpeg">
      <reference
        value="example"/>
    </value>
</observationMedia>
```

Figure 15: Response Media Pattern Example with reference

### 5.3 Response Reference Range Pattern

[criterion: templateId 2.16.840.1.113883.10.20.33.4.3]

The Response Reference Range Pattern is used to hold lower and upper boundaries for the question response in the context of this implementation guide. For example, in case of Figure 16, the value entered should be of the type 'INT' between '0' and '24'.

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

Table 16: Response Reference Range Pattern Contexts

Name	XPath	Card	Verb	Data Type	CONF#	Fixed Value
	referenceRange[templateId/@root = '2.16.840.1.113883.10.20.33.4.3']					
	@typeCode	1..1	<b>SHALL</b>	CD	CONF:149	REFV
	templateId	1..1	<b>SHALL</b>		CONF:150	
	@root	1..1	<b>SHALL</b>		CONF:151	2.16.840.1.113883.10.20.33.4.3
	observationRange	1..1	<b>SHALL</b>		CONF:152	
	text	0..1	<b>MAY</b>		CONF:153	
	value	1..1	<b>SHALL</b>		CONF:154	
	@xsi:type	1..1	<b>SHALL</b>		CONF:155	
minimumValue	low	1..1	<b>SHALL</b>		CONF:156	
maximumValue	high	1..1	<b>SHALL</b>		CONF:157	

Table 17: Response Reference Pattern Constraints Overview

1. **SHALL** contain exactly one [1..1] @typeCode="REFV" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:149).
2. **SHALL** contain exactly one [1..1] templateId (CONF:150) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.3" (CONF:151).
3. The referenceRange **SHALL** contain exactly one [1..1] observationRange (CONF:152).
  - a. **MAY** contain zero or one [0..1] text (CONF:153).
  - b. **SHALL** contain exactly one [1..1] value (CONF:116) such that it
    - i. **SHALL** contain exactly one [1..1] @xsi:type (CONF:155).
    - ii. **SHALL** contain exactly one [1..1] low (CONF:156).
    - iii. **SHALL** contain exactly one [1..1] high (CONF:157).

```

<referenceRange
  typeCode="REFV">
  <!--templateID for the Response Reference Range Pattern-->
  <templateId
    root="2.16.840.1.113883.10.20.33.4.3"/>
  <observationRange>
    <value
      xsi:type="IVL_INT">
      <low
        value="0"/>
      <high
        value="24"/>
    </value>
  </observationRange>
</referenceRange>

```

Figure 16: Response Reference Range Pattern Example

## 5.4 Numeric Response Pattern Observation

[precondition: templateId 2.16.840.1.113883.10.20.33.4.4]

The Numeric Response 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

Response Reference Range Pattern template may also be associated with this pattern indicating the expected range of observation/value (i.e. answer to the question).

Used By:	Contains Entries:
<a href="#">Response Organizer</a> (required)	<a href="#">Response Media Pattern</a>
<a href="#">Analog Slider Response Pattern Observation</a> (required)	<a href="#">Response Reference Range Pattern</a> <a href="#">Question Help Text Pattern Observation</a>

*Table 18: Numeric Question Response Pattern Contexts*

Name	XPath	Card	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.33.4.4']					
	@classCode	1..1	<b>SHALL</b>		CONF:158	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	<b>SHALL</b>		CONF:159	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	<b>SHALL</b>		CONF:160	
	@root	1..1	<b>SHALL</b>		CONF:161	2.16.840.1.113883.10.20.33.4.4
questionId	id	1..*	<b>SHALL</b>		CONF:161	
question	code	1..1	<b>SHALL</b>	CE	CONF:163	
	@code	1..1	<b>SHALL</b>		CONF:164	
	@codeSystem	1..1	<b>SHALL</b>		CONF:165	
	originalText	1..1	<b>SHALL</b>		CONF:166	
	languageCode	0..1	<b>SHOULD</b>		CONF:167	
	statusCode	1..1	<b>SHALL</b>		CONF:168	
	@code	1..1	<b>SHALL</b>		CONF:169	2.16.840.1.113883.5.14 (ActStatus) = completed
answerNumeric	value	1..1	<b>SHALL</b>		CONF:170	
	@xsi:type	1..1	<b>SHALL</b>		CONF:171	INT, REAL or TS
	entryRelationship	0..1	<b>MAY</b>		CONF:172	
	@typeCode	1..1	<b>SHALL</b>	CD	CONF:173	SUBJ
	observation	1..1	<b>SHALL</b>		CONF:174	
	entryRelationship	0..1	<b>SHOULD</b>		CONF:175	
	@typeCode	1..1	<b>SHALL</b>	CD	CONF:176	REFR
associatedMedia	observationMedia	1..1	<b>SHALL</b>		CONF:177	
	referenceRange	0..*	<b>SHOULD</b>		CONF:178	
QFDD reference	reference	1..1	<b>SHALL</b>		CONF-DK:28	

*Table 19: Numeric Response Pattern Constraints Overview*

1. **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:158).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:159).
3. **SHALL** contain exactly one [1..1] templateId (CONF:160) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.4" (CONF:161).
4. **SHALL** contain at least one [1..\*] id (CONF:162).
5. **SHALL** contain exactly one [1..1] code (CONF:163).
  - a. This code **SHALL** contain exactly one [1..1] @code (CONF:164).
  - b. This code **SHALL** contain exactly one [1..1] @codeSystem (CONF:165).
  - c. This code **SHALL** contain exactly one [1..1] originalText (CONF:166).
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:167).

7. **SHALL** contain exactly one [1..1] statusCode (CONF:168).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:169).
8. **SHALL** contain exactly one [1..1] value (CONF:170)
  - a. **SHALL** contain exactly one [1..1] @xsi:type, where the value of @xsi:type could be "INT", "REAL" or "TS" (CONF:171).
9. **MAY** contain zero or one [0..1] entryRelationship (CONF:172).
  - a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:173).
  - 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:174).
10. **SHOULD** contain zero or one [0..1] entryRelationship (CONF:175).
  - a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:176).
  - b. **SHALL** conform to the Response Media Pattern template (templateid 2.16.840.1.113883.10.20.33.4.2) (CONF:177)
11. **SHOULD** contain zero or more [0..\*] Response Reference Range Pattern template (templateId 2.16.840.1.113883.10.20.33.4.3) (CONF:178).
12. **SHALL** contain exactly one [1..1] reference External References (CONF-DK:28)

```

<observation
  classCode="OBS" moodCode="EVN">
  <!--templateID for the Numeric Response Pattern-->
  <templateId
    root="2.16.840.1.113883.10.20.33.4.4"/>
  <id
    extension="b0e99a2a-2c3a-4f0f-a7eb-5287bbd0174d" root="1.2.208.184"/>
  <code
    code="q4768"
    codeSystem="1.2.208.N.N.N"
    codeSystemName="Some Table">
    <originalText>Hvor mange timer sov du sidste nat?</originalText>
  </code>
  <value
    value="7"
    xsi:type="INT"/>
  <referenceRange
    typeCode="REFV">
    <!--templateID for the Response Reference Range Pattern-->
    <templateId
      root="2.16.840.1.113883.10.20.33.4.3"/>
    <observationRange>
      <value
        xsi:type="IVL_INT">
        <low
          value="0"/>
        <high
          value="24"/>
      </value>
    </observationRange>
  </referenceRange>
  <reference
    typeCode="REFR">
    <templateId
      root="1.2.208.184.6.1"/>
    <externalDocument
      classCode="DOC">
      <id
        <!-- extension refers to the machine-readable questionnaire definition (QFDD) -->
        extension="fe4da12f-f99a-4634-a5d9-5ab2d93c85b1"
        root="2.16.840.1.113883.4.873"/>
      <code
        code="74468-0"
        codeSystem="2.16.840.1.113883.1.6"
        displayName="Questionnaire Form Definition Document"/>
    </externalDocument>
  </reference>
</observation>

```

*Figure 17: Numeric Response Pattern Observation Example*

## 5.5 Multiple Choice Response Pattern Observation

[observation: templateId 2.16.840.1.113883.10.20.33.4.5]

The Multiple Choice Response Pattern Observation is used to hold response from a multiple choice question where a user can select multiple options. Question Options Pattern Observation template may be also be associated with this pattern indicating the minimum and maximum number of options that should have been selected by a user.

Used By:	Contains Entries:
<a href="#">Discrete Slider Response Pattern Observation</a>	<a href="#">Response Media Pattern</a>
<a href="#">Response Organizer (required)</a>	<a href="#">Response Reference Range Pattern</a>
<a href="#">Discrete Slider Response Pattern Observation (required)</a>	<a href="#">Question Help Text Pattern Observation</a>
	<a href="#">Question Options Pattern Observation</a>
	<a href="#">Text Response Pattern Observation</a>

*Table 20: Multiple Choice Response Pattern Observation Contexts*

Name	XPath	Card	Verb	DataType	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.33.4.5']					
	@classCode	1..1	<b>SHALL</b>		CONF:179	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	<b>SHALL</b>		CONF:180	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	<b>SHALL</b>		CONF:181	
	@root	1..1	<b>SHALL</b>		CONF:182	2.16.840.1.113883.10.20.33.4.5
questionId	id	1..*	<b>SHALL</b>	CE	CONF:183	
question	code	1..1	<b>SHALL</b>	CE	CONF:184	
	@code	1..1	<b>SHALL</b>		CONF:185	
	@codeSystem	1..1	<b>SHALL</b>		CONF:186	
	originalText	1..1	<b>SHALL</b>		CONF:187	
	languageCode	0..1	<b>SHOULD</b>		CONF:188	
	statusCode	1..1	<b>SHALL</b>		CONF:189	
	@code	1..1	<b>SHALL</b>		CONF:190	2.16.840.1.113883.5.14 (ActStatus) = completed
selectedAnswerOptions	value	0..*	<b>SHOULD</b>		CONF:191	
	@xsi:type	1..1	<b>SHALL</b>		CONF:192	CE
	@code	1..1	<b>SHALL</b>		CONF:193	
	@codeSystem	1..1	<b>SHALL</b>		CONF:194	
	@displayName	1..1	<b>SHALL</b>		CONF:195	
	entryRelationship	0..*	<b>SHOULD</b>		CONF:196	
	@typeCode	1..1	<b>SHALL</b>	CD	CONF:197	SUBJ
helpText or questionOptions	observation	1..1	<b>SHALL</b>		CONF:198	
	entryRelationship	0..1	<b>SHOULD</b>		CONF:200	
	@typeCode	1..1	<b>SHALL</b>	CD	CONF:201	REFR
associatedMedia	observationMedia	1..1	<b>SHALL</b>		CONF:202	
associatedTextResponse	observation	1..1	<b>SHALL</b>		CONF:203	
QFDD reference	reference	1..1	<b>SHALL</b>		CONF-DK:29	

*Table 21: 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:179).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:180).
3. **SHALL** contain exactly one [1..1] templateId (CONF:181) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.5" (CONF:182).
4. **SHALL** contain at least one [1..\*] id (CONF:183).
5. **SHALL** contain exactly one [1..1] code (CONF:184).
  - a. This code **SHALL** contain exactly one [1..1] @code (CONF:185).

- b. This code **SHALL** contain exactly one [1..1] @CodeSystem (CONF:186).
- c. This code **SHALL** contain exactly one [1..1] originalText (CONF:187).
- 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:188).
- 7. **SHALL** contain exactly one [1..1] statusCode (CONF:189).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" (**Codesystem:** ActStatus 2.16.840.1.113883.5.14) (CONF:190).
- 8. **SHOULD** contain zero or many [0..\*] value (CONF:191).
  - a. **SHALL** contain exactly one [1..1] @xsi:type="CE" (CONF:192).
  - b. **SHALL** contain exactly one [1..1] @code (CONF:193).
  - c. **SHALL** contain exactly one [1..1] @CodeSystem (CONF:194).
  - d. **SHALL** contain exactly one [1..1] @displayName (CONF:195).
- 9. **SHOULD** contain zero or many [0..\*] entryRelationship (CONF:196) such that it
  - a. **SHALL** contain exactly one [1..1] @typeCode="SUBJ" (**CodeSystem:** HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:197).
  - b. **SHALL** contain exactly one [1..1] Question Help Text Pattern Observation (CONF:198).
  - c. **SHALL** contain exactly one [1..1] Question Options Pattern Observation (CONF:199).
- 10. **SHOULD** contain zero or one [0..1] entryRelationship (CONF:200).
  - a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] @typeCode="REFR" (**CodeSystem:** HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:201).
  - b. **SHALL** contain exactly one [1..1] Response Media Pattern template (templateId: 2.16.840.1.113883.10.20.33.4.2) (CONF:202).
  - c. **SHALL** contain exactly one [1..1] Text Response Pattern Observation template (templateId: 2.16.840.1.113883.10.20.33.4.6) (CONF:203).
- 11. **SHALL** contain exactly one [1..1] reference External References (CONF-DK:29)

```

<observation
  classCode="OBS" moodCode="EVN">
  <!--templateID for the Multiple Choice Response Pattern-->
  <templateId
    root="2.16.840.1.113883.10.20.33.4.5"/>
  <id
    extension="23b8ba08-3825-4bfd-a87a-fb91f76b03fe" root="1.2.208.184"/>
  <code
    code="q11-451"
    codeSystem="1.2.208.N.N.N"
    codeSystemName="Some Table"
    displayName="Behov for konsultation">
    <originalText>Hvad er dit behov i forhold til en konsultation?</originalText>
  </code>
  <value
    code="A11-451.3"
    codeSystem="1.2.208.N.N.N"
    codeSystemName="Some Table"
    displayName="Jeg vil gerne have en tid i ambulatoriet"
    xsi:type="CE"/>
  <entryRelationship
    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"/>
      <value
        xsi:type="IVL_INT">
        <!--minimum options-->
        <low
          value="1"/>
        <!--maximum options-->
        <high
          value="1"/>
      </value>
    </observation>
  </entryRelationship>
</observation>

```

**Figure 18: Multiple Choice Response Pattern Observation Example 1**

```

<observation
  classCode="OBS"
  moodCode="EVN">
  <!--templateID for the Multiple Choice Response Pattern-->
  <templateId
    root="2.16.840.1.113883.10.20.33.4.5"/>
  <id
    extension="f64972ee-7f50-4d63-b324-e2e0ffd591eb"
    root="1.2.208.184"/>
  <code
    code="q11-454"
    codeSystem="1.2.208.N.N.N"
    codeSystemName="Some Table"
    displayName="Årsag høj puls">
    <originalText>Venligst vælg nogle årsager (højest 4) til din høje puls</originalText>
  </code>
  <value
    code="A11-454.2"
    codeSystem="1.2.208.N.N.N"
    codeSystemName="Some Table"
    displayName="Jeg havde en meget stresset dag på arbejdet"
    xsi:type="CE"/>
  <value
    code="A11-454.4"
    codeSystem="1.2.208.N.N.N"
    codeSystemName="Some Table"
    displayName="Jeg glemte at tage min medicin om morgenen"
    xsi:type="CE"/>
  <entryRelationship
    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"/>
      <value
        xsi:type="IVL_INT">
        <!--minimum options-->
        <low
          value="1"/>
        <!--maximum options-->
        <high
          value="4"/>
      </value>
    </observation>
  </entryRelationship>
  <reference
    typeCode="REFR">
    <templateId
      root="1.2.208.184.6.1"/>
    <externalDocument
      classCode="DOC">
      <id
        <!-- extension refers to the machine-readable questionnaire definition (QFDD) -->
        extension="fe4da12f-f99a-4634-a5d9-5ab2d93c85b1"
        root="2.16.840.1.113883.4.873"/>
      <code
        code="74468-0"
        codeSystem="2.16.840.1.113883.1.6"
        displayName="Questionnaire Form Definition Document"/>
    </externalDocument>
  </reference>
</observation>

```

**Figure 19: Multiple Choice Response Pattern Observation Example 2**

## 5.6 Text Response Pattern Observation

[observation: templateId 2.16.840.1.113883.10.20.33.4.6]

The Text Question Pattern Observation is used to hold response from a text question where the expected answer is free text.

Used By:	Contains Entries:
<a href="#">Response Organizer</a> (required)	<a href="#">Response Media Pattern</a>
	<a href="#">Question Help Text Pattern Observation</a>

Table 22: Text Response Pattern Contexts

Name	XPath	Card	Verb	DataType	CONF#	Fixed Value
observation[templateId/@root = '2.16.840.1.113883.10.20.33.4.6']						
	@classCode	1..1	<b>SHALL</b>		CONF:204	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	<b>SHALL</b>		CONF:205	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	<b>SHALL</b>		CONF:206	
	@root	1..1	<b>SHALL</b>		CONF:207	2.16.840.1.113883.10.20.33.4.6
questionId	id	1..*	<b>SHALL</b>		CONF:208	
question	code	1..1	<b>SHALL</b>	CE	CONF:209	
	@code	1..1	<b>SHALL</b>		CONF:210	
	@codeSystem	1..1	<b>SHALL</b>		CONF:211	
	originalText	1..1	<b>SHALL</b>		CONF:212	
	languageCode	0..1	<b>SHOULD</b>		CONF:213	
	statusCode	1..1	<b>SHALL</b>		CONF:214	
	@code	1..1	<b>SHALL</b>		CONF:215	2.16.840.1.113883.5.14 (ActStatus)=completed
	value	1..1	<b>SHALL</b>		CONF:216	
	@xsi:type	1..1	<b>SHALL</b>		CONF:217	ST
	entryRelationship	0..1	<b>MAY</b>		CONF:218	
	@typeCode	1..1	<b>SHALL</b>	CD	CONF:219	SUBJ
helpText	observation	1..1	<b>SHALL</b>		CONF:220	
	entryRelationship	0..1	<b>SHOULD</b>		CONF:221	
	@typeCode	1..1	<b>SHALL</b>	CD	CONF:222	REFR
associatedMedia	observationMedia	1..1	<b>SHALL</b>		CONF:223	
QFDD reference	reference	1..1	<b>SHALL</b>		CONF-DK:30	

Table 23: Text Response Pattern Observation Constraints Overview

1. **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:204).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:205).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:206) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.6" (CONF:207).
4. **SHALL** contain at least one [1..\*] id (CONF:208).
5. **SHALL** contain exactly one [1..1] code (CONF:209).
  - a. This code **SHALL** contain exactly one [1..1] @code (CONF:210).
  - b. This code **SHALL** contain exactly one [1..1] @codeSystem (CONF:211).
  - c. This code **SHALL** contain exactly one [1..1] @originalText (CONF:212).
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:213).
7. **SHALL** contain exactly one [1..1] statusCode (CONF:214).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:215).
8. **SHALL** contain exactly one [1..1] value (CONF:216).
  - a. **SHALL** contain exactly one [1..1] @xsi:type="ST" (CONF:217).
9. **MAY** contain zero or one [0..1] entryRelationship (CONF:218).

- a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:219).
  - 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:220).
10. **SHOULD** contain zero or one [0..1] entryRelationship (CONF:221).
- a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:222).
  - b. **SHALL** conform to the Response Media Pattern template (templateId 2.16.840.1.113883.10.20.33.4.2) (CONF:223).
11. **SHALL** contain exactly one [1..1] reference External References (CONF-DK:30).

```

<observation
  classCode="OBS"
  moodCode="EVN">
  <!--templateID for the Text Response Pattern-->
  <templateId
    root="2.16.840.1.113883.10.20.33.4.6"/>
  <id
    extension="4687c8a0-a84b-4237-9fdc-ddb8e351bc41"
    root="1.2.208.184"/>
  <code
    code="q1"
    codeSystem="1.2.208.N.N.N"
    codeSystemName=" Some Table "
    displayName=" Problemer ifm. Epilepsi">
    <originalText>Medfører din epilepsi (anfall/behandling) alvorlige begrænsninger for dig? (fx sociale begrænsninger)</originalText>
  </code>
  <value
    xsi:type="ST">Ja, jeg må ikke køre bil længere og kan ikke bare tage en bus, fordi jeg er bange for at få nye anfald.</value>
  <reference
    typeCode="REFR">
    <templateId
      root="1.2.208.184.6.1"/>
    <externalDocument
      classCode="DOC">
      <id
        <!-- extension refers to the machine-readable questionnaire definition (QFDD) -->
        extension="fe4dal2f-f99a-4634-a5d9-5ab2d93c85b1"
        root="2.16.840.1.113883.4.873"/>
      <code
        code="74468-0"
        codeSystem="2.16.840.1.113883.1.6"
        displayName="Questionnaire Form Definition Document"/>
    </externalDocument>
  </reference>
</observation>

```

**Figure 20: Text Response Pattern Observation Example**

## 5.7 Analog Slider Response Pattern Observation

[observation: templateId 2.16.840.1.113883.10.20.33.4.7]

The Analog Slider Response Pattern is used to hold response to a Visual Analog Slider Question that models a visual analogue scale (VAS)<sup>4</sup> [5]. 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:				
Response Organizer (required)	Numeric Response Pattern Observation				

Table 24: Analog Slider Response Pattern Contexts

Name	XPath	Card	Verb	DataType	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.33.4.7']					
	templateId	1..1	<b>SHALL</b>		CONF:224	
	@root	1..1	<b>SHALL</b>		CONF:224A	2.16.840.1.113883.10.20.33.4.4
	templateId	1..1	<b>SHALL</b>		CONF:226	
	@root	1..1	<b>SHALL</b>		CONF:227	2.16.840.1.113883.10.20.33.4.7
	referenceRange	1..1	<b>SHALL</b>		CONF:228	
	@typeCode	1..1	<b>SHALL</b>	CD	CONF:229	REFV
	observationRange	1..1	<b>SHALL</b>		CONF:230	
	value	1..1	<b>SHALL</b>		CONF:231	
	@xsi:type	1..1	<b>SHALL</b>		CONF:232	GLIST_PQ
startOfScale	head	1..1	<b>SHALL</b>		CONF:233	
stepSize	increment	1..1	<b>SHALL</b>		CONF:234	
endOfScale	@denominator	1..1	<b>SHALL</b>		CONF:235	
QFDD reference	reference	1..1	<b>SHALL</b>		CONF-DK:31	

Table 25: Analog Slider Response Pattern Observation Constraints Overview

1. **SHALL** conform to the [Numeric Response Pattern Observation](#) template (CONF:224) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.4" (CONF:224A).
2. **SHALL NOT** contain [Response Reference Range Pattern](#) template (templateId 2.16.840.1.113883.10.20.33.4.3) (CONF:225).
3. **SHALL** contain exactly one [1..1] templateId (CONF:226) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.7" (CONF:227).
4. **SHALL** contain exactly one [1..1] referenceRange (CONF:228).
  - a. **SHALL** contain exactly one [1..1] @typeCode="REFV" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:229).
  - b. **SHALL** contain exactly one [1..1] observationRange (CONF:230).
  - c. **SHALL** contain exactly one [1..1] value (CONF:231) such that it
    - i. **SHALL** contain exactly one [1..1] @xsi:type="GLIST\_PQ" (CONF:232).
      1. **SHALL** contain exactly one [1..1] head (CONF:233).
      2. **SHALL** contain exactly one [1..1] increment (CONF:234).
      3. **SHALL** contain exactly one [1..1] @denominator (CONF:235).
5. **SHALL** contain exactly one [1..1] reference [External References](#) (CONF-DK:31).

```
<observation
  classCode="OBS"
  moodCode="EVN">
  <!--templateID for the Numeric Question Pattern Observation-->
```

<sup>4</sup> 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](http://www.cebp.nl/vault_public/filesystem/?ID=1478) (Accessed on 17-March-2013)]

<sup>5</sup> HL7 Implementation Guide for CDS Release 2.0: Questionnaire Form Definition Document, Release 1, April 2013.

```

<templateId
  root="2.16.840.1.113883.10.20.32.4.6"/>
<!--templateID for the Analog Slider Response Pattern-->
<templateId
  root="2.16.840.1.113883.10.20.32.4.9"/>
<id
  extension="fc605512-baa5-49fc-924c-cc2af5623309"
  root="1.2.208.184"/>
<code
  code="q17-2346"
  codeSystem="1.2.208.184"
  codeSystemName="Some Table"
  displayName="Periode med smerte">
  <originalText>Hvor stor en del af døgnet har du smerter? Angiv det i %</originalText>
</code>
<value
  unit="%"
  value="50"
  xsi:type="PQ"/>
<referenceRange
  typeCode="REFV">
  <observationRange>
    <value
      denominator="100"
      xsi:type="GLIST_PQ">
      <head
        value="0"/>
      <increment
        value="1"/>
    </value>
  </observationRange>
</referenceRange>
<reference
  typeCode="REFR">
  <templateId
    root="1.2.208.184.6.1"/>
  <externalDocument
    classCode="DOC">
    <id
      extension="fe4da12f-f99a-4634-a5d9-5ab2d93c85b1"
      root="2.16.840.1.113883.4.873"/>
    <code
      code="74468-0"
      codeSystem="2.16.840.1.113883.1.6"
      displayName="Questionnaire Form Definition Document"/>
  </externalDocument>
</reference>
</observation>

```

**Figure 21: Analog Slider Response Pattern Observation Example**

## 5.8 Discrete Slider Response Pattern Observation

[observation: templateId 2.16.840.1.113883.10.20.33.4.8]

The Discrete Slider Response Pattern Observation is used to hold the response from a discrete slider question. This is similar to Multiple Choice Response Pattern Observation however the user can only select one option, hence the high value in the Question Options Pattern Observation is fixed to "1".

Used By:	Contains Entries:					
	<a href="#">Multiple Choice Response Pattern Observation</a>					

*Table 26: Discrete Slider Response Pattern Contexts*

Name	XPath	Card	Verb	DataType	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.33.4.8']					
	templateId	1..1	<b>SHALL</b>		CONF:236	
	@root	1..1	<b>SHALL</b>		CONF:236A	2.16.840.1.113883.10.20.33.4.5
	templateId	1..1	<b>SHALL</b>		CONF:237	
	@root	1..1	<b>SHALL</b>		CONF:238	2.16.840.1.113883.10.20.33.4.8
response	value	1..1	<b>SHALL</b>		CONF:239	
	entryRelationship/observation/value/high/@value	1..1	<b>SHALL</b>	INT	CONF:240	1
QFDD reference	reference	1..1	<b>SHALL</b>		CONF-DK:32	

*Table 27: Discrete Slider Response Pattern Observation Constraints Overview*

1. **SHALL** confirm to [Multiple Choice Response Pattern Observation](#) template (CONF:236) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.5" (CONF:236A).
2. **SHALL** contain exactly one [1..1] templateId (CONF:237) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.8" (CONF:238).
3. **SHALL** contain exactly one [1..1] value (CONF:239)
4. 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:240).
5. **SHALL** contain exactly one [1..1] reference [External References](#) (CONF-DK:32).

```

<observation
  classCode="OBS"
  moodCode="EVN">
  <!--templateID for the Multiple Choise Response Pattern-->
  <templateId
    root="2.16.840.1.113883.10.20.33.4.5"/>
  <!--templateID for the Discrete Slider Response Pattern-->
  <templateId
    root="2.16.840.1.113883.10.20.33.4.8"/>
  <id
    extension="0427c096-190e-4b0d-9b82-221e76c592d7"
    root="1.2.208.184"/>
  <code
    code="q19-78A"
    codeSystem="1.2.208.N.N.N"
    codeSystemName="Some Table"
    displayName="Sideeffekter af medicin">
    <originalText>Hvordan vurderer du sideeffekterne af din medicin?</originalText>
  </code>
  <value
    code="A19-78.4"
    codeSystem="1.2.208.N.N.N"
    codeSystemName=" Some Table "
    displayName="Betydelige"
    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"/>
    </observation>
  </entryRelationship>
</observation>

```

```

<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 always be 1 in case of discrete slider-->
  <high
    value="1"/>
</value>
</observation>
</entryRelationship>
<reference
  typeCode="REFR">
<templateId
  root="1.2.208.184.6.1"/>
<externalDocument
  classCode="DOC">
<id
  <!-- extension refers to the machine-readable questionnaire definition (QFDD) -->
  extension="fe4da12f-f99a-4634-a5d9-5ab2d93c85b1"
  root="2.16.840.1.113883.4.873"/>
<code
  code="74468-0"
  codeSystem="2.16.840.1.113883.1.6"
  displayName="Questionnaire Form Definition Document"/>
</externalDocument>
</reference>
</observation>

```

**Figure 22: Discrete Slider Response Pattern Observation Example**

## 5.9 External References

Used By:	Contains Entries:
<a href="#">Numeric Response Pattern Observation</a> <a href="#">Multiple Choice Response Pattern Observation</a> <a href="#">Text Response Pattern Observation</a> <a href="#">Analog Slider Response Pattern Observation</a> <a href="#">Discrete Slider Response Pattern Observation</a>	

**Table 28: Response Organizer Contexts**

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/reference

Name	XPath	Card	Verb	DataType	CONF#	Fixed Value
	reference	1..1	<b>SHALL</b>	CD		
	@typeCode	1..1	<b>SHALL</b>			REFR
	templateId	1..1	<b>SHALL</b>	II		
	@root	1..1	<b>SHALL</b>			1.2.208.184.6.1
	externalDocument	1..1	<b>SHALL</b>	CD		
	@classCode	1..1	<b>SHALL</b>			DOC
Document Id	Id	1..1	<b>SHALL</b>	II		
	@root	1..1	<b>SHALL</b>			2.16.840.1.113883.4.873
	@extension	1..1	<b>SHALL</b>			An URI specified as a unique UUID for the related QFDD
Document Type	code	1..1	<b>SHALL</b>	CE		
	@code	1..1	<b>SHALL</b>			74468-0
	@codeSystem	1..1	<b>SHALL</b>			2.16.840.1.113883.1.6
	@displayName	1..1	<b>SHALL</b>			Questionnaire Form Definition Document

**Table 29: External Document Pattern Overview**

1. **SHALL** contain [1..1] reference elements such that it:
  - a. **SHALL** contain exactly one [1..1] @TypeCode="REFR".
2. **SHALL** contain exactly one [1..1] templateId such that it
  - a. **SHALL** contain exactly one [1..1] @root="1.2.208.184.6.1".
3. **SHALL** contain exactly one [1..1] externalDocument such that it
  - a. **SHALL** contain exactly one [1..1] @classCode="DOC".
4. **SHALL** contain exactly one [1..1] document id that uniquely identifies the external document by
  - a. Exactly one [1..1] @root and
  - b. Exactly one [1..1] @extension (UUID)
5. **SHALL** contain exactly one [1..1] Document Type code that identifies the type of the external document using The LOINC codeSystem i.e. code:
  - a. **SHALL** contain exactly one [1..1] @code="74468-0"
  - b. **SHALL** contain exactly one [1..1] @codeSystem= "2.16.840.1.113883.1.6"
  - c. **SHALL** contain exactly one [1..1] @displayName= "Questionnaire Form Definition Document"

The following exemplifies a reference to a QFDD with UUID: fe4da12f-f99a-4634-a5d9-5ab2d93c85b1

```
<reference
  typeCode="REFR">
  <templateId
    root="1.2.208.184.6.1"/>
  <externalDocument
    classCode="DOC">
    <id
      extension="fe4da12f-f99a-4634-a5d9-5ab2d93c85b1"
      root="2.16.840.1.113883.4.873"/>
    <code
      code="74468-0"
      codeSystem="2.16.840.1.113883.1.6"
      displayName="Questionnaire Form Definition Document"/>
  </externalDocument>
</reference>
```

*Figure 23: HL7 CDA QFDD Linking Example*

### 5.9.1 Generate QRD

A reference to the machine-readable questionnaire definition (QFDD) must be inserted for each question in a questionnaire response document.

The reference is an URI specified as a unique UUID version 4 for the related QFDD and can be extracted from the QFDD file by using the XPath below:

**QFDD XPath:** /ClinicalDocument/id/@extension

### 5.9.2 Present QRD content

To present the content of a QRD properly, the related QFDD shall be known by the presenting system.

To resolve this reference to the related QFDD, an URL-address must be built. The UUID extension (see section 5.9.1) shall be inserted as a part of the URL. Further details can be found in document “Link resolving between QFDD and QRD”. Reference to the document can be found here: [1.6.2 CDA content](#).

## 6 APPENDIX A: TEMPLATE IDS USED IN QRD

TemplateId	Description
1.2.208.184.13.1	QRD-DK document header (root OID)
1.2.208.184.13.1.1.1	QRD-DK document level templateId
2.16.840.1.113883.10.20.32.2.1 (Open)	Information only section templateId
2.16.840.1.113883.10.20.32.2.2	Copy Right section templateId
2.16.840.1.113883.10.20.32.4.20	Question Options Pattern Observation
2.16.840.1.113883.10.20.32.4.21	Copy Right observation templateId
2.16.840.1.113883.10.20.32.4.19	Question help text observation templateId
2.16.840.1.113883.10.20.33.2.1	QRD Section level templateId
2.16.840.1.113883.10.20.33.4.1	Response organizer level templateId
2.16.840.1.113883.10.20.33.4.2	Response media templateId
2.16.840.1.113883.10.20.33.4.3	Response reference range templateId
2.16.840.1.113883.10.20.33.4.4	Numeric response observation templateId
2.16.840.1.113883.10.20.33.4.5	Multiple choice response observation templateId
2.16.840.1.113883.10.20.33.4.6	Text response observation templateId
2.16.840.1.113883.10.20.33.4.7	Analog slider response observation templateId
2.16.840.1.113883.10.20.33.4.8	Discrete slider response observation templateId
1.2.208.184.6.1	External References

Table 30: Template Ids used in QRD