**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.

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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 HTTPS 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. | 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 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.

1. 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.

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** | 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 *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) 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. | |
| **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** | 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. | |
| **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>*

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, 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 definiton, for requesting and receiving forms, and submitting data captured in forms in a standardized and structured format.

This supplement is based on the work of the ONC’s [S&I Framework SDC Initiative](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 definitions, developed guidance to assist in implementation, and conducted pilots for evaluation of SDC.

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

## X.1 SDC Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in 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 |
| 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 option: 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.*

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)

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

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.

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 Section Q.2.1)
* SDC HTML Package (Refer Section Q.3.1)
* SDC URI Form (Refer Section Q.4.1)

The Form Filler MAY 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 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.

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 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 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.

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 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 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 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, 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 Section Q.5).

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 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 Retrieve Form [ITI-34] transaction:

* 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 Retrieve Form [ITI-34] transaction:

* 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 Retrieve Form [ITI-34] transaction:

* 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 Retrieve Form [ITI-34] transaction:

* 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).

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.

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. | |
| 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

### 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 sdemonstrates 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 feasiblility 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

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

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.

##### 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;
* 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

* 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;
* 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

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

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

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

When Dr. Hab sees the patient in the office, he opens up the patient’s EHR. After recording the visit data in the EHR, Dr. Hab requests the EHR to display the pre-authorization form. Dr. Hab 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.4.2.2.2 Capture and Submit Pre-Authorization Process Flow



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

##### 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;
* 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.

##### 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-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.

##### X.4.2.2.5 Post-conditions

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

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

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

##### X.4.2.3.1 Use Case with Extraction Specification 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. 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.

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

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.

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.4.2.3.2 Use Case with Extraction Specification Process Flow



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

##### X.4.2.3.3 Pre-conditions:

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

* The EHR system performs the role of a Form Filler;
* The EHR system knows how to request appropriate form;
* The 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;
* The provider requests the form through the EHR, providing patient data for pre-population;
* The EHR auto-populates the form, supplementing the pre-population done by the form repository;
* The provider completes any missing data and confirms the pre-populated and auto-populated data in the form;
* The data from the completed form is submitted to the public health agency;
* An archive copy is kept.

##### X.4.2.3.5 Post-conditions

* The public health agency stores and uses the data from the completed form;
* An archived copy of the completed form has been stored.

## X.5 SDC Security Considerations

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 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.

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.

### 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.

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

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

Appendices

Not applicable

Volume 2 – Transactions

Add section 3.Y

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

Section not applicable.

Appendices

Not Applicable

Volume 2 Namespace Additions

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

Volume 3 – Content Modules

# 5. Namespaces and Vocabularies

Add to section 5 Namespaces and Vocabularies

Not Applicable

# 6. Content Modules

## 6.3.1 CDA Document Content Modules

Section not applicable.

## 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.

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 |

<prepopData>

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

<realmCode code="US"/>

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

</ClinicalDocument>

</prepopData>

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

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 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.

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 |  |

<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>

##### Q.2.2 SDC XML 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\_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 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 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.

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” |

<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>

<!--Please note the use of constrained value “XML” above-->

<responseCode/>

</RetrieveFormResponse>

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

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.

##### 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.

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 |  |

<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>

##### 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.

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.

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” |

<RetrieveFormResponse

xmlns="urn:ihe:iti:rfd:2007"

xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"

xmlns:sdc="urn:ihe:qrph:sdc:2014">

<form>

<Structured>

<sdc:sdc\_html\_package>

<sdc:supplemental\_data>

<!-- Contains supplemental data related to the form instance e.g. generation date, pre-pop data, special instructions, etc. -->

</sdc:supplemental\_data>

<sdc:form\_info>

<!-- Contains mapping, and administrative info; this is the same content as from the form design package -->

</sdc:form\_info>

<sdc:sdc\_html\_form>

<!—The HTML form with as CDATA text -->

<![CDATA[

<html>This contains the SDC-compliant HTML form </html>

]]>

</sdc:sdc\_html\_form>

</sdc:sdc\_html\_package>

</Structured>

<instanceID>2.3.4.5.6</instanceID>

</form>

<contentType>HTML</contentType>

<!—Please note the use of constrained value “HTML” above-->

<responseCode/>

</RetrieveFormResponse>

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

The Form Filler claiming this content module option SHALL be able to make a request as per 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

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.

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

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

<RetrieveFormRequest

xmlns="urn:ihe:iti:rfd:2007"

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>

##### 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”

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” |

<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>3.4.5.6.7</instanceID>

</form>

<contentType>Unstructured</contentType>

<!--Please note the use of constrained value “Unstructured” above-->

<responseCode/>

</RetrieveFormResponse>

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

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.

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.

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.

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 ifThe repeat number for this instance 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 |  |
| +++++@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 |  |

<?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>

## 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

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 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.

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 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

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 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.

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 /patient/administrativeGenderCode. | 1..1 | string |
| +contact | Contact contains information regarding whom to contact for more information about the DEX Mapping Specification. | 0..\* |  |

#### Q.6.2.1 Contact

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

Table Q.6.2-2: 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 C-8 |
| +organization | Organization contains contact information of an organization. | 1..1 | Table C-1 |
| +role | Role contains information regarding the specified responsibilities of the individual listed to contact. | 0..1 | Table C-10 |

### 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.

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..\* |  |
| +@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 C-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.6.3-2 |
| +form\_language | Represents the selection of languages used to express style, logic, format and textual aspects of the form design. | 1..1 | Table Q.6.3-3 |
| +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

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.6.3-2: 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 C-2 |
| +purpose\_for\_registry | Purpose for registry describes the purpose for the registry. | 0..1 | Table C-2 |
| +manual\_for\_registry | Manual for registry describes the manual for the registry. | 0..1 | Table C-2 |
| +specification\_for\_interface | Specification for Interface identifies the interface of the form. | 0..1 | Table C-5 |

#### Q.6.3.2 Form Language

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

Table 5.1Q.6.3-3: Form Language

|  |  |  |  |
| --- | --- | --- | --- |
| Element Name | Element Desciption | 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 C-7 |
| +style\_language | Style Language describes the style language used to place Form Design Element instances in place on the form. | 0..1 | Table C-2 |
| +logic\_language | Logic Language is used to describe semantic dependencies between instances of Form Design. | 0..1 | Table C-2 |
| +format\_language | Format Language describes the regular expression language used. | 0..1 | Table C-2 |
| +textual\_language | Textual Language specifies the primary native human language used. | 0..1 | Table C-2 |

#### 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.6.3-4: 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 the range in which it may be used. | 0..1 | Table C-11 |
| +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 C-1 |
| ++contact | Contact describing the Contact that may be contacted regarding stewardship. | 0..1 | Table Q.6.2-2 |
| +document\_reference | Document reference describes any document referenced by the form. | 0..\* | Table C-2 |
| +organization | Organization describes the organization where the form is registered. The organization SHALL be structured as ISO Attribute Organization, which is described in Appendix C. | 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 C-1 |
| ++contact | Contact describing the Contact that may be contacted regarding stewardship. | 0..1 | Table Q.6.2-2 |
| +creation\_date | Creation Date which is the date the registration element was created. | 1..1 | Datetime |
| +last\_change\_date | Last change date is the date the registration element was last changed. | 0..1 | Datetime |
| +change\_description | Change description describes what has changed since the prior version of the registration element. | 0..1 | string |
| +explanatory\_comment | Explanatory comment contains descriptive comments about the registration element. | 0..1 | string |
| +origin | Origin describes the source for the registration element. | 0..1 | string |

### Q.6.4 Form Design

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

Table Q.6.4.-1: Form Design

| Elemenet Name | Element Description | Card | Data Type |
| --- | --- | --- | --- |
| form\_design | The form design segment is the primary component of the SDC specification. It represents the design of a specific form. The primary elements of the form design are sections and questions, and may include instructions and related media such as images. |  |  |
| +@form\_design\_identifier | Unique identifier | 1..1 | anyURI |
| +designation | Designation allows the form designer to designate a name for the form.. | 1..\* | Table C-7 |
| +classifier | Classifier refers to a classification scheme. | 0..\* | Table C-6 |
| +media | Media refers to elements, such as audio, image or video that may be used in the section. | 0..\* | Table Q.6.4.-2 |
| +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.-2: 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 |
| ++@type | The attriute 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 indiciating the initial behavior of the element e.g. enabled or disabled. | 1..1 | string |

#### 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.-3: Section

| Element Name | Element Description | Card | Data Typet |
| --- | --- | --- | --- |
| 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 |
| +ruleNote 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 |
| +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.6.4-2 |
| +question | Questions are questions in the form. | 0..\* | Table Q.6.4-4 |
| +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 C. | 0..1 | string |

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

#### Q.6.4.3 Question

Questions make a request for information. The information is captured in a response field. There are 3 types of response fields, each with a set of applicable attributes and rules constraining the answer. These are: List Field, Text Field, and Lookup Field. The following table describes the components of a question element:

Table Q.6.4.-4: 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 Question is enabled for data entry when the form is initially displayed. | 1..1 | string |
| +@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 |
| +ruleNote 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 |
| +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\_identitifier | Question Identifier. | 0..1 | string |

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

Appendices

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

Appendix A – <Appendix A Title>

Appendix A text goes here.

<Add Title>

Appendix A.1 text goes here

Appendix B – <Appendix B Title>

Appendix B text goes here.

Appendix C – List of SDC Form Elements and Attributed Inherited from ISO/IEC 19763-13 and ISO/IEC 11179-3

## C.1 Base Elements from ISO/IEC Standards

### C.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.

TableC-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 |  |

### C.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.

TableC-2: Reference Document

|  |  |  |  |
| --- | --- | --- | --- |
| Element Name | Element Description | Card | Data Type |
| reference\_document |  |  |  |
| +identifier | Identifer for the Reference\_Document | 0..1 | string |
| +document\_type | Description of the type of Reference\_Document | 0..1 | Table C-3 |
| +language | Language of the natural language used in the Reference\_Document | 0..\* | Table C-4 |
| +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 C-1 |
| +uri | uri for Reference\_Document | 0..1 | string |

### C.1.3 Document Type

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

Table C-3: 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 |  |

### C.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.

Table C-4: 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\_identifer | identifies an extension to a language\_identifier | 1..\* | string |
| +private\_use\_qualifier | qualifier whose meaning is defined solely by private agreement | 0..1 | string |

### C.1.5 Interface

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

**Table C-5: 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 |

### C.1.6 Designatable Item

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

**Table C-6: Designatable\_Item**

| Element Name | Element Description | Card | Data Type |
| --- | --- | --- | --- |
| designatable\_item |  | 1..1 |  |
| +designation | Designation of Designatable\_item | 1..\* | Table C-7 |
| +definition | Definition of Designatable\_item | 0..\* | Table C-6 |
| ++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 |

### C.1.7 Designation

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

**Table C-7: 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 |

### C.1.8 Individual

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

**Table C-8: 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 C-9 |

### C.1.9 FHIR Mail Address

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

**Table C-9: 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 |

### C.1.10 Role

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

**Table C-10: 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 |  |

### C.1.11 State

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

**Table C-11: 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 |  |

### C.1.12 Text Field

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

**Table C-12: Text Field**

| Element Name | Element Description | Card | Data Type |
| --- | --- | --- | --- |
| text\_field |  |  |  |
| +multiselect |  | 0..1 | boolean |
| +default\_value | An optional default value for the input field when nothing is entered, where the maximum multiplicity is one. | 0..1 | string |
| +default\_value\_read\_only | An optional indicator of whether the default value, if specified, can be edited, where the maximum multiplicity is one. | 0..1 | boolean |
| +maximum\_character\_quantity | An optional maximum number of characters that the Input\_Field may accept. If this value is missing there is no limit on the number of characters the field may accept. Its value may come mapping 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](#_Number) |
| +next\_relevant\_element | An explicity reference to the next element to be shown in the form design | 0..1 |  |

### C.1.13 List Field

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

### C.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”,

### C.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 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 C-15: 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

Add the following terms to the IHE Namespace: