**Integrating the Healthcare Enterprise**



**IHE Quality, Research, and Public Health**

**Technical Framework Supplement**

**Structured Data Capture   
(SDC)**

**Draft in preparation for Public Comment**

<The IHE Documentation Specialist will change the title to just “Draft for Public Comment” upon publication for public comment; leave “as is” until then.>

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**Foreword**

This is a supplement to the IHE QRPH Technical Framework <VX.X>. 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 <Month XX, 201x> for Public Comment. Comments are invited and may be submitted at [http://www.ihe.net/<domain>/<domain>comments.cfm](http://www.ihe.net/Technical_Framework/public_comment.cfm). In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by <Month XX, 201X>.

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: [www.ihe.net](http://www.ihe.net).

Information about the IHE <Domain Name> domain can be found at: <http://www.ihe.net/Domains/index.cfm>.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at: <http://www.ihe.net/About/process.cfm> and <http://www.ihe.net/profiles/index.cfm>.

The current version of the IHE <Domain name>Technical Framework can be found at: <http://www.ihe.net/Technical_Framework/index.cfm>.

*<Comments may be submitted on IHE Technical Framework templates any time at* [*http://ihe.net/ihetemplates.cfm*](http://ihe.net/ihetemplates.cfm)*. Please enter comments/issues as soon as they are found. Do not wait until a future review cycle is announced.*

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# Introduction to this Supplement

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) 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](http://wiki.siframework.org/Structured+Data+Capture+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 documents1. 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
* IETF HTTTPS and TLS v1.0 standard
* W3C SOAP
* OASIS SAML
* ISO/IEC 19763-13
* 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 Log message content and QRPH-36 transaciton

## Open Issues and Questions

|  |  |  |
| --- | --- | --- |
| Item # | Section | Question |
| 1. | X.3 | Determine whether IHE Profile DSG is functional equivalent to XAdES. If so, it needs to be added to the grouping. |
| 2. | 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. |
| 3. | 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. |
| 4. | Q.5 | Consider future CP to constrain the <sdc:supplemental\_data> schema to conform to the same scheme used for <sdc:submitted\_data> |
| 5 | 5.0 | Invented section numbering scheme, since none was defined in the template that allowed inclusion of other text. |

## Closed Closed Issues:

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 Vol III.

# 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

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:

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** | Clinical Document Architecture (CDA) is a XML-based clinical content standard specified by HL7 that defines the structure of clinical documents like the CCD. | |
| **Common Data Elements (CDEs)** | Data elements that are developed, maintained and used based on *commonly* 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) | |
| **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/Template** | A form or template 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 Internationaland membership-driven Standard Development Organization (SDO) based in the United States with international affiliates. | |
| **MFI** | Meta-model for Framework Interoperability (MFI) form complian– -- an ISO 19763-13 standard. | |
| **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 45 CFR 160.103, where ‘CFR’ means ‘Code of Federal Regulations’, and, as defined, is 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 it is performed by the Form Repository, where as Auto-population is always performed by EHR system. | |
| **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 physicians/investigators 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. | |
| **SOAP** | An XML-based messaging protocol. | |
| **S&I** | Standards and Interoperability Framework that 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>*

Section not applicable.

# X Structured Data Capture (SDC) Profile

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 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 definiton, for requesting, 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](http://wiki.siframework.org/Structured+Data+Capture+Initiative). The SDC initiative has developed Use Cases, identified national standards for the structure of CDE’s and Form Model definition, developed guidance to assist in implementation, and conducted pilots for evaluation of SDC.

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 the Technical Frameworks General Introduction Appendix A at <http://www.ihe.net/Technical_Framework/index.cfm>.

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

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 |

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](#_Q.1_SDC_Pre-Pop) |
| SDC XML Package | O | Q.2.1 |
| SDC HTML Package | O | Q.3.1 |
| SDC URI Form | O | Q.4.1 |
| SDC Submission Data | 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 |

This solution leverages experience and usage patterns for forms developed and implemented from efforts such as those represented by Retrieve Form for Data (RFD) profiles developed and promulgated by Integrating the Healthcare Enterprise (IHE). RFD has been used in some clinical care settings, administrative reporting settings, and in FDA-regulated clinical research.

In the formulation of the SDC solution plan, a great deal of attention was given to the identification of a form standard that would be technology and platform neutral and support the diversity of users and uses for structured data capture involving EHRs. The solution plan supports two approaches to form representation - XML-based form definitions and HTML-based form instances. The RFD profile for retrieval of forms, the initiative builds upon successful use of the RFD profile in conjunction with HTML to describe both the content and presentation of forms. While an entire body of tools and technologies is associated with HTML, there was also a clearly voiced need to have available a standard definition of the contents of a form. To support both of these approaches this solution has incorporated the above-mentioned modularity whereby a form, defined in xml can also be exchanged in HTML format.

# X.1.1 Actor Descriptions and Actor Profile Requirements

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.

In SDC, the system fulfilling 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 Section Q.2.1)
* SDC HTML Package (Refer Section Q.3.1)
* SDC URI Form (Refer Section Q.4.1)

The Form Filler SHALL support SDC Submission Data content module (Refer Section Q.5) to submit completed form data. In addtion, 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 Section X.2.5).

The transactions supported by the Form Filler SHALL follow the security considerations, including XAdES digital signatures 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.

The system fulfilling the Form Manager’s role in SDC Profile SHALL support all of the following content modules:

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

The transactions supported by the Form Manager SHALL follow the security considerations, including XAdES digital signatures 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.

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

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

The transactions supported by Form Processor SHALL follow the security considerations, including XAdES digital signatures as outlined 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 transaction – ArchiveSourceDocuments [QRPH-36], defined in CRD Profile in QRPH TF.

The transactions supported by Form Archiver SHALL follow the security considerations, including XAdES digital signatures as outlined in Section X.5.

#### X.1.1.5 Form Receiver

The Form Receiver is defined in the RFD profile in ITI TF-1.

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

The transactions supported by Form Receiver SHALL follow the security considerations, including XAdES digital signatures 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 the 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  *<either reference TF-3 or the applicable X.2.x subsection below table>* |
| --- | --- | --- |
| 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 |  |

Note 1: *Form Filler SHALL support at least one of these option: SDC XML Package, SDC HTML Package, or SDC URI 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 ITI-34:

* In order to claim conformance to this option, the Form Filler SHALL implement SDC Pre-Pop content module (Refer Section 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 generated when requesting it using ITI-34:

* In order to claim conformance to this option, the Form Filler SHALL implement SDC XML Package content module (Refer Section 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. 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 ITI-34:

* In order to claim conformance to this option, the Form Filler SHALL implement SDC HTML Package content module (Refer Section Q.3.1).

### 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 ITI-34:

* In order to claim conformance to this option, the Form Filler SHALL implement SDC URI Form content module (Refer 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.

* 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

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).

If this is a content profile, and actors from this profile are grouped with actors from a workflow or transport profile, the Content Bindings reference column references any specifications for mapping data from the content module into data elements from the workflow or transport transactions.

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. Notes are used to highlight this situation.

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 | |  | |
| XUA X-Service User | | ITI TF- 1: 13.4 | |  | |
| Form Manager | ATNA Secure Node or ATNA Secure Application | | ITI TF- 1: 9.4 | |  | |
| XUA X-Service User | | ITI TF- 1: 13.4 | |  | |
| Form Processor | | ATNA Secure Node or ATNA Secure Application | | ITI TF- 1: 9.4 | |  | |
| XUA X-Service User | | ITI TF- 1: 13.4 | |  | | |
| Form Archiver | | ATNA Secure Node or ATNA Secure Application | | ITI TF- 1: 9.4 | |  | |
| XUA X-Service User | | ITI TF- 1: 13.4 | |  | | |
| Form Receiver | ATNA Secure Node or ATNA Secure Application | | ITI TF- 1: 9.4 | |  | |
| XUA X-Service User | | ITI TF- 1: 13.4 | |  | |

## 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 one demonstrates the feasibleility for both pre-population and auto-population to be used in one form completion process. Use case two shows that it is also possible to use SDC to display a form, which has no EHR data applied. Use case three illustrates the use of auto-population only in a pre-authorization setting.

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/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: General

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.4.2.1.1 General 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. 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. In this case, the Form Manager, pre-populates the form with data received from EHR using DEX-derived extraction specification.

The EHR system renders the retrieved form after auto-populating form data (when this functionality is supported by the EHR system). The provider verifies the auto-populated data, adds any missing data and then submit 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.

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 they were submitted.

##### X.4.2.1.2 General Process Flow



Figure X.4.2.1.2-1: SDC Profile General Process Flow

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 form repository is known and contains the appropriate form;
* The EHR is able to submit data for pre-population;
* The EHR is ableto map data from its own data storage to data required in the form;

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 which the enhanced forms repository uses to pre-populate the form;
* 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.

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.4.2.2 Use Case #2: Retrieve form using a URI

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.4.2.2.1 Retrieve form using a URI Use Case Description

A research study coordinator is in charge of sponsored research at the research site. The study has serveral 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, 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.

##### X.4.2.2.2 Retrieve form using URI Process Flow



Figure X.4.2.2-2: Retrieve form using an URI Process Flow in SDC Profile

Pre-conditions:

* 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 knows the source of the URI to obtain access to the appropriate form.

Main Flow:

* 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 directs to that URL to display the form.
* The study coordinator completes the form through its display within the EHR user interface;
* The study coordinator submits the completed form to the external repository, and to the archive;

Post-conditions:

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

#### X.4.2.3 Use Case #3: Capture and Submit Pre-Authorization

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

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.

When Dr. Hab sees the patient in the office, he opens up the patient’s EHR record. 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 from 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.4.2.3.2 Capture and Submit Pre-Authorization Process Flow



Figure X.4.2.3-1: Capture and Submit Pre-Authorization Flow in SDC Profile

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 already knows the endpoints to submit pre-authorizaiton 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.

Main Flow:

* Dr. Hab is made aware of the requirement for pre-authorization.
* Dr. Hab’s EHR retrieves the pre-authorizaton 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.

Post-conditions:

* Data from the compelted from has been sent to the insurer.
* The insurer has received, stored, and processed the pre-authorizaton data.

## X.5 SDC Security Considerations

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

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.

The requirements for transport security are therefore based on the traversal of organizational boundaries:

* Transactions traversing organizational boundaries (e.g. over untrusted/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.

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 node in order to authenticate the endpoints and secure the communications channel.

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.

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.

XAdES Digital Signature

SDC transactions can contain numerous elements and those elements are inter-related.  There will be times that 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.  Thus, although some individual elements can be digitally signed we still need to be able to sign the entire payload.  This profile enables the use of the XAdES digital signature standard when this is required.

## X.6 SDC Cross Profile Considerations

Not applicable

Appendices

Not applicable

Volume 2 – Transactions

Add section 3.Y

## 3.Y <Transaction Name [Domain Acronym-#]>

Section not applicable.

Appendices

<Detailed cross transaction relationships or mapping details are described in an appendix in Volume 2x. Volume 2 appendices may be informational or normative. Immediately after the title of a Volume 2 appendix, provide a very explicit statement defining whether this new appendix is informative or normative.>

Not Applicable

Volume 2 Namespace Additions

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

<Please explicitly identify all new OIDs, UIDs, URNs, etc., defined specifically for this profile. These will be added to the IHE TF General Introduction namespace appendix when it becomes available. These items should be collected from the sections above, and listed here as additions when this document is published for Trial Implementation. This section will be deleted prior to inclusion into the Technical Framework as Final Text, but should be present for publication of Public Comment and Trial Implementation.>

Volume 3 – Content Modules

<The current version of the supplement template only addresses HL7 v3 CDA Content Modules. All CDA Content Modules will go in Section 6 of Volume 3 of each domain’s Technical Framework document. In the future, this supplement template may have additional sections for DICOM Content Modules (section 7 of Volume 3) and other types of Content Modules (section 8, etc., of Volume 3).

<Please note that prior to the release of the new template set, some domains may have defined CDA Content Modules in Volume 2 (e.g., PCC); however, going forward CDA Content Modules will be defined in Volume 3.>

# 5. Namespaces and Vocabularies

Add to section 5 Namespaces and Vocabularies

<Note that the code systems already defined in the Technical Framework of this domain may (but not required) be replicated here just to aid in the supplement review as a standalone document. Also note that the Section 5 table numbers and names are already defined in the TF Volume 3.>

Add new sections 5X.X. SDC namespace specific element definition

## 5.1 SDC Form Definition Model

### 5.1.1 Scope and Approach

SDC Forms address the need for systems to interoperate by exchanging data that has been defined as part of a structured document, or form. This section is an overview of representation of the form. The role of forms in interoperability is recognized by the ISO/IEC 19763-13 (MFI-13) forms standard where it is stated.

*“…it is essential that the business information requirements that are met by the data stored in these systems are understood so that suitable data exchange mechanisms can be developed.*

*Not only does this require a clear understanding of the meaning of the data, it also frequently requires the coordination of data capture. Where data input is manual, an important source of data semantics is the design of the form used for data entry. Inspecting the form design can provide additional semantics and context."*

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 elements.

The SDC Form Definition is based on ISO/IEC 19763-13 Metamodel for Forms Registration (MFI-13). 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/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-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.

Used in concert, MFI-13 provides the facilities to record reusable form semantics, and MDR-3 provides the facilities to record reusable data descriptions. Together, both standards can support the rapid design and reuse of forms, wrap and hide the complexity of semantic annotation from subject matter experts, and provide a ready reference of associations and transformations for users seeking to collect and use interoperable data.

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 forms XML that contains multiple other entities.

### 5.1.2 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 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 similar question across different forms. Through the mapping document, the questions and their answers may be found to be based on concept systems 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, and thus should also be present in an alternative data element specification in order to ensure that the meaning of questions and answers are well specified and unambiguous.

Table 5.1.2-1: Mapping Package

| Name | Relative Location | Card | Data Type |
| --- | --- | --- | --- |
| Mapping Package | /SDCForm:form\_package/mapping\_package | 1..1 |  |
| @ Mapping Package ID | @mapping\_package\_identifier | 1..1 | String |
| @Form Design ID | @form\_design\_identifier | 1..1 | String |
| MDR Mapping | /MDR\_Mapping | 0..1 |  |
| @MDR Mapping ID | @mdr\_mapping\_identifier | 1..1 | String |
| Question to Data Element Association | /question\_element\_data\_element\_association | 0..N |  |
| Data Element Scoped ID | /data\_element\_scoped\_identifier | 1..1 | String |
| Question Element ID | /question\_element\_identifier | 1..1 | String |
| Association type | /association\_type | 1..1 | String |
| DEX Mapping specification | /dex\_mapping\_specification | 0..1 |  |
| Content Model | /content Model | 1..1 |  |
| Id | /id | 1..1 | String |
| Name | /name | 1..1 | String |
| Type | /Type | 1..1 | String |
| Mapping Script | /mappingScript | 1..1 | String |
| Contact | /contact | 0..N | String |

#### 5.1.2.1 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.

Table 5.1.2-2: Contact

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Data Type |
| Contact | /contact | 0..N |  |
| Individual | / individual | 0..1 |  |
| Organization | / organization | 1..1 |  |
| Role | / role | 0..1 |  |

### 5.1.3 Administrative Package

The Administrative Segment 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 5.1.3-1 Administrative Package

| Name | Relative Location | Card | Data Type |
| --- | --- | --- | --- |
| Administrative Package | /SDCForm:form\_package/administrative\_package | 1..1 |  |
| Submission Rule | /submission\_rule | 1..N |  |
| @Form ID | @form\_ identifier | 1..1 | String |
| @Rule IDand Version | @rule\_id\_and\_version | 0..N | String |
| Destination | /destination | 0..N |  |
| Endpoint | /endpoint | 0..N | anyURI |
| Description | /description | 0..1 | String |
| Organization | /organization | 0..1 |  |
| Compliance Rule | /compliance\_rule | 1..N |  |
| Expression | /expression | 0..N | String |
| Origin Summary | /originating\_registry\_summary | 1..1 |  |
| Form language | /form\_language | 1..1 |  |
| Contact information | /contacts | 0..N |  |
| Registration information | /registration | 0..1 |  |

#### 5.1.3.1 Origin Summary

The Administrative Segment 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 5.1.3-2: Origin Summary

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Data Type |
| Origin Summary | /administrative\_package/originating\_registry\_summary | 1..1 |  |
| Registry Organization | /registry\_organization | 1..1 | String |
| Reference Standard ID | /reference\_standard\_identifier | 1..1 | String |
| SLA for registry | /SLA\_for\_registry | 0..1 | String |
| Purpose for registry | /purpose\_for\_registry | 0..1 | String |
| Manual for registry | /manual\_for\_registry | 0..1 | String |
| Specification | /specification\_for\_interface | 0..1 | String |

#### 5.1.3.2 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.

Table 5.1.3-3: Form Language

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Data Type |
| Form Language | /administrative\_package /form\_language | 1..1 |  |
| @identifier | @identifier |  | String |
| Designatable Item | /designation | 0..N | String |
| Style Language | /style\_language | 0..1 | String |
| Logic Language | /logic\_language | 0..1 | String |
| Format Language | /format\_language | 0..1 | String |
| Textual Language | /textual\_language | 0..1 | String |

#### 5.1.3.3 Registration

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

Table 5.1.3-4: Registration

| Name | Relative Location | Card | Data Type |
| --- | --- | --- | --- |
| Registration | /administrative\_package /registration |  |  |
| +State | +/state | 0..1 | String |
| +Submission record | +/submission\_record | 0..1 |  |
| ++Organization | ++/organization | 1..1 | string |
| ++Contact | ++/contact | 0..1 | string |
| +Document reference | +/document\_reference | 0..N | string |
| +Organization | +/organization | 0..1 | string |
| +Registration status date | +/registration\_status\_date | 0..1 | string |
| +Stewardship record | +/stewardship\_record | 1..N |  |
| ++Organization | ++/organization | 0..1 | string |
| Contact | /contact | 0..1 | string |
| Creation date | /creation\_date | 1..1 | string |
| Last change date | /last\_change\_date | 0..1 | string |
| Change description | /change\_description | 0..1 | string |
| Explanatory comment | /explanatory\_comment | 0..1 | string |
| Origin | /origin | 0..1 | string |

### 5.1.4 Form Design

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

Table 5.1.4.-1: Form Design

| Name | Relative Location | Card | Data Type |
| --- | --- | --- | --- |
| Form Design | /SDCForm:form\_package/form\_design |  |  |
| @ID | @form\_design\_identifier | 1..1 | anyURI |
| Designation | /designation | 1..N |  |
| Classifier | /classifier | 0..N |  |
| Media | /media | 0..N |  |
| Security and Privacy | /security\_and\_privacy | 0..N |  |
| Header | /header | 0..1 |  |
| Section | /section | 0..N |  |
| Footer | /footer | 0..1 |  |

#### 5.1.4.1 Media

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

Table 5.1.4.-2: Media

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Data Type |
| Media | /form\_design/media | 0..N |  |
| Cardinality | /cardinality | 0..1 |  |
| Minimum | /minimum | 1..1 | Integer |
| Maximum | /maximum | 1..1 | String |
| Rule | /rule | 0..N |  |
| Expression | /expression | 1..N | String |
| Audio | /audio | 0..N |  |
| Uri | /uri | 1..1 | anyURI |
| Type | @type | 1..1 | String |
| Image | /image | 0..N |  |
| Uri | /uri | 1..1 | anyURI |
| Type | @type | 1..1 | String |
| Video | /video | 0..N |  |
| Uri | /uri | 1..1 | anyURI |
| Type | @type | 1..1 | String |
| @Initial state | @initial state |  | String |

#### 5.1.4.2 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 5.1.4.-3: Section

| Name | Relative Location | Card | Data Typet |
| --- | --- | --- | --- |
| Section | /form\_design/Section\_Element | 0..N |  |
| @initial state | @initial\_state |  | String |
| Cardinality | /cardinality | 0..1 |  |
| Minimum | /minimum | 1..1 | Integer |
| Maximum | /maximum | 1..1 | String |
| Rule | /rule | 0..N |  |
| Expression | /expression | 1..N | String |
| Section Title | /section\_title | 0..1 | String |
| Section Number | /section\_number | 0..1 | String |
| Ordered | /ordered | 0..1 | Boolean |
| Section Instruction | /section\_instruction | 0..N | String |
| Additional Instruction | /additional\_instruction | 0..N | String |
| Contained Section | /contained\_section | 0..N | String |
| Section Order | /section\_order | 0..1 | String |
| Media | /media | 0..N | String |
| Question | /question | 0..N | String |
| additional text | /additional\_text | 0..N | String |
| Next relevant element ID | /next\_relevant\_element | 0..1 | String |
| Section ID | /section\_identifier | 0..1 | String |

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

Table 5.1.4.-4: Question

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Data Type |
| Question | /section/base\_question |  |  |
| @initial state | @initial\_state |  | String |
| Scoped Identifier | @data\_element\_scoped\_identifier | 0..1 | Identifier |
| Cardinality | /cardinality | 0..1 |  |
| Minimum | /minimum | 1..1 | Integer |
| Maximum | /maximum | 1..1 | String |
| Rule | /rule | 0..N |  |
| Expression | /expression | 1..N | String |
| Question prompt | /question\_prompt | 0..1 | String |
| Question number | /question\_number | 0..1 | String |
| Question instruction | /question\_instruction | 0..1 | String |
| Additional instruction | /additional\_instruction | 0..N | String |
| Text\_field | /text\_field | 0..1 | String |
| List\_field | /list\_field | 0..1 | String |
| Lookup field | /lookup\_field | 0..1 | String |
| Text after question | /text\_after\_question | 0..1 | String |
| Question order | /question\_order | 0..1 | String |
| Question ID | /question\_identitifier | 0..1 | String |

# 6. Content Modules

<Authors’ notes: This section of the supplement template is only for HL7 v3 CDA Content Module definitions. Please delete the entire section 6.3.1 if the Content Module is based on DICOM or another standard.

Please note that the template for DICOM or other types of content modules (other than CDA) has not yet been defined, although DICOM modules will eventually go into Volume 3 Section 7; yet another type of content module will go into Volume 3 Section 8, etc.>

## 6.3.1 CDA Document Content Modules

Section not applicable.

## Q. SDC Content Modules

#### Q.1 SDC Pre-Pop Content Module

This is a constraint on <prepopData> element defined in RFD profile. In SDC, the <prepopData> element SHALL contain ONLY CDA-R2 document(s) and SHALL NOT be a nil construct.

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

<prepopData>

<ClinicalDocument xmlns="urn:hl7-org:v3">

<realmCode code="US"/>

<!-- Valid CDA-R2 document -->

</ClinicalDocument>

</prepopData>

The Form Filler SHALL supply the pre-pop data.

The Form Manager and Form Processor SHALL be capable to receive the pre-pop data.

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 may also 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

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

This is a constraint on <encodedResponse> and <formID> elements defined in RFD profile. In SDC, 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/Form Processor.

| Element Name | Description | Card. | Verb | Data Type | Value Constraint |
| --- | --- | --- | --- | --- | --- |
| encodedResponse | Specifies how the form is to be returned. | 1..1 | Required | 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 | Required | string |  |

<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=12345.2</formID>

<encodedResponse>true</encodedResponse>

<archiveURL />

<context xsi:nil="true"/>

<instanceID xsi:nil="true"/>

</workflowData>

</RetrieveFormRequest>

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

##### Q.2.2 SDC XML Package – Response

This is a constraint on <structured> element defined in RFD profile. In SDC, the <structured> element SHALL contain a single <sdc:sdc\_xml\_package> element.

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 <sdc:supplemental\_data> element. These additional information/packages are separate and independent of the form design and included to other functionality at Form Filler end – such as auto-population. The Form Manager sometimes plays the role of a Form Designer and compiles the final SDC XML package.

| Element Name | Description | Card. | Verb | 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 | May |  |  |
| sdc\_xml\_package | The wrapper element container for the SDC-compliant form package | 1..1 | May |  |  |
| form\_package | The xml element containing MFI-13 based form design and associated files as explained in Section 5.1 | 1..1 | May | anyXML |  |
| contentType | The type of the returned form. | 1..1 | Required | string | Value SHALL be “XML” |

<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>

<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>

<sdc:form\_package>

<!-- —Contains Administrative, stylesheet, mapping, and form definition; all of the required info for form definition -->

<sdc:mapping\_package>

<!--Mapping informaiton e.g. DEX mapping, goes here-->

</sdc:mapping\_package>

<sdc:administrative\_package>

<!-- Administrative information goes here -->

</sdc:administrative\_package>

<sdc:stylesheet>

<!--include any style sheet information here -->

</sdc:stylesheet>

<sdc:form\_design>

<!--Contains the form design, (e.g.question-answer sets, skip logic, etc.) -->

</sdc:form\_design>

</sdc:form\_package>

</sdc:sdc\_xml\_package>

</Structured>

<instanceID>1.2.3.4.5</instanceID>

</form>

<contentType>XML</contentType>

<responseCode/>

</RetrieveFormResponse>

Form Manager/Form Processor SHALL ensure that the <structured> element contains only a single <sdc:sdc\_xml\_package> element “true” when returning SDC XML Package.

Form Manager/Form Processor SHALL ensure that the <contentType> element always have value “XML” when returning SDC XML Package.

#### Q.3 SDC HTML Package Content Module

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.

##### Q.3.1 SDC HTML Package – Request

This is a constraint on <encodedResponse> and <formID> elements defined in RFD profile. In SDC, 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/Form Processor.

| Element Name | Description | Card. | Verb | Data Type | Value Constraint |
| --- | --- | --- | --- | --- | --- |
| encodedResponse | Specifies how the form is to be returned. | 1..1 | Required | Boolean | Value SHALL be “true” |

<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=12345.2</formID>

<encodedResponse>true</encodedResponse>

<archiveURL />

<context xsi:nil="true"/>

<instanceID xsi:nil="true"/>

</workflowData>

</RetrieveFormRequest>

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

##### Q.3.2 SDC HTML Package – Response

This is a constraint on <structured> element defined in RFD profile. In SDC, the <structured> element SHALL contain a single <sdc:sdc\_html\_package> element.

The HTML package contains HTML instance of the form as well as other additional information form 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.

| Element Name | Description | Card. | Verb | Data Type | Value Constraint |
| --- | --- | --- | --- | --- | --- |
| Structured | The xml element container for the return of encoded, structured form content. | 0..1 | May. |  |  |
| sdc\_html\_package | The wrapper element container for the SDC-compliant HTML form package | 0..1 | May |  |  |
| form\_info | The xml element containing supporting information e.g. mapping info, admin info, etc. | 0..1 | May |  |  |
| contentType | The type of the returned form. | 1..1 | Required | string | Value SHALL be “HTML” |

<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>1.2.3.4.5</instanceID>

</form>

<contentType>HTML</contentType>

<responseCode/>

</RetrieveFormResponse>

Form Manager/Form Processor SHALL ensure that the <structured> element contains only a single <sdc:sdc\_html\_package> element “true” when returning SDC HTML Package.

Form Manager/Form Processor SHALL ensure that the <contentType> element always have value “HTML” when returning SDC HTML Package.

#### Q.4 SDC URI Form Content Module

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 a 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

This is a constraint on <encodedResponse> element defined in RFD profile. In SDC, the <encodedResponse> element SHALL be “false”.

| Element Name | Description | Card. | Verb | Data Type | Value Constraint |
| --- | --- | --- | --- | --- | --- |
| encodedResponse | Specifies how the form is to be returned. | 1..1 | Required | Boolean | Value SHALL be “false” |

<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=12345.2</formID>

<encodedResponse>false</encodedResponse>

<archiveURL />

<context xsi:nil="true"/>

<instanceID xsi:nil="true"/>

</workflowData>

</RetrieveFormRequest>

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

##### Q.4.2 SDC URI Form – Response

| Element Name | Description | Card. | Verb | Data Type | Value Constraint |
| --- | --- | --- | --- | --- | --- |
| URL | The xml element container for the return of a pointer to the form. | 0..1 | May | anyURI |  |
| contentType | The type of the returned response. | 1..1 | Required | String | Value shall be “UNSTRUCTURED” |

<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](http://www.weBeForms.com/1.2.3.4.5)

</URL>

<instanceID>1.2.3.4.5</instanceID>

</form>

<contentType>UNSTRUCTURED</contentType>

<responseCode/>

</RetrieveFormResponse>

Form Manager/Form Processor SHALL ensure that the <contentType> element always has value “UNSTRUCTURED” when returning Form URI information.

#### Q.5 SDC Submission Data Content Module

This is a constraint on <submitFormRequest> element defined in RFD profile. In SDC, the <submitFormRequest> element SHALL carry 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, 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 fine balance between sending sufficienet data alogn 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.

| Element Name | Description | Card. | Verb | Data Type | Value Constraint |
| --- | --- | --- | --- | --- | --- |
| SubmitFormRequest | The top-level container element | 1..1 | Required |  |  |
| +form\_data | The xml element that contains the form data | 1..1 | Required |  |  |
| +@form\_name | Name of the form | 0..1 | May | String | None |
| +@form\_design\_identifier | Identifier for the form design | 1..1 | Required | String | None |
| +@form\_representation\_identifier | Identifier for the representation or modality of the form design. | 1..1 | Required | String | None |
| ++Header | The xml element container for Header question-answer set | 0..1 | Required |  |  |
| ++Body | The xml element container for Body question-answer set | 1..1 | Required |  |  |
| ++++Question | The xml element identifying the Question | 0..\* | May |  |  |
| +++++@section\_identifier | identifier for the section of the form to which the question belongs | 1..1 | Required | String | None |
| +++++@parent\_identifier | Identifier of the parent element, this may be a section, question or list\_itemquestion | 0..1 | May | String | None |
| +++++@question\_prompt | Question text as it appears in the form | 1..1 | Required | String | None |
| +++++@question\_repeat | Indicator ifThe repeat number for this instance if the the question is repeated multiple times, e.g. 1, 2, 3 | 1..1 | Required | String | None |
| +++++@question\_identifier | Unique identifier for the question | 1..1 | Required | String | None |
| +++++@data\_element\_identifier | Identifier for an SDC the data element | 0..1 | May | String | None |
| +++++@datatype | The datatype of the response. | 1..1 | Required | String | None |
| +++++@unit\_of\_measure | Value indicating the unit of measure | 0..1 | May | String | None |
| +++++@pattern | The datatype pattern, e.g. HHMM | 0..1 | May | String | None |
| ++++Response | The response to the question | 1..\* | Required | String | None |
| ++++@list\_item\_prompt | The prompt for the list item | 0..1 | May | String | None |
| ++++@list\_item\_identifier | The unique identifier for the list item | 0..1 | May | String | None |
| +++++@value\_meaning\_standard \_code | The standard code for the list item when based on a value set. | 0..1 | May | String | None |
| +++++@value meaning\_standard code\_system\_identifier | Includes the standard code system and version number | 0..1 | May | String | None |
| +++++ fill-in | The response for a list field fill-in e.g. “Specify” or “Other” | 0..\* | May | String | None |

<?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="string\_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>

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.

Appendices

*<Add any applicable appendices below; NA if none.>*

Appendix A – <Appendix A Title>

Appendix A text goes here.

* 1. <Add Title>

Appendix A.1 text goes here

Appendix B – <Appendix B Title>

Appendix B text goes here.

* 1. <Add Title>

Appendix B.1 text goes here.

Volume 3 Namespace Additions

Add the following terms to the IHE Namespace:

<Please explicitly identify all new OIDs, UIDs, URNs, etc., defined specifically for this profile. These will be added to the IHE TF General Introduction namespace appendix when it becomes available. These items should be collected from the sections above by the author, and listed here as additions when this document is published for Trial Implementation. This section will be deleted prior to inclusion into the Technical Framework as Final Text, but should be present for publication of Public Comment and Trial Implementation.>

Volume 4 – National Extensions

Add appropriate Country section

4 National Extensions

4.I National Extensions for <Country Name or IHE Organization>

<A template for Volume 4 is included in this document for completeness; however, National Extensions are typically developed after a profile has been published for Trial Implementation. If you are developing a new profile for Public Comment, it is recommended that this section be marked “Not Applicable”.>

<Avoid using this section if you can, this is “only if absolutely necessary”. Differences add cost to implementation and testing and can reduce interoperability. Review carefully to determine if the national use case truly requires a difference in the profile mechanisms rather than just differences in system configuration.>

< National Extensions can add requirements above and beyond IHE, but NOT relax requirements. This would prevent Connectathon results based on national testing being recognized elsewhere. For more information, see <http://wiki.ihe.net/index.php?title=National_Extensions_Process>.>

The format of this section is not strongly specified due to the varying nature of national extensions. For an example of National Extensions, see Radiology TF Volume 4.>

4.I.1 Comment Submission

This national extension document was authored under the sponsorship and supervision of <sponsor name>, who welcome comments on this document and the IHE <country> initiative. Comments should be directed to:

<Name, organization, title, email address>

4.I.2 <Profile Name> <(Profile Acronym)>

<Add info or tables>

#### 4.I.2.1<Profile Acronym> <Type of Change>

<Add info or tables>

#### 4.I.2.2<Profile Acronym> <Type of Change>

<Add info or tables>

# 4.I+1.1 National Extensions for <Country Name or IHE Organization>

*<Repeat (and increment) the section above as needed for additional National Extensions>*