Integrating the Healthcare Enterprise

IHE Quality, Research, and Public Health Technical Framework Supplement

Structured Data Capture
(SDC)

Trial Implementation

Date: October 27, 2015

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Foreword

This is a supplement to the IHE Quality, Research and Public Health Technical Framework V0.1. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on October 27, 2015 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Quality, Research and Public Health Technical Framework. Comments are invited and may be submitted at http://www.ihe.net/QRPH_Public_Comments.

This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend Section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **bold strikethrough**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

General information about IHE can be found at: http://ihe.net.

Information about the IHE IT Infrastructure domain can be found at: http://ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at: http://ihe.net/IHE_Process and http://ihe.net/Profiles.

The current version of the IHE IT Infrastructure Technical Framework can be found at: http://ihe.net/Technical_Frameworks/.

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Introduction to this Supplement

The Structured Data Capture (SDC) Content Profile provides specifications to enable an Electronic Health Record (EHR) system or other application to retrieve a data capture form and submit data from the completed form. The SDC Profile utilizes the IHE Retrieve Form for Data Capture (RFD) Profile and an ISO/IEC 19763-13 Meta-model for Framework Interoperability (MFI) form registration. This profile also supports optional use IHE Data Element Exchange (DEX) Profile for retrieving metadata of the data elements used to annotate structured form elements.

This supplement is based on the work of the Office of the National Coordinator (ONC) Standards & Interoperability (S&I) Framework SDC Initiative. The SDC initiative has developed use cases, identified national standards for the structure of Common Data Elements and form model definition, developed guidance to assist in implementation, and conducted pilots for evaluation of SDC.

This supplement also references the following documents. The reader should review these documents as needed:

- IT Infrastructure Technical Framework Volume 1

- IT Infrastructure Technical Framework Volume 2

- IT Infrastructure Technical Framework Volume 3

- HL7® CDA® R2 and other standards documents referenced in Volume 1 and Volume 2

- IT Infrastructure Technical Framework Supplement: Retrieve Form for Data Capture (RFD) Profile

- IT Infrastructure Technical Framework Supplement: Audit Trail and Node Authentication (ATNA) Integration Profile

- IHE Infrastructure Technical Framework Supplement: Consistent Time (CT) Profile

- IETF HTTPS and TLS v1.0 standard

- W3C SOAP

- OASIS SAML

- ISO/IEC 11179-3:2013 Metadata Registries - Part 3 Registry metamodel and basic attributes

- ISO/IEC CD 19763-13 Metamodel for Forms Registration

- Optionally, QRPH Technical Framework Supplement: Data Element Exchange (DEX) Profile

- Optionally, the IHE XUA Profile for user assertions

- Optionally, QRPH Clinical Research Document (CRD) Profile for definition of Audit
205   Log message content and QRPH-36 transaction

Open Issues and Questions

SDC Profile – Open Issues and Questions

Item #	Section	Question
1.	Q.5	Consider future Chance Proposal (CP) to constrain the <sdc:supplemental_data> schema to conform to the same scheme used for <sdc:submitted_data>
2.	5.0	IHE Template Issue: Invented section numbering scheme, since none was defined in the template that allowed inclusion of other text.

Closed Issues:

210   1. Does SDC include a Transaction or Content Module? SDC doesn't provide you with new transactions, but instead allows you to include content sections that reference relevant sections. The constraints to the transactions (structured, unstructured, or URL) will be explained in Volume 3.

2. Why does SDC Profile use XAdES instead of IHE DSG? SDC use case requires digital
215   signature to be inclusive (part of the transaction) rather than being included as a separate document, which is not supported by IHE DSG Profile and hence the use of XAdES.

3. Will <sdc:form_info> element within SDC HTML Package contain a reference to SDC XML Package? The SDC HTML Package contains the mapping package, admin package, submission rules info, etc., which provides Form Filler with enough information
220   without having to refer to the SDC Form Definition. The Form Manager/Form Processor does have an option to send this information, if they choose to do so.

4. How do we add a note indicating that the reason for having SDC Submission Data content module optional is the lack of SDC compliant forms? Based on the public comments received, this was changed to a Required content module and hence no need to
225   add a separate note.

_____

General Introduction

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

Appendix A - Actor Summary Definitions

230   *Add the following actors to the IHE Technical Frameworks General Introduction list of Actors:*

No new actors.

Appendix B - Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

235   No new transactions.

_____

Glossary

Add the following glossary terms to the IHE Technical Frameworks General Introduction Glossary.

Glossary Term	Definition
Auto-Population	When an EHR system automatically fills in form fields with data that are already available within the system's database.
CCD®	Continuity of Care Document (CCD®) is document specification standard specified by HL7®/ASTM and commonly used for electronic document exchange. CCD® is based on HL7®'s Clinical Document Architecture (CDA®).
CDA®	The HL7® Version 3 Clinical Document Architecture (CDA®) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange between healthcare providers and patients. It defines a clinical document as having the following six characteristics: 1) Persistence, 2) Stewardship, 3) Potential for authentication, 4) Context, 5) Wholeness and 6) Human readability.
Common Data Elements (CDEs)	Standardized data element descriptions for collection and exchange of data of common interest to a particular community, and thus the community has agreed to share their definition, management and use. CDEs share a common set of attributes which facilitates their reuse in different settings, and are intended to aide in interoperability and data reuse.
Completed Form	A form where all the fields contain data – through a combination of pre-population, auto-population, and manual edits, and is ready for submission.
Data Element (DE)	A data element is a unit of data for which the definition, identification, representation, and permissible values are specified by a set of attributes and considered in context to be indivisible.
DEX	Data Element Exchange (DEX) is an IHE Profile that enables the retrieval of metadata from a metadata registry.
Enhanced Form Repository	A form repository with capability to pre-populate form with the data received from the Form Filler.
External Data Repository	A database, outside of the EHR system, where completed forms data can be stored.

Glossary Term	Definition
Form	A form with data entry fields that will be filled out by an end user or provider.
Form Repository	An authoritative source for forms.
HL7®	Health Level Seven is a not-for-profit, American National Standards Institute (ANSI)-accredited health care focused International and membership-driven Standard Development Organization (SDO) based in the United States with international affiliates.
MFI	Metamodel Framework for Interoperability (MFI) -- an ISO/IEC 19763 standard.
MFI-13	Metamodel Framework for Interoperability (MFI) – ISO/IEC 19763-13 Metamodel for Forms Registration
ONC	The U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology.
Partially Completed Form	A pre-populated and/or auto-populated form served by the EHR to the provider that contains data for most fields.
PHI	Protected Health Information, as defined in the United States Code of Federal Regulations (Part 45 CFR 160.103) and, as referenced in Section 13400 of Subtitle D ('Privacy') of the HITECH Act.
Pre-Population	When an Enhanced Form Repository fills in form fields using data sent by the Form Filler along with the retrieve request. This activity is distinguished from Auto-population in that Pre-population is performed by the Form Manager using an Enhanced Form Repository, whereas Auto-population is always performed by Form Filler.
RFD	Information Technology Infrastructure (ITI) Technical Framework Supplement: Retrieve Form for Data Capture (RFD) Profile that provides a means for the retrieval and submission of completed forms data between clinical or research settings and electronic data capture systems or other data collection agencies.
SAML	Security Assertion Markup Language is an Extensible Markup Language standard that allows a user to log on once for affiliated but separate Web sites.
SDC Form Definition	A standardized set of attributes describing the semantics and syntax of a form design so that it may be rendered consistently in any suitable information system and can be validated using SDC Schema. Based on ISO/IEC 19763-13 with SDC extensions. This is not a fillable form.

Glossary Term	Definition
SDC Schema	A W3C schema for an ISO/IEC 19763-13 compliant form, with SDC extensions.
SDC XML Package	A collection of XML data, meeting the SDC Schema, that includes the particular SDC Form Definition represented as a set of standardized XML elements, along with mapping information, administrative information including submission and compliance instructions, and (optional) supplemental data. The package is represented in SDC Content modules and may also be persisted as a collection of files.
SDC HTML Package	A collection of files that contains an HTML form instance derived from an SDC Form Definition, along with (optional) mapping information, (optional) administrative information, and (optional) supplemental data. The package is represented in SDC Content modules and may also be persisted as a collection of files. The HTML form instance is a fillable form.
SOAP	Simple Object Access Protocol: An XML-based messaging protocol.
S&I	Standards and Interoperability Framework is an open forum sponsored by ONC's Office of Standards & Interoperability (OSI) to advance harmonization and implementation of specifications that support national healthcare priorities. SDC is an S&I Framework initiative.

240 # Volume 1 – Profiles

Copyright Licenses

Elements and Attributes Adapted from ISO/IEC 19763-13 and ISO/IEC 11179-3, © copyright ISO/IEC 2014.

Domain-specific additions

245 Section not applicable.

X Structured Data Capture (SDC) Profile

With EHR adoption expanding across the globe, the volume and detail of information captured by healthcare organizations and providers is growing exponentially. The SDC Content Profile provides specifications to enable an EHR system, or other application, to retrieve a data capture form and submit data from a completed form. The SDC Profile utilizes IHE RFD Profile and an ISO/IEC 19763-13 based form definition, for requesting and receiving forms, and submitting data captured in forms in a standardized and structured format.

This supplement is based on the work of the ONC's S&I Framework SDC Initiative. The SDC initiative has developed use cases, identified national standards for the structure of DE's and form definitions, developed guidance to assist in implementation, and conducted pilots for evaluation of SDC.

Generally, an IHE Content Module is intended to provide implementation guidance for a set of standards from disparate sources. This SDC Profile builds upon the IHE RFD Profile and could reference or be referenced by other IHE profiles, white papers, or supplements.

X.1 SDC Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in IT Infrastructure Technical Volume, (ITI TF-1): Integration Profiles Appendix A at http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf (a work in progress).

Figure X.1-1 shows the actors directly involved in the SDC Profile and the relevant transactions between them.
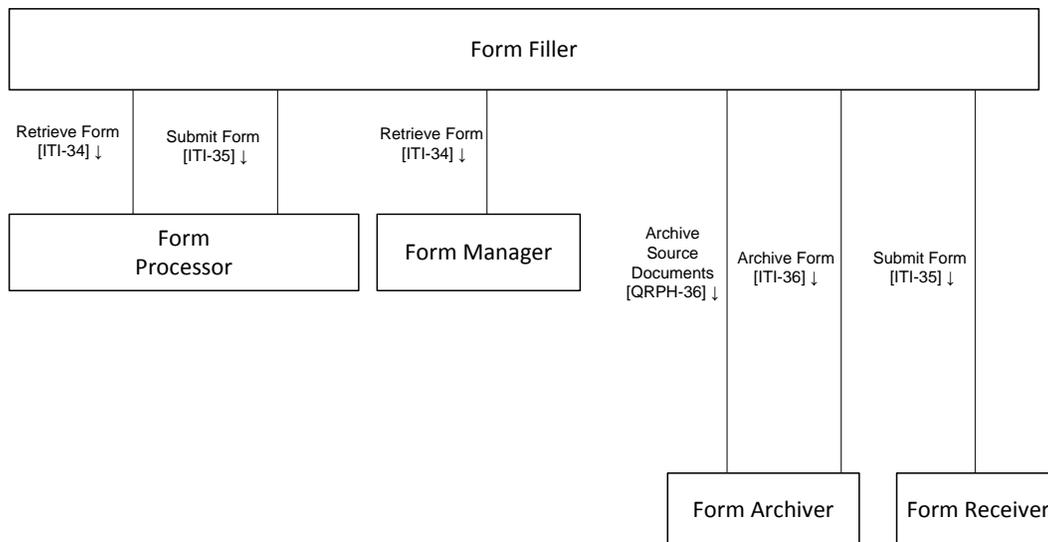
Figure X.1-1: SDC Actor Diagram

270   Table X.1-1 lists the transactions for each actor directly involved in the SDC Profile. To claim compliance with this Profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Table X.1-1: SDC Profile - Actors and Transactions

Actors	Transactions	Optionality	Reference
Form Filler	Retrieve Form [ITI-34]	R	ITI TF-2b: 3.34
	Submit Form [ITI-35]	R	ITI TF-2b: 3.35
	Archive Form [ITI-36]	O	ITI TF-2b: 3.36
	Archive Source Documents [QRPH-36]	O	QRPH TF-2: 3.36
Form Manager	Retrieve form [ITI-34]	R	ITI TF-2b: 3.34
Form Receiver	Submit Form [ITI-35]	R	ITI TF-2b: 3.35
Form Processor	Submit Form [ITI-35]	R	ITI TF-2b: 3.35
	Retrieve Form [ITI-34]	R	ITI TF-2b: 3.34
Form Archiver	Archive Form [ITI-36]	R	ITI TF-2b: 3.36
	Archive Source Documents [QRPH-36]	R	QRPH TF-2: 3.36

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Table X.1-2: SDC Profile – Actors and Content Modules

Actors	Content Module	Optionality	Section in Vol. 3
Form Filler	SDC Pre-Pop	O	Q.1
	SDC XML Package [Note 1]	O	Q.2.1
	SDC HTML Package [Note 1]	O	Q.3.1
	SDC URI Form [Note 1]	O	Q.4.1
	SDC Submission Data	R	Q.5
Form Manager	SDC Pre-Pop	O	Q.1
	SDC XML Package	R	Q.2.2
	SDC HTML Package	R	Q.3.2
	SDC URI Form	R	Q.4.2
Form Processor	SDC Pre-Pop	O	Q.1
	SDC XML Package	R	Q.2.2
	SDC HTML Package	R	Q.3.2
	SDC URI Form	R	Q.4.2
	SDC Submission Data	R	Q.5
Form Receiver	SDC Submission Data	R	Q.5

Note 1: Form Filler SHALL support at least one of these options: SDC XML Package, SDC HTML Package, or SDC URI Form.

This SDC Profile builds upon the IHE RFD Profile and HTML in describing both the content
280 and presentation of (data entry) forms. It identifies a form standard and the following two
approaches to form representation that are technology and platform-neutral:

1. XML-based form definitions (defines form design based on SDC Schema in Volume 3)

2. HTML-based form instances (display and presentation of data)

X.1.1 Actor Descriptions and Actor Profile Requirements

285 Most requirements are documented in Transactions (Volume 2) and Content Modules (Volume
3). This section documents any additional requirements on profile's actors.

X.1.1.1 Form Filler

The Form Filler is defined in the RFD Profile in ITI TF-1, thus it supports all required
constraints from RFD Profile.

290 In SDC, the system implementing the Form Filler's role SHALL support at least one of the
following three content modules and MAY support all three content modules:

- SDC XML Package (see QRPH TF-3: Q.2.1)

- SDC HTML Package (see QRPH TF-3: Q.3.1)

- SDC URI Form (see QRPH TF-3: Q.4.1)

295 The Form Filler SHALL support SDC Submission Data content module (QRPH TF-3: Q.5).

The Form Filler MAY support one or all of the following:

- SDC Pre-pop (see QRPH TF-3: Q.1)

- SDC Auto-pop (see QRPH TF-1: X.2.5)

- Archive Form (see ITI TF-2b: 3.36)

300 - Archive Source Document (see QRPH TF-2: 3.36)

See the security considerations in Section X.5.

X.1.1.2 Form Manager

The Form Manager is defined in the RFD Profile in ITI TF-1, thus it supports all required
constraints from RFD Profile.

305 The system implementing the Form Manager's role in SDC Profile SHALL support all of the
following content modules:

- SDC XML Package content module (see QRPH TF-3: Q.2.2)

- SDC HTML Package content module (see QRPH TF-3: Q.3.2)

- SDC URI Form content module (see QRPH TF-3: Q.4.2)

310 The Form Manager MAY support SDC Pre-Pop content module (see QRPH TF-3: Q.1).

See the security considerations in Section X.5.

X.1.1.3 Form Processor

The Form Processor is defined in the RFD Profile in ITI TF-1, thus it supports all required constraints from RFD Profile.

315 The system implementing the Form Processor's role in SDC Profile SHALL support <u>all</u> of the following content modules:

- SDC XML Package content module (see QRPH TF-3: Q.2.2)

- SDC HTML Package content module (see QRPH TF-3: Q.3.2)

- SDC URI Form content module (see QRPH TF-3: Q.4.2)

320 - SDC Submission Data content module (see QRPH TF-3: Q.5)

The Form Processor MAY support SDC Pre-Pop content module (see QRPH TF-3: Q.1).

See the security considerations in Section X.5.

X.1.1.4 Form Archiver

The Form Archiver is defined in the RFD Profile in ITI TF-1 and there is an additional optional
325 transaction – ArchiveSourceDocuments [QRPH-36], defined in the QRPH CRD Profile.

See the security considerations in Section X.5.

X.1.1.5 Form Receiver

The Form Receiver is defined in the RFD Profile in ITI TF-1, thus it supports all required constraints from RFD Profile.

330 The Form Receiver SHALL receive the structured form data as submitted by the Form Filler using SDC Submission Data content module (see QRPH TF-3: Q.5).

See the security considerations in Section X.5.

X.2 SDC Actor Options

Options that may be selected for each actor in this profile, if any, are listed in Table X.2-1.
335 Dependencies between options when applicable are specified in notes.

Table X.2-1: SDC - Actors and Options

Actor	Option Name	Reference
Form Filler	SDC Pre-Pop	QRPH TF-1: X.2.1
	SDC XML Package [Note 1]	QRPH TF-1: X.2.2
	SDC HTML Package [Note 1]	QRPH TF-1: X.2.3
	SDC URL Form [Note 1]	QRPH TF-1: X.2.4
	SDC Auto-Pop	QRPH TF-1: X.2.5
	Archive Form	ITI TF-2b: 3.36
	Archive Source Documents	QRPH TF-2: 3.36
Form Manager	SDC Pre-Pop	QRPH TF-1: X.2.6
Form Processor	SDC Pre-Pop	QRPH TF-1: X.2.7
Form Archiver	None	
Form Receiver	None	

Note 1: Form Filler SHALL support at least one of these options: SDC XML Package, SDC HTML Package, or SDC URI
340   Form.

X.2.1 Form Filler: SDC Pre-Pop Option

This option defines the requirements placed on submission of pre-population data. The Form Filler's support for the SDC Pre-Pop Option determines how pre-population data is generated by Form Fillers when requesting form using Retrieve Form [ITI-34] transaction:

345   • In order to claim conformance to this option, the Form Filler SHALL implement SDC Pre-Pop content module (see QRPH TF-3: Q.1).

X.2.2 Form Filler: SDC XML Package Option

This option defines the requirement placed on requesting and retrieving an SDC XML Package. The Form Filler's support for this option determines how a request for an SDC XML Package is
350   generated when requesting it using Retrieve Form [ITI-34] transaction:

   • In order to claim conformance to this option, the Form Filler SHALL implement SDC XML Package content module (see QRPH TF-3: Q.2.1).

X.2.3 Form Filler: SDC HTML Package Option

This option defines the requirement placed on requesting and retrieving an SDC HTML Package.
355   The Form Filler's support for this option determines how an SDC HTML Package is requested and rendered when the Form Fillers retrieve it using Retrieve Form [ITI-34] transaction:

   • In order to claim conformance to this option, the Form Filler SHALL implement SDC HTML Package content module (see QRPH TF-3: Q.3.1).

X.2.4 Form Filler: SDC URL Form Option

360 This option defines the requirement placed on requesting and retrieving form URI. The Form
Filler's support for the this option determines how a response providing URI to an SDC form is
handled when the Form Filler retrieves the information using Retrieve Form [ITI-34] transaction:

- In order to claim conformance to this option, the Form Filler SHALL implement SDC
  URI Form content module (see QRPH TF-3: Q.4.1).

365 ### X.2.5 Form Filler: SDC Auto-Pop Option

This option defines the requirements placed on supporting auto-population before rendering the
requested form.

- In order to claim conformance to this option, the Form Filler SHALL support SDC XML
  Package Option and/or SDC HTML Package Option.

370 - In order to claim conformance to this option, the Form Filler SHALL automatically
  supply some additional form data from the Form Filler data store before rending the form
  for human data entry.

The details of how auto-pop is performed is out of scope for this profile.

X.2.6 Form Manager: SDC Pre-Pop Option

375 This option defines the requirements placed on being able to receive pre-population data. The
Form Manager's support for the SDC Pre-Pop Option determines Form Manager's capability to
receive pre-population data sent by Form Fillers when requesting form using Retrieve Form [ITI-
34] transaction:

- In order to claim conformance to this option, the Form Manager SHALL be able to
380 receive pre-population data as per SDC Pre-Pop content module (see QRPH TF-3: Q.1).

Conformance to this option only means that Form Manager will have the ability to receive a
request from Form Filler with pre-population data. The details of how Form Manager will use
this data to pre-populate the form is out of scope for this Profile.

X.2.7 Form Processor : SDC Pre-pop Option

385 This option defines the requirements placed on being able to receive pre-population data. The
Form Processor's support for the SDC Pre-Pop Option determines Form Processor's capability to
receive pre-population data sent by Form Fillers when requesting form using Retrieve Form [ITI-
34] transaction:

- In order to claim conformance to this option, the Form Processor SHALL be able to
390 receive pre-population data as per SDC Pre-Pop content module (see QRPH TF-3: Q.1).

Conformance to this option only means that Form Processor will have the ability to receive a request from Form Filler with pre-population data. The details of how Form Processor will use this data to pre-populate the form is out of scope for this Profile.

X.3 SDC Required Actor Groupings

395   Actor(s) which are required to be grouped with another Actor(s) are listed in this section. The grouped Actor MAY be from this profile or a different domain/profile. These mandatory required groupings, plus further descriptions if necessary, are given in the table below.

An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile *in addition to* all of the transactions required for the grouped

400   actor (Column 2).

Section X.5 describes some optional groupings that may be of interest for security considerations.

Table X.3-1: SDC - Required Actor Groupings

SDC Actor	Actor to be grouped with	Reference	Content Bindings Reference
Form Filler	CT Time Client	ITI TF-1: 7.1	N.A.
Form Manager	CT Time Client	ITI TF-1: 7.1	N.A.
Form Processor	CT Time Client	ITI TF-1: 7.1	N.A.
Form Archiver	CT Time Client	ITI TF-1: 7.1	N.A.
Form Receiver	CT Time Client	ITI TF-1: 7.1	N.A.

405   ## X.4 SDC Overview

X.4.1 Concepts

SDC provides for two ways to insert already captured EHR data to forms: pre-population and auto-population. Each process is described in turn below, and three use cases are provided which illustrate the timing and locus of activities for these two central concepts. Use Case 1

410   demonstrates the use of SDC to display a form, which has no EHR data applied. Use Case 2 illustrates the use of auto-population only in a pre-authorization setting. Use Case 3 shows the feasibility for both pre-population and auto-population to be used in one form completion process.

In addition to illustrating the various permutations of pre-population and auto-population, the use

415   cases also illustrate use of SDC in three settings: research, public health reporting, and quality reporting.

X.4.1.1 Pre-Population

420   The first of two ways to apply EHR data to a form is called pre-population. In this approach, the EHR exports a standard document, typically a templated CDA®, to an external actor which uses the data from the document to populate fields in the form. In this profile, this capability will be supported by Form Manager or Form Processor. The pre-population capability is also described in the RFD Retrieve Form transaction, with CRD describing the mechanism as it applies to a research use case.

X.4.1.2 Auto-Population

425   SDC enables a capability for a Form Filler, such as an EHR system, to apply data directly to the form. In this approach, the data element definitions within the form would be interpreted by the EHR system, and corresponding instance data would be retrieved from the EHR database and applied to the form. The mechanism to accomplish this is out of scope for the profile.

X.4.2 Use Cases

430   ### X.4.2.1 Use Case #1: Retrieve form using a URL

In this use case, the EHR retrieves the form using a URL without providing patient data. There is no pre-population or auto-population. The setting is a research study conducted at a healthcare site.

X.4.2.1.1 Retrieve form using a URL - Use Case Description

435   A research study coordinator is in charge of sponsored research at the research site. The study has several patients enrolled as subjects that require them to make study visits at the research site. When subject Jones arrives for a research related visit, the study coordinator, acting within the site's EHR system, requests the URL for the appropriate form for the research. From a research electronic data capture system, the provider uses the URL to navigate to the form (based

440   on SDC Form Definition) and enter the required data.

X.4.2.1.2 Retrieve form using URL - Process Flow
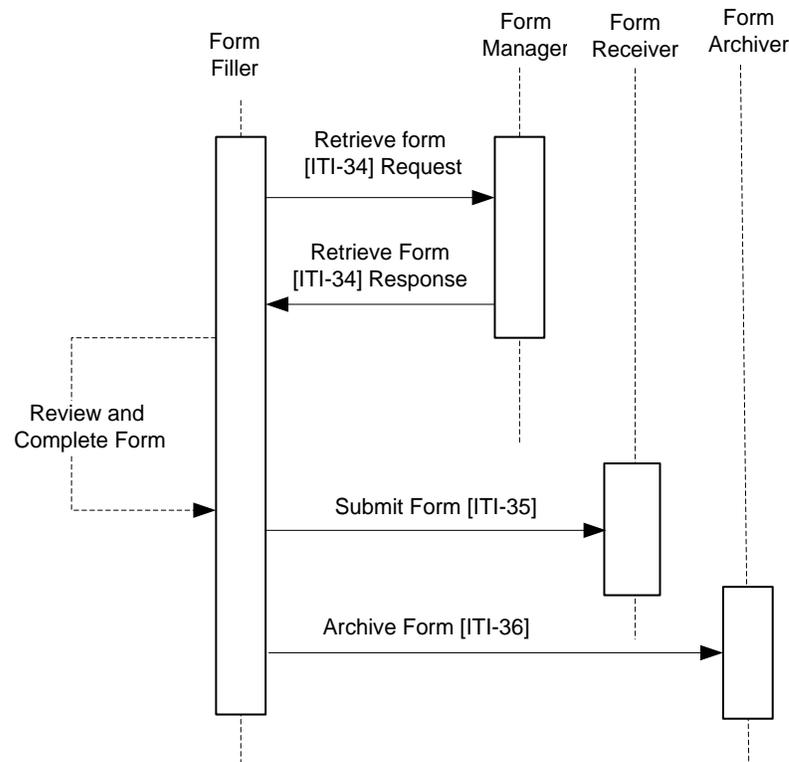
Figure X.4.2.1.2-1: Retrieve form using an URL - Process Flow diagram

X.4.2.1.3 Pre-conditions

445
- The EHR system performs the role of a Form Filler;

- A patient enrolled as a subject in a research study arrives for a study visit at which a form completion is required;

- The EHR system knows the source of the URL to obtain access to the appropriate form.

X.4.2.1.4 Main Flow

450
- A study coordinator retrieves a research form, which is hosted by a research system external to the healthcare site, through the site's EHR. The Form Manager returns a URL, and the EHR system directs to that URL to display the form (based on SDC Form Definition);

- The study coordinator completes the form through its display within the EHR user
455   interface;

- The study coordinator submits the completed form to the external repository, and to the archive.

X.4.2.1.5 Post-conditions

- The research system stores the data captured on the form.

460 ### X.4.2.2 Use Case #2: Capture and Submit Pre-Authorization

This use case illustrates auto-population with an SDC form, with no pre-population, using a pre-authorization setting.

X.4.2.2.1 Capture and Submit Pre-Authorization - Use Case Description

Dr. R. E. Hab has a patient who needs an electric wheelchair. The patient needs to obtain pre-
465 authorization from their insurer to confirm that the wheelchair will be covered. The insurer makes forms available electronically including the pre-authorization form. The insurer requires that the form be submitted by the patient's provider.

When Dr. Hab sees the patient in the office, he opens up the patient's EHR. After recording the visit data in the EHR, Dr. Hab requests the EHR to display the pre-authorization form. Dr. Hab
470 uses an EHR that has the ability to process and render SDC forms. Dr. Hab requests the form from within the EHR. The EHR has been configured to electronically retrieve the pre-authorization forms from the insurer without submitting PHI data. The insurer electronically returns the form in an SDC compliant format.

The EHR displays the form with the data fields completed for data items already available within
475 the EHR. Dr. Hab completes the form and verifies the pre-filled fields. When the form is completed Dr. Hab uses the EHR submit function to electronically submit the form. The EHR asks Dr. Hab to provide his credentials to electronically sign the form. Dr. Hab enters his credentials and the EHR electronically submits the form data to the insurer.

X.4.2.2.2 Capture and Submit Pre-Authorization - Process Flow
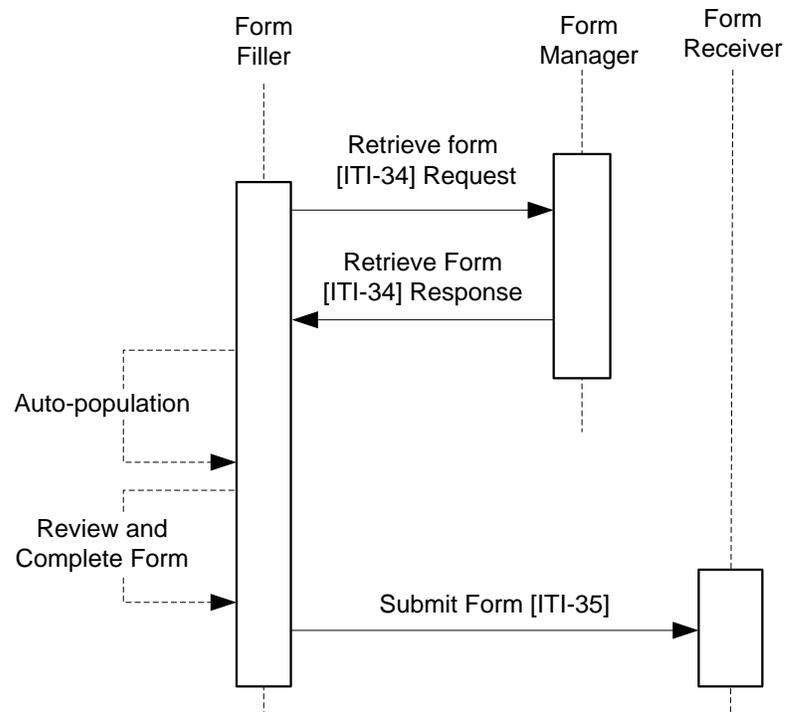
480

Figure X.4.2.2.2-1: Capture and Submit Pre-Authorization – Process Flow diagram

X.4.2.2.3 Pre-conditions

- The EHR system performs the role of a Form Filler;
- 485
- The EHR is pre-configured to know which form is required;
- The EHR is able to map data from its own data storage to data required in the pre-authorization form, for the purpose of auto-population;
- The EHR already knows the endpoints to submit pre-authorization form request;
- The EHR is able to digitally sign the pre-authorization form;
- 490
- The EHR is able to submit data from the completed form to the insurer;
- The insurer is able to return an electronic version of the requested form;
- The insurer is able to receive and process data submitted from the completed form.

X.4.2.2.4 Main Flow

- Dr. Hab is made aware of the requirement for pre-authorization;

495   • Dr. Hab's EHR retrieves the pre-authorization form;

• The EHR auto-populates the form, and presents it on screen for Dr. Hab;

• Dr. Hab completes and digitally signs the form;

• The data from the completed form is sent to the insurer.

X.4.2.2.5 Post-conditions

500   • Data from the completed form has been sent to the insurer;

• The insurer has received, stored, and processed the pre-authorization data.

X.4.2.3 Use Case #3: Use Case with Extraction Specification

The SDC Initiative developed a general use case that illustrates both pre-population by an enhanced forms repository and auto-population by the EHR. The setting for this use case is
505   public health reporting.

X.4.2.3.1 Use Case with Extraction Specification – Use Case Description

A Provider has identified a patient with a reportable condition. Using an existing EHR system, the Provider submits an electronic request for an appropriate form from the jurisdictional public health organization or entity.

510   The EHR system, acting as the Form Filler, requests and retrieves the appropriate form from the enhanced form repository acting as the Form Manager. In many cases, the Form Filler, may send already collected information about the patient along with the request for appropriate form. The EHR provides a standard export document to the Form Manager for use in the pre-population step. In this case, the Form Manager uses an extraction specification for the appropriate form that
515   provides explicit location information for each data element required by the form – this information is contained in the mapping information section in the SDC Form Definition. This extraction specification comes from the IHE DEX Retrieve Metadata transaction, in which the DEX Metadata Consumer goes to a Metadata Source, in this case a public metadata repository, to find the metadata associated with each data element in the standards export document.
520   Included in this metadata are XPath statements that explicitly lead to the correct instance data in the EHR export document.

The EHR additionally auto- populates the remaining open sections of the form using a similar DEX-derived extraction specification and the mapping information available with the SDC form.

The EHR system renders the retrieved form after pre-populating and auto-populating form data
525   (when this functionality is supported by the EHR system). The provider verifies the pre- and auto-populated data, adds any missing data, and then submits the structured form data to the Public Health Organization. The Provider receives a response that confirms that the report was successfully submitted electronically and received by the public health information system.

530 At the time of the request, the EHR indicates what archive option, if any, should be used. The Form Archiver maintains the data as read only so they are an indisputable and auditable record of the reporting. The archive may be maintained by the EHR or by an independent service on behalf of the provider. The archive option specifies information necessary to connect to the archive and may include any combination of the following: the information that was sent with the request; the form template; the form data returned after being auto-populated; and/or the form data as
535 they were submitted.

Note: The use of the IHE DEX Profile is shown to simply illustrate how pre- and auto-population can be performed using another IHE Profile. The use of DEX is out of scope for this Profile.

X.4.2.3.2 Use Case with Extraction Specification - Process Flow
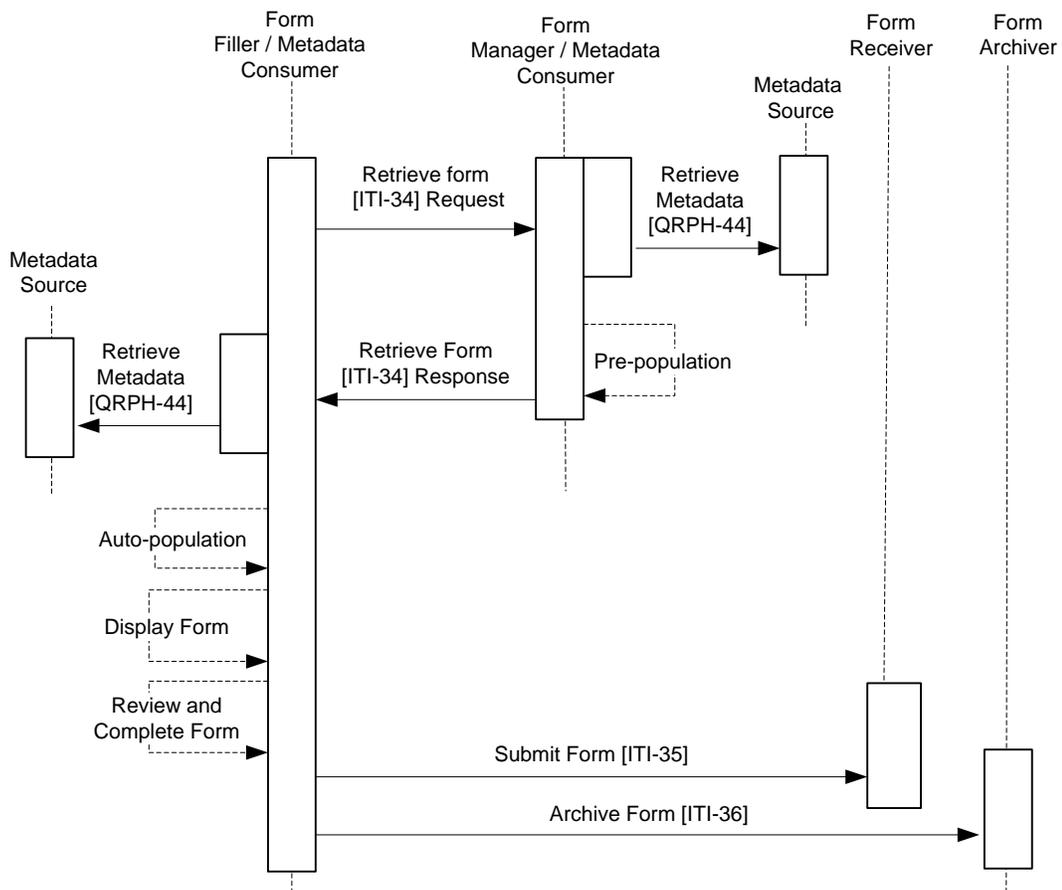
540

Figure X.4.2.3.2-1: SDC Profile Use Case with Extraction Specification - Process Flow diagram

X.4.2.3.3 Pre-conditions:

This process is invoked when a healthcare provider is required to submit a report to a public
health agency. Necessary pre-conditions include:

- The EHR system performs the role of a Form Filler;

- The EHR system knows how to request appropriate form;

- The Metadata Repository perform the role of a Metadata Source;

- The form repository is known and contains the appropriate form;

- The EHR is able to submit data for pre-population;

- The EHR is able to map data from its own data storage to data required in the form;

- The Metadata Repository has the definitions of the elements used in the form.

X.4.2.3.4 Main Flow

- The provider is made aware of a required public health report;

- The provider requests the form through the EHR, providing patient data for pre-population;

- The EHR auto-populates the form, supplementing the pre-population done by the form repository;

- The provider completes any missing data and confirms the pre-populated and auto-populated data in the form;

- The data from the completed form is submitted to the public health agency;

- An archive copy is kept.

X.4.2.3.5 Post-conditions

- The public health agency stores and uses the data from the completed form;

- An archived copy of the completed form has been stored.

X.5 SDC Security Considerations

All SDC actors SHOULD be grouped with a Secure Node or Secure Application Actor in the
ATNA Profile.

When SDC actors are grouped with an ATNA Secure Node or Secure Application, that means
full compliance with the ATNA requirements, i.e.,

- SDC actors that also support ATNA SHALL be able to secure their required transactions according to the requirements in the ITI-19 Authenticate Node transaction (ITI TF-2a: 3.19).

575
- SDC actors that also support ATNA SHALL be able to audit their required transactions according to the requirements in the ITI-20 Record Audit Event transaction (ITI TF-2a: 3.20 and Section X.5.1 below).

In accordance with the ATNA Profile (ITI TF-1:9), when configured for use on a physically secured network, SDC implementations may use the normal connection mechanisms, i.e., there may be environments where SDC actors do not need to do mutual TLS as defined in ITI-19.

580 However, when configured for use in an environment not on a physically secured network, SDC implementations SHOULD use a secure channel such that defined in ITI-19. It is expected that the payload used in this use case will cross affinity domains and therefore transport encryption is required.

X.5.1 Use of IHE ATNA for Recording Security Audit Events

585 The Record Audit Event [ITI-20] transaction is a foundational component that is used to record audit events throughout an implementation.

In order to address identified security risks all actors in SDC SHOULD implement Audit Trail and Node Authentication (ATNA) Profile. This will assure that only highly trusted systems can communicate and that all changes are recorded in the audit log.

590 Implementers should refer to the IHE ATNA Profile for specific implementation guidance and conformance criteria. Message content is defined in the IHE QRPH Clinical Research Document (CRD) Trial Implementation Supplement in QRPH TF-2: 5.Z3 Audit Record Considerations.

X.5.2 XAdES Digital Signature

SDC transactions can contain numerous elements and those elements are inter-related. There will
595 be times when it is critical that a receiver in an SDC transaction be assured that the contents of the entire transaction payload were not altered in transit and the transaction is signed by the sender.

If digital signature is required by the trading partners, XAdES digital signature standard SHALL be used.

600 ## X.5.3 Consistent Time (CT)

See Section X.3. This grouping will assure that all systems have a consistent time clock to assure a consistent timestamp for audit logging.

X.5.4 Cross Enterprise User Authentication (XUA)

605

In order to address identified security risks, all actors in SDC MAY be grouped with Cross Enterprise User Authentication (XUA) Profile actors as appropriate. This grouping will assure that only highly trusted persons can communicate.

Appendices

Not applicable

610 # Volume 2 – Transactions

Section not applicable.

Appendices

Not applicable

615

Volume 2 Namespace Additions

Add the following terms to the IHE General Introduction Appendix G:

None

620

Volume 3 – Content Modules

5 Namespaces and Vocabularies

Add to Section 5 Namespaces and Vocabularies

Not applicable

625 6 Content Modules

6.3.1 CDA® Document Content Modules

Section not applicable.

Q SDC Content Modules

Q.1 SDC Pre-Pop Content Module

630 This Content Module further constraints the <prepopData> element as defined in Retrieve Form transaction [ITI-34] in the RFD Profile. The <prepopData> element SHALL contain ONLY CDA®-R2 document(s) and SHALL NOT be a nil construct.

Table Q.1-1: SDC Pre-Pop Content Module Element Constraints

Element Name	Description	Card.	Optionality	Data Type	Value Constraint
prepopData	The context element that may be used to contain content for the purposes of pre-population. This will contain the CDA R2 document containing the relevant patient information for pre-population	1..1	R	anyXML	None

635

```
<prepopData>
    <ClinicalDocument xmlns="urn:hl7-org:v3">
        <realmCode code="US"/>
        <!-- Valid CDA-R2 document -->
    </ClinicalDocument>
</prepopData>
```
640

This constraint may be further refined by other content profiles, e.g., a specific type of CDA®-R2 document(s) may be specified. This constraint also may be further refined by other content profiles by specifying how the Form Manager and Form Processor use the pre-pop data.

Q.2 SDC XML Package Content Module

645

Form Filler claiming this content module option SHALL be able to make a request as per Section Q.2.1 for an SDC XML Package and SHALL use the returned SDC XML Package as per Section Q.2.2 to render and capture data using the SDC XML Package.

650

All Form Managers and Form Processors SHALL be able to respond to a request for an SDC XML Package as per Section Q.2.1 and SHALL return an SDC XML Package as per Section Q.2.2.

Q.2.1 SDC XML Package – Request

This Content Module further constraint the <prepopData> and <formID> element as defined in Retrieve Form transaction [ITI-34] in the RFD Profile. The <encodedResponse> element

655 SHALL be "true". The <formID> will be a value that has been determined to represent an SDC format as managed by the responding Form Manager or Form Processor. If there are multiple versions, they will be distinguished with unique form ID values.

Form Filler SHALL ensure that the <encodedResponse> element always have value "true" when requesting SDC XML Package.

660

Table Q.2.1-1: SDC XML Package-Request Content Module Element Constraints

Element Name	Description	Card.	Optionality	Data Type	Value Constraint
encodedResponse	Specifies how the form is to be returned.	1..1	R	boolean	Value SHALL be "true"
formID	The identifier of a form. In SDC a form is uniquely defined by its form_design_ID	1..1	R	string	

665

670

```
<RetrieveFormRequest
    xmlns="urn:ihe:iti:rfd:2007"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
    >
    <prepopData xsi:nil="true" />
    <!--Note: In this example, we are only showing the request for XML
Form Definition and hence are not using the pre-pop data-->
    <workflowData>
        <formID>http://myrepo.gov/form_design_id=12345.1/xml</formID>
        <encodedResponse>true</encodedResponse>
            <!--Please note the use of constrained value "true" above-->
```

```
675              <archiveURL />
                 <context xsi:nil="true"/>
                 <instanceID xsi:nil="true"/>
             </workflowData>
         </RetrieveFormRequest>
```

Note: In the above example, the entire URI is a form ID and shown as a suggested example only.
680   In reality, this will be decided by the trading partners.

Q.2.2 SDC XML Package – Response

This Content Module further constrains the <Structured> element as defined in Retrieve Form
transaction [ITI-34] in the RFD Profile. The <Structured> element SHALL contain a single
<sdc:sdc_xml_package> element.

685   The SDC XML package contains the form design information within a single <form_design>
element. The package also contain other required information -- Administrative information
<sdc:administrative_package>, mapping information <sdc:mapping_package>, and
<sdc:stylesheet>. It may also contain form related supplemental information within a single
element <sdc:supplemental_data>. These additional information packages are separate and
690   independent of the form design and included in other functionality at the Form Filler end – such
as auto-population.

The Form Manager and Form Processor SHALL ensure that the <structured> element contains
only a single <sdc:sdc_xml_package> element "true" when returning SDC XML Package.

The Form Manager and Form Processor SHALL ensure that the <contentType> element always
695   have value "XML" when returning SDC XML Package.

Table Q.2.2-1: SDC XML Package-Response Content Module Element Constraints

Element Name	Description	Card.	Optionality	Data Type	Value Constraint
Structured	The XML element container for the return of encoded, structured form content. The Structured element SHALL contain one sdc_xml_package.	1..1	R		
+sdc_xml_package	The wrapper element container for the SDC-compliant form package.	1..1	R		SHALL conform to SDC Schema
++supplemental_data	The XML element containing additional data related to the form.	0..1	O	anyType	
++form_package	The XML element containing ISO 19763-	1..1	R		

Element Name	Description	Card.	Optionality	Data Type	Value Constraint
	13 based form design and associated files as explained in Section Q.6.				
contentType	The type of the returned form.	1..1	R	string	Value SHALL be "XML"

```
700   <RetrieveFormResponse
       xmlns="urn:ihe:iti:rfd:2007"
       xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
       xmlns:sdc="urn:ihe:qrph:sdc:2014">
          <form>
              <Structured>
705               <sdc:sdc_xml_package>
                      <sdc:supplemental_data>
                          <!-- Contains supplemental data related to the form instance
       e.g., form generation date, specific instruction, pre-pop data, etc. -->
                      </sdc:supplemental_data>
710                   <sdc:form_package>
                          <!-- —Contains Administrative, stylesheet, mapping, and form
       definition; all of the required info for form definition -->
                          <sdc:mapping_package>
                              <!--Mapping information e.g., DEX mapping, goes here-->
715                       </sdc:mapping_package>
                          <sdc:administrative_package>
                              <!-- Administrative information goes here -->
                          </sdc:administrative_package>
                          <sdc:stylesheet>
720                           <!--include any style sheet information here -->
                          </sdc:stylesheet>
                          <sdc:form_design>
                              <!--Contains the form design, (e.g., question-answer
       sets, skip logic, etc.) -->
725                           </sdc:form_design>
                      </sdc:form_package>
                  </sdc:sdc_xml_package>
              </Structured>
              <instanceID>1.2.3.4.5</instanceID>
730       </form>
          <contentType>XML</contentType>
              <!--Please note the use of constrained value "XML" above-->
          <responseCode/>
       </RetrieveFormResponse>
```

735 Q.3 SDC HTML Package Content Module

The Form Filler claiming this content module option SHALL be able to make a request as per Section Q.3.1 for an SDC HTML Package and SHALL retrieve an SDC HTML Package as per Section Q.3.2 to render and capture data.

All Form Manager and Form Processors SHALL be able to respond to a request for SDC HTML
740 Package as per Section Q.3.1 and SHALL return an SDC HTML Package as per Section Q.3.2.

Q.3.1 SDC HTML Package – Request

This Content Module further constrain the <encodedResponse> and <formID> elements as
defined in Retrieve Form transaction [ITI-34] in the RFD Profile. The <encodedResponse>
element SHALL be "true". The <formID> will be a value that has been determined to represent
745 an SDC format as managed by the responding Form Manager and Form Processor. If there are
multiple versions, they will be distinguished with unique form ID values.

The Form Filler SHALL ensure that the <encodedResponse> element always have value "true"
when requesting SDC HTML Package.

750 **Table Q.3.1-1: SDC HTML Package-Request Content Module Element Constraints**

Element Name	Description	Card.	Optionality	Data Type	Value Constraint
encodedResponse	Specifies how the form is to be returned.	1..1	R	boolean	Value SHALL be "true"
formID	The identifier of a form. In SDC a form is uniquely defined by its form_design_ID	1..1	R	string	

```
<RetrieveFormRequest
      xmlns="urn:ihe:iti:rfd:2007"
      xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
      >
      <prepopData xsi:nil="true" />
      <!--Note: for this example, we are presuming no pre-pop data-->
<workflowData>
      <formID>http://myrepo.gov/form_design_id=12345.2/html</formID>
      <encodedResponse>true</encodedResponse>
          <!--Please note the use of constrained value "true" above-->
      <archiveURL />
      <context xsi:nil="true"/>
      <instanceID xsi:nil="true"/>
      </workflowData>
</RetrieveFormRequest>
```

Note: In the above example, the entire URI is a form ID and shown as a suggested example only.
In reality, this will be decided by the trading partners.

Q.3.2 SDC HTML Package – Response

770 This Content Module further constraints the <Structured> element as defined in Retrieve Form transaction [ITI-34] in the RFD Profile. The <structured> element SHALL contain a single <sdc:sdc_html_package> element.

The HTML package contains an HTML instance of the form as well as other additional information from related supplemental information <supplemental_data>. The additional
775 information packages are separate and independent of form design. The Form Manager compiles the final package, which includes form design.

The Form Manager and Form Processor SHALL ensure that the <structured> element contains only a single <sdc:sdc_html_package> element "true" when returning SDC HTML Package.

The Form Manager and Form Processor SHALL ensure that the <contentType> element always
780 have value "HTML" when returning SDC HTML Package.

Table Q.3.2-1: SDC HTML Package-Response Content Module Element Constraints

Element Name	Description	Card.	Optionality	Data Type	Value Constraint
Structured	The XML element container for the return of encoded, structured form content.	1..1	R		
+sdc_html_package	The wrapper element container for the SDC-compliant HTML form package.	1..1	R		SHALL conform to SDC Schema
++supplemental_data	The XML element containing additional data related to the form.	0..1	O	anyXML	
++form_info	The XML element containing supporting information e.g., mapping info, admin info, etc.	0..1	O	anyXML	
++sdc_html_form	The XML element containing the HTML form instance.	1..1	R		
contentType	The type of the returned form.	1..1	R	string	Value SHALL be "HTML"

785
```
<RetrieveFormResponse
 xmlns="urn:ihe:iti:rfd:2007"
 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns:sdc="urn:ihe:qrph:sdc:2014">
```

```
     <form>
        <Structured>
           <sdc:sdc_html_package>
              <sdc:supplemental_data>
                 <!-- Contains supplemental data related to the form instance
e.g., generation date, pre-pop data, special instructions, etc. -->
              </sdc:supplemental_data>
              <sdc:form_info>
                 <!-- Contains mapping, and administrative info; this is the
same content as from the form design package -->
              </sdc:form_info>
              <sdc:sdc_html_form>
                 <!—The HTML form with as CDATA text -->
                 <![CDATA[
                    <html>This contains the SDC-compliant HTML form </html>
                 ]]>
              </sdc:sdc_html_form>
           </sdc:sdc_html_package>
        </Structured>
        <instanceID>2.3.4.5.6</instanceID>
     </form>
     <contentType>HTML</contentType>
        <!—Please note the use of constrained value "HTML" above-->
     <responseCode/>
</RetrieveFormResponse>
```

Q.4 SDC URI Form Content Module

The Form Filler claiming this content module option SHALL be able to make a request as per Section Q.4.1 for SDC URI Form and SHALL retrieve the SDC URI Form per Section Q.4.2.

All Form Managers and Form Processors SHALL be able to respond to a request for SDC URI Form as per Section Q.4.1 and SHALL return SDC URI Form as per Section Q.4.2.

Q.4.1 SDC URI Form – Request

This Content Module further constraints the <encodedResponse> element as defined in Retrieve Form transaction [ITI-34] in the RFD Profile. The <encodedResponse> element SHALL be "false".

The Form Filler SHALL ensure that the <encodedResponse> element always has value "false" when requesting Form URI information.

825

Table Q.4.1-1: SDC Form URI-Request Content Module Element Constraints

Element Name	Description	Card.	Optionality	Data Type	Value Constraint
encodedResponse	Specifies how the form is to be returned.	1..1	R	boolean	Value SHALL be "false"

```
    <RetrieveFormRequest
      xmlns="urn:ihe:iti:rfd:2007"
830   xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
      <prepopData xsi:nil="true" />
      <workflowData>
          <formID>http://myrepo.gov/form_design_id=12345.3/url</formID>
          <encodedResponse>false</encodedResponse>
835          <!--Please note the use of constrained value "false" above-->
          <archiveURL />
          <context xsi:nil="true"/>
          <instanceID xsi:nil="true"/>
        </workflowData>
840   </RetrieveFormRequest>
```

Note: In the above example, the entire URI is a form ID and shown as a suggested example only. In reality, this will be decided by the trading partners.

Q.4.2 SDC URI Form – Response

845 This Content Module further constrains the <contentType> element as defined in Retrieve Form transaction [ITI-34] in the RFD Profile. The <contentType> element SHALL always have value "Unstructured"

The Form Manager and Form Processor SHALL ensure that the <contentType> element always has value "Unstructured" when returning Form URI information.

850 **Table Q.4.2-1: SDC Form URI-Response Content Module Element Constraints**

Element Name	Description	Card.	Optionality	Data Type	Value Constraint
URL	The XML element container for the return of a pointer to the form.	1..1	R	anyURI	
contentType	The type of the returned response.	1..1	R	string	Value SHALL be "Unstructured"

```
    <RetrieveFormResponse
      xmlns="urn:ihe:iti:rfd:2007"
      xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
855   xmlns:sdc="urn:ihe:qrph:sdc:2014">
      <form>
          <URL>
              <!--URL FOR THE INSTANCE OF THIS FORM GOES HERE-->
              www.weBeForms.com/1.2.3.4.5
860          </URL>
          <instanceID>3.4.5.6.7</instanceID>
        </form>
```

```
        <contentType>Unstructured</contentType>
            <!--Please note the use of constrained value "Unstructured" above-->
865     <responseCode/>
</RetrieveFormResponse>
```

Q.5 SDC Submission Data Content Module

This Content Module further constrains the <submitFormRequest> element as defined in Submit Form transaction [ITI-35] in the RFD Profile. The <submitFormRequest> element SHALL carry
870 a single <sdc:form_data> element containing form data as question-answer pairs.

The SDC Submission Data content module specifies the structure in which the form data needs to be sent to the Form Receiver. Using this content module, the Form Filler sends only relevant data instead of sending the entire form itself. The structure of the form data is defined in a manner to create a fine balance between sending sufficient data along with necessary context
875 information so that Form Receiver can re-create the form and its data, if necessary. The context and relevant information are derived from the SDC XML Form Definition and can be very easily referenced using the appropriate form ID information.

The Form Filler SHALL be able to generate and submit structured form data as shown above.

The Form Receiver SHALL be able to receive and process the submitted form data.

880 The Form Receiver SHALL be able to re-create the form and its data as it was at the moment of submission.

Table Q.5-1: SDC Submission Data Content Module Element Constraints

Element Name	Description	Card.	Optionality	Data Type	Value Constraint
SubmitFormRequest	The top-level container element	1..1	R		
+form_data	The XML element that contains the form data	1..1	R		
+@form_name	Name of the form	0..1	O	string	
+@form_design_identifier	Identifier for the form design	1..1	R	string	
+@form_representation_identifier	Identifier for the representation or modality of the form design.	1..1	R	string	
++Header	The XML element container for Header question-answer set	0..1	R		
++Body	The XML element container for Body question-answer set	1..1	R		

Element Name	Description	Card.	Optionality	Data Type	Value Constraint
+++Question	The XML element identifying the Question	1..*	R		
+++@parent_identifier	Identifier of the parent element, this may be a section, question or list_itemquestion	0..1	O	string	
+++@section_identifier	identifier for the section of the form to which the question belongs	1..1	R	string	
+++@question_identifier	Unique identifier for the question	1..1	R	string	
+++@data_element_identifier	Identifier for an SDC the data element	0..1	O	string	
+++@question_prompt	Question text as it appears in the form	1..1	R	string	
+++lookup_uri		0..1	O		
+++@question_repeat	Indicator if the question is repeated multiple times, e.g., 1, 2, 3	1..1	R	string	
+++@datatype	The datatype of the response.	1..1	R	string	
+++@unit_of_measure	Value indicating the unit of measure	0..1	O	string	
+++@pattern	The datatype pattern, e.g., HHMM	0..1	O	string	
++++Response	The response to the question	1..*	R	string	
++++@item_prompt	The prompt for the list item	0..1	O	string	
++++@item_identifier	The unique identifier for the list item	0..1	O	string	
++++@value_meaning_standard_code	The standard code for the list item when based on a value set.	0..1	O	string	
++++@value meaning_standard code_system_name	The name for the code system associated with this possible choice	0..1	O	string	
++++@value meaning_standard code_system_identifier	The identifier for the code system associated with this possible choice	0..1	O	string	

Element Name	Description	Card.	Optionality	Data Type	Value Constraint
++++@value_meaning_standard_code_system_version	The version for the code system associated with this possible choice	0..1	O	string	
++++@fill-in	The response for a list field fill-in e.g., "Specify" or "Other"	0..*	O	string	

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```xml
<?xml version="1.0" encoding="UTF-8"?>
<rfd:SubmitFormRequest xmlns:sdc="http://nlm.nih.gov/sdc/form"
xmlns:rfd="urn:ihe:iti:rfd:2007">
 <!-- This is the format in which form Filler will submit form data to Form
Receiver -->
    <sdc:form_data form_design_identifier="HERF/1.2"
form_representation_identifier="html">
        <sdc:header>
            <sdc:question section_identifier="HERF/header"
question_identifier="HERF/DE2" question_prompt="Event ID" question_repeat="1"
datatype="string">
                <sdc:response>378407202</sdc:response>
            </sdc:question>
        </sdc:header>
        <sdc:body>
            <sdc:question section_identifier="HERF/SEC01.1"
question_identifier="HERF/DE9a" question_prompt="Event Discovery Date"
question_repeat="1" datatype="date" >
                <sdc:response>10/21/2013</sdc:response>
            </sdc:question>
            <sdc:question section_identifier="ExampleHERF/SEC01"
question_identifier="ExampleHERF/LookUp" question_prompt="Gender"
question_repeat="1" datatype="string">
                <sdc:response>Male</sdc:response>
            </sdc:question>
        </sdc:body>
    </sdc:form_data>
</rfd:SubmitFormRequest>
```

Q.6 SDC Form Definition Model

915 SDC Forms address the need for systems to interoperate by exchanging data that has been defined as part of a structured document or form. Here we provide an overview for the approach and representation of the SDC form definition model.

Q.6.1 Scope and Approach

The role of forms in interoperability is recognized by the ISO/IEC 19763-13 Metamodel for Forms Registration (MFI-13) standard on which the SDC Form Definition is based. The standard
920 defines a universal metamodel for forms devoid of specific domain knowledge, which allows documentation and registration of form designs, both paper and electronic, from any and all sources. MFI-13 inherits from ISO/IEC11179 MDR-3 (MDR-3), which provides classes and

types that support the identification, naming, registration, and administration of form designs and other supporting documents. The form design can be associated with appropriate entity-
925 relationship diagrams or data models so that data and semantics may be faithfully exchanged between systems and so that those data may be compared, joined, or composed for analysis. This is accomplished through the mapping of questions on the form to data elements that are part of data or information models.

The basic structure of an SDC form contains one or more sections, sections contain one or more
930 questions. Each response to a question, an answer, is stored as a discrete unit of data. Sometimes the answer to one question determines the next question or section that should be presented, or is used in a calculation of data value(s). All of these different types of items are referred to as Form Elements.

The sections below describe the SDC form package, which includes the following: mapping
935 package, administrative package, style sheet and form design. The use of the term package indicates a section within XML forms that contain multiple other entities.

Q.6.2 Mapping Package

This package describes mappings between question elements and data elements for the purpose of defining the semantics, data representation, and input constraints of the question and its
940 answer. The mappings can be based on either MDR-3 data elements, or some other data element specification. Reusable data elements provide a way to use a similar question across different forms. Through the mapping document, the questions and their answers may be found to be based on vocabularies such as LOINC, SNOMED, or other terminologies, ontologies, or taxonomies. The relationship to concepts provides precise meaning for the questions and their
945 answers and is part of MDR-3 data element standard.

Table Q.6.2-1: Mapping Package

Element Name	Element Description	Card	Data Type
mapping_package	Describes mappings between question elements and data elements for the purpose of defining semantics. Note: Either mapping_package or question element level use of mapping to external data elements should be used throughout an instance of SDC Form Definition. The mapping information should not be present twice in the form design. See @+data_element_scoped_identifier or @+association_type.	1..1	
+@mapping_package_identifier	A unique identifier for the mapping package	1..1	string
+@form_design_identifier	A unique identifier for the form design	1..1	string
++mdr_mapping	Enumeration of instances describing the association between questions on the form and	0..1	

Element Name	Element Description	Card	Data Type
	compliant metadata registry data elements		
++@mdr_mapping_identifier	A unique identifier for mdr mapping	1..1	string
+question_element_data_element_association	Mapping of a question element to a data element in a metadata registry	0..*	
++data_element_scoped_identifier	The data element ID is the unique identifier of a specific registered data element mapped to a specific question element in this form design. Either mapping_package or question element level use of mapping to external data elements should be used throughout an instance of SDC Form Definition. The mapping information should not be present twice in the form design.	1..1	string
++question_element_identifier	Element ID uniquely identifying the question element that maps to a data element through this instance	1..1	string
++association_type	A category describing the association. SDC uses value same_as. It implies that the metadata is used exactly as described in the CDE.	1..1	string
+dex_mapping_specification	Indicates a map from a form element to an element in an external content model. For example, from a form question to a CCDA entry template	0..1	
++content_model	Identifies the standard in which the target element is presented. For example: Administrative gender code within a CCD document. The content model for this example is 2.16.840.1.113883.10.20.1astm/HL7/CCD.	1..1	
+++id	ID is the unique identification for this standard.	1..1	string
+++name	Name is the name of the content model.	1..1	string
++type	Type indicates the technology used for the mapping and it is limited to a DEX mapping specification type valueset:., SQL, SPARQL, XPATH.	1..1	string
++mappingScript	Mapping script is the actual mapping. For example, in the example above for Administrative gender code, the mapping specification type is XPATH and the mapping script is /ClinicalDocument/recordTarget/patientRole/patient/administrativeGenderCode.	1..1	string
+contact	Contact contains information regarding whom to contact for more information about the DEX Mapping Specification.	0..*	

Q.6.2.1 Contact

950 A contact element provides information regarding a person or organization that can be contacted for additional information. Contact specifies a role, and or individual within an organization to whom information items, material objects, or person(s) can be sent to or from.

Table Q.6.2.1-1: Contact

Element Name	Element Description	Card	Data Type
Contact	A contact element provides information regarding a person or organization that can be contacted for additional information. Contact specifies a role, and or individual within an organization to whom information items, material objects, or person(s) can be sent to or from.	0..*	
+individual	Individual contains contact information of an individual.	0..1	Table A.1.7-1
+organization	Organization contains contact information of an organization.	1..1	Table A.1.1-1
+role	Role contains information regarding the specified responsibilities of the individual listed to contact.	0..1	Table A.1.9-1

Q.6.3 Administrative Package

955 The Administrative Package contains multiple elements that provide information such as provenance, source etc. for the form and includes details about the registry from which the form design was retrieved, contact information, classifications, languages used, and style information.

Table Q.6.3-1: Administrative Package

Element Name	Element Description	Card	Data Type
administrative_package	The Administrative Segment includes details about the registry from which the form design was retrieved, contact information, classifications, languages used, and style information.	1..1	
+submission_rule	Submission rule contains information about where to submit a completed form.	1..*	string
+@form_ identifier	A unique identifier for the form.	1..1	string
+@rule_id_and_version	Identifier for the rule and version number information.	0..*	string
++destination	Destination is where the form should be sent.	0..*	
+++endpoint	Endpoint is where the form will be submitted.	0..*	anyURI
+++description	Description describes the destination.	0..1	string
+++organization	Organization is the organization responsible for the endpoint of the form.	0..1	Table A.1.1-1
+compliance_rule	The Administrative Segment includes details about the registry from which the form design was	1..*	string

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Element Name	Element Description	Card	Data Type
	retrieved, contact information, classifications, languages used, and style information.		
++expression	compliance rule contains information about where to submit a completed form.		String
+originating_registry_summary	Captures details regarding details regarding the form repository from which the instance of the SDC form was retrieved.	1..1	Table Q.6.3.1-1
+form_language	Represents the selection of languages used to express style, logic, format and textual aspects of the form design.	1..1	Table Q.6.3.2-1
+contacts	Destination is where the form should be sent.	0..*	Table Q.6.2.1-1
+registration	Captures details about the registration state, registration steward and submitter, reference documents, origin and latest change description for the form definition.	0..1	Table Q.6.3.3-1

960 Q.6.3.1 Origin Summary

The Administrative Package contains exactly one Origin Summary. The Origin Summary documents the registry to which this form has been registered. The summary may refer to an individual registry system or an aggregate of registry systems.

965 **Table Q.6.3.1-1: Origin Summary**

Element Name	Element Description	Card	Data Type
originating_registry_summary	The Origin Summary documents the registry to which this form has been registered. The summary may refer to an individual registry system or an aggregate of registry systems.	1..1	
+registry_organization	Registry Organization has details about the organization to which the form is registered.	1..1	Table A.1.1-1
+reference_standard_identifier	Reference Standard ID identifies the reference standard.	1..1	string
+SLA_for_registry	SLA for registry identifies the SLA for the registry.	0..1	Table A.1.2-1
+purpose_for_registry	Purpose for registry describes the purpose for the registry.	0..1	Table A.1.2-1
+manual_for_registry	Manual for registry describes the manual for the registry.	0..1	Table A.1.2-1
+specification_for_interface	Specification for Interface identifies the interface of the form.	0..1	Table A.1.5-1

Q.6.3.2 Form Language

The Administrative Package contains exactly one Form Language. Form Language represents the selection of languages used to express style, logic, format and textual aspects of the form design.

970

Table Q.6.3.2-1: Form Language

Element Name	Element Description	Card	Data Type
form_language	The Administrative Segment contains exactly one form language. Form language represents the selection of languages used to express style, logic, format and textual aspects of the form design.	1..1	
+@identifier	A unique identifier	1..1	string
+designation	Designatable Items allow a metadata registry to support the association of a designation or definition for the specified Designatable Item.	0..*	Table A.1.6-1
+style_language	Style Language describes the style language used to place Form Design Element instances in place on the form.	0..1	Table A.1.2-1
+logic_language	Logic Language is used to describe semantic dependencies between instances of Form Design.	0..1	Table A.1.2-1
+format_language	Format Language describes the regular expression language used.	0..1	Table A.1.2-1
+text_language	Text Language specifies the primary native human language used for Text_Element on the Form	0..1	Table A.1.2-1

Q.6.3.3 Registration

The Administrative Package contains exactly one Registration describing the state, submission record, document references, stewardship record and creation date of the form.

975

Table Q.6.3.3-1: Registration

Element Name	Element Description	Card	Data Type
Registration	The Administrative Segment contains exactly one registration capturing details about the registration state, registration steward and submitter, reference documents, origin and latest change description for the form definition.		
+state	State describes the timeline of the form, including the range in which it may be used.	0..1	Table A.1.10-1
+submission_record	Submission record contains information regarding an individual or organization to contact for submission purposes.	0..1	
++organization	Organization contains details regarding the Organization that is the steward of the form.	1..1	Table A.1.1-1
++contact	Contact describing the Contact that may be	0..1	Table Q.6.2.1-1

Element Name	Element Description	Card	Data Type
	contacted regarding stewardship.		
+document_reference	Document reference describes any document referenced by the form.	0..*	Table A.1.2-1
+organization	Organization describes the organization where the form is registered. The organization SHALL be structured as ISO Attribute Organization, which is described in Appendix A.	0..1	string
+registration_status_date	Registration status date is the date the registration status was updated.	0..1	Datetime
+stewardship_record	Stewardship record is the record of stewards for the form, providing information about the organization and contact.	1..*	
++individual		0..1	
++organization	Organization contains details regarding the Organization that is the steward of the form.	0..1	Table A.1.1-1
++contact	Contact describing the Contact that may be contacted regarding stewardship.	0..1	Table Q.6.2.1-1
+creation_date	Creation Date which is the date the registration element was created.	1..1	Datetime
+last_change_date	Last change date is the date the registration element was last changed.	0..1	Datetime
+change_description	Change description describes what has changed since the prior version of the registration element.	0..1	string
+explanatory_comment	Explanatory comment contains descriptive comments about the registration element.	0..1	string
+origin	Origin describes the source for the registration element.	0..1	string

Q.6.4 Form Design

The Form Design Package contains specifications for the unambiguous creation of semantically equivalent forms that can be represented in different applications and media (i.e., HTML, CSV, 980 MS Word).

Table Q.6.4-1: Form Design

Element Name	Element Description	Card	Data Type
form_design	The form design segment is the primary component of the SDC specification. It represents the design of a specific form. The primary elements of the form design are sections and questions, and may include instructions and related media such as images.		
+@form_design_identifier	Unique identifier	1..1	anyURI
+designation	Designation allows the form designer to	1..*	Table A.1.6-1

Element Name	Element Description	Card	Data Type
	designate a name for the form..		
+classifier	Classifier refers to a classification scheme.	0..*	Table A.1.6-1
+media	Media refers to elements, such as audio, image or video that may be used in the section.	0..*	Table Q.6.4.1-1
+security_and_privacy	Security and privacy specifies security and privacy rules related to the form design.	0..*	string
+header	Header provides text and questions displayed at the beginning of the form.	0..1	Table Q.6.4.2-1
+section	Section defines the structure of a section in the form.	0..*	Table Q.6.4.2-1
+footer	Footer defines the structure of a footer on the form.	0..1	Table Q.6.4.2-1

Q.6.4.1 Media

An instance of an image, audio, or video element within a Form. This is reserved for future use, and included only for completeness.

985

Table Q.6.4.1-1: Media

Element Name	Element Description	Card	Data Type
Media	Media represents an instance of an image, audio or video element within a Form.	0..*	
+cardinality	Cardinality defines the minimum and maximum number of times a form design element instance may be repeated by the creator of the form based on this design.	0..1	Table Q.6.4.1.1-1
+rule Note 3	Rules describe functional dependencies and constraints upon data entry relevant to the semantics of the completed form.	0..*	
++expression	Expression elements describe the rule.	1..*	string
+audio	The container element showing the type of Audio file.	0..*	
++uri	The uri is the web location where the audio element may be retrieved.	1..1	anyURI
++@type	The attribute containing type of the audio file format type- e.g., MP4, 3GP, 3G2, .mj2, .dvb, .dcf, .m21.	1..1	string
+image	The container element showing the type of image file.	0..*	
++uri	The uri is the web location where the image element may be retrieved.	1..1	anyURI
++@type	The attribute containing the type of the image file format – e.g., MP4, 3GP, 3G2, .mj2, .dvb,	1..1	string

Element Name	Element Description	Card	Data Type
	.dcf, .m21.		
+video	This container element showing the type of the video file..	0..*	
++uri	The uri is the web location where the image element may be retrieved.	1..1	anyURI
++@type	The attribute containing the type of the video file format	1..1	string
+@initial state	The value of initial state SHALL be "enabled" or "disabled".	1..1	string

Note 3: Rule expression language is currently not defined at this point in time. Any value in the expression SHALL not be considered to be computable.

990 **Q.6.4.1.2 Cardinality**

Cardinality defines the minimum and maximum number of times a form design element instance may be repeated by the creator of the form.

Table Q.6.4.1.2-1: Cardinality

Element Name	Element Description	Card	Data Type
+cardinality	Cardinality defines the minimum and maximum number of times a form design element instance may be repeated by the creator of the form.	0..1	
++minimum	Minimum sets the minimum number of times the element may be repeated.	1..1	Integer
++maximum	Maximum sets the maximum number of times the element may be repeated.	1..1	Integer

995

Q.6.4.3 Question

Questions make a request for information. The information is captured in a response field. There are 3 types of response fields, each with a set of applicable attributes and rules constraining the answer. These are: List Field, Text Field, and Lookup Field. While questions on the forms may
1000 be designed using any of the 3 types, only one of the 3 types may be used for an individual Question. The following table describes the components of a question element:

Table Q.6.4.3-1: Question

Element Name	Element Description	Card	Data Type
Question	Questions make a request for information. The information is captured in a response field. There are 3 types of response fields,		

Element Name	Element Description	Card	Data Type
	each with a set of applicable attributes and rules constraining the answer. These are: List Field, Text Field, and Lookup Field.		
+@initial_state	Initial State determines whether or not the Question is enabled for data entry when the form is initially displayed. The value SHALL be "enabled" or "disabled"	1..1	string
+@data_element_scoped_identifier	Data Element Scoped identifier – a globally unique identifier for an externally (outside of the form) defined data element. Either mapping_package or question element level use of mapping to external data elements should be used throughout an instance of SDC Form Definition. The mapping information should not be present twice in the form design.	0..1	Identifier
@+association_type	A category describing the association. SDC uses value same_as It implies that the metadata is used exactly as described in the CDE. Note: Either mapping_package or question element level use of mapping to external data elements should be used throughout an instance of SDC Form Definition. The mapping information should not be present twice in the form design. See @+data_element_scoped_identifier or mapping_package.	1..1	string
+cardinality	Cardinality defines the minimum and maximum number of times a form design element instance may be repeated by the a creator of the form based on this design:	0..1	Table Q.6.4.1.1-1
+rule Note	Rules describe functional dependencies and constraints upon data entry relevant to the semantics of the completed form	0..*	
++expression Note	Expressions describe the rule.	1..*	String
+question_prompt	Question prompt includes information about the question being asked.	0..1	Table A.1.16
+question_number	Question number provides identification of the question.	0..1	Table A.1.16
+question_instruction	Question instruction provides directions on how to answer the question.	0..1	Table A.1.16
+additional_instruction	Additional instructions provide additional instruction regarding the question.	0..*	Table A.1.16
+text_field	Text field is a response field in which any value may be entered, subject to pattern, maximum length and unit of measure and constraints applicable to the datatype. Note: while questions on the forms may	0..1	Table A.1.12

Element Name	Element Description	Card	Data Type
	be designed using any of the 3 types of response fields, only one may be used for an individual Question.		
+list_field	List field is a response field in which a list of predefined answers are allowed. . Note: while questions on the forms may be designed using any of the 3 types of response fields, only one may be used for an individual Question.	0..1	Table A.1.13
+lookup_field	Lookup field is a response field option which is also a reference via an endpoint 0..1 that supports displaying a set of valid choices from an externally defined source, where the members of the choice set may vary with time and between implementations. Note: while questions on the forms may be designed using any of the 3 types of response fields, only one may be used for an individual Question.	0..1	Table A.1.15
+text_after_question	Text after question is text that the form user will read after the question. Note: +text_after_question@+type value SHALL be either 'tooltip' or 'help'"	0..1	Table A.1.16
+question_order	Question order indicates the position of the question amongst other questions in the same section.	0..1	string
+question_identitifier	Question Identifier.	0..1	string

Note: Rule/expression is currently a string. These strings are designed for human readability and are not computable.

Q.6.4.2 Section

Sections are distinct parts of the form that groups questions for a similar purpose. The main elements of a section are instructions and questions.

Table Q.6.4.2-1: Section

Element Name	Element Description	Card	Data Type
Section_Element	Sections are distinct parts of the form that groups questions for a similar purpose. The main elements of a section are instructions and questions.	0..*	
+@initial_state	The attribute indicating the initial behavior of the element. The value SHALL be "enabled" or "disabled".		string
+cardinality	Cardinality defines the minimum and maximum number of times a form design element instance may be repeated by the creator of the form.	0..1	Table Q.6.4.1.1-1

Element Name	Element Description	Card	Data Type
+rule ^{Note 3}	Rules describe functional dependencies and constraints upon data entry relevant to the semantics of the completed form.	0..*	
++expression	Expression elements describe the rule.	1..*	string
+section_title	Section title gives a title to the section.	0..1	Table A.1.16
+section_number	Section number provides identification for the section.	0..1	Table A.1.16
+ordered	Ordered is a flag indicating if the order of child form design element instances is semantically important.	0..1	Boolean
+section_instruction	Section instructions provide directions for completing the section.	0..*	Table A.1.16
+additional_instruction	Additional instructions provide additional instructions for completing the section.	0..*	Table A.1.16
+contained_section	Contained sections are sections defined within the section.	0..*	Table Q.6.4.3-1
+section_order	Section order describes the order of the sections relative to each other.	0..1	Table A.1.16
+media	Media represents an instance of an image, audio or video element within a Form.	0..*	Table Q.6.4.1-1
+question	Questions are questions in the form.	0..*	Table Q.6.4.3-1
+additional_text	Additional text contains additional text to be displayed within the section. The value SHALL be "tooltip", "help".	0..*	
+next_relevant_element	Next relevant element ID identifies the next relevant element.	0..1	string
+section_identifier	The identifier SHALL be structured as ISO Attribute identifier, which is described in Appendix A.	0..1	string

1010   Note 3: Rule expression language is currently not defined at this point in time. Any value in the expression SHALL not be considered to be computable.

Appendices

Appendix A – List of SDC Form Elements and Attributes Adapted from ISO/IEC 19763-13 and ISO/IEC 11179-3, © copyright ISO/IEC 2014

1015 ## A.1 Base Elements from ISO/IEC Standards

A.1.1 Organization

Organization is a class, each instance of which models an organization, which is a unique framework of authority within which individuals act, or are designated to act, towards some purpose. For additional details, reference: ISO/IEC 11179-3.

1020

Table A.1.1-1: Organization Class

Element Name	Element Definition	Card	Data Type
Organization			
+name	Sign for organization	1..*	Sign
+mail_address	Postal address for organization	0..1	Postal_Address
+email_address	Email address for organization	0..*	String
+phone_number	Phone number for organization	0..*	Phone_Number
+uri	Uri for organization	0..1	String

A.1.2 Reference Document

A Reference Document records information about any document referenced in the form design.
1025 For additional details, reference: ISO/IEC 11179-3.

Table A.1.2-1: Reference Document

Element Name	Element Description	Card	Data Type
reference_document			
+identifier	Identifier for the Reference_Document	0..1	string
+document_type	Description of the type of Reference_Document	0..1	Table A.1.3-1
+language	Language of the natural language used in the Reference_Document	0..*	Table A.1.4-1
+notation	formal syntax and semantics used within the Reference_Document	0..1	string
+title	title of the Reference_Document	0..1	string

Element Name	Element Description	Card	Data Type
+provider	Organization that maintains or carries an official copy of the Reference_Document	0..1	Table A.1.1-1
+uri	uri for Reference_Document	0..1	string

A.1.3 Document Type

1030   *Document Type* specifies the document type of a *Reference Document.* For additional details, reference: ISO/IEC 11179-3.

Table A.1.3-1: Document_Type

Element Name	Element Description	Card	Data Type
+document_type		0..1	
++identifier	identifies the type of document	0..1	string
++description	describes the type of document	0..1	string
++scheme_reference	identification scheme from which the identifier and/or description are drawn	0..1	string

1035   **A.1.4 Language Identification**

Language_Identification describes a language as spoken (or written, signed or otherwise signaled) by human beings for communication of information to other human beings. Computer languages such as programming languages are explicitly excluded. For additional details, reference: ISO/IEC 11179-3.

1040

Table A.1.4-1: Language

Element Name	Element Description	Card	Data Type
Language_Identification			
+language identifier	Identifier for the language	1..1	language_code
+script_identifier	identifies the set of graphic characters used for the written form of one or more languages	0..1	string
+geopolitical_territory	identifies a specific country, territory, or region whose linguistic variations apply	0..1	string
+variant_identifier	identifies a language variant, which indicates additional, well-recognized variations that define a language or its dialects that are not covered by other available identifiers	0..*	string
+extension_identifer	identifies an extension to a language_identifier	0..1	string

Element Name	Element Description	Card	Data Type
+private_use_qualifier	qualifier whose meaning is defined solely by private agreement	0..1	string

A.1.5 Interface

Interface provides details regarding the interface for the form to interact with. For additional
1045   details, reference: ISO/IEC 11179-3.

Table A.1.5-1: Interface

Element Name	Element Description	Card	Data Type
Interface			
+identifier	Identifier of the Interface	0..1	string
+name	Name of the interface	0..1	string
+description	Description of the interface	0..1	String
+URL	URL of the interface	0..1	String
+version	Version of the interface	0..1	String

A.1.6 Designation

1050   The *Designation* describes the name, language and convention. For additional details, reference: ISO/IEC 11179-3. This is reserved for future use, and included only for completeness.

Table A.1.6-1: Designation

Element Name	Element Description	Card	Data Type
Designation			
+dcontext	Provides context on the type of designation	1..1	String
+sign	Sign on the type of designation	1..1	Sign
+language	Language of designation	0..1	String
+namespace	Namespace id of designation	0..*	Identifier
+convention	Convention id of designation	0..*	Identifier
+definition	Definition of Designatable_item	0..*	Definition

1055 ## A.1.7 Individual

An individual is defined as a single human being. Information regarding the individual should be collected as described below. For additional details, reference: ISO/IEC 11179-3.

Table A.1.7-1: Individual

Element Name	Element Description	Card	Data Type
Contact		0..*	
+name	Sign that designates the individual	1..1	Sign
+title	Name of the position held by the individual	0..1	Sign
+mail_address	Postal address for the individual	0..1	Postal_Address
+email_address	Email address for the individual	0..*	String
+phone_number	Phone numbers for the individual	0..1	Phone_Number
+fhir_mail_address	FHIR mail address for the individual	0..*	Table A.1.8-1

1060

A.1.8 FHIR® Mail Address

Below is a description of a Mail address structure defined by *Fast Healthcare Interoperability Resources (FHIR)*

1065 **Table A.1.8-1: FHIR® Mail Address Data Elements**

Element Name	Element Description	Card	Data Type
fhir_mail_address			
+use	Use of the postal address	0..1	String
+text	Text of postal address	0..*	String
+line	Line of postal address	0..*	String
+city	City on postal address	0..1	String
+state	State on postal address	0..*	String
+zip	Zip code on postal address	0..1	String
+country	Country on postal address	0..1	String

A.1.9 Role

A role is specified responsibilities of an individual. Below is the structure to describe a role. For additional details, reference: ISO/IEC 11179-3.

1070

Table A.1.9-1: Role Data Elements

Element Name	Element Description	Card	Data Type
Role	Specifies responsibilities of an individual.		
+title	The formal position or title of the responsible individual.	0..1	String
+mail_addresses	Postal address by which one may reach the individual.	0..1	Table A.1.8-1
+email_addresses	Email address by which one may reach the individual.	0..1	String
+phone_numbers	Phone number by which one may reach the individual.	0..1	Phone_Number

A.1.10 State

A S*tate* is a collection of information about the *Registration* of an *Administered Item*. For additional details, reference: ISO/IEC 11179-3.

Table A.1.10-1: State Data Elements

Element Name	Element Description	Card	Data Type
State			
+registration_status	Designation of the status in the registration life-cycle of an Administered_Item	1..1	String
+effective_date	Date and time an Administered_Item became/becomes available to registry users	1..1	Datetime
+until_date	Date and time the Registration of an Administered_Item by a Registration_Authority in a registry is no longer effective	0..1	Datetime
+administrative_note	General note(s) about the Registration	0..1	String
+administrative_status	Designation of the status in the administrative process of a Registration_Authority	1..1	String
+previous_state	Immediately prior collection of administrative information (3.2.3) about registration	0..1	String

A.1.11 Response

A form design has no answers, only questions, responses and constraints. Questions may have prompts which hold the main semantics of the answer that is to be placed in the Response, question numbers and additional instructions. Response may be a Text_Field which allows the entry of numbers and strings, a

List_Field which allows the user to select from a menu of List_Items, and a Lookup_Field which fetches the currently available valid values for an answer from a web service or a database view.

A.1.12 Text Field

Text Field represents a field in which any value may be entered, subject to the pattern and length constraints. For additional details, reference: ISO/IEC 19763-13.

1090

Table A.1.12-1: Text Field

Element Name	Element Description	Card	Data Type
text_field	Text_Field is a metaclass each instance of which represents a field constraints.		
+multiselect	The optional number of answers to the question that may be provided where the maximum multiplicity is one. The default is "false" meaning that the input field only allows a single answer	0..1	boolean
+default_value	An optional default value for the input field when nothing is entered, where the maximum multiplicity is one.	0..1	string
+default_value_read_only	An optional indicator of whether the default value, if specified, can be edited, where the maximum multiplicity is one.	0..1	boolean
+maximum_character_quantity	An optional maximum number of characters that the Input_Field may accept. If this value is missing there is no limit on the number of characters the field may accept. Its value may be mapped to an ISO/IEC 11179 Data Element.	0..1	string.
+unit_of_measure	NOTE: Unit_Of_Measure [ISO/IEC 11179:2013, 11.4.2.1 An optional textual name for the measurement when the input field is a physical quantity, where the maximum multiplicity is one. Its value may be set through a mapping to an ISO/IEC 11179 Data Element.	0..1	Unit of Measure
++@schema_name	Name of schema	1..*	string
+datatype	Text that identifies the type of data to be stored for the answer.. Its value may be set through mapping to an ISO/IEC 11179 Data Element.	0..1	Table A.1.17
+format	An optional template for the structure of the presentation of the value(s). Note: its value may be set through mapping to an ISO/IEC 11179 Data Element.	0..1	string
+next_relevant_element	An explicit reference to the next element to be shown in the form design	0..1	identifier
+default_element	An optional element defining the default value for the question. It may be set by pointing to the identifier of an existing list item, or explicitly defined.	0..1	Choice

Element Name	Element Description	Card	Data Type
++list_item_identifier	The identifier of the list item for this question that should be used as the default value in the user does not select a response.	0..1	identifier
++default	The definition of a default value and its prompt.	0..1	Same datatype as the response field
+++value	An optional default value for the response	1..1	string
+++default_prompt	The text prompt for the default value.	0..1	Table A.1.16 (Text Element)
++read_only	An optional indicator of whether the default value for the response can be edited,	1..1	boolean
+datatype		0..1	Table A.1.17

A.1.13 List Field

List Field represents a field in which only predefined answers are allowed. A list field contains all items within Text Field, with the additional elements listed below. For additional details,
1095   reference: ISO/IEC 19763-13.

Table A.1.13-1: List Field

Element Name	Element Description	Card	Data Type
list_field	List Field is a metaclass each instance of which represents a field in which only predefined answers are allowed		
+ordered	A flag that indicates whether or not the order of child List_Field instances is semantically significant, where the maximum multiplicity is one.	1..1	boolean
+fill_in	A flag that indicates whether or not the user is allowed to enter a value that is not amongst the set of List_Items specified	0..1	boolean
+list_item	The set of pre-defined list items that are allowed answers to the question where the minimum multiplicity is two and the maximum multiplicity is unbounded.	2..N	
++value	the actual data value to be stored when the user selects this item	1..1	Defined by the datatype for the question
++item_number	A text element allowing list item order to be displayed to the user	0..1	Table A.1.16
++item_prompt	A text prompt for the possible value..	1..1	Table A.1.16

Element Name	Element Description	Card	Data Type
++additional_instruction	A text element providing additional instruction for choosing a possible value	0..1	Table A.1.16
++value_meaning	A text element intended to explain the meaning of a possible value	0..1	Table A.1.16
++fill_in	A flag that indicates whether or not the user is allowed to enter a value along with this possible value	0..1	boolean
++guard	Defines follow on question to be completed for the possible choice.	0..1 Choice	Table A.1.14
++item_prompt_xhtml	An html representation of the item prompt, may include HTML markup,.	0..1	anyType
++media_element	a medial element that represents some image, audio or video element as a possible choice	0..N	Table Q.6.4.1-1
++value_meaning_terminology_ code	The code associated with this possible choice	0..1	String
++value_meaning_terminology_ code_name	The name for the code associated with this possible choice	0..1	String
++value_meaning_terminology_ code_system	The terminology system name for the code associated with this possible choice	0..1	String
++value_meaning_terminology_ code_system_identifer	The terminology system identifier for the code associated with this possible choice	0..1	String
++value_meaning_terminology_ code_system_version	The terminology system version for the code associated with this possible choice	0…1	String
++list_item_order	If the list is ordered, an explicit order for this item, not displayed to the end users.	0..1	String
++list_item_identifier			

A.1.14 Guard

1100   Guard indicates an action to be taken if this List_Item is selected. The action indicated by the type should be executed against the set of Form_Design_Elements. This is reserved for future use, and included only for completeness.

Table A.1.14-1: Guard

Element Name	Element Description	Card	Data Type
Guard	An enumeration of values describing the type of guard in operation on a particular	0..N choice	Guard_State_Type string **hide"** and **"show"**
+guarded_element_identifier	The identifier of an element within the form to be used as the follow-on question.	0..1	string

Element Name	Element Description	Card	Data Type
+guarded_element	An element contained the follow-on section or questions	0..N	
++section	An embedded follow on section for this possible choice	0..N	Table A.6.4.2
++question	Embedded follow on question(s) for this possible choice.	0..N	Table A.6.4.3

1105

A.1.15 Lookup Field

Lookup Field represents a response field which is a reference via an endpoint 0..1 that supports displaying a set of valid choices from an externally defined source, where the members of the choice set may vary with time and between implementations. For additional details, reference:
1110   ISO/IEC 19763-13.

Table A.1.15-1: Lookup Field

Element Name	Element Description	Card	Data Type
lookup_field		0..1	Table A.1.12-1
+end_point	The location of the endpoint providing the value; a service or function call, a URI call that returns the value list where the maximum multiplicity is unbounded.	0..*	anyURI

A.1.16 Text Element

1115   Text Element is a textual presentation element of a form intended to instruct or explain to the user of the form what the data should mean, how it should be completed and any actions that must be taken with the completed form. For additional details, reference: ISO/IEC 19763-13.

Table A.1.16-1: Text Element

Element Name	Element Description	Card	Data Type
++cardinality	Cardinality defines the minimum and maximum number of times a form design element instance may be repeated by the a creator of the form	0..1	Table Q.6.4.1.1-1
++rule[Note 3]	Rules describe functional dependencies and constraints upon data entry relevant to the semantics of the completed form.	0..*	
+++expression	Expression elements describe the rule.	1..*	string
++label	Optional name, label or identifier	0..1	string
++style	Optional set of statements in some style language	0..N	string

Element Name	Element Description	Card	Data Type
	about the element where		
++representation	Optional association to a Media element for representation of a Text Element	0..N	
+++cardinality	Cardinality defines the minimum and maximum number of times a form design element instance may be repeated by the a creator of the form	0..1	Table Q.6.4.1.1-1
+++rule[Note 3]	Rules describe functional dependencies and constraints upon data entry relevant to the semantics of the completed form.	0..*	
++++expression	Expression elements describe the rule.	1..*	string

1120

A.1.17 Datatype

A datatype is a set of distinct values, characterized by properties of those values and by operations on those values. The datatypes are based on W3C types. The following table shows the list of datatypes:

1125

Table A.1.17-1: Datatypes

Datatypes
+string
++reg_ex
++pattern
++minimum_characters
++maximum_characters
+integer
++minimum_value
++maximum_value
+decimal
++minimum_value
++maximum_Value
++fractionDigits
+string_date
++pattern
+international_dateTime
++pattern
+string_time
++pattern
++timezone
+duration

Datatypes
+file
++mime_Type
++max_Size

Volume 3 Namespace Additions

Add the following terms to the IHE Namespace:

1130   None