

Integrating the Healthcare Enterprise



5 **IHE Quality, Research, and Public Health
Technical Framework Supplement**

10 **Structured Data Capture
(SDC)**

15 **Draft for Public Comment**

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25 **Please verify you have the most recent version of this document. See [here](#) for Trial Implementation and Final Text versions and [here](#) for Public Comment versions.**

Foreword

30 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 June 6, 2014 for Public Comment. Comments are invited and may be submitted at http://www.ihe.net/QRPH_Public_Comments. In order to be considered in development of the Trial Implementation version of the supplement, comments must be received 35 by July 5, 2014

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.

<i>Amend section X.X by the following:</i>
--

40 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.

45 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 50 <http://ihe.net/Profiles>.

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

55

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Introduction to this Supplement

165 The Structured Data Capture (SDC) Content Profile provides specifications to enable an
electronic health record 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)
170 form compliance model. This profile also supports optional use IHE Data Element Exchange
(DEX) Profile for retrieving and submitting forms in a standardized and structured format.

This supplement is based on the work of the Office of the National Coordinator [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
175 of SDC.

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

- IT Infrastructure Technical Framework Volume 1
- 180 • 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
- 185 • IT Infrastructure Technical Framework Supplement: Audit Trail and Node
Authentication (ATNA) Integration Profile
- IETF HTTPS and TLS v1.0 standard
- W3C SOAP
- OASIS SAML
- 190 • ISO/IEC 19763-13
- Optionally, QRPH Technical Framework Supplement: Data Element Exchange (DEX)
Profile
- Optionally, the IHE XUA Profile for user assertions
- 195 • Optionally, QRPH Clinical Research Document (CRD) Profile for definition of Audit
Log message content and QRPH-36 transaction

Open Issues and Questions

Item #	Section	Question
1.	Q.3	For SDC HTML Package, the <sdc:form_info> should contain a reference to the SDC XML Package. This may be considered for a CP in future.
2.	Q.5	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. Will submit a CP in future to change this optionality to a requirement.
3.	Q.5	Consider future CP to constraint the <sdc:supplemental_data> schema to conform to the same scheme used for <sdc:submitted_data>
4.	5.0	IHE Template Issue: Invented section numbering scheme, since none was defined in the template that allowed inclusion of other text.

Closed Issues:

1. Does SDC include a Transaction or Content Module?: SDC doesn't have new transactions, but can include the content sections to reference the 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? The main reason that SDC Profile chose using XAdES over IHE DSG Profile is that SDC use case required electronic signatures to be inclusive (part of the transaction) rather than being included as a separate document.

General Introduction

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

210 **Appendix A - Actor Summary Definitions**

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

No new actors.

Appendix B - Transaction Summary Definitions

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

No new transactions.

Glossary

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

220

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)	Data elements that are developed, maintained and used based on <i>commonly</i> agreed-upon principles by a user community are called Common Data Elements (CDEs).
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.
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 forms data can be stored.
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.

Glossary Term	Definition
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	MetamodelFramework for Interoperability (MFI) -- an ISO/IEC 19763 standard.
MFI-13	Metamodel Framework for Interoperability (MFI) – ISO/IEC 19763-13 standard for Form 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 a 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, where as 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 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	An ISO/IEC 19763-13 (MFI) based XML definition of a form that can be validated using SDC Schema. This is not a fillable form.
SDC XML Package	A collection of files that includes SDC Form Definition, along with mapping information, administrative information, and (optional) supplemental data.
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 HTML form instance is a fillable form.

Glossary Term	Definition
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.

Volume 1 – Profiles

Copyright Licenses

Section not applicable.

Domain-specific additions

225 Section not applicable.

X Structured Data Capture (SDC) Profile

230 With electronic health record (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 electronic health record 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.

235 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 CDE’s and Form Model definitions, developed guidance to assist in implementation, and conducted pilots for evaluation of SDC.

240 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

245 This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at http://www.ihe.net/Technical_Frameworks (a work in progress).

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

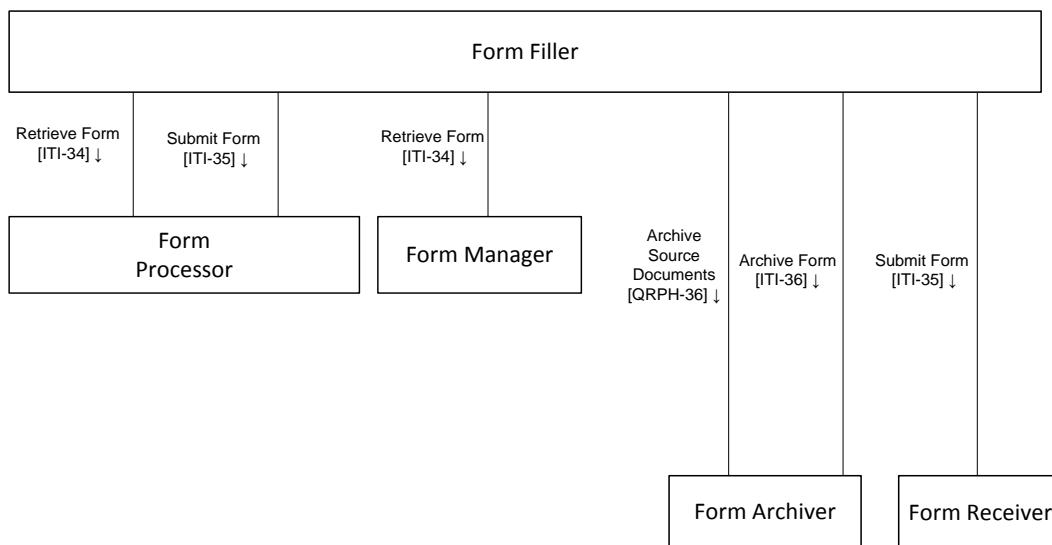


Figure X.1-1: SDC Actor Diagram

250 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

255

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 ^{Note 2}	O	Q.5
Form Manager	SDC Pre-Pop	R	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	R	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.

Note 2: Form Filler will need to support base RFD submission, if it is not supporting SDC Submission Data Content Module.

260

This SDC Profile builds upon the IHE RFD Profile and HTML in describing both the content 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)
- 265 2) HTML-based form instances (display and presentation of data)

To support both of these approaches this profile has incorporated the above options (whereby a form, defined in XML, can also be exchanged in HTML format. Form definition vs. form instance.

X.1.1 Actor Descriptions and Actor Profile Requirements

- 270 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 Actor is defined in the RFD Profile in ITI TF-1, thus it supports all required constraints from RFD Profile.

- 275 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 (Refer to Section Q.2.1)
- SDC HTML Package (Refer to Section Q.3.1)
- SDC URI Form (Refer to Section Q.4.1)

- 280 The Form Filler MAY support SDC Submission Data content module (Refer Section Q.5) to submit completed form data. In addition, the Form Filler MAY support the generation of the pre-population data in the form of the SDC Pre-Pop content module (Refer Section Q.1). The Form Filler MAY also support the SDC Auto-Pop Option (Refer to Section X.2.5).

- 285 The transactions supported by the Form Filler SHALL follow the security considerations as outlined in Section X.5.

X.1.1.2 Form Manager

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

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

- SDC SDC Pre-Pop content module (Refer to Section Q.1)
- SDC XML Package content module (Refer to Section Q.2.2)

- SDC HTML Package content module (Refer to Section Q.3.2)
- SDC URI Form content module (Refer to Section Q.4.2)

295 The transactions supported by the Form Manager SHALL follow the security considerations as outlined in Section X.5.

X.1.1.3 Form Processor

The Form Processor Actor is defined in the RFD Profile in ITI TF-2, thus it supports all required constraints from RFD Profile.

300 The system implementing the Form Processor’s role in SDC Profile SHALL support all of the following content modules:

- SDC SDC Pre-Pop content module (Refer to Section Q.1)
- SDC XML Package content module (Refer to Section Q.2.2)
- SDC HTML Package content module (Refer to Section Q.3.2)
- SDC URI Form content module (Refer to Section Q.4.2)
- SDC Submission Data content module (Refer to Section Q.5)

305

The transactions supported by Form Processor SHALL follow the security considerations as outlined in Section X.5.

X.1.1.4 Form Archiver

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

The transactions supported by Form Archiver SHALL follow the security considerations as outlined in Section X.5.

X.1.1.5 Form Receiver

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

The Form Receiver SHALL receive the structured form data as submitted by the Form Filler using SDC Submission Data content module (Refer to Section Q.5).

320

The transactions supported by Form Receiver SHALL follow the security considerations as outlined 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. 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	X.2.1
	SDC XML Package ^{Note 1}	X.2.2
	SDC HTML Package ^{Note 1}	X.2.3
	SDC URI Form ^{Note 1}	X.2.4
	SDC Auto-Pop	X.2.5
	Archive Form	ITI TF-2b:3.36
	Archive Source Documents	QRPH TF-2: 3.36
Form Manager	None	
Form Processor	None	
Form Archiver	None	
Form Receiver	None	

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

X.2.1 Form Filler: SDC Pre-Pop Option

330 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:

- In order to claim conformance to this option, the Form Filler SHALL implement SDC Pre-Pop content module (Refer to Section Q.1).

X.2.2 Form Filler: SDC XML Package Option

335 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 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 (Refer to Section Q.2.1).

X.2.3 Form Filler: SDC HTML Package Option

340 This option defines the requirement placed on requesting and retrieving an SDC HTML Package. 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 (Refer to Section Q.3.1).

345 **X.2.4 Form Filler: SDC URI Form Option**

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:

- 350 • In order to claim conformance to this option, the Form Filler SHALL implement SDC URI Form content module (Refer to Section Q.4.1).

X.2.5 Form Filler: SDC Auto-Pop Option

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

- 355 • In order to claim conformance to this option, the Form Filler SHALL support SDC XML Package Option or SDC HTML Package Option.
- In order to claim conformance to this option, the Form Filler SHALL automatically supply some additional form data.

X.3 SDC Required Actor Groupings

360 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 actor (Column 2).

In some cases, required groupings are defined as at least one of an enumerated set of possible actors; this is designated by merging column one into a single cell spanning multiple potential grouped actors.

365 Section X.5 describes some optional groupings that may be of interest for security considerations and Section X.6 describes some optional groupings in other related profiles.

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

SDC Actor	Actor to be grouped with	Reference	Content Bindings Reference
Form Filler	ATNA Secure Node or ATNA Secure Application	ITI TF- 1: 9.4	N.A.
	XUA X-Service User	ITI TF- 1: 13.4	N.A.
Form Manager	ATNA Secure Node or ATNA Secure Application	ITI TF- 1: 9.4	N.A.
	XUA X-Service User	ITI TF- 1: 13.4	N.A.
Form Processor	ATNA Secure Node or ATNA Secure Application	ITI TF- 1: 9.4	N.A.

SDC Actor	Actor to be grouped with	Reference	Content Bindings Reference
	XUA X-Service User	ITI TF- 1: 13.4	N.A.
Form Archiver	ATNA Secure Node or ATNA Secure Application	ITI TF- 1: 9.4	N.A.
	XUA X-Service User	ITI TF- 1: 13.4	N.A.
Form Receiver	ATNA Secure Node or ATNA Secure Application	ITI TF- 1: 9.4	N.A.
	XUA X-Service User	ITI TF- 1: 13.4	N.A.

X.4 SDC Overview

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

X.4.1.1 Pre-Population

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

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.

X.4.2 Use Cases

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

395 In this use case, the EHR retrieves the form using a URI 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 URI Use Case Description

400 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 and enter the required data.

405 X.4.2.1.2 Retrieve form using URI Process Flow

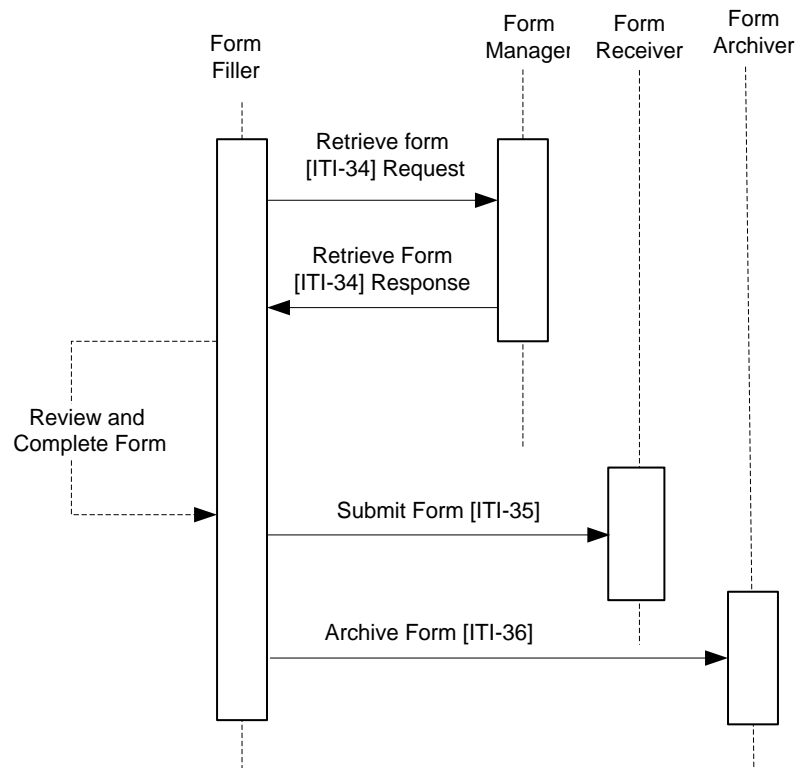


Figure X.4.2.1.2-2: Retrieve form using an URI Process Flow in SDC Profile

X.4.2.1.3 Pre-conditions

- The EHR system performs the role of a Form Filler;
- 410 • 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 URI to obtain access to the appropriate form.

X.4.2.1.4 Main Flow

- 415 • 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;
- The study coordinator completes the form through its display within the EHR user interface;
- 420 • 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.

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

425 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

430 Dr. R. E. Hab has a patient who needs an electric wheelchair. The patient needs to obtain pre-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.

435 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 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 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

440 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

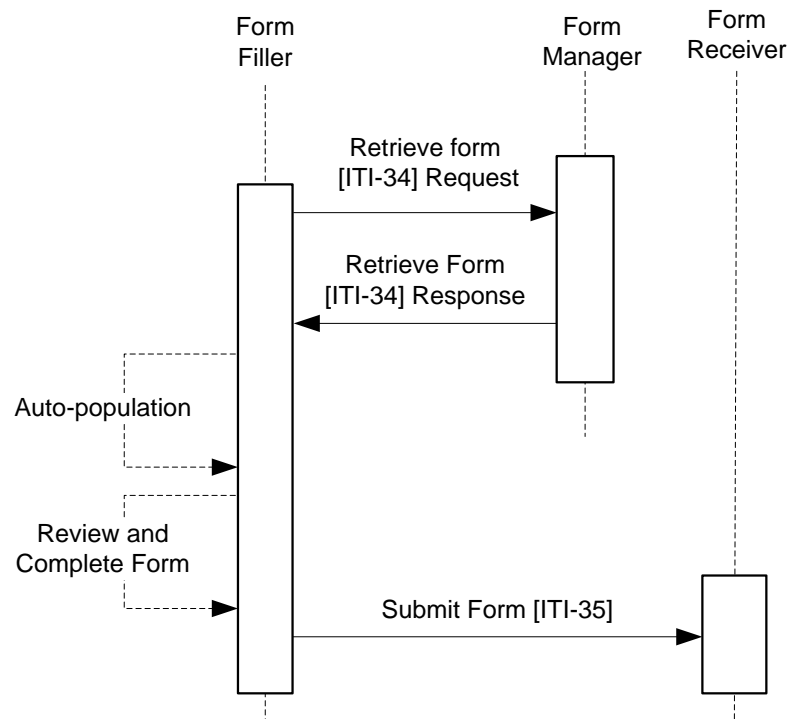


Figure X.4.2.2.2-1: Capture and Submit Pre-Authorization Flow in SDC Profile

445 X.4.2.2.3 Pre-conditions

- The EHR system performs the role of a Form Filler;
- 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;
- 450 • The EHR already knows the endpoints to submit pre-authorization form request;
- The EHR is able to digitally sign the pre-authorization form;
- 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.

455 **X.4.2.2.4 Main Flow**

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

460

X.4.2.2.5 Post-conditions

- 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

465 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 public health reporting.

X.4.2.3.1 Use Case with Extraction Specification Description

470 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.

475 The EHR system, acting as the Form Filler, requests and retrieves the appropriate form from the 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 provides explicit location information for each data element required by the form. 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. Included in this metadata are XPath statements that explicitly lead to the correct instance data in the EHR export document.

480

The EHR additionally auto- populates the remaining open sections of the form using a similar DEX-derived extraction specification.

485 The EHR system renders the retrieved form after pre-populating and auto-populating form data (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.

490 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; 495 the form template; the form data returned after being auto-populated; and/or the form data as they were submitted.

X.4.2.3.2 Use Case with Extraction Specification Process Flow

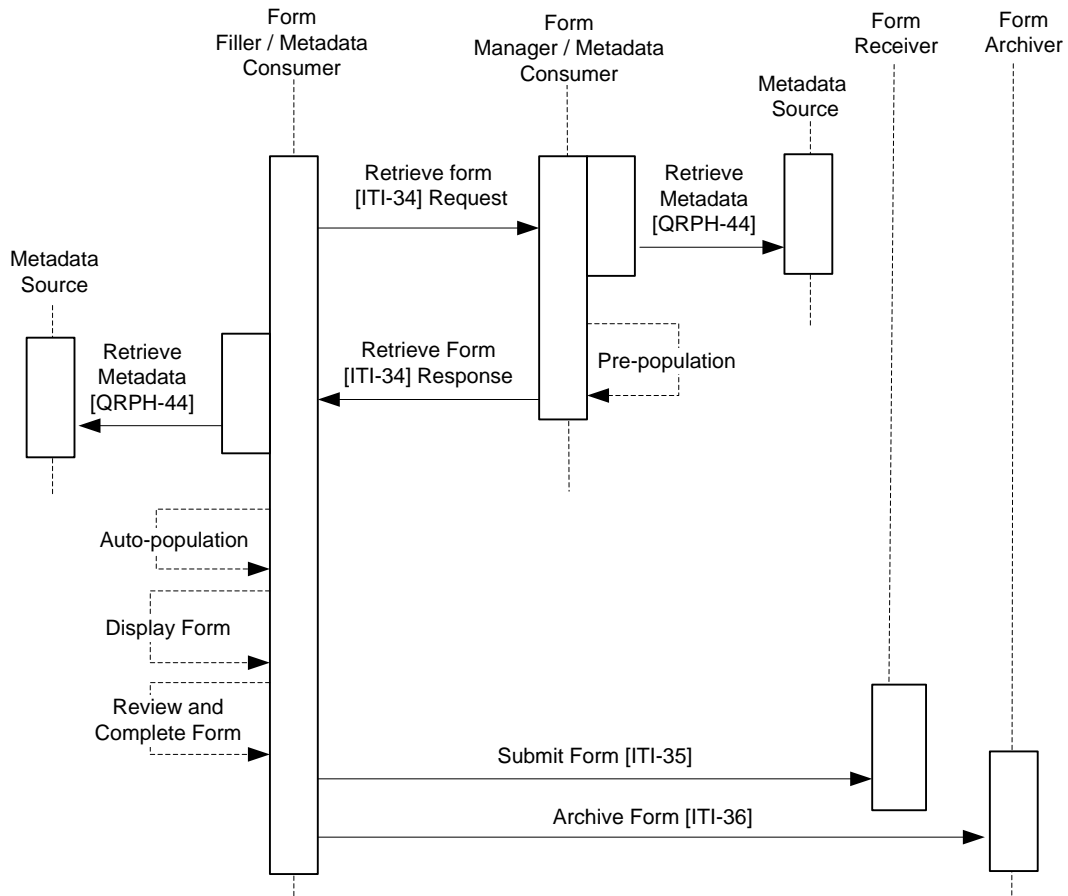


Figure X.4.2.3.2-1: SDC Profile Use Case with Extraction Specification Process Flow

500 **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;
- 505 • 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.

X.4.2.3.4 Main Flow

- The provider is made aware of a required public health report;
- 510 • 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;
- 515 • 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;
- 520 • An archived copy of the completed form has been stored.

X.5 SDC Security Considerations

The security considerations for a content module are dependent upon the security provisions defined by the grouped actor(s).

525 In accordance with the IHE ITI-1:9, when configured for use on a physically secured network, the normal connection mechanisms may be used. However, when configured for use in an environment not on a physically secured network, implementations shall use a secure channel such as the TLS protocol. It is expected that the payload used in this use case will cross affinity domains and therefore transport encryption is required.

530 The requirements for transport security are therefore based on the traversal of organizational boundaries and are applicable to all participating actors executing transactions for this profile:

- Transactions traversing organizational boundaries (e.g., over untrusted or non-secured network) **SHALL** use SOAP
- **SHALL** use TLS v. 1.0 or greater in order to provide a secure channel

- **SHALL** use IHE ATNA for Node Authentication and Recording Security Audit Events.

535 The underlying specifications listed in the IHE Audit Trail and Node Authentication (ATNA) Integration Profile help protect confidentiality and integrity, and use cryptographic mechanisms to ensure that both endpoints are mutually authenticated. Note that IHE ATNA allows each secure node to use the access control technology of its choice to authenticate users, but requires the use of bi-directional certificate-based node authentication for connections to and from each
540 node in order to authenticate the endpoints and secure the communications channel.

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

The Record Audit Event transaction is a foundational component that is used to record audit events throughout an implementation.

545 Implementers should refer to the IHE ATNA Profile for specific implementation guidance and conformance criteria. Message content is defined in the IHE Clinical Research Document (CRD) Profile in Section 5.Z3 Audit Record Considerations.

X.5.2 XAdES Digital Signature

550 SDC transactions can contain numerous elements and those elements are inter-related. There will 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. This profile enables the use of the XAdES digital signature standard when this is required.

X.6 SDC Cross Profile Considerations

Not applicable

555

Appendices

Not applicable

Volume 2 – Transactions

Section not applicable.

Appendices

560

Not applicable

Volume 2 Namespace Additions

<i>Add the following terms to the IHE General Introduction Appendix G:</i>
--

565

None

Volume 3 – Content Modules

5 Namespaces and Vocabularies

570

<i>Add to section 5 Namespaces and Vocabularies</i>

Not applicable

6 Content Modules

6.3.1 CDA Document Content Modules

Section not applicable.

575 Q. SDC Content Modules

Q.1 SDC Pre-Pop Content Module

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

580

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

585

```

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

```

590

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

595

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

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

Q.2.1 SDC XML Package – Request

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

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

605

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	

610

```

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

```

615

620

Q.2.2 SDC XML Package – Response

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

630 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 independent of the form design and included in other functionality at the Form Filler end – such as auto-population. The Form Manager sometimes plays the role of a Form Designer and 635 compiles the final SDC XML package.

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 have value “XML” when returning SDC XML Package.

640

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.	0..1	O		
+sdc_xml_package	The wrapper element container for the SDC-compliant form package.	1..1	R		
++supplemental_data	The XML element containing additional data related to the form.	0..1	O	anyXML	
++form_package	The XML element containing ISO 19763-13 based form design and associated files as explained in Section Q.6.	1..1	R		
contentType	The type of the returned form.	1..1	R	string	Value SHALL be “XML”

645

```

<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_xml_package>

```

```
650         <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>
655         <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-->
           </sdc:mapping_package>
660         <sdc:administrative_package>
           <!-- Administrative information goes here -->
           </sdc:administrative_package>
           <sdc:stylesheet>
           <!--include any style sheet information here -->
665         </sdc:stylesheet>
           <sdc:form_design>
           <!--Contains the form design, (e.g., question-answer
           sets, skip logic, etc.) -->
           </sdc:form_design>
670         </sdc:form_package>
           </sdc:sdc_xml_package>
           </Structured>
           <instanceID>1.2.3.4.5</instanceID>
675         </form>
           <contentType>XML</contentType>
           <!--Please note the use of constrained value "XML" above-->
           <responseCode/>
         </RetrieveFormResponse>
```

Q.3 SDC HTML Package Content Module

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

685 Q.3.1 SDC HTML Package – Request

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

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

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	

695

```

<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>

```

700

705

710 Q.3.2 SDC HTML Package – Response

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

715 The HTML package contains an HTML instance of the form as well as other additional information from related supplemental information <supplemental_data>. The additional 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.

720 The Form Manager and Form Processor SHALL ensure that the <contentType> element always 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.	0..1	O		
+sdc_html_package	The wrapper element container for the SDC-compliant HTML form package.	1..1	R		
++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"

725

730

735

740

745

```

<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>

```

750

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

Q.4 SDC URI Form Content Module

755

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

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

Q.4.1 SDC URI Form – Request

760

This Content Module further constraints the <encodedResponse> element as defined in Retrieve Form transaction [ITI-34] in 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.

765

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”

770

```
<RetrieveFormRequest
  xmlns="urn:ihe:iti:rfd:2007"
  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>
    <!--Please note the use of constrained value "false" above-->
    <archiveURL />
    <context xsi:nil="true"/>
    <instanceID xsi:nil="true"/>
  </workflowData>
</RetrieveFormRequest>
```

775

780

Q.4.2 SDC URI Form – Response

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

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

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.	0..1	O	anyURI	
contentType	The type of the returned response.	1..1	R	string	Value SHALL be “Unstructured”

790

```

<RetrieveFormResponse
  xmlns="urn:ihe:iti:rfd:2007"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  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
    </URL>
    <instanceID>3.4.5.6.7</instanceID>
  </form>
  <contentType>Unstructured</contentType>
  <!--Please note the use of constrained value "Unstructured" above-->
  <responseCode/>
</RetrieveFormResponse>

```

795

800

Q.5 SDC Submission Data Content Module

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

810 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 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.

815 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.

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

820

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		
++++Question	The XML element identifying the Question	1..*	R		
+++++@section_identifier	identifier for the section of the form to which the question belongs	1..1	R	string	
+++++@parent_identifier	Identifier of the parent element, this may be a section, question or list_itemquestion	0..1	O	string	
+++++@question_prompt	Question text as it appears in the form	1..1	R	string	
+++++@question_repeat	Indicator if the the question is repeated multiple times, e.g., 1, 2, 3	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	
+++++@datatype	The datatype of the response.	1..1	R	string	

Element Name	Description	Card.	Optionality	Data Type	Value Constraint
++++@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	
++++@list_item_prompt	The prompt for the list item	0..1	O	string	
++++@list_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_identifier	Includes the standard code system and version number	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 version="1.0" encoding="UTF-8"?>
<rfd:SubmitForm 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:SubmitForm>

```


850 **Q.6 SDC Form Definition Model**

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

855 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
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
860 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-
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
865 data or information models.

The basic structure of an SDC form contains one or more sections, sections contain one or more
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
870 Elements.

The sections below describe the SDC form package, which includes the following: mapping
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

875 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
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
880 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
answers and is part of MDR-3 data element standard.

885

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	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 compliant metadata registry data elements	0..1	
++@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.	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. For example, 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	1..1	string

Element Name	Element Description	Card	Data Type
	/patient/administrativeGenderCode.		
+contact	Contact contains information regarding whom to contact for more information about the DEX Mapping Specification.	0..*	

Q.6.2.1 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.

890

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.1.8-1
+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.1.10-1

Q.6.3 Administrative Package

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.

895

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..*	

Element Name	Element Description	Card	Data Type
+@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 retrieved, contact information, classifications, languages used, and style information.	1..*	
++expression	Submission rule contains information about where to submit a completed form.		String
+originating_registry_summary	Captures details regarding the origin of the form.	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..*	
+registration	Endpoint is where the form will be submitted.	0..1	

Q.6.3.1 Origin Summary

900 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.

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	string
+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	0..1	Table A.1.2-1

Element Name	Element Description	Card	Data Type
	registry.		
+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

905 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.

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.1.7-1
+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
+textual_language	Textual Language specifies the primary native human language used.	0..1	Table A.1.2-1

910 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.

Table Q.6.3.3-1: Registration

Element Name	Element Description	Card	Data Type
Registration	The Administrative Segment contains exactly one registration describing the state, submission record, document references, stewardship record and creation date of the form.		
+state	State describes the timeline of the form, including	0..1	Table

Element Name	Element Description	Card	Data Type
	the range in which it may be used.		A.1.11-1
+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 contacted regarding stewardship.	0..1	Table Q.6.2.1-1
+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..*	
++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

915 **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, MSWord).

920

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		

Element Name	Element Description	Card	Data Type
	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 designate a name for the form..	1..*	Table A.1.7-1
+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..*	
+header	Header provides text and questions displayed at the beginning of the form.	0..1	
+section	Section defines the structure of a section in the form.	0..*	
+footer	Footer defines the structure of a footer on the form.	0..1	

Q.6.4.1 Media

An instance of an image, audio, or video element within a Form.

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	
++minimum	Minimum sets the minimum number of times the media element may be repeated.	1..1	Integer
++maximum	Maximum sets the maximum number of times the media element may be repeated.	1..1	Integer
+rule	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

Element Name	Element Description	Card	Data Type
++@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, .dcf, .m21.	1..1	string
+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 attribute indicating the initial behavior of the element e.g., enabled or disabled.	1..1	string

925 **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.		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	
++minimum	Minimum sets the minimum number of times the media element may be repeated.	1..1	Integer
++maximum	Maximum sets the maximum number of times the media element may be repeated.	1..1	Integer
+rule ^{Note 3}	Rules describe functional dependencies and constraints upon data entry relevant to the semantics of the completed form.	0..*	
++expression	Expressions describe the rule.	1..*	string

Element Name	Element Description	Card	Data Type
+section_title	Section title gives a title to the section.	0..1	string
+section_number	Section number provides identification for the section.	0..1	string
+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..*	string
+additional_instruction	Additional instructions provide additional instructions for completing the section.	0..*	string
+contained_section	Contained sections are sections defined within the section.	0..*	string
+section_order	Section order describes the order of the sections relative to each other.	0..1	string
+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.	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

930 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.

Q.6.4.3 Question

935 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. The following table describes the components of a question element:

Table Q.6.4.3-1: Question

Element Name	Element Description	Card	Data Type
base_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.		
+@initial_state	Initial State determines whether or not the	1..1	string

Element Name	Element Description	Card	Data Type
	Question is enabled for data entry when the form is initially displayed.		
+@data_element_scoped_identifier	Data Element Scoped identifier uniquely identifies the data element that this Question is based on.	0..1	Identifier
+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	
++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
+rule ^{Note}	Rules describe functional dependencies and constraints upon data entry relevant to the semantics of the completed form	0..*	
+expression	Expressions describe the rule.	1..*	string
+question_prompt	Question prompt includes information about the question being asked.	0..1	string
+question_number	Question number provides identification of the question.	0..1	string
+question_instruction	Question instruction provides directions on how to answer the question.	0..1	string
+additional_instruction	Additional instructions provide additional instruction regarding the question.	0..*	string
+text_field	Text field is a field in which any value may be entered, subject to pattern, maximum length and unit of measure and constraints applicable to the datatype.	0..1	
+list_field	List fields is a field in which a list of predefined answers are allowed..	0..1	Table C-14
+lookup_field	Lookup field is a reference via an endpoint to a URI call that returns a set of valid choices from an externally defined source, where the members of the choice set may vary with time and between implementations.	0..1	
+text_after_question	Text after question is text that the form user will read after the question.	0..1	string
+question_order	Question order indicates the position of the question amongst other questions in the same section.	0..1	string
+question_identifier	Question Identifier.	0..1	string

Note: 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 Attributed Inherited from ISO/IEC 19763-13 and ISO/IEC 11179-3

A.1 Base Elements from ISO/IEC Standards

945 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.

950

Table A.1.1-1: Organization Class

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

A.1.2 Reference Document

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

955

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	
+title	title of the Reference_Document	0..1	string
+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
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A.1.3 Document Type

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

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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	

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.

965

Table A.1.4-1: Language

Element Name	Element Description	Card	Data Type
Language_Identification			
+language identifier	Identifier for the language	1..1	string
+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_identifier	identifies an extension to a language_identifier	1..*	string
+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 details, reference: ISO/IEC 11179-3.

970

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 Designatable Item

975 A Designatable Item is any element that is to be designated (named) and/or defined. For additional details, reference: ISO/IEC 11179-3.

Table A.1.6-1: Designatable_Item

Element Name	Element Description	Card	Data Type
designatable_item		1..1	
+designation	Designation of Designatable_item	1..*	Table A.1.7-1
+definition	Definition of Designatable_item	0..*	Table A.1.6-1
++text	Text on Definition of Designatable_item	1..1	string
++language	Language of designatable_item	0..1	string
++source	Source of designatable_item	0..1	
+classifier	Classifier for designatable_item	0..*	
++@type	Type attribute for deisgnatable_Item		string
+@identifier	Identifier for designatable_item		Identifier

A.1.7 Designation

980 The *Designation* describes the name, language and convention. For additional details, reference: ISO/IEC 11179-3.

Table A.1.7-1: Designation

Element Name	Element Description	Card	Data Type
Designation			
+designation_context	Provides context on the type of designation	1..1	string
+sign	Sign on the type of designation	1..1	
+language	Language of designation	0..1	string
+namespace	Namespace id of designation	0..*	Identifier

+convention	Convention id of designation	0..*	Identifier
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A.1.8 Individual

985 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.1.8-1: Individual

Element Name	Element Description	Card	Data Type
Contact		0..*	
+name	Sign that designates the individual	1..1	
+title	Name of the position held by the individual	0..1	
+mail_address	Postal address for the individual	0..1	
+email_address	Email address for the individual	0..*	string
+phone_number	Phone numbers for the individual	0..1	
+fhir_mail_address	Fhir mail address for the individual	0..*	Table A.1.9-1

A.1.9 FHIR Mail Address

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

Table A.1.9-1: 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.1.10 Role

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

Table A.1.10-1: 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	
+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	

A.1.11 State

1000 A *State* is a collection of information about the *Registration* of an *Administered Item*. For additional details, reference: ISO/IEC 11179-3.

Table A.1.11-1: 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	1..1	Datetime
+administrative_note	general note(s) about the Registration	1..1	
+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	

A.1.12 Text Field

1005 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](#).

Table A.1.12-1: Text Field

Element Name	Element Description	Card	Data Type
text_field			
+multiselect		0..1	boolean

Element Name	Element Description	Card	Data Type
+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	string
+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	

A.1.13 List Field

1010 List Field represents a field in which only predefined answers are allowed. For additional details, reference: ISO/IEC 19763-13.

A.1.14 Guard

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. The element is enumerated using “Guard_State_Type”,

1015 A.1.15 Lookup Field

Lookup Field represents a field which – like a List Field – has a valid list of answers from a defined domain, but where the members of the domain vary with time and between implementations: e.g., a view providing a valid set of active customer IDs for a sales order

1020 system; a terminology approved for tagging an experimental result; a web service; open issue lookup in bug tracking software. For additional details, reference: ISO/IEC 19763-13.

Table A.1.15-1: Lookup Field

Element Name	Element Description	Card	Data Type
lookup_field		0..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

Volume 3 Namespace Additions

1025 *Add the following terms to the IHE Namespace:*

None