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| Structured Data Capture |
| Implementation Guide Document  Version for Trial Implementation |
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Version History

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| 1.0 | <mm/dd/yy> |  | First complete release for Community consensus voting |
| 1.1 | 03/14/2014 |  | Section 2.1 – Added explanation on use of IHE DEX profile as one of the available tools supporting for pre- and auto-population  Sections 2.3.2.1.2and 2.3.2.2.2 – Added information about the new <sdc:supplemental\_data> element  Section 2.3.2.3.1 – Updated example and Table 8 to match correctly  Section 2.5.4.2 – Updated Table 12 to match with SDCForm Schema  Section 2.5.6.2 – Updated Table 15 and added last two bullets to match with SDCForm Schema  Section 2.5.6.2.3 – Updated Table 18 and added explanation for attributes initial\_state and data\_element\_scoped\_identifier  Removed old Appendix C: Specifications References  Re-numbered all Appendices  Updated Appendix D: SDC Data Element Attributes  Added Appendix F: Open Items  Corrected typos and made minor editorial changes throughout the document |

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# Introduction

The Structured Data Capture (SDC) Initiative seeks to link clinical data, captured within the Electronic Health Record (EHR) system during clinical encounters, to supplemental systems that collect structured patient data within forms. For example, consider a clinician treating a patient who is participating in a clinical trial or comparative effectiveness research (CER). First, the clinician would select the applicable electronic case report form (eCRF) in the EMR. Some information in the CRF would be automatically populated with current data derived from the EHR, and the remainder of the form’s data would be entered in response to standardized questions posed by the eCRF. The eCRF data will be captured in a structured form, and ultimately aggregated and transferred to end users as required for the particular use case.

SDC requires that the question/answer (data element) structure of EHR forms be specified in a standardized, interoperable and reproducible way. As a consequence, SDC requires the definition of metadata for forms and data elements, in a manner relevant to EHRs and entities using EHR data. Therefore SDC aims to leverage synergistic government and health care industry efforts underway related to standards definition, and representation to facilitate capture, reporting, and analysis. The standards and guidance incorporated into this implementation guide were based on the requirements defined in the [Structured Data Capture Initiative Standards and Interoperability Framework Use Case document](http://wiki.siframework.org/Structured+Data+Capture+Use+Case). Users of this implementation guide will benefit greatly from review of the SDC Use Case document.

## Initiative Overview

The Structured Data Capture (SDC) Initiative identifies and recommends standards for the interoperable representation and transmission of the following:

* Standard form designs;
* Minimum data element attributes for the purpose of using them in form designs;
* Query for form without patient data;
* Query for form with patient data submitted (to Enhanced Form/Template Repository) for pre-population;
* Return form without pre-populated patient data;
* Return a form with pre-populated patient data;
* Submit completed form data to an external data repository.

The SDC architecture consists of a set of building blocks that begins with question/answer sets that are based on data elements (DEs). In the SDC architecture, these question/answer sets are aggregated and structured into a description of a computerized data-entry form. The form design is a blueprint for the form and is represented in SDC using XML Schema, regardless of the technology (e.g., HTML, XAML, Flash, Java, .NET, etc.) used to implement the design.

This implementation model optionally enables an EHR or enhanced Form/Template Repository (FTR) to set data values in a form prior to that form being rendered for a user. For clarity, we use the term *pre-populate* to refer to this process when it is performed by an enhanced FTR prior to returning the form to the EHR user, and use the term *auto-populate* when this process is performed by the EHR system after receiving the form template or form from an FTR.

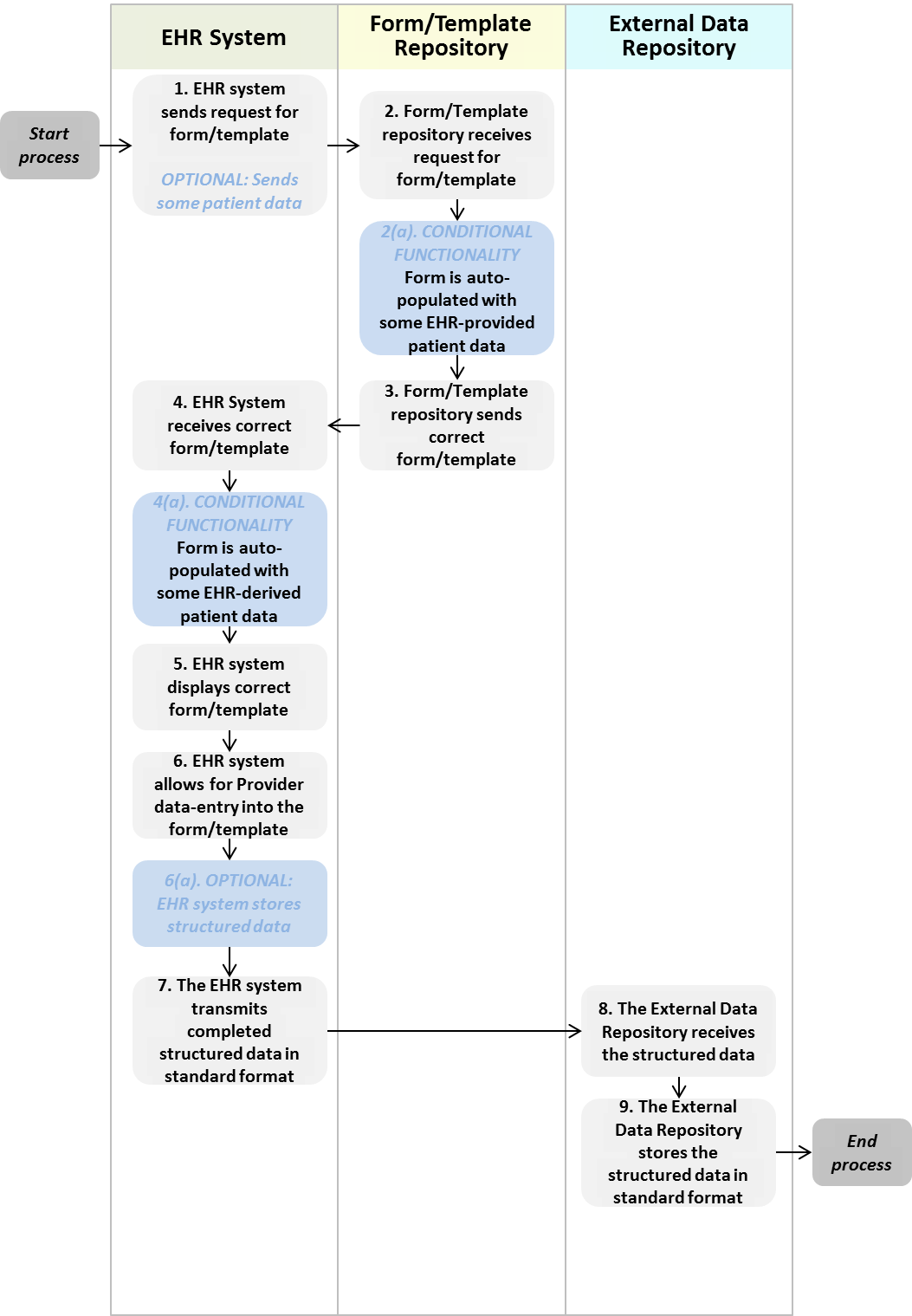
In addition to the above, this document provides specifications and guidelines for:

* The representation of DEs attributes used in forms in a consistent manner, wherein the attributes of the DEs and the attributes of Question/Answers in form designs are consistent in naming, structure and semantic content;
* The creation of form designs in the SDC XML format;
* Guidance on auto-population of forms by an EHR.

As applicable this implementation guide addresses data transmission security, limitation of access to appropriate personnel, data integrity, accountability, and adherence to suitable well-accepted informatics and networking standards.

The generic SDC workflow is pictured in Figure 1.

Figure : Generic Workflow



*Note: The diagram depicts the optional storage of the completed form by the EHR. This can occur when the EHR stores a copy of the form as they send it to the External Data Repository or by the external data repository returning a copy of the form to the sender who can store in an internal version of the forms repository.*

* 1. **Background**

With electronic health record (EHR) adoption rising across the U.S., the volume and detail of information captured by healthcare organizations and providers is growing exponentially. Although health care providers and others use various sources and methods to capture and synthesize patient-level data, EHRs have the highest potential to provide timely and relevant data in a form that is quickly usable for quality and safety improvement, patient-safety event reporting, population health, determination of coverage and research. EHR data obtained during episodes of care will become increasingly valuable to healthcare organizations striving to leverage electronic information to drive efficiency and quality. Such use of EHR data is sometimes labeled “secondary” use or “reuse.”

Once captured, aggregated and analyzed, these combined data can be used to identify trends, predict outcomes and influence patient care, drug development and therapy choices.

Various clinical and health services research groups and specialty societies are actively engaged in independent initiatives to standardize data collection across projects in their domains in order to maximize the utility of the resulting datasets for subsequent research. These include efforts to consistently represent panels and assessment instruments using standard names and codesets, such as are carried in LOINC panel/forms, which include widely used clinical, government forms ranging from the Surgeon Generals Family History to PROMIS patient assessments. Relevant to this effort, the Regenstreif Institute and NLM have developed a tool to render active web forms from the structures, content and codes carried in LOINC panels.

In addition to standardizing transactions for information exchange, government-sponsored efforts have begun to develop common definitions and representations of data elements. These include:

* National Library of Medicine (NLM) work with other NIH Institutes and Centers to identify and coordinate initiatives to designate and promote the use of Common Data Elements, many of which will be useful for Patient Centered Outcomes Research (PCOR), to promote data harmonization and reuse in research, surveillance, and patient registries;
* The Agency for Healthcare Research and Quality (AHRQ) development of a comparable library of terms and Common Formats based on ISO/IEC 11179[[1]](#endnote-1) to standardize data collected and reported for patient safety events;
* National Cancer Institute (NCI) specifications for an extensive set of Standard Case Report Forms (CRFs) shared across all NCI cooperative groups for conducting clinical trials using NCI defined Common Data Elements (CDEs) that are registered in caDSR, an ISO/IEC 11179 metadata registry.

## Purpose

This implementation guide provides implementers with guidance on how to achieve conformance with the standards recommended by the Office of the National Coordinator for Health Information Technology (ONC) Standards & Interoperability Framework (S&I), SDC Initiative.

## Intended Audience

This implementation guide is intended to be informative to the following audiences:

* Healthcare Providers and Clinical Informaticians;
* Patients;
* Clinical/PCOR Research Community and CER/PCOR Thought Leaders and organizations;
* [Patient Safety Organizations (PSOs)](http://www.pso.ahrq.gov/);
* Privacy and Security Experts;
* Patient Advocates;
* Biopharmaceutical Firms;
* Device manufacturers;
* Government Agencies
* Vendors of EHR/EMR systems
* Research Institutions
  + Health Information Exchange (HIE), Data Warehouse/Data Mart, Electronic Data Capture (EDC) and Patient Safety Event Reporting Systems, Incidence Reporting systems providers;
* Standards-Related Organizations: Standards Development Organizations (SDOs), vocabulary/terminology organizations, standards setting organizations:
  + Value Set authors (e.g. AMA) and Value Set repositories (e.g. VSAC, PHIN VADS);
* Healthcare payers;
* Professional liability carriers;
* Healthcare Professional associations.

## Organization of This Guide

This guide is organized into the following sections:

* Introduction and overview;
* Implementation approach including guidance on transaction, data elements, form definition, and auto-population;
* Appendices that provide acronyms and key terms, conformance statements, and references.

### Conformance Verbs (Keywords)

Conformance Verb (also known as keywords) is defined throughout this implementation guide using **BOLD** and CAPS to denote the conformance criteria to be applied.

The keywords shall, shall not, should, should not, may, and May not in this document are to be interpreted as described in the *HL7 Version 3 Publishing Facilitator's Guide*[[2]](#endnote-2):

* SHALL: an absolute requirement;
* SHALL NOT: an absolute prohibition against inclusion;
* SHOULD/SHOULD NOT: best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course;
* MAY/MAY NOT: truly optional; can be included or omitted as the author decides with no implications.

Much of the conformance requirements are specified in the underlying standards. The **SHALL** and **SHALL NOT** conformance verbs relating to requirements that are only defined in this implementation guide are underlined as well for distinction.

### Cardinality

The following table represents the *Cardinality* of elements within this guide. *Cardinality* is defined by the minimum and maximum number of times that the data element may appear.

The cardinality indicators are interpreted with the following format “m…n” where m represents the least and n the most.

Table : Cardinality

| Cardinality | Description |
| --- | --- |
| 0..0 | The element SHALL NOT be present |
| 0..1 | The element MAY be omitted and has at most one occurrence |
| 1..1 | The element SHALL appear once and only once |
| 0..n | The element MAY be omitted or may repeat up to n times |
| 1..n | The element SHALL appear at least once, and MAY repeat up to n times |
| 0..\* | The element MAY be omitted, or it MAY repeat an unlimited number of times |
| 1..\* | The element SHALL appear at least once, and MAY repeat an unlimited number of times |
| m..n | The element SHALL appear at least m times, and at most, n times |
| 2..2 | The element SHALL appear two and only two times |
| 3..3 | The element SHALL appear three and only three times |

# Implementation Approach

This guide supports the following implementation objectives:

* Support incorporation of SDC capabilities into systems;
* Provide an overview of the standards and specifications used for SDC, and to explain how each standard contributes to SDC implementation;
* Specify how the full stack of base standards can be leveraged to standardize SDC;
* Indicate where and how the documentation for each supporting standard/specification may be obtained.

This implementation guide focuses not only on the structure of the in-scope transactions, but also on how those transactions can leverage semantics through the use of ISO/IEC 11179 standard data elements and thereby take advantage of standard terminologies, value sets and taxonomies such as SNOMED-CT.

## Solution Plan Overview

**SDC Assumptions:** This solution plan provides a standards-based approach that automates the capture and reporting of data using forms. This plan assumes the following:

* Capture of the data in the form within an EHR (or similar system);
* Form design packages (section2.5) will be authored, managed and provided for use by authoritative FTRs;
* Copies of form design packages provided by forms design owners will be held, managed, and provided by an existing FTR system external to the EHR;
* *Optional:* An enhanced FTR system will be able to pre-populate forms with supplied patient data;
* *Optional:* An EHR system may be able to auto-populate forms based on data in its database.
* Captured data will be sent to a system known as the External Data Repository

**SDC Modularity:** This solution plan establishes sufficient modularity to enable a broad range of usage patterns. This modularity supports:

* Pre-population of a form by an Enhanced FTR;
* Auto-population of a form by the EHR;
* Multiple authoritative FTRs may supply various forms and templates to a given user, EHR or institution.
* EHR-derived patient data that may be used in pre- and auto-population;
* Communication of information related to patient consent directives for the disclosure of personal health information;
* Ability to provide digital signatures for the transactions as a whole in addition to the use of digital signatures for those elements within a transaction that support them;
* Multiple External Data Repository endpoints.

**SDC Solution Components:**

**Generic Forms and HTML:** This IG provides standards for implementing interoperable data entry forms, regardless of technology. Many different technologies are used for creating computer-based data entry forms in EHR systems. However, HTML is overwhelmingly the most widespread technology for displaying forms on web pages, including clinically-relevant web forms. Therefore, support for HTML forms is highly desirable, especially as an initial SDC pilot implementation. While an entire body of tools and technologies is associated with HTML for displaying forms, HTML forms must be constrained to the SDC standard definitions for form design and metadata-based data element representation.

The solution plan supports two options for forms – XML-based form design (using the SDC Schema defined herein) and SDC-compliant HTML form, both are markup languages. The former is designed to describe the form definition and data, the latter is designed to display data and is concerned more with how the data looks.

**Request Form for Data (RFD):** The standards associated with form definition and transmission using RFD[[3]](#endnote-3) are in development at the time of this guidance but final resolution is expected prior to full and final issuance of both the REST/OAuth and SOAP/SAML version of the set of SDC transaction standards (section2.3).

**Form Metamodel:** In the formulation of this SDC solution plan, a great deal of attention was given to the identification of a form metamodel standard that would be technology and platform neutral and support the diversity of users and uses for structured data capture involving EHRs. After evaluating many metamodel options, the SDC team selected ISO/IEC 19763 Metamodel framework for interoperability-Part 13: Metamodel (MFI-13)[[4]](#endnote-4). Although considerable customization and constraint of the base MFI-13 model was required for SDC use, MFI-13 provides an excellent foundation for standardizing the metadata model representing question/answer sets, their assembly into interoperable forms, and their strong relationship to ISO 11179 data elements.

The SDC implementation of MFI-13 is thus a foundational metamodel for all SDC-compliant forms, including the HTML form example included in this guide.

**Pre-population and Auto-population:** There are various tools available that can be used to support the pre- and auto-population functionality. This solution plan shows use of an IHE DEX profile as an optional tool to achieve this functionality. It is included because the DEX profile is used to provide direct access to CCD information stored in the EHR.

### SDC Base Standards

The SDC solution plan leverages the following base standards:

* The IHE RFD profile for Retrieving forms3;
* The TLS v1.0 standard for security in-transit[[5]](#endnote-5);
* The SOAP transport standards for Web services[[6]](#endnote-6);
* ISO/IEC 11179-3 (MDR-3) for Data Element definition1;
* ISO/IEC 19763-13 (MFI-13) for Form definition4;
* IHE ATNA profile for Secure Application or Secure Node[[7]](#endnote-7);
* Optionally, SAML for Authentication[[8]](#endnote-8);
* Optionally, the IHE XUA profile for authenticating identity of the user[[9]](#endnote-9);
* Optionally, the C-CDA CCD templates for patient data[[10]](#endnote-10);
* Optionally, the HL7 Privacy Consent Directive standard for patient consent information[[11]](#endnote-11);
* Optionally, the XAdES Digital Signature for ensuring authenticity[[12]](#endnote-12);
* Optionally, the IHE DEX for pre- and auto-population[[13]](#endnote-13).

### SDC Solution Plan

This section discusses the structured data capture flows for three types of Transactions:

* **Transaction 1: Form/Template Request and Response without patient data**: the form/template transaction graphic (see Figure 2) show exchanges wherein an EHR requests and receives a blank form from a FTR;
  + **1A Request for Form/Template:** EHR System sends request for an SDC form to FTR;
  + **1A Response with Form/Template:** FTR sends the requested form design, an empty SDC-compliant HTML form, or the URI for the form to EHR. The response package will include an Administrative section (optional Compliance Rules and optional Submission Rules), a Mapping section (Data Element/Question and DEX/CDA mapping), and a Style Sheet (e.g., css and/or xslt) section. The Administrative Section contains optional Compliance Rules and optional Submission Rules;

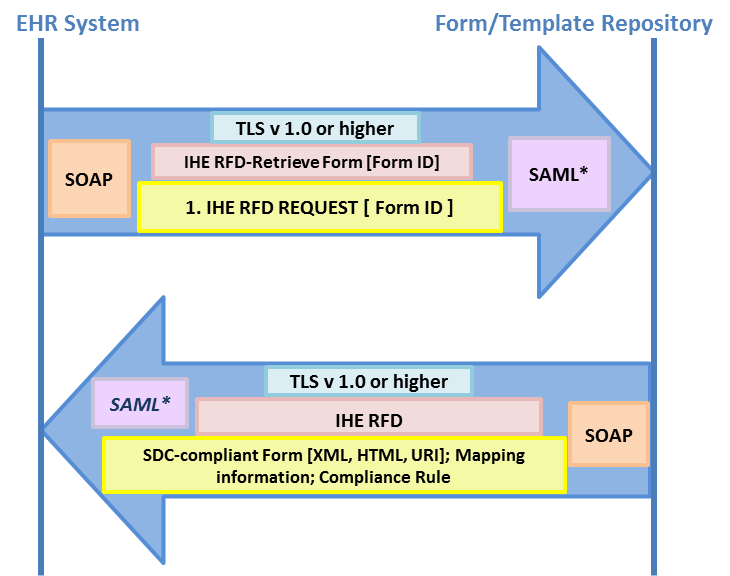
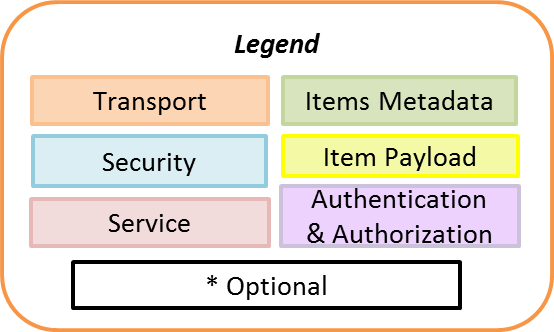
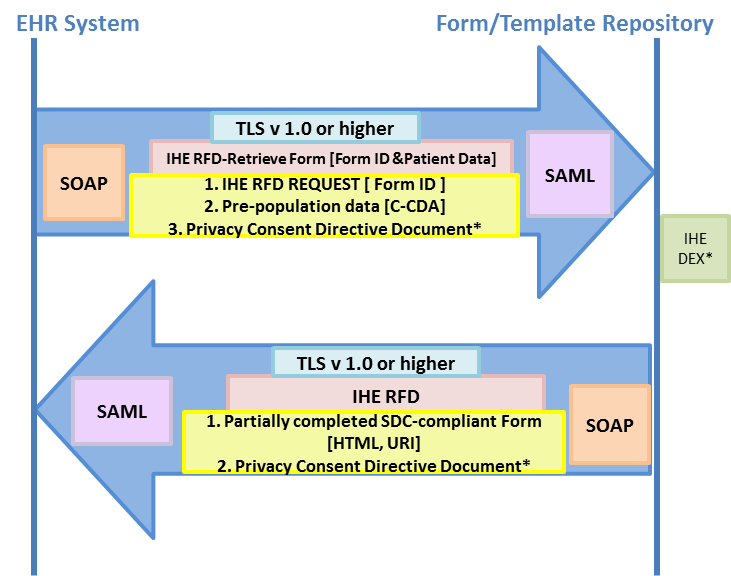
Figure 2: Transaction 1A: Form/Template Request and Response without Patient Data

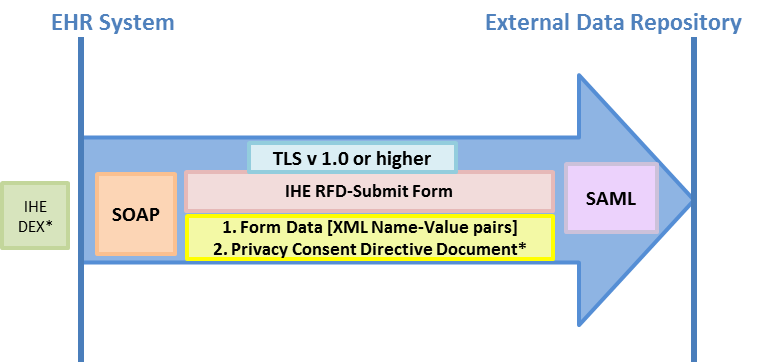
Figure : Solution Plan diagram Legends



* **Transaction 1B: Form/Template Request and Response with Patient Data**: the form/template transaction with patient data graphic (see Figure 4) show exchanges wherein an EHR requests an SDC-complaint HTML form and provides data (in C-CDA format) that can be used by the Enhanced FTR to pre-populate values in the form prior to the form being returned;
  + **1B. Request with Patient Data Exchange:** The EHR sends a request for an HTML form, together with structured patient data to the Enhanced FTR. Optionally, a relevant patient consent directive document may be included in this transaction;
  + **1B. Response with Patient Data Exchange:** Enhanced FTR uses the submitted data to pre-populate (partially fill) the form and sends back the partially-filled SDC-compliant HTML form and optionally may send Mapping file, Compliance Rules, and relevant patient consent directive document(s);

Figure 4: Form/Template Request and Response with Patient Data

* **Transaction 2: Data Submission from Structured Form**: The form data transaction graphic (Figure 5) shows an exchange that conveys the structured data, captured on a form, to an External Data Repository;

Figure 5: Data Submission from Structured Form

## Actors

Table 2 outlines the business actors that are participants in the information exchange requirements for the generic SDC scenario. The system or system actor has roles (e.g., send, receive, publish) and actions which involve exchanging content.

The actors/systems designated in Table 2 are core to the Use Case but do not preclude the use of other actors/systems to be added based upon the information and system requirements of the specific implementation.

The text with asterisks (\*) denotes “Optional” or “Conditional” functionality where defined.

Table : Actors and Roles

| Actor / System | Role |
| --- | --- |
| Provider / EHR System | * Identifies necessary form/template\* * Inputs data into form * Reviews and saves completed form \* |
| EHR System | * Sends requests for form/template * Receives form/template * Displays form/template * Auto-populates form\* * Stores complete form data\* * Sends completed form data |
| Form/Template Repository | * Receives form/template request * Sends form/template |
| Enhanced Form/Template Repository | * Receives form/template request * Pre-populates form * Sends pre-populated form |
| External Data Repository | * Receives completed form data |

### Out of Scope Capabilities for Actors

EHR System – The SDC Initiative does not define how an EHR would identify or select from a list of available forms or appropriate form template repositories (e.g., that are available to a specific user, or needed for a specific patient). The SDC initiative will benefit from innovations that will include the use of clinical decision support to identify circumstances when a specific form is appropriate or needed. In addition, the SDC Initiative does not prescribe the nature or extent of any documentation that an EHR system might establish to identify what forms have been accessed, when they were accessed and by whom.

Form/Template Repository – There could be circumstances in which the FTR can offer or support logic that may refine the specific form returned based on information contained in the request other than the form ID being requested. For example, a request might be for a form identified as a Pertussis Report Form but the FTR could refine that request to return the form that is specific to the jurisdiction where the patient resides.

Enhanced Form/Template Repository –The technical mechanism for pre-populating an HTML form is out of scope in this edition of the Implementation Guide.

External Data Repository (EDR) – The role for this actor is very limited in the IG. The wide-range of potential actions that an EDR might take are out-of-scope. As is shown in Figure 1 the EDR provides the data consumer with access to the SDC data. How the EDR provides access to the SDC data for the data consumers is out of scope. There are several facets related to how the EDR provides access, including: the format of the data it provides, when it provides those data, and to whom it provides the data. The EDR will often need to reconstitute the data it receives in a format that can be used by the data consumer. For example, the EDR may use the captured data to construct and send an HL7 V2.X message, the original SDC form design in XML or HTML, a CDA document, or any other form (such as the FDA form 3500A). Some data consumers may need to receive data in “real time” as the external data repository receives it, whereas other data consumers may need data to be “batched” and sent on a scheduled basis. Lastly, it may be that some structure data captured may need to be distributed to more than one data consumer. All of these are relevant but are out of scope for this IG; in general, these transactions are established based on a relationship between the external data repository and its data consumer(s). It should also be noted that, under some use cases, the EDR function could result in data being retained or archived by the EHR system itself, such as in the case of documentation of prior approvals for services or devices. The SDC team strongly encourages all EDRs to preserve the SDC data structures and metadata to facilitate downstream interoperability.

## Transaction Overview

### SDC Transaction Base Standards

The exchanges supporting the transactions for this implementation guide will use the same pattern of transport, security in transit, and transaction level authentication standards.

#### SOAP

The SOAP header establishes specific routing information for an exchange of data.

The following example shows the structure of the SOAP Header and how a Retrieve Form request is provided.

<soap:Envelope xmlns:soap="http://www.w3.org/2003/05/soap-envelope" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:xsd="http://www.w3.org/2001/XMLSchema">

<soap:Header>

<wsa:To>http://localhost:4040/axis2/services/someservice</wsa:To>

<wsa:MessageID>urn:uuid:76A2C3D9BCD3AECFF31217932910053</wsa:MessageID>

<wsa:Action soap:mustUnderstand="1">urn:ihe:iti: 2007:RetrieveForm</wsa:Action>

</soap:Header>

The SOAP Header **SHALL NOT** contain specific Personal Health Information (PHI) within the specific header elements itself. This meets the use case requirement to not expose data in the header of a response to a data query that might indirectly expose additionally protected patient data to an intermediary, and only exposing the information necessary to achieve the mechanism (see Appendix B).

#### SAML

The SOAP Header SHALL contain a SAML assertion. The implementer SHOULD refer to the IHE XUA profile for a complete set of SAML attributes (see Appendix B). The SAML assertion provides information about the requesting system. The use of IHE XUA profile provides the capability to convey information such as “allowed purposes” and “allowed users” for the request.

For a pull-based implementation approach, the SAML request/response mechanism **SHALL** be used, as shown in the example below:

<o:Security s:mustUnderstand="1" xmlns:o="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd" xmlns:u="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-1.0.xsd">

…

<Assertion ID="\_9bbc4440-7bb3-482b-86b9-e4b6b474b07e" IssueInstant="2013-10-21T19:37:43.086Z" Version="2.0" xmlns="urn:oasis:names:tc:SAML:2.0:assertion">

<Issuer>https://idp.integration.theOrganizationsName.org/SAML2</Issuer>

<Signature xmlns="http://www.w3.org/2000/09/xmldsig#">

…

</Signature>

…

</Assertion>

</o:security>

Implementers can also refer to the esMD Exchange Specification 1.0[[14]](#endnote-14), which specifically highlights examples of how to structure a SAML Assertion within a SOAP Header.

The SOAP body contains the specific payload that is being transported.

* Transaction that uses SOAP **SHALL** end with a response message that is SOAP encoded.

#### Transport Layer Security (TLS) and Node Authentication

The needs for transport layer security are the same as those provided by the XD\* Profiles and form the basis for transport layer security and node authentication for this implementation guide. The XD\* profiles and their transactions are all encrypted so that only the intended recipient can decrypt them. XD\* profiles support bi-directional (Mutual) authentication using digital certificate identities, and integrity controls chaining back to those same digital identities.

In accordance with the IHE ITI TF (Vol 2a pg. 136), 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 using TLS 1.0 or greater 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) (see Appendix B);
  + **SHALL** utilize TLS 1.0 or greater in order to provide a secure channel (Appendix B);
  + **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.

Implementers should reference the NwHIN Messaging Platform Specification[[15]](#endnote-15) for instructions on how to implement TLS (see Appendix B).

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, as patient data is exchanged during Transaction 1B: Form Request and Response, and Transaction 2: Data submission from structured form.

Table 3: Record Audit Event

|  |  |  |
| --- | --- | --- |
| Implementation Approach | Required Standards/Profiles | Optional Standards/Profiles |
| Record Audit Event | ASTM E2147 | IHE ATNA  This guidance recommends flexibility for implementers to select the standard for the audit record format. |

This implementation guide recommends usage of the IHE ATNA profile for capturing auditable events. Implementers should refer to the IHE ATNA profile for specific implementation guidance and conformance criteria (see Appendix B). Message content is defined in the IHE Clinical Research Document (CRD)[[16]](#endnote-16) 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 IG enables the use of the XAdES digital signature standard when it is required.

* Signature – allows the required information for a digital signature for the entire transaction document.
* For details on the creation and processing of the XAdES signature for this IG and an example seeAppendix C.

#### RFD

The Retrieve Form for Data Capture Profile (RFD) provides a method for gathering data within a user’s current application to meet the requirements of an external system. RFD supports the retrieval of a form from a form source, the display and completion of the form, and the return of instance data from the display application to a receiving application. In addition, RFD provides a mechanism to amend data that was previously captured.

RFD offers the capability to leverage industry standards that address both the structure and content of forms used for data capture. RFD permits automatic form population – that is, have the form delivered with host application database values inserted into appropriate fields of a form, and provides a generic mechanism by which this can be accomplished. Some key benefits of RFD are as follows:

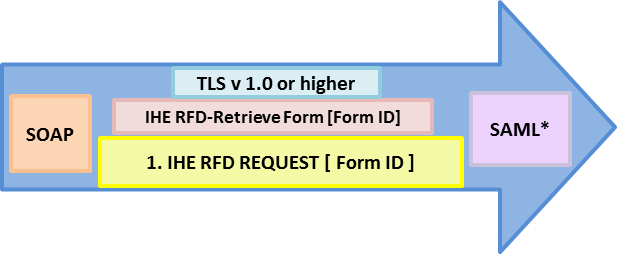
* Ability to fill in form data within a user's current application;
* Standardized interaction for filling form data.

### SDC Transaction Details

#### Transaction 1A: Form/Template Request and Response without patient data

#### Request without Patient Data

Figure : Request without Patient Data



This exchange is requesting a blank (not auto-populated) form. This request is based on the RFD Retrieve Form Request (ITI -34) specification. ITI-34 provides two top level parameters for the request: <prepopData> and <workflowData>. Since Transaction 1A is not requesting pre-populated form, there will not be any content for <prepopData>. ITI-34 requires that the transaction explicitly indicate that no prepopData are provided. This is done with the entry <prepopData xsi:nil="true" />.

An example of Transaction 1A Request for an SDC Form URI is shown below:

<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>

An example of a Transaction 1A Request for an SDC form design is shown below:

<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>

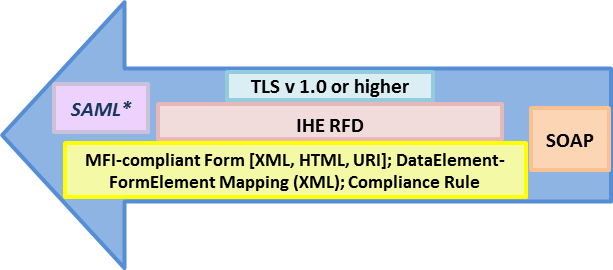
Table : Elements for Request without Patient Data

| Element Name | Element Description | Card. | Verb | Data Type |
| --- | --- | --- | --- | --- |
| prepopData | The context element that may be used to contain content for the purposes of pre-population. | 1..1 | Required; may be nil. | xs:any |
| workflowData | The context element that contains workflow specific values. | 1..1 | Required | Xml element |
| formID | The identifier of a form. In SDC a form is uniquely defined by its form\_design\_ID | 1..1 | Required | xs:string |
| encodedResponse | Specifies how the form is to be returned: encoded within the response or as a URL. | 1..1 | Required | xs:Boolean |
| archiveURL | The endpoint of an optional Archiver to which form data are to be submitted. | 1..1 | Required; may be nil. | xs:anyURI |
| Context | The element that may contain additional context content. | 1..1 | Required; may be nil. | xs:any |
| instanceID | The xml element containing the value of a form instance | 1..1 | Required; may be nil. | xs:string |

* For Transaction 1A Request, the <encodedResponse> element **SHALL** have value “true” when requesting either the XML form design or SDC-compliant blank HTML form.
* For Transaction 1A Request, the <encondedResponse> **SHALL** have value “false” when requesting for a form URI.

#### Response without Patient Data

Figure : Response without Patient Data



This exchange is returning a blank (not pre-populated) form. This response is based on the RFD Retrieve Form Request (ITI -34) specification. ITI-34 provides three top level parameters for the response: <form>, <contentType>, and <responseCode>.

For this IG, we specify one subentry under <Structured> — <sdc:sdc\_xml\_package> or <sdc:sdc\_html\_package >. If the <contentType> is XML, then the MFI-13 compliant XML form (see details below) is sent within the <sdc:sdc-xml\_package > element. Alternately if the <contentType> is HTML, then the SDC-compliant HTML form is inserted within the <sdc:sdc\_html\_package > element as shown below.

An example of returning a URL for a form is shown below:

<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>

An example of a Transaction 1A: Response returning a native MFI-13 SDC form is shown below:

<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 definition e.g. form generation date, specific instruction, etc. -->

</sdc:supplemental\_data>

<sdc:form\_package>

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

<sdc:mapping\_package>

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

</sdc:mapping\_package>

<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>

Table : Elements for Response without Patient Data

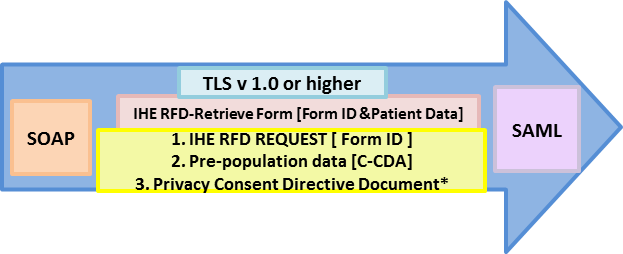
| Element Name | Element Description | Card. | Verb | Data Type |
| --- | --- | --- | --- | --- |
| Form | The xml element container for the form.  The form element Shall contain one of: {Structured, Unstructured, URL} | 1..1 | Required | urn:ihe:iti:rfd:2007:formDataType |
| Structured | The xml element container for the return of encoded, structured form content. The Structured element SHALL contain one of: {sdc\_xml\_package or sdc\_html\_package} | 0..1 | May | xs:any |
| sdc\_xml\_package | The wrapper element container for the SDC-compliant form package | 0..1 | May |  |
| Supplemental\_data | The xml element containing supplemental data associated to the form definition | 0..1 | May | Xs:anyXML |
| form\_package | The xml element containing MFI-13 based form design and associated files. See Section 2.5 for details. | 0..1 | May |  |
| sdc\_html\_package | The wrapper element container for the SDC-compliant HTML form package | 0..1 | May |  |
| Supplemental\_data | The xml element containing supplemental data associated to the HTML form | 0..1 | May | Xs:anyXML |
| form\_info | The xml element containing supporting information e.g. mapping info, admin info, etc. | 0..1 | May |  |
| sdc\_html\_form | The xml element containing the SDC-compliant HTML form instance. | 0..1 | May |  |
| URL | The xml element container for the return of a pointer to the form. | 0..1 | May, but Required with the Form Request that has encodedResponse value of FALSE. | xs:anyURI |
| instanceID | The xml element containing the value of a form instance | 0..1 | May | xs:string |
| contentType | The type of the returned form — either XML or HTML | 1..1 | Required; may be nil. Has no meaning when the Form Request encodedResponse value is FALSE. | xs:string |
| responseCode | Indicates any required details such as errors, warnings, or informational messages in response to request | 1..1 | Required; may be nil. | xs:string |

* For Transaction 1A Response, the <unstructured> element **SHALL NOT** be used for this IG.
* For Transaction 1A Response, the <structured> element, when used **SHALL** be at least one of the following: <sdc\_xm\_package> or <sdc\_html\_package>.
* For Transaction 1A Response, the <contentType> **SHALL** contain value “XML” for response containing MFI-13 based form definition;
* For Transaction 1A Response, the <contentType> **SHALL** contain value “HTML” for response containing SDC-compliant HTML form instance.

#### Transaction 1B: Form/Template Request and Response with patient data

#### Request with Patient Data

Figure : Request with Patient Data



This exchange is requesting a pre-populated form. This request is based on the RFD Retrieve Form Request (ITI-34) specification just like Transaction 1A Request. There are two differences:

* The first difference is that the Transaction 1B Request will have a C-CDA document inserted in the <prepopData> section (rather than the nil specified in Transaction 1A Request);
* The second difference is that it may have an HL7CDA R2 based Privacy Consent Directive document (compliant to CDA R2, Privacy Consent Directive, Release 1 Implementation Guide). If present, that will be inserted under the <context> section.

<RetrieveFormRequest

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

xmlns:xsi=”<http://www.w3.org/2001/XMLSchema-instance>”

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

>

<prepopData>

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

<realmCode code="US"/>

<!-- lots of juicy stuff goes here in a real CDA -->

</ClinicalDocument>

</prepopData>

<workflowData>

<formID> http://myrepo.gov/ form\_design\_id=12345.2</formID>

<encodedResponse>true</encodedResponse>

<archiveURL />

<context>

<sdc:consent>

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

<realmCode code="US"/>

<!-- consent directive content -->

</ClinicalDocument>

</sdc:consent>

</context>

<instanceID xsi:nil="true"/>

</workflowData>

</RetrieveFormRequest>

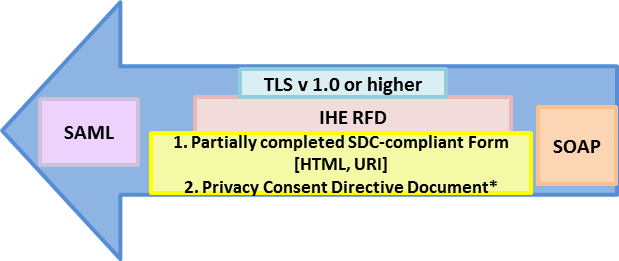
Table : Elements for Request with Patient Data

| Element Name | Element Description | Card. | Verb | Data Type |
| --- | --- | --- | --- | --- |
| prepopData | The context element that may be used to contain content for the purposes of auto-population. | 1..1 | Required | xs:any |
| workflowData | The context element that contains workflow specific values. | 1..1 | Required | Xml element |
| formID | The identifier of a form | 1..1 | Required | xs:string |
| encodedResponse | Specifies how the form is to be returned: encoded within the response or as a URL | 1..1 | Required | xs:Boolean |
| archiveURL | The endpoint of an optional Archiver to which form data are to be submitted. | 1..1 | Required; may be nil. | xs:anyURI |
| Context | The element that may contain additional context content. It is expected that the content of this element is defined by domain specific profiles and implementation guides, such as Clinical Research Domain (CRD) (see IHE\_QRPH\_Suppl\_CRD.pdf). | 1..1 | Required; may be nil. | xs:any |

* For Transaction 1B Request, the <encodedResponse> element **SHALL** have value “true” when requesting for SDC-compliant partially filled HTML form.
* For Transaction 1B Request, the <encondedResponse> **SHALL** have value “false” when requesting for a partially filled form URI.

#### Response with Patient Data

Figure : Response with Patient Data



An example of a Transaction 1B: Response returning an SDC-compliant partially filled HTML form is shown below:

<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 definition e.g. form generation date, specific instruction, 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 any necessary scripts 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>

Table : Elements for Response with Patient Data

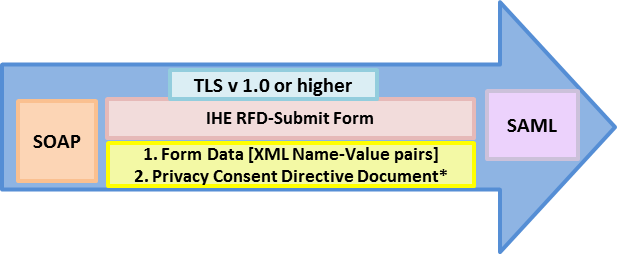
| Element Name | Element Description | Card. | Verb | Data Type |
| --- | --- | --- | --- | --- |
| Form | The xml element container for the form.  The form element Shall contain one of: {Structured, Unstructured, URL} | 1..1 | Required | urn:ihe:iti:rfd:2007:formDataType |
| Structured | The xml element container for the return of encoded, structured form content. | 0..1 | May. | xs:any |
| sdc\_html\_package | The wrapper element container for the SDC-compliant HTML form package | 0..1 | May |  |
| Supplemental\_data | The xml element containing supplemental data associated to the form definition | 0..1 | May |  |
| form\_info | The xml element containing supporting information e.g. mapping info, admin info, etc. | 0..1 | May |  |
| sdc\_html\_form | The xml element containing the SDC-compliant HTML form instance. | 0..1 | May |  |
| URL | The xml element container for the return of a pointer to the form. | 0..1 | May, but Required with the Form Request has encoded  Response value of false. | xs:anyURI |
| instanceID | The xml element containing the value of a form instance | 0..1 | May | xs:string |
| contentType | The type of the returned form | 1..1 | Required; may be nil. Has no meaning when the Form Request encodedResponse value is false. | xs:string |
| responseCode | Indicates any required details such as errors, warnings, or informational messages in response to request | 1..1 | Required; may be nil. | xs:string |

* For Transaction 1B Response, the <unstructured> element **SHALL NOT** be used for this IG.
* For Transaction 1B Response, the <structured> element, when used, **SHALL** contain one <sdc\_html\_package>.
* For Transaction 1B Response, the <contentType> **SHALL** contain value “HTML” for response containing SDC-compliant partially filled HTML form.

#### Transaction 2: Data Submission from Structured Form

#### Data Submission from Structured Form

Figure : Data Submission from Structured Form



This exchange is submitting the form data to an external data repository. This is based on the RFD Submit Form Request (ITI -35) specification which allows the <SubmitFormRequest> to contain any XML. For SDC submission, <form\_data> element will contain <sdc:question> element with relevant attributes to uniquely identify the question and determine hierarchy within the form. Each <sdc:question> element will contain response data within <sdc:response> element.

A response is expected for this submission of data to the External Data Repository. This response could be a simple acknowledgement, an error message, or request for additional information. The definition of valid Responses is currently considered out of scope.

* The transmitted data SHALL be sufficient to be able to recreate the form instance, whose data is being submitted.

<rfd:SubmitForm xmlns:sdc="http://nlm.nih.gov/sdc/form" xmlns:rfd="urn:ihe:iti:rfd:2007">

<!-- This is how the submission response will be defined -->

<sdc:form\_data form\_name="Healthcare Event Reporting Form (HERF) Hospital" 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:question section\_identifier="HERF/header" question\_identifier="HERF/DE30" question\_prompt="Initial Report Date" question\_repeat="1" datatype="string\_date" pattern="MM/DD/YYYY">

<sdc:response>09/30/2013</sdc:response>

</sdc:question>

</sdc:header>

<sdc:body>

<sdc:question parent\_identifier="HERF/DE3/A3" section\_identifier="HERF/SEC01.1" question\_identifier="HERF/DE9a" question\_prompt="Event Discovery Date" question\_repeat="1" datatype="string\_date" pattern="MM/DD/YYYY">

<sdc:response>10/21/2013</sdc:response>

</sdc:question>

<sdc:question section\_identifier="HERF/SEC01" question\_identifier="HERF/DE30" question\_prompt="Which of the following categories are associated with the event or unsafe condition?" question\_repeat="1" datatype="integer">

<sdc:response item\_prompt="Fall" list\_item\_identifier="HERF/DE21/A48" value\_meaning\_standard\_code="" value\_meaning\_standard\_code\_system\_identifier="" fill\_in="false">DE21.A48</sdc:response>

<sdc:response item\_prompt="Venous Thromboembolism" list\_item\_identifier="HERF/DE21/A64" value\_meaning\_standard\_code="" value\_meaning\_standard\_code\_system\_identifier="" fill\_in="false">DE21.A64</sdc:response>

<sdc:response item\_prompt="Other" list\_item\_identifier="HERF/DE21/A66" value\_meaning\_standard\_code="" value\_meaning\_standard\_code\_system\_identifier="" fill\_in="true">Tornado</sdc:response>

<sdc:question section\_identifier="ExampleHERF/SEC01" question\_identifier="ExampleHERF/LookUp" question\_prompt="Gender" question\_repeat="1" datatype="ISO111404 CHARACTER" uri="http://nciterms.nci.nih.gov/ncitbrowser/ajax?action=create\_src\_vs\_tree&amp;vsd\_uri=http://ncit:Neoplasm">

<sdc:response

value\_meaning\_standard\_code="C46109" value\_meaning\_standard\_code\_system\_name="NCI Thesaurus" value\_meaning\_standard\_code\_sytem\_identifier="2.16.840.1.113883.3.26.1" value\_meaning\_standard\_code\_sytem\_version="13.11d">Male Gender</sdc:response>

</sdc:question>

</sdc:body>

</sdc:form\_data>

</rfd:SubmitForm>

Table : Elements for Data Submission

| Element Name | Description | Card. | Verb | Data Type |
| --- | --- | --- | --- | --- |
| SubmitFormRequest | The top-level container element | 1..1 | Required | xs:any |
| form\_data | The xml element that contains the form data | 1..1 | Required | xs:any |
| @form\_name | Name of the form | 0..1 | May | Of type String |
| @form\_design\_identifier | Identifier for the form design | 1..1 | Required | Of type String |
| @form\_representation\_identifier | Identifier for the representation or modality of the form design | 1..1 | Required | Of type String |
| 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 | Of type String |
| @parent\_identifier | Identifier of the parent element, this may be a section, question or list\_itemquestion | 0..1 | May | Of type String |
| @question\_prompt | Question text as it appears in the form | 1..1 | Required | Of type 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 | Required | Of type String |
| @question\_identifier | Unique identifier for the question | 1..1 | Required | Of type String |
| @data\_element\_scoped\_identifier | Identifier for an SDC the data element | 0..1 | May | Complex type representing a globally unique SDC data element |
| @datatype | The datatype of the response | 1..1 | Required | Datatype |
| @unit\_of\_measure | Value indicating the unit of measure | 0..1 | May | Of type String |
| @pattern | The datatype pattern, e.g. HHMM | 0..1 | May | Of type String |
| Response | The response to the question | 1..\* | Required | Of type String |
| @item\_prompt | The prompt for the list item | 1..1 | Required | Of type String |
| @list\_item\_identifier | The unique identifier for the list item | 1..1 | Required | Of type String |
| @value\_meaning\_standard \_code | The standard code for the list item when based on a value set | 0..1 | May | Of type Sting |
| @value meaning\_standard code\_system\_identifier | Includes the standard code system and version number | 0..1 | May | Of type String |
| fill-in | The response for a list field fill-in e.g. “Specify” or “Other” | 0..\* | May | Of type String |

* For Transaction 2, the <SubmitFormRequest> element **SHALL** contain one <form\_data> element.

## SDC Data Elements (DEs), DE Attributes and DE Repositories

### Overview

Meaningful data exchange and use between information systems requires robust definition and consistent use of data elements. A data element is a unit of data for which the definition, identification, representation, and permissible values are specified by a set of attributes. For example, “Patient Date of Birth” is a data element, which contains information about patient’s birth date. The value supplied for this data element is usually a date specific to year, month and day (e.g. 1970-07-22).

Data elements that are developed, maintained and used based on *commonly* agreed-upon principles by a user community are called *common data elements* (CDEs). A characteristic of CDEs is their *reusability* in a variety of studies, which supports *consistent* aggregation and analysis of data *across* clinical research studies and potentially other domains. As stated by ISO “One of the prerequisites for a correct and proper use and interpretation of data is that both users and owners of data have a common understanding of the meaning and descriptive characteristics (e.g., representation) of that data. To guarantee this shared view, a number of basic DE *attributes* or DE *metadata* need to be defined”[[17]](#footnote-1). Some questions that DE attributes (DE metadata) address are:

* Who owns the DE? (e.g. DE authors and stewards);
* What is the meaning of the DE? (e.g. clinical, administrative, demographics);
* How is the DE named and identified? (e.g. DE name, identifier, version);
* How current is the DE? (e.g. DE creation date, last change date, effective start date, effective end date);
* How is the DE value represented? (e.g. free text, vocabulary codes, numeric value).

Data elements and data element attributes are stored within repositories (or registries), which are databases maintained by various organizations. For example, the cancer Data Standards Repository (caDSR) is maintained by National Cancer Institute and used to store and exchange common data elements used in clinical trials. Several stakeholders such as NIH centers, CDISC and academic organizations deposit and manage data elements for clinical trials within caDSR. Similarly, the United States Health Information Knowledgebase (USHIK) is an on-line, publicly accessible repository of healthcare related data and metadata that provides support to a variety of users involved in measurement of clinical quality of care, and patient safety and public health reporting. Repositories that intend to ensure consistent representation and reuse of data elements across settings need to agree on a common set of characteristics that will be used to define, manage and share data elements both *within* and *across* repositories.

### Existing standards and repositories

SDC initiative performed environmental scan and reviewed existing repositories that define and maintain data elements and value sets, such as caDSR, FHIR, VSAC, USHIK, PHIN VADS, and others. The purpose of this environmental scan was to gain an understanding of commonalities and differences in how CDEs and CDE attributes are defined and used in various organizations; the analysis revealed that there are areas of both similarities and differences across entities. Specifically, the analysis showed that critical DE attributes such as Conceptual Domain, Value Domain, Value Set and Code System do not have equivalent meaning and use across repositories and exchange protocols such as caDSR (NCI), VSAC (NLM) and FHIR (HL7). SDC initiative intends to align definitions and use of CDE attributes across repositories by proposing *common* attribute syntax.

Rather than creating new sets of attributes for CDEs, SDC initiative examined following resources for metadata definition:

* ISO/IEC 11179 — Part 3, “Registry metamodel and basic attributes” is a metadata standard for defining representation of data elements, as well as underlying repository responsibilities and functions[[18]](#footnote-2). The standard is mostly used in public sector by US government agencies such as National Cancer Institute (caDSR) and US Environmental Protection Agency, and by some international statistics organizations.
* IHE Data Element Exchange (DEX) profile is a trial implementation profile for healthcare domain, developed by Integrating the Healthcare Enterprise that is based on ISO/IEC 11179 standard, which provides guidance on how elements on a form can be mapped to data sources[[19]](#footnote-3). IHE DEX profile defines an array of attributes specific to data elements, value domain, value sets, coding systems, content and mapping specification.

While ISO/IEC 11179-3 provides a *framework* for defining and associating attributes within a repository, the DEX provides an example of explicit *data element exchange* implementation of the standard in a health context. In other words, while ISO/IEC 11179-3 is designed to describe the metadata for data elements, and by design is generic, IHE DEX is explicitly focused on *data exchanged* in health contexts, and thus useful in describing how data is exchanged for SDC forms. SDC initiative’s core objective is to provide explicit guidance on how data elements should be consistently defined and used on SDC forms, in concert with certified electronic health records. SDC leverages IHE DEX attributes for data exchange since it defines attributes that are more directly related to the SDC initiative, while still based upon the ISO/IEC 11179-3 standard.

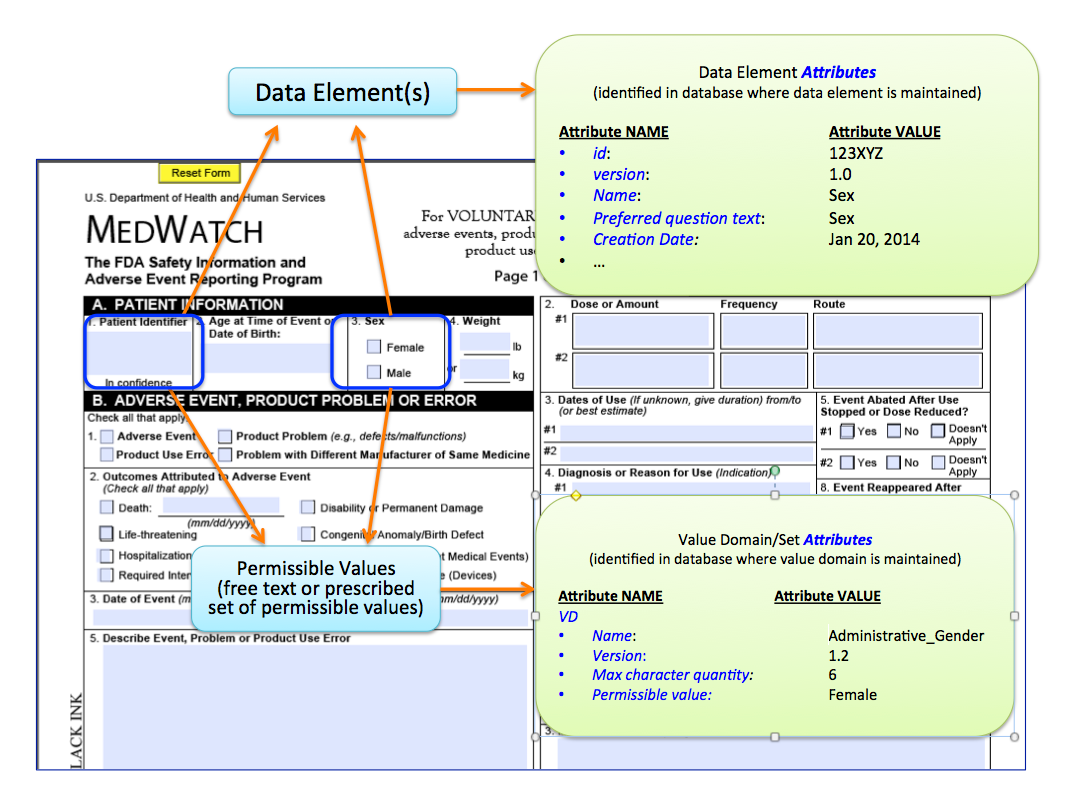
To ensure alignment between IHE DEX attributes and SDC attributes, the proposed SDC attributes list within this Implementation Guide provides direct maps to those attributes defined in IHE DEX profile. The proposed list of attributes within this Implementation Guide will be evaluated in the SDC pilot phase and, based on pilot activity, modifications to the attribute list may be identified.

### Data Elements *Attributes* (Metadata)

This implementation guide does not define specific data elements for proposed common use, but rather provides a set of attributes (aka. metadata) that support the *definition* and *use of CDEs on SDC forms*. For example, SDC Initiative does not define explicit CDEs such as “Patient Date of Birth” or “Patient ID” but rather identifies the DE *attributes* or *metadata* that *describe* these CDEs such as data element *name, id, version,* *Creation Date, Effective Date, Steward Organization Name*,etc.

The following graphic explains the difference between data elements and data element attributes using FDA MedWatch form. The MedWatch form is used by healthcare professionals to report to the FDA adverse events associated with the use of specific drug, medical device or other medical products. The form contains data elements that capture information about adverse events such as *Patient Identifier, Date of Birth, Sex, Weight, Product Name, Manufacturer, etc.*

Figure : Data Elements vs Data Element Attributes

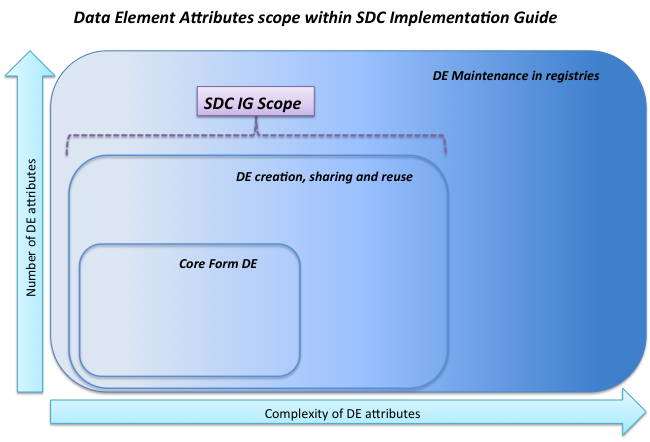


Within SDC initiative, data element attributes are conceptually grouped in three categories based on the extent to which they define SDC areas of interest:

* Core attributes required for SDC forms;
* Attributes required to create, share and reuse DEs;
* Attributes required to maintain DEs in registries.

The scope of this SDC Implementation guide is to define a *minimum* set of attributes required to create a DE and to describe a DE on SDC forms. These minimum sets of attributes will be tested and validated during the SDC pilot stage and may be further refined based on pilot outcomes.

Figure : Scope of SDC Data Element Attributes



### Assumptions about data sources and permissible values

SDC initiative envisions that forms will be populated by data sources originating from EHRs. The assumption is that such EHRs are certified for Meaningful Use and are therefore required to use specific codesets and vocabularies. The SDC Form model will support the design of forms that use their own lists of values.

For example, the MedWatch form in the graphic shown above lists Female and Male as permissible values for the Data Element “Sex.” However, Meaningful Use certified EHRs are required to use codes from *Administrative Gender (HL7 V3)* value set (OID: 2.16.840.1.113883.1.11.1) with codes M, F and U. A MedWatch form filler will therefore need to map EHR source values M and F to permissible values Male and Female on the form in order to accurately retrieve and populate the form. It should also be noted that the MedWatch form permits only two values (Male and Female), whereas Meaningful Use permits three codes (M, F, U).

The assumption is that SDC forms will be based on SDC Data Element, rather than defining questions and answer lists within the form, as in the MedWatch example. However, in the clinical domain, Meaningful Use harmonized this approach by adopting *one specific set* of permissible values that are required to be used for exchange of clinical data across the healthcare universe: M and F. This harmonization *minimizes variability* in representation of data and *facilitates semantic interoperability* and use of clinical data since transcoding is not required. (Note that each EHR *may* internally choose to define local codes for male and female, but if such data is sent to an EHR at another hospital, then Meaningful Use required codes need to be used.)

The goal of semantic data exchange is most readily achieved once there is a *single, universally adopted* coding system for representing a value (such as administrative gender) that does not require translation and mapping.

#### SDC Attributes used for creation, sharing and reuse of DE

Appendix D provides a list of attributes for data elements intended for use in creating SDC forms and in SDC data exchange. The purpose of identifying a set of minimum data element attributes is two-fold:

* Support search/retrieval/discovery across extant repositories, potentially even non- ISO/IEC 11179 repositories;
* Advise holders of paper forms who are NOT affiliated with an existing repository on the minimum information needed to define their data elements, so that they can be ingested in a repository, reviewed for “uniqueness” relative to extant DEs and incorporated into working forms definitions.

The attributes are organized into following groups:

* + Identifying and Definitional Attributes: identify and define the data element (leveraged from ISO/IEC 11179-3);
  + Representational Attributes: specify the set of representation values such as value sets and value domain (leveraged from ISO/IEC 11179-3);
  + Mapping Attributes: map data elements to data elements and sources of data within EHR (leveraged from ISO/IEC 19763-13 and IHE DEX profile).

The SDC attributes align attributes already recorded by major repositories, at least in intent. The list identifies key attributes that address content and representation. SDC pilots and continued activities may expand this list to include additional attributes that facilitate management of data elements in a registry. The structure of SDC attributes is further explained in Appendix D.

#### Core DE attributes required for SDC forms

When a Question is mapped to a Data Element in the *MDR Mapping Package*, specific attributes of the data element are expected to be the basis for attributes in the Question. These attributes are:

Table : DE Attributes used in Questions

|  |  |
| --- | --- |
| **Data Element Attribute** | **Question Attribute** |
| Data Element | Question |
| Preferred Text Reference Document, or Alternate Text Reference Document | Question Prompt |
| Value Domain | Response |
| Datatype (mandatory) | Datatype (Mandatory) |
| Format (optional) | Datatype/../Pattern (optional) |
| maximum character quantity (optional) | maximum character quantity (optional) |
| unit of measure (optional) | unit of measure (optional) |
| Permissible Value (optional) | List Item (optional) |
| Permitted Value (this could be a standard code) | Value |
| Value Meaning/Value Set Member preferred name | Item Prompt |
| Value Meaning/Value Set member description or definition | Value Meaning |
| Value set member code | Value Meaning/Value set member code, |
| Value Set member code system name | Value Set member code system name |
| Value Set member code system id (OID) | Value Set member code system id (OID) |
| Value Set member code system Version | Value Set member code system Version |
| Described Value Domain Reference | Lookup Field |
| Value Set URI | Endpoint URI |

* + - 1. **Mapping Questions to Data Element on Forms**

Linking SDC forms questions and ISO/IEC 11179 data elements is achieved through the ISO/IEC 19763-13 MDR\_Mapping class, expressed in the Mapping Package (see Forms Section).

The MDR\_Mapping class is a Documentation element, not a Form Design element. In other words, a Question on a form must have all of its attributes specified in the form design as either a user-entered value, a choice from a list, or as a "Lookup Field" in which case the URL or URI for the lookup list must be incorporated into the Question design. It is expected that these data element will meet meaningful use criteria, and if enumerated, will be based on standardized value sets. The Lookup Fields are anticipated to point to well defined coding systems or subsets of them.

Mapping association for SDC purposes is constrained to “Implements.”

* When the mapping association between a question and data element is “Implements,” this indicates that the creator of the mapping has asserted that the question has been faithfully created from the specified MDR element without change), meaning that the question text, the list of items if enumerated, should be an exact match of the data element. A data element that is based on an externally defined code set, instead of an explicit enumeration, would correlate to a “Lookup Field.” Lookup fields are useful when the response may come from a dynamic list of values that are permitted to changes over time, such as standard codes for a diagnosis. For example, the data element instructs that the response is to be captured using codes from a particular part of ICD-10, specified by a rule or pointed to a node in the ICD-10 hierarchy, and allows any code that is a valid child.
* The form designer is responsible for assuring that the mapping is correct. For example, if the answer list is further constrained, the form designer has to specify the constrained answer list accordingly.

### Future of SDC attributes

SDC initiative scope is to define basic attributes required to create data elements and include them in SDC forms. At the time of writing this IG, the ownership, structure, characteristics and business rules of repositories that will host data elements were unknown. In the future, the list of attributes may be further refined and expanded based on input from community members and based on characteristics of repositories that will host data elements. Specifically, attributes that address data elements *maintenance* and *governance* may be newly defined to satisfy operational needs of repositories.

## Structure and Overview of MFI Form Model Definition

* + 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. Having described representation of data elements, 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.

This Implementation Guide recommends the SDC form be 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 approach to sharing form designs is through electronic transactions between a forms repository and an EHR or other data collection system. This is described in detail by the Transaction 1A and Transaction 1B Requests outlined in Sections 2.3.2.1.1 and 2.3.2.2.1 respectively.

The SDC Initiative recommends using SDC Forms or pre-specified SDC Form Sections to represent standardized patient assessment instruments and community-specified panels (such as blood pressure, Glasgow Coma Score and quality of life assessment), which contain multiple data elements and specific wording, question order and rules. It is anticipated that through the SDC pilots and implementation, the available options for representing such complex data will be enhanced and strengthened and best practices for how to represent these complex sets of questions will emerge.

* + 1. **SDC Form Definition**

SDC forms are based on MFI-13, but are specialized for use in healthcare in the choice of data elements and form design. All identifiers in this guide are a composite of the registration organization identifier, the item identifier (form, section, question, etc.) and the version.

* The SDC form **SHALL** be represented as a root form\_package element which **SHALL** be the root element of the form definition file.
* The SDC form\_package element SHALL have an attribute of a form\_design\_identifier.

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.

More information about data types listed in the Comments column of any of the tables can be found in Appendix E or the Glossary.

### Mapping Package

#### Overview

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, as long as the specification includes the attributes needed for the SDC form as specified in Table 9: DE Attributes used in Questions. 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.

#### Package Details

The Mapping package contains information about the mapping of questions on the ISO/IEC 19763-13 compliant SDC form to ISO/IEC 11179-3 data elements or similar data element specification.

Table : Mapping Package

| Name | Relative Location | Card | Comments |
| --- | --- | --- | --- |
| Mapping Package | /SDCForm:form\_package/mapping\_package | 1..1 |  |
| @ Mapping Package ID | @mapping\_package\_identifier | 1..1 | Of type String |
| @Form Design ID | @form\_design\_identifier | 1..1 | Of type String |
| MDR Mapping | /MDR\_Mapping | 0..1 |  |
| @MDR Mapping ID | @mdr\_mapping\_identifier | 1..1 | Of type String |
| Question to Data Element Association | /question\_element\_data\_element\_association | 0..N |  |
| Data Element Scoped ID | /data\_element\_scoped\_identifier | 1..1 | Of type String |
| Question Element ID | /question\_element\_identifier | 1..1 | Of type String |
| Association type | /association\_type | 1..1 | Of type String |
| DEX Mapping specification | /dex\_mapping\_specification | 0..1 |  |
| Content Model | /content Model | 1..1 |  |
| Id | /id | 1..1 | Of type String |
| Name | /name | 1..1 | Of type String |
| Type | /Type | 1..1 | Of type String |
| Mapping Script | /mappingScript | 1..1 | Of type String |
| Contact | /contact | 0..N | Of type [Contact](#_Contact_1) |

* Each *Mapping Package* **MAY** have zero or one *MDR Mapping* which is an enumeration of instances describing the association between questions on the form and compliant metadata registry data elements (or similar specification) or content models in EHR systems where the data can be found.
  + Each *MDR Mapping* **MAY** have one or more *question to data element associations. Question to data element associations* can map a question element to a data element in a metadata registry.
    - Each question to data element association **SHALL** have exactly one data element scoped ID. The data element ID is the unique identifier of a specific registered data element mapped to a specific question element in this form design.
    - Each question to data element association **SHALL** have exactly one *association type*, which is a category describing the association. For SDC the *association type* **SHALL** be restricted to have value *same\_as*. It implies that the metadata is used exactly as described in the CDE.
    - Each *question to data element association* **SHALL** have exactly one *question element ID* uniquely identifying the question element that maps to a data element through this instance of the *question to data element association*.
    - Each *question to data element association* **MAY** have one or more *DEX mapping specification.* *DEX mapping specification* is used to indicate 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.
    - Each *DEX mapping specification* **SHALL** have exactly one *content model. 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.
      * Each *Content Model* **SHALL** have exactly one *ID. ID* is the unique identification for this standard.
      * Each *Content Model* **SHALL** have exactly one *name. Name* is the name of the content model
    - Each *DEX mapping specification* **SHALL** have exactly one *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.
    - Each *DEX mapping specification* **SHALL** have exactly one *mapping script* which 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.
  + Each *question to data element association* **MAY** have zero or more *Contact. Contact* contains information regarding whom to contact for more information about the DEX Mapping Specification. The Contact **SHALL** be structured as described in [#](#_2.5.2.1.3__Contact) 2.5.3.2.1.

Figure : Example of Mapping Package (condensed)



##### Contact

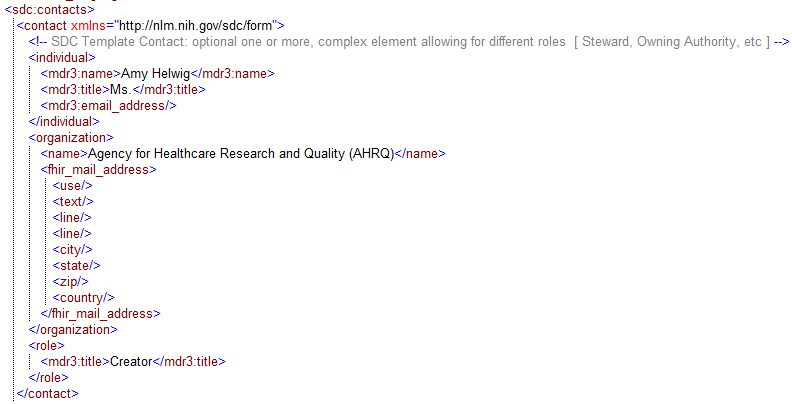
A contact element provides information regarding a person or organization that can be contacted for additional information. Contact specifies a role, and or individual within an organization to whom information items, material objects, or person(s) can be sent to or from.

Table : Contact

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Comments |
| Contact | /contact | 0..N |  |
| Individual | / individual | 0..1 | Of type [Individual](#_Individual) |
| Organization | / organization | 1..1 | Of type [Organization](#_1._Organization) |
| Role | / role | 0..1 | Of type [Role](#_Role) |

* Each *Contact* **MAY** contain zero or one *Individual*. *Individual* contains contact information of an individual. The *Individual* element **SHALL** be of ISO data type *Individual,* which is described in Appendix E.
* Each *Contact* **SHALL** contain exactly one *Organization. Organization* contains contact information of an organization. The *Organization* **SHALL** be of ISO data type *Organization,* which is described in Appendix E.
* Each *Contact* **MAY** contain zero or one *Role*. *Role* contains information regarding the specified responsibilities of the individual listed to contact. The *Role* **SHALL** be of ISO data type *Role,* which is described in Appendix E.

Figure : Example of Contact



### Administrative Package

#### Package Overview

The Administrative Segment includes details about the registry from which the form design was retrieved, contact information, classifications, languages used, and style information.

#### Package Details

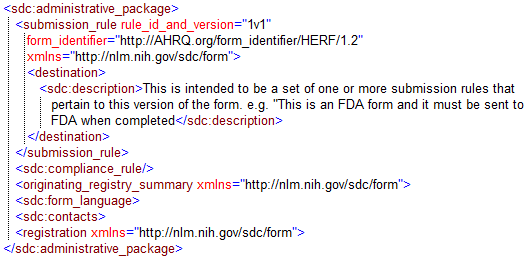
The Administrative Segment contains multiple elements that provide information such as provenance, source etc. for the form.

Table Administrative Package

| Name | Relative Location | Card | Comment |
| --- | --- | --- | --- |
| Administrative Package | **/SDCForm:form\_package/administrative\_package** | 1..1 |  |
| Submission Rule | /submission\_rule | 1..N |  |
| @Form ID | @form\_ identifier | 1..1 | Of type String |
| @Rule IDand Version | @rule\_id\_and\_version | 0..N | Of type String |
| Destination | /destination | 0..N |  |
| Endpoint | /endpoint | 0..N | Of type anyURI |
| Description | /description | 0..1 | Of type String |
| Organization | /organization | 0..1 | Of type [Organization](#_1._Organization) |
| Compliance Rule | /compliance\_rule | 1..N |  |
| Expression | /expression | 0..N | Of type String |
| Origin Summary | /originating\_registry\_summary | 1..1 |  |
| Form language | /form\_language | 1..1 | Of type [Form Language](#_Form_Language) |
| Contact information | /contacts | 0..N | Of type [Contact](#_Contact) |
| Registration information | /registration | 0..1 | Of type [Administered Item](#_Administered_Item) |

* Each *Administrative package* **SHALL** have exactly one *submission rule. Submission rule* contains information about where to submit a completed form.
  + Each *submission rule* **SHALL** have exactly one *destination. Destination* iswhere the form should be sent.
    - Each destination **MAY** have zero or more *endpoints*. *Endpoint* is where the form will be submitted.
    - Each destination **MAY** have zero or one *description*. *Description* describes the destination.
    - Each destination **MAY** have zero or one *organization*. *Organization* is the organization responsible for the endpoint of the form. The Organization element **SHALL** be of ISO data type Organization, which is described in Appendix E.
* Each *Administrative package* **SHALL** have exactly one *Compliance rule. Compliance rule* describes a design aspect that must be specified for an instance of Form Design to be considered a valid instance of a Form Template.
  + Each *Compliance rule* **SHALL** have exactly one *Expression. Expression* describes what a compliance rule is.
* Each *Administrative package* **SHALL** contain exactly one *Origin Summary. Origin Summary* captures details regarding the origin of the form. The Origin Summary **SHALL** be structured as described in [#2.5.2.1.1 Origin Summary](#_2.5.2.1.1__Origin).
* Each *Administrative package* **SHALL** contain exactly one *Form Language. Form Language* describes style, logic, format and textual aspects of the language for the form. The *Form Language* **SHALL** be structured as described in [#2.5.2.2 Form Language](#_2.5.2.1.2__Form).
* Each Administrative package **MAY** contain zero or more *Contact information. Contact information* isfor an individual, organization, and or role that may be contacted if the user needs more information. The Contact **SHALL** be structured as described in [#2.5.2.3 Contact](#_2.5.2.1.3__Contact).
* Each Administrative package **MAY** contain zero or one *Registration information. Registration information* includes information regarding the state, record, references and stewardship of the form. The Registration Information **SHALL** be structured as described in [#2.5.2.4 Registration](#_2.5.2.1.4__Registration).

Figure : Example of Administrative Package



##### Origin Summary

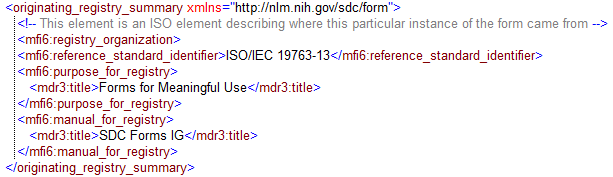
The *Administrative* Segmentcontains exactly one *Origin Summary*. The *Origin Summary* documents the registry to which this form has been registered. The summary may refer to an individual registry system or an aggregate of registry systems.

Table 11: Origin Summary

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Comments |
| Origin Summary | /administrative\_package/originating\_registry\_summary | 1..1 |  |
| Registry Organization | /registry\_organization | 1..1 | Of type [Organization](#_1._Organization) |
| Reference Standard ID | /reference\_standard\_identifier | 1..1 | Of type String |
| SLA for registry | /SLA\_for\_registry | 0..1 | Of type [Reference Document](#_Reference_Document) |
| Purpose for registry | /purpose\_for\_registry | 0..1 | Of type [Reference Document](#_Reference_Document) |
| Manual for registry | /manual\_for\_registry | 0..1 | Of type [Reference Document](#_Reference_Document) |
| Specification | /specification\_for\_interface | 0..1 | Of type [Interface](#_Interface) |

* Each *Origin Summary* **SHALL** contain exactly one *Registry Organization*. *Registry Organization* has details about the organization to which the form is registered. The Registry Organization **SHALL** be structured as ISO Attribute Organization which is described in Appendix E.
* Each Origin Summary **SHALL** contain exactly one *Reference Standard ID. Reference Standard ID* identifies the reference standard.
* Each Origin Summary **MAY** contain zero or one *Service Level Agreement (SLA)* *for registry. SLA for registry* identifies the SLA for the registry. The SLA for registry **SHALL** be structured as ISO Attribute Reference Document which is described in Appendix E.
* Each Origin Summary **MAY** contain zero or one *Purpose for registry. Purpose for registry* describes the purpose for the registry. The Purpose for registry **SHALL** be structured as ISO Attribute Reference Document which is described in Appendix E.
* Each Origin Summary **MAY** contain zero or one *Manual for registry. Manual for registry* describes the manual for the registry. The *Manual for registry* **SHALL** be structured as ISO Attribute Reference Document which is described in Appendix E.
* Each *Origin Summary* **MAY** contain zero or one *Specification for Interface. Specification for Interface* identifies the interface of the form. *The Specification for Interface* **SHALL** be structured as ISO Attribute *Interface* which is described in Appendix E.

Figure : Example of Origin Summary



##### Form Language

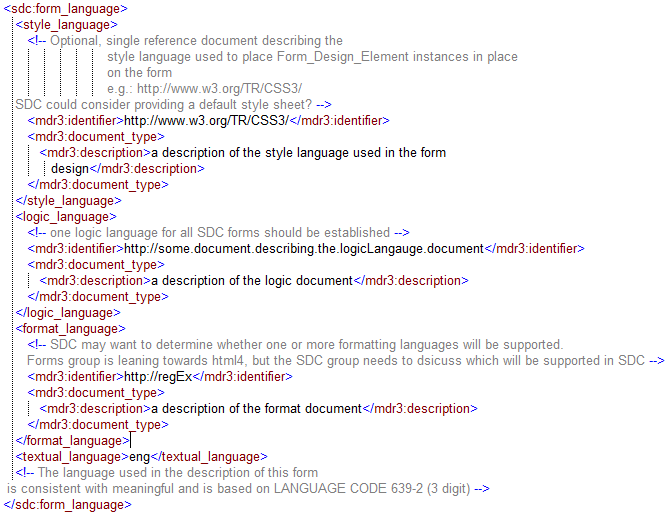
The *Administrative Segment*contains exactly one *form language*. Form language represents the selection of languages used to express style, logic, format and textual aspects of the form design.

Table 12: Form Language

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Comments |
| Form Language | /administrative\_package /form\_language | 1..1 |  |
| @identifier | @identifier |  | Of type [Identifier](#_Identifier) |
| Designatable Item | /designation | 0..N | Of type [Designatable Item](#_Designatable_Item) |
| Style Language | /style\_language | 0..1 | Of type [Reference Document](#_Reference_Document) |
| Logic Language | /logic\_language | 0..1 | Of type [Reference Document](#_Reference_Document) |
| Format Language | /format\_language | 0..1 | Of type [Reference Document](#_Reference_Document) |
| Textual Language | /textual\_language | 0..1 | Of type String |

* Each *Form Language* **MAY** contain zero or more *Designatable Items. Designatable Items* allow a metadata registry to support the association of a designation or definition for the specified Designatable Item*. Designatable Item* **SHALL** be structured as ISO Attribute *Designatable Item* which is described in Appendix E.
* Each *Form Language* **MAY** contain zero or more *Style Language*. *Style Language* describes the style language used to place Form Design Element instances in place on the form. *Style Language* **SHALL** be structured as ISO Attribute *Reference Document* which is described in Appendix E.
* Each *Form Language* **MAY** contain zero or more *Logic Language*. *Logic Language* is used to describe semantic dependencies between instances of Form Design. *Logic Language* **SHALL** be structured as ISO Attribute *Reference Document* which is described in Appendix E.
* Each *Form Language* **MAY** contain zero or more *Format Language*. *Format Language* describes the regular expression language used. *Format Language* **SHALL** be structured as ISO Attribute *Reference Document* which is described in Appendix E.
* Each *Form Language* **MAY** contain zero or more *Textual Language*. *Textual Language* specifies the primary native human language used. *Textual Language* **SHALL** be of ISO data type *Reference Document* which is described in Appendix E.

Figure : Example of Form Language



##### Registration

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

Table : Registration

| Name | Relative Location | Card | Comments |
| --- | --- | --- | --- |
| Registration | /administrative\_package /registration |  |  |
| State | /state | 0..1 | Of type [State](#_State) |
| Submission record | /submission\_record | 0..1 |  |
| Organization | /organization | 1..1 | Of type [Organization](#_1._Organization) |
| Contact | /contact | 0..1 | Of type [Contact](#_Contact) |
| Document reference | /document\_reference | 0..N | Of type [Reference Document](#_Reference_Document) |
| Organization | /organization | 0..1 | Of type [Organization](#_1._Organization) |
| Registration status date | /registration\_status\_date | 0..1 | Of type Datetime |
| Stewardship record | /stewardship\_record | 1..N |  |
| Organization | /organization | 0..1 | Of type [Organization](#_1._Organization) |
| Contact | /contact | 0..1 | Of type [Contact](#_Contact) |
| Creation date | /creation\_date | 1..1 | Of type [Datetime](#_Datetime) |
| Last change date | /last\_change\_date | 0..1 | Of type [Datetime](#_Datetime) |
| Change description | /change\_description | 0..1 | Of type Text |
| Explanatory comment | /explanatory\_comment | 0..1 | Of type Text |
| Origin | /origin | 0..1 | Of type Text |

* Each *registration* **MAY** contain zero or one *state. State* describes the timeline of the form, including the range in which it may be used. The *state* **SHALL** be structured as ISO Attribute *state,* which is described in Appendix E.
* Each *registration* **MAY** contain zero or one *submission record.* S*ubmission record* contains information regarding an individual or organization to contact for submission purposes. The *submission record* **SHALL** be structured as ISO Attribute *Submission Record,* which is described in Appendix E.
* Each *registration* **MAY** contain zero or one *document reference. Document reference* describes any document referenced by the form. The *document reference* **SHALL** be structured as ISO Attribute Reference document*,* which is described in Appendix E.
* Each *registration* **MAY** contain zero or one *organization. Organization* describes the organizationwhere the form is registered. The *organization* **SHALL** be structured as ISO Attribute Organization*,* which is described in Appendix E.
* Each *registration* **MAY** contain zero or one *registration status date. Registration status date* is the date the registration status was updated. The *registration status date* **SHALL** be structured as ISO Attribute Datetime*,* which is described in Appendix E.
* Each *registration* **SHALL** contain one or more *stewardship records. Stewardship record* is the record of stewards for the form, providing information about the organization and contact.
  + Each *stewardship record* **SHALL** contain one or more *Organization. Organization* contains details regarding the Organization that is the steward of the form. The *Organization* **SHALL** be structured as ISO Attribute Organization*,* which is described in Appendix E.
  + Each *stewardship record* **SHALL** contain one or more *Contact. Contact* describing the Contact that may be contacted regarding stewardship. The *Contact* **SHALL** be structured as [#2.5.2.3 Contact](#_2.5.2.1.3__Contact).
* Each *registration* **SHALL** contain exactly one *creation date. Creation Date* which is the date the registration element was created. The *creation date* element **SHALL** be structured as ISO Attribute Datetime*,* which is described in Appendix E.
* Each *registration* **MAY** contain zero or one *last change date. Last change date* is the date the registration element was last changed. The *last change date* element **SHALL** be structured as ISO Attribute Datetime*,* which is described in Appendix E.
* Each *registration* **MAY** contain zero or one *change description. Change description* describes what has changed since the prior version of the registration element.
* Each *registration* **MAY** contain zero or one *explanatory comment. Explanatory comment* contains descriptive comments about the registration element.
* Each *registration* **MAY** contain zero or one *origin.* O*rigin* describes the source for the registration element.

Figure : Example of Registration (condensed)



### Stylesheet

The *Stylesheet indicates* specifications about the form including transformations and/or regarding colors, font, white space, indentation etc. Stylesheet element allows a form creator/designer to specify a stylesheet used to render the form design in a browser. SDC will provide a default stylesheet for most cases. Examples of types of stylesheets that may be included are Extensible Stylesheet Language Transformation (XSLT) and Cascading Style Sheet (CSS). XSLT is a language used most often to transform between XML documents or from one representation to another, such as XML to HTML or CSV (text); Cascading Style Sheet (CSS) is a language used to describe the look and formatting of a web document written in a markup language such as HTML or XHTML.

### Form Design

#### Overview

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.

#### Details

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 : Form Design

| Name | Relative Location | Card | Comment |
| --- | --- | --- | --- |
| Form Design | /SDCForm:form\_package/form\_design |  |  |
| @ID | @form\_design\_identifier | 1..1 | Of type anyURI |
| Designation | /designation | 1..N | Of type [Designation](#_Designation) |
| Classifier | /classifier | 0..N | Of type [Designatable Item](#_Designatable_Item) |
| Media | /media | 0..N | Of type [Media](#_Media) |
| Security and Privacy | /security\_and\_privacy | 0..N | Of type String |
| Header | /header | 0..1 | Of type [Section](#_Section) |
| Section | /section | 0..N | Of type [Section](#_Section) |
| Footer | /footer | 0..1 | Of type [Section](#_Section) |

* Each *Form Design* **SHALL** contain one or more *designation. Designation* allows the form designer to designate a name for the form*. The designation* **SHALL** be structured as ISO Attribute designation.
* Each *Form Design* **SHALL** contain zero or one *classifier. Classifier* refers to a classification scheme*. The classifier***SHALL** be structured as ISO Attribute Designatable item.
* Each *Form Design* **SHALL** contain one or more *media. Media* refers to elements, such as audio, image or video that may be used in the section. *The Media* element **SHALL** be structured as described in [#2.5.3.4.2 Media](#_2.5.2.4.2__Media).
* Each *Form Design* **SHALL** contain one or more *security and privacy. Security and privacy* specifies security and privacy rulesrelated to the form design.
* Each *Form Design* **SHALL** contain zero or one *header. Header* provides text and questions displayed at the beginning of the form*.* The header **SHALL** be structured as Section described in #[2.5.3.4.3](#_2.5.2.4.3__Section) Section.
* Each *Form Design* **SHALL** contain zero or more *section*. *Section* defines the structure of a section in the form*. The section* **SHALL** be structured as described in #[2.5.3.4.3](#_2.5.2.4.3__Section) Section.
* Each *Form Design* **SHALL** contain zero or one *footers. Footer* defines the structure of a footer on the form*. The footer* **SHALL** be structured as described in #2.5.3.4.4 Section.

Figure : Example of form Design (condensed)



##### Media

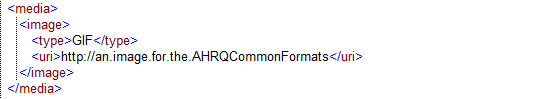
Media represents an instance of an image, audio or video element within a Form.

Table : Media

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

* The *Media Element* **SHALL** have an *Initial state* attribute and is an extension of MFI-13. *Initial State* is used across the SDC form package to indicate the initial behavior of an element. Its enumeration value may be set to *enabled*, which means that the element should be available for use. Alternatively, if its enumeration value is set to *disabled*, it means that the element should be unavailable for use.
* Each *Media Element* **MAY** have zero or one *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.
  + Each *Cardinality* element **MAY** have a *minimum. Minimum* sets the minimum number of times the media element may be repeated.
  + Each *Cardinality* element **MAY** have a *maximum. Maximum* sets the maximum number of times the media element may be repeated.
* Each *Media Element* **MAY** have zero or more *rules. Rules* describe functional dependencies and constraints upon data entry relevant to the semantics of the completed form.
  + Each *rule* **SHALL** have one or more *expression* elementsdescribing the rule.
* Each *Media Element* **MAY** have one or more *Audio* elements. The Audio elements **SHALL** beselected from SDC list of valid audio types. ISO base media file formats include: [MP4](http://en.wikipedia.org/wiki/MP4), [3GP](http://en.wikipedia.org/wiki/3GP), 3G2, [.mj2](http://en.wikipedia.org/wiki/JPEG_2000#Motion_JPEG_2000), .dvb, .dcf, .m21. The SDC list of valid audio types will be determined during the pilots stage.
  + Each *Audio element* **SHALL** have exactly one *uri.* The *uri* isthe web location where the audio element may be retrieved.
* Each *Media Element* **MAY** have one or more *Image* elements. The Image element **SHALL** beselected from SDC list of valid image types. ISO base media file formats include: [MP4](http://en.wikipedia.org/wiki/MP4), [3GP](http://en.wikipedia.org/wiki/3GP), 3G2, [.mj2](http://en.wikipedia.org/wiki/JPEG_2000#Motion_JPEG_2000), .dvb, .dcf, .m21. The SDC list of valid image types will be determined during the pilot stage.
  + Each *Image element* **SHALL** have exactly one *uri.* The *uri* is the web location where the image element may be retrieved.
* Each *Media Element* **MAY** have one or more *Video* elements. The *Video* element **SHALL** beselected from SDC list of valid video types. ISO base media file formats include: [MP4](http://en.wikipedia.org/wiki/MP4), [3GP](http://en.wikipedia.org/wiki/3GP), 3G2, [.mj2](http://en.wikipedia.org/wiki/JPEG_2000#Motion_JPEG_2000), .dvb, .dcf, .m21. The SDC list of valid video types will be determined during the pilot stage.
  + Each *Video element* **SHALL** have exactly one *uri.* The *uri* is the web location where the video element may be retrieved.

Figure : Example of Media



##### Section

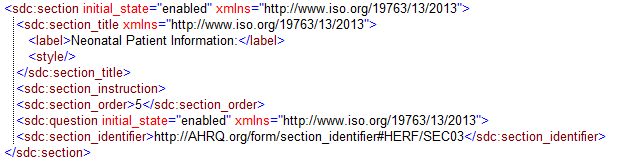
Sections are distinct parts of the form that groups questions for a similar purpose. The main elements of a section are instructions and questions.

Table : Section

| Name | Relative Location | Card | Comment |
| --- | --- | --- | --- |
| Section | /form\_design/Section\_Element | 0..N |  |
| @initial state | @initial\_state |  | Of type [Initial State](#_Initial_State-) |
| Cardinality | /cardinality | 0..1 |  |
| Minimum | /minimum | 1..1 | Of type Integer |
| Maximum | /maximum | 1..1 | Of type String |
| Rule | /rule | 0..N |  |
| Expression | /expression | 1..N | Of type String |
| Section Title | /section\_title | 0..1 | Of type [Prompt](#_Prompt) |
| Section Number | /section\_number | 0..1 | Of type [Number](#_Number) |
| Ordered | /ordered | 0..1 | Of type Boolean |
| Section Instruction | /section\_instruction | 0..N | Of type [Text Element](#_Text_Element) |
| Additional Instruction | /additional\_instruction | 0..N | Of type [Text Element](#_Text_Element) |
| Contained Section | /contained\_section | 0..N | Of type [Section](#_Section) |
| Section Order | /section\_order | 0..1 | Of type String |
| Media | /media | 0..N | Of type [Media](#_Media) |
| Question | /question | 0..N | Of type [Question](#_Question) |
| additional text | /additional\_text | 0..N | Of type [Text Element](#_Text_Element) |
| Next relevant element ID | /next\_relevant\_element | 0..1 | Of type [Identifier](#_Identifier) |
| Section ID | /section\_identifier | 0..1 | Of type [Identifier](#_Identifier) |

* The *Section* **SHALL** have an *Initial state* attribute and is an extension of MFI-13. *Initial State* is used across the SDC form package to indicate the initial behavior of an element. Its enumeration value may be set to *enabled*, which means that the element should be available for use. Alternatively, if its enumeration value is set to *disabled*, it means that the element should be unavailable for use.
* Each *Section* **MAY** have zero or one *Cardinality. Cardinality* defines the minimum and maximum number of times a form design element instance may be repeated by the creator of the form.
  + Each *Cardinality* element **MAY** have a *minimum. Minimum* sets the minimum number of times the media element may be repeated.
  + Each *Cardinality* element **MAY** have a *maximum. Maximum* sets the maximum number of times the media element may be repeated.
* Each *Section* **MAY** have zero or more *rules. Rules* describe functional dependencies and constraints upon data entry relevant to the semantics of the completed form.
  + Each *rule* **MAY** have one or more *expression*s. *Expressions* describe the rule.
* Each *Section* **MAY** have zero or one *section title. Section title* gives a title to the section.
* Each *Section* **MAY** have zero or one *section number. Section number* provides identification for the section.
* Each *Section* **MAY** have zero or one *ordered.* *Ordered* is a flag indicating if the order of child form design element instances is semantically important.
* Each *Section* **MAY** have zero or more *section instructions. Section instructions* provide directions for completing the section.
* Each *Section* **MAY** have zero or more *additional instructions. Additional instructions* provide additional instructions for completing the section.
* Each *Section* **MAY** have zero or more *contained sections. Contained sections* are sections defined within the section.
* Each *Section* **MAY** have zero or more *section order. Section order* describes the order of the sections relative to each other.
* Each *Section* **MAY** have zero or more *media.* Media represents an instance of an image, audio or video element within a Form. *The Media* **SHALL** be structured as described in [Section](#_2.5.2.4.2__Media) 2.5.6.2.1.
* Each *Section* **MAY** have zero or more *questions. Questions* are questions in the form. The *question* **SHALL** be structured as described in Section 2.5.6.2.3.
* Each *Section* **MAY** have zero or more *additional text. Additional text* contains additional text to be displayed within the section.
* Each *Section* **MAY** have zero or more *next relevant element ID. Next relevant element ID* identifies the next relevant element.
* Each *Section* **MAY** have zero or more *identifiers. Identifiers* uniquely identify the section. The *identifier* **SHALL** be structured as ISO Attribute identifier, which is described in Appendix E.

Figure : Example of Section



##### Question

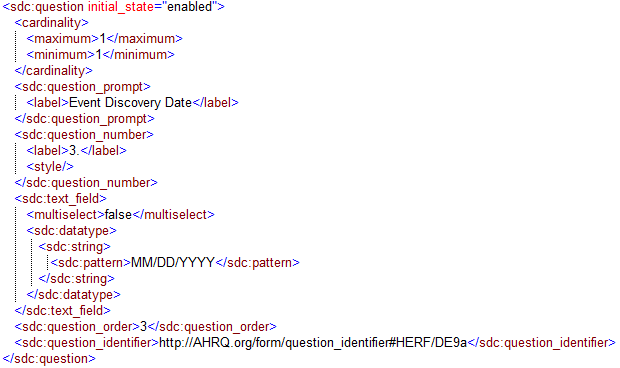
*Question*s make a request for information. The information is captured in a *response field.* There are 3 types of *response fields*, each with a set of applicable attributes and rules constraining the answer. These are: *List Field*, *Text Field*, and *Lookup Field.* The following table describes the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

Table : Question

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Comments |
| Question | /section/base\_question |  |  |
| @initial state | @initial\_state |  | Of type [Initial State](#_Initial_State) |
| Scoped Identifier | @data\_element\_scoped\_identifier | 0..1 | Of type identifier |
| Cardinality | /cardinality | 0..1 |  |
| Minimum | /minimum | 1..1 | Of type Integer |
| Maximum | /maximum | 1..1 | Of type String |
| Rule | /rule | 0..N |  |
| Expression | /expression | 1..N | Of type String |
| Question prompt | /question\_prompt | 0..1 | Of type [Prompt](#_Prompt) |
| Question number | /question\_number | 0..1 | Of type [Number](#_Number) |
| Question instruction | /question\_instruction | 0..1 | Of type [Text Element](#_Text_Element) |
| Additional instruction | /additional\_instruction | 0..N | Of type [Text Element](#_Text_Element) |
| Text\_field | /text\_field | 0..1 | Of type [Text Field](#_Text_Field) |
| List\_field | /list\_field | 0..1 | Of type [List Field](#_List_Field) |
| Lookup field | /lookup\_field | 0..1 | Of type [Lookup Field](#_Lookup_Field) |
| Text after question | /text\_after\_question | 0..1 | Of type [Text Element](#_Text_Element) |
| Question order | /question\_order | 0..1 | Of type String |
| Question ID | /question\_identitifier | 0..1 | Of type [Identifier](#_Identifier) |

* Each Question **MAY** have one *initial\_state*. Initial State determines whether or not the Question is enabled for data entry when the form is initially displayed.
* Each Question **MAY** have one *data\_element\_scoped\_identifier*. Data Element Scoped identifier uniquely identifies the data element that this Question is based on.
* Each *Question* **MAY** have zero or one *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:
  + Each *Cardinality* element **MAY** have a *minimum. Minimum* sets the minimum number of times the element may be repeated.
  + Each *Cardinality* element **MAY** have a *maximum. Maximum* sets the maximum number of times the element may be repeated.
* Each *Question* **MAY** have zero or more *rules. Rules* describe functional dependencies and constraints upon data entry relevant to the semantics of the completed form:
  + Each *rule* **MAY** have one or more *expression*s*. Expressions* describe the rule.
* Each *Question* **MAY** have zero or one *question prompt. Question prompt* includes information about the question being asked.
* Each *Question* **MAY** have zero or one *question number. Question number* provides identification of the question.
* Each *Question* **MAY** have zero or one *question instruction.* Q*uestion instruction* provides directions on how to answer the question.
* Each *Question* **MAY** have zero or more *additional instructions. Additional instructions* provide additional instruction regarding the question.
* Each *Question* **SHALL** provide one of three *response* field types: *text field, list field or lookup field:*
  + - Each *response* field**MAY have** *unit of measure, default, default read only, maximum character quantity, multiselect,* and *datatype.*
    - *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. The *Text Field* **SHALL** be structured as ISO Attribute Text Field*,* which is described in Appendix E.
    - *List fields* is a field in which a list of predefined answers are allowed. The *List Field* **SHALL** be structured as ISO Attribute *List Field,* which is described in Appendix E.
      * *List Field* contains one or more *List Items* each of which consists of a data *Value* and optional descriptive fields, including a *prompt*, the *value meaning*, *value meaning standard code/identifier,* *media element*, *guard* (for simple skip pattern), and *rules* that contain a more complex action based on the selection of the *list item.* A List Field may also have a ‘fill-in’ field where the user may enter a value that is not among the list items.
    - *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. The *Lookup Field* **SHALL** be structured as ISO Attribute *Lookup Field,* which is described in Appendix E.
      * An example of a lookup field is a view providing a valid set of active patient IDs from an EHR system; a terminology approved for tagging an experimental result; a web service; a spreadsheet or html page with the permitted choices for the *question.*
      * The response list SHALL be the provided by the lookup field service. The selection of a response should return a data value that uniquely identifies the choice within the endpoint***.***
* Each *Question* **MAY** have zero or one *text after question. Text after question* is text that the form user will read after the question.
* Each Question **MAY** have zero or one *question order. Question order* indicates the position of the question amongst other questions in the same section.

Figure : Example of Question



## Auto-Population Guidance

As noted in the Introduction Section, auto-population is distinguished from pre-population based on the process being executed by the EHR.

The process of pre-filling a form from a data source requires the same type of information no matter what system is performing the task (the EHR or the Enhanced Form Template Repository).

To pre-fill, a system needs:

* A form with each question data element having an identifier;
* A data source with source data elements being “locatable”; and
* A mapping that indicates for each form element to be auto-populated the “location” of the corresponding source data element in this source.

This IG provides question definitions with identifiers, forms that reference those identifiers, and mapping specifications for data element definitions for different sources. Using these three features a system can determine which form elements can be either auto-populated or pre-populated based on the existence of a mapping to that form element from a source element. How the system executes this process is up the system and is not prescribed by this IG.

If the Enhanced Form Template Repository system is performing pre-population how it performs this task is obviously dependent on the source data submitted to it (both the type of CDA source document as well as the actual contents of that document).

If the EHR system is performing auto-population it has the freedom to use whatever data sources it has access to. Clearly, it could generate a document and use that document for auto-population (this document would not need to be persisted). However, the EHR in all likelihood has its own proprietary data stored and presuming it knows where to locate a defined data element in that data storage it could use those data. Since the data storage is proprietary, this IG does not endeavor to define that but rather enables the EHR to essentially establish its own mapping of source data elements from its data storage.

## Pre-conditions and Post-conditions

The Pre-Conditions and Post-Conditions section describes the state of the system, from a technical perspective, that must be true before an operation, process, activity or task can be executed. It lists what needs to be in place before executing the information exchange as described by the Functional Requirements and Dataset requirements.

Table : Pre and Post Conditions

| Exchanges | Pre/Post | System | Condition |
| --- | --- | --- | --- |
| 1A: Request without Patient Data | Pre | EHR | EHR is able to request the form in compliance with this implementation guide |
| EHR system is able to demonstrate authority to access the forms repository and the form requested |
| Forms Repository | Forms Repository has available standardized forms or templates, compliant with this implementation guide; Provide the designated form from the Form Authority, if the Form Repository itself is not acting as the form Authority |
| Post | EHR | EHR has submitted the form request |
| Forms Repository | Forms Repository has received the form request |
| 1A: Response without Patient Data | Pre | EHR | EHR is able to receive and process forms in the format specified in this implementation guide |
| Forms Repository | Forms Repository is able to provide the requested form in a format that complies with this implementation guide |
| Post | EHR | EHR has received the requested form |
| Forms Repository | Forms Repository has sent the requested form |
| 1B: Request with Patient Data | Pre | EHR | Forms requestor has obtained any necessary patient consents to send the patient’s data to the forms repository |
| EHR is able to request the form in compliance with this implementation guide |
| EHR is able to provide pre-population data specific to the form being requested in compliance with this implementation guide |
| EHR is able to demonstrate any required patient consent in compliance with this implementation guide |
| EHR system is able to demonstrate authority to access the forms repository and the form requested |
| Forms Repository | Forms Repository has available standardized forms or templates, compliant with this implementation guide; Provide the designated form from the Form Authority, if the Form Repository itself is not acting as the form Authority |
| Forms repository is able to receive and process pre-population data |
| Forms Repository is able to comply with privacy and consent directive |
| Post | EHR | EHR has submitted the form request, pre-population data, and any required patient consent |
| Forms Repository | Forms Repository has received the form request, pre-population data, and any required patient consent |
| 1B: Response with Patient Data | Pre | EHR | EHR is able to receive and process forms with pre-populated data |
| Forms Repository | Forms Repository is able to pre-populate forms in compliance with this implementation guide |
| Post | EHR | EHR has received the requested form with the pre-populated data |
| Forms Repository | Forms repository has sent the form with the pre-populated data |
| 2: Data Submission from Structured Form | Pre | EHR | Data Submitter has obtained any necessary patient consents to send patient’s data to the data repository |
| EHR is able to demonstrate any required patient consent in compliance with this implementation guide |
| EHR system is able to demonstrate authority to submit data to the repository |
| EHR is able to send structured data in a form that is compliant with this implementation guide |
| Data Repository | Data Repository is able to comply with privacy and consent directive |
| Data Repository is able to receive and process structured data and consent directives that comply with this implementation guide |
| Post | EHR | EHR has submitted the form data and any required patient consent |
|  | Data Repository | Forms Repository has received the form request and any required patient consent |

# Suggested Enhancements

Section Description: In this section, identify gaps in base standards referenced in this document and list the suggested enhancements. The suggestion should provide additional details such as proposed resolution, additional work required, and identify a possible owner against each suggestion.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Requested Enhancement/problem | Detail | Proposed Resolution | Additional work required | Suggested Owner or Point of Contact |
| IHE RFD—return XML versions of forms in addition to HTML/URI |  | Change to Profile | Yes | George Cole |
| ISO/IEC 11973-13 – refinement to reflect forms data needs of US as expressed by SDC and other |  | Refinements submitted for review and ultimately approved by ISO for at least US use | Yes | Denise Warzel |
|  |  |  |  |  |

If the gaps are identified for multiple standards used in this IG, please use a separate table and sub-section for each standard.

Appendix A

Acronyms and Glossary

Acronyms

| Terms/Acronyms | Working Definition |
| --- | --- |
| 21 CFR part 11 | Code of Federal Regulations Title 21, Part 11 offers guidelines on electronic records and electronic signatures |
| 38 USC § 7332 | Confidentiality of certain medical records |
| AHRQ | Agency for Healthcare Research and Quality |
| API | Application Programming Interface |
| ASPE | Assistant Secretary for Planning and Evaluation |
| ASTER | Adverse Spontaneous Triggered Events Reports |
| ASTER-D | Adverse Spontaneous Triggered Events Reporting for Devices |
| caDSR | Cancer Data Standards Registry and Repository |
| CDC | Centers for Disease Control |
| CDE | Common Data Elements |
| CER | Comparative Effectiveness Research |
| EDC | Electronic Data Capture |
| EDM | Electronic Data Methods |
| EHR | Electronic Health Record |
| ePRO | Electronic Patient-Reported Outcome |
| FDA | Food and Drug Administration |
| HITECH | Health Information Technology for Economic and Clinical Health Act of 2009 |
| IHE | Integrating the Healthcare Enterprise |
| NCI | National Cancer Institute |
| NIH | National Institutes of Health |
| NLM | National Library of Medicine |
| ONC | Office of the National Coordinator for Health Information Technology |
| PCOR | Patient-Centered Outcomes Research |
| PhenX | Consensus measures for Phenotypes and eXposures |
| RFD | Retrieve Form for Data Capture |
| S&I | Standards and Interoperability |
| SDC | Structured Data Capture |
| SDO | Standards Delivery Organization |
| VSAC | Value Set Authority Center |
| XML | Extensible Markup Language (XML) is a markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine-readable. |

Glossary

| Term | Definition |
| --- | --- |
| Archiver | An archiver is a functional program or standard that creates read only (uneditable) copies of health records to be stored by an EHR system in an internal or external repository. The archiver can also be internal or external to the EHR system. |
| Auto-Populate | When form fields are automatically filled in for certain, common, or cross-walked data elements for the user by the system. |
| Cache | A mechanism for temporary storage of a document, prior to being permanently saved. |
| Clinical Informaticians | Professionals who practice clinical informatics (increasingly known as informaticians) collaborate with other health care and information technology professionals to promote patient care that is safe, efficient, effective, timely, patient-centered, and equitable. Clinical informaticians transform health care by analyzing, designing, implementing, and evaluating information and communication systems that enhance individual and population health outcomes, improve patient care, and strengthen the clinician-patient relationship. |
| Common Data Elements (CDEs) | Common Data Elements are data elements defined in a standard and structured manner, expressing the needs of a certain domain, implying both purpose (such as improving data quality or promoting data sharing) and a governance process for the identification of the term. For the purposes of the SDC initiative, Common Data Elements are unambiguously and uniquely defined both in human readable terms and using the standard terminologies and vocabularies required for “Meaningful Use” of EHRs, as determined in accordance with the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). A standard format for CDEs will be identified in the Standards & Harmonization Phase of the initiative. |
| Common Formats | Agency for Healthcare Research and Quality (AHRQ) coordinates the development of Common Formats for reporting patient safety events to Patient Safety Organizations (PSOs). |
| Consent Directive | “Consent Directives are the consumer-based set of options regarding the consumer's preferences in regards to the control (access, use, disclosure, collection, etc.) of their electronic health records.” [[20]](#footnote-4) |
| Digest | The result of applying a hash function to a message. Also known as “hash value.” A hash function is a function that maps a bit string of arbitrary length to a fixed length bit string. Approved hash functions are specified in FIPS 180-3 and are designed to satisfy the following properties: (1) (One-way) it is computationally infeasible to find any input that maps to any new pre-specified output, and (2) (Collision resistant) it is computationally infeasible to find any two distinct inputs that map to the same output. |
| Digital Signature | (NIST). The result of a transformation of a message by means of a cryptographic system using keys such that a Relying Party can determine: (1) whether the transformation was created using the private key that corresponds to the public key in the signer’s digital certificate; and (2) whether the message has been altered since the transformation was made.  The use of the terms “Digital Signature,” “Digitally Signed,” “Signed” and other variations are used in the context as described in this document. |
| eCRF (Electronic Case Reporting Form) | Electronic questionnaire specifically used in clinical trial research. The Case Report Form is the tool used by the sponsor of the clinical trial to collect data from each participating site. All data on each patient participating in a clinical trial are held and/or documented in the CRF, including adverse events. |
| Entity | An “entity” is an organization or a person that fulfills a role, e.g., Signer, Payer, Provider. |
| External Data Repository | A database, outside of the EHR system, where external data is stored. |
| External Form | Any template/form that is not formatted with SDC standards. |
| Federal Agencies | Organizations within the federal government that deliver, regulate or provide funding for health and health care |
| Form/Template | Refers to a form or template with data entry fields that will be filled out by an end user or provider. |
| Health Insurance Portability and Accountability Act (HIPAA) | Health Insurance Portability and Accountability Act (1996): act that protects health insurance coverage for workers and their families when they change or lose their jobs; The basic privacy policy relating an individual's protected health information, providers and payers. |
| Healthcare Information Exchange (HIE) System Vendors | An organization which develops, sells, and sometimes installs, an HIE for customer organizations. |
| Healthcare Payer/Purchaser | A third-party entity that establishes indications and limitations of coverage for payments or underwrites coverage for healthcare expense. |
| Healthcare Professionals (Also referred to as Individual Providers) | Healthcare providers with patient care responsibilities (including physicians, advanced practice nurses, physician assistants, nurses, psychologists, emergency care providers, home health providers, definitive care providers, pharmacists) and other personnel involved in patient care. |
| Incident | In patient safety, a patient safety event that reached a patient and either resulted in no harm (no harm incident) or harm (harm incident). The concept “reached a patient” encompasses any action by a healthcare practitioner or worker or healthcare circumstance that exposes a patient to harm. For example: if a nurse gives a patient an incorrect medication to take and the patient recognizes it as such and refuses to take it, an incident has occurred. |
| Integration Profile | IHE Integration Profiles specify precisely how standards are to be used to address these needs, eliminating ambiguities, reducing configuration and interfacing costs, and ensuring a higher level of practical interoperability. IHE is now truly multi-domain with Integration Profiles for Radiology, Cardiology, Laboratory and Information Technology (IT) Infrastructure, which enable interoperability both within and across multiple enterprises. |
| Learning Health System | “A Learning Health System (LHS) is one in which progress in science, informatics, and care culture align to generate new knowledge as an ongoing, natural by-product of the care experience, and seamlessly refine and deliver best practices for continuous improvement in health and health care.” |
| Metadata | A set of data that describes and gives information about other data. |
| Non-repudiation | (NIST). A service that is used to provide assurance of the integrity and origin of data in such a way that the integrity and origin can be verified by a third party. This service prevents an entity from successfully denying involvement in a previous action. |
| Patient Advocates | A person who helps a patient work with others who have an effect on the patient's health, including doctors, insurance companies, employers, case managers, and lawyers. A patient advocate helps resolve issues about health care, medical bills, and job discrimination related to a patient's medical condition. |
| Patient Safety Event | A patient involved event that has compromised the safety of a patient or patients. These events are each addressed in different ways according to the severity of the incident. |
| Patient Safety Event Reporting System Vendors | Patient Safety Event Reporting Systems: applications which may, among other things, generate, send, or receive Patient Safety Event Reports |
| Patients | Members of the public who require healthcare services from ambulatory, emergency department, physician’s office, and/or a public health agency/department. |
| Presentation | Refers to the development of a front end or graphical user interface (GUI). |
| Privacy and Security Experts | Professional in designing, implementing, and administering comprehensive privacy and security protection programs in all types of healthcare organizations, aligned with regulation and healthcare reform. |
| Provider | A provider describes any medical personnel that may come in contact with the patient, handle a patient's EHR Form, or provide a patient with medical care. This includes, but is not limited to personnel that handle transitional care or direct care. The following are examples of providers: doctors, nurse practitioners, nurses, unit clerks, clinical researchers, medical residents, EMTs, emergency care personnel, medical aids, etc. |
| Provider Organizations | Organizations that are engaged in or support the delivery of healthcare. These organizations include but are not limited to hospitals, ambulatory centers, provider practices, integrated delivery systems, preferred provider organizations, health maintenance organizations, accountable care organizations, academic health systems, and professional societies. |
| Patient Safety Organizations (PSOs) | Organizations that share the goal of improving the quality and safety of health care delivery, including public or private entities, profit or not-for-profit entities, provider entities such as hospital chains, and other entities that establish special components. |
| Public Health Agency | An entity under the jurisdiction of the U.S. Department of Health and Human Services, tribal organization, State level and/or city/county level administration that serves a public health function. |
| Public Health Information System Vendors/Suppliers | Applications which may, among other things, receive Public health Reports |
| Registration Authority | (NIST). An entity that is responsible for identification and authentication of certificate subjects, but that does not sign or issue certificates (i.e., a Registration Authority is delegated certain tasks on behalf of an authorized CA). |
| Reportable Condition | A reportable condition is a condition that can be considered of great public interest and importance. State and local health organizations require that these conditions be reported when they are diagnosed by doctors or laboratories. |
| Repository for CDE | Entity responsible for Storage and retrieval for Common Data Elements. |
| Research Organizations | Organizations that conduct research activities in certain health, medical, biopharmaceutical, or similar fields to address challenges that could benefit a broad group of people. These organizations include academic research organizations such as universities and medical schools, biopharmaceutical companies, biomedical device companies, health research foundations, Federal health research agencies, etc. |
| Signer | The use of the term “Signer” indicates the entity that has applied a Digital Signature to a SDC transaction as described in this implementation guide. All other participants who may otherwise sign a document are out of scope. |
| Standards Organizations | Organizations whose purpose is to define, harmonize and integrate standards that will meet clinical and business needs for sharing information among organizations and for system interoperability. Includes Standards Development Organizations (SDOs) as accredited by the American National Standards Institute (ANSI), as well as consortia and other standards bodies. |
| Surveillance Case Report | Form used for public health reporting of infectious diseases |
| System Packages | The action when form data concatenates or “packages” itself in a manner that is fit for transmission and storage on a database. |
| User Stories | Any potential scenario that involves an End user accessing the system. |
| Vocabulary & Terminology Owners | Organization whose purpose it is to define, harmonize, and maintain clinical terminologies and vocabulary that will meet information sharing needs to drive towards system interoperability and standardization. |

Appendix B

Conformance Statements List

The following table summarizes all conformance statements that are required for complying with the SDC implementation guide:

|  |  |  |
| --- | --- | --- |
| Conformance Statement | Document Section | Related Exchanges |
| The SOAP Header **SHALL NOT** contain specific PHI within the specific header elements itself. | 0 |  |
| The SOAP Header **SHALL** contain a SAML assertion.  The implementer **SHOULD** refer to the IHE XUA profile for a complete set of SAML attributes | 2.3.1.2 |  |
| Implementers **SHOULD** reference the NwHIN Messaging Platform Specification for instructions on how to implement TLS | 2.3.1.3 |  |
| Transactions traversing organizational boundaries (e.g. over untrusted/non-secured network) utilizing SOAP:  **SHALL** utilize TLS 1.0 or greater in order to provide a secure channel (Appendix B)  **SHALL** use IHE ATNA for Recording Security Audit Events | 2.3.1.3 |  |
| Implementers **SHOULD** refer to the IHE ATNA profile for specific implementation guidance and conformance criteria | 2.3.1.3 |  |
| SDC Data Elements **SHALL** be defined uniquely and unambiguously, consistent with ISO/IEC 11179-3  SDC Data Elements **SHALL** include a description referencing or URL to mapping resources needed to assist an EHR in the instantiation of that SDC form, |  |  |
| SDC CDEs in a properly specified SDC Form **MAY** be regularly versioned and updated consistent with the updating of the underlying Meaningful Use health data standards and Value Set Authority Center (VSAC) value sets. |  |  |
| Data Element registries maintained by non-governmental authorities **SHOULD** adhere to the metadata attributes and principles in ISO/IEC 111793. |  |  |

Appendix C

Digital Signature Specification

Digital Signature Processes

This section describes the standards, and process required to create a Digital Signature and apply it to a SDC transaction. The following sections describe the detailed requirements:

* Defines the standards and process for creating a Digital Signature;
* Defines the standards and process for adding the Digital Signature to an SDC transaction;
* Defines the process for validating the Digital Signatures on a Signed SDC transaction.

Notes:

* The UTC incorporated in each Digital Signature will permit the Recipient to determine the order in which each signature was applied.

Creating a Digital Signature

This section identifies the Digital Signature Standards and process used to create a Digital Signature using an X.509v3 signing certificate.

Digital Signature Standard

The standard used in this guide to sign an SDC transaction is XAdES, an extension to the W3C XML Digital Signature (XML-DSIG).

Computation of the Digest

When digitally signing an SDC transaction, the Digest of the Signed Data Object is the entire XML content of the transaction starting with, and including ,<\_\_\_> and ending with, and including, </\_\_\_>, The Digest is computed using the method defined in XML-DSIG on the XML contents and SignedProperties.

Signature Process

The signer creates the XAdES Digital Signature and populates it with all required elements including:

* The signer’s public X.509v3 signing certificate;
* The Digest of the XML payload (see 3.1.2 and the SignedProperties);
* The Signed Digest;
* The following signed elements:
  + Coordinated Universal Time (UTC);
  + Role (see Table 4.5);
  + Signature Purpose (see Table 4.5).

Conformance Statements: XAdES-X-L

**SDC-1:** XAdES digital signatures **SHALL** include the signer’s public X.509v3 certificate in the SigningCertificate property element

**SDC -2:** XAdES digital signatures **SHALL** include Coordinated Universal Time (UTC)

**SDC -3:** XAdES digital signatures **SHALL** include a valid Role

**SDC -4:** XAdES digital signatures **SHALL** include a valid Signature Purpose

Verifying an XAdES-based Signature

A Recipient is the receiver of the SDC transaction and must verify the signature using the following steps to verify the identity of the Signer and the integrity of the SDC transaction.

Verifying the Signers Signature

* Verify the X.509v3 Certificate contained in the X509Certificate element. Specifically, verify that:
  + The certificate is current at the time of signature;
  + The certificate has been issued for an acceptable purpose;
  + The trust anchor is acceptable by verifying the complete chain to the issuing CA’s root certificate;
  + The certificate has not been revoked by reviewing the OCSP response or signed CRL.
* Verify that the signature date is appropriate;
* Verify that the role of the signer is appropriate;
* Verify that the signature purpose is appropriate;
* Decrypt the signed Digest with the public key from the X.509v3 public digital certificate;
* Compute the Digest of the SDC transaction;
* Verify that the signed Digest matches the computed Digest;

If any of these steps fails, the Signature cannot be verified.

Data Requirements

The tables in this section list the data elements and data element sets that will be available within the certificate information, document signature, and delegation of rights assertion of the SDC transaction. Each data element listed below is necessary for some aspect of the Use Case; however, the table does not specify exactly how they may be used together.

Signing Certificate Information

Table : Signing Certificate Information

| Data Element | Usage | Cardinality | Data Element Description | Additional Notes |
| --- | --- | --- | --- | --- |
| Version | R | [1..1] | Version of X.509 | All must be version 3(X.509v3) |
| Serial Number | R | [1..1] | Unique Serial Number of Certificate from the CA |  |
| Algorithm ID | R | [1..1] | Algorithm used by the CA to sign the certificate |  |
| Issuer | R | [1..1] | Name of CA that issued certificate |  |
| Validity | R | [1..1] | Period of time for which the certificate is valid | Not Before, Not After |
| Subject | R | [1..1] | Subject Name -- Name of whom the certificate is issued to |  |
| Subject Public Key Info | R | [1..1] | The subject’s public key |  |
| Issuer Unique Identifier | R | [1..1] |  |  |
| Subject Unique Identifier | C(R/O) | [1..1] |  |  |
| Extensions | R | [1..\*] | Describes specific purpose of use, values, and critical or non-critical identifier | Object Identifier for each extension; non-repudiation “flag” must be set |
| Certificate Signature Algorithm | R | [1..1] | Algorithm used to sign the certificate |  |
| Certificate Signature | R | [1..1] |  |  |

Document Signature (XAdES Elements)

Table : Document Signature

| Data Element | Usage | Cardinality | Data Element Description | Additional Notes |
| --- | --- | --- | --- | --- |
| Signature | O | [0..1] | Root element of an XML digital signature |  |
| SignedInfo | R | [1..1] | Used to specify the canonicalization algorithm, a signature algorithm, and one or more references | May also contain an optional ID attribute that will allow it to be referenced by other signatures and objects. |
| CanonicalizationMethod | R | [1..1] | Specifies the canonicalization algorithm applied to the SignedInfo element prior to performing signature calculations. Indicates method used for canonicalizing XML node sets resulting after retrieving (and processing when required) the data objects covered by the time-stamp token(s) | When not present, the standard canonicalization method as specified by XML-DSIG *MUST* be used |
| SignatureMethod | R | [1..1] | Specifies the algorithm used for digital signature generation and validation. | This algorithm identifies all cryptographic functions involved in the signature operation (e.g. hashing, public key algorithms, MACs, padding, etc.) |
| Reference | RE | [0..\*] | Specifies a digest algorithm and digest value, and optionally an identifier of the object being signed, the type of the object, and/or a list of transforms to be applied prior to digesting. The identification (URI) and transforms describe how the digested content was created. | The Type attribute facilitates the processing of referenced data. An optional ID attribute permits a Reference to be referenced from elsewhere. |
| Transforms | RE | [0..1] | Contains an ordered list of Transform elements |  |
| Transform | R | [1..\*] | Describes how the signer obtained the data object that was digested. The output of each Transform serves as input to the next Transform. The input to the first Transform is the result of dereferencing the URI attribute of the Reference element. The output from the last Transform is the input for the DigestMethod algorithm. | If the Transforms element is used, at least one Transform element must be used.  When transforms are applied the signer is not signing the native (original) document but the resulting (transformed) document |
| DigestMethod | R | [1..1] | Identifies the digest algorithm to be applied to the signed object |  |
| DigestValue | R | [1..1] | Contains the base64 encoded value of the digest |  |
| SignatureValue | R | [1..1] | Contains the actual base64 encoded value of the digital signature |  |
| KeyInfo | RE | [0..1] | Contains public key information for validating signatures. May contain keys, names, certificates, and other PKI management information. | If KeyInfo is omitted, the recipient is expected to be able to identify the key based on application context. |
| KeyName | O | [0..1] | Contains a string value which may be used by the signer to communicate a key identifier to the recipient. | The name of the digital signer is required, but it is not required that KeyName be used. |
| KeyValue | O | [0..1] | Contains a single public key that may be useful in validating the signature | Must contain exactly one of any of the following elements:  1. DSAKeyValue  2. RSAKeyValue  3. Externally-defined public keys values represented as PCDATA or element types from an external namespace |
| RetrievalMethod | O | [0..1] | Conveys a reference to KeyInfo information that is stored at another location. For example, several signatures in a document might use a key verified by an X509v3 certificate chain appearing once in the document or remotely outside the document; each signature's KeyInfo can reference this chain using a single RetrievalMethod element instead of including the entire chain with a sequence of X509Certificate elements. |  |
| X509Data | R | [1..1] | Contains one or more identifiers of keys or X509 certificates (or certificates' identifiers or a revocation list). Must contain at least one or more [1..\*] of the following elements: X509IssuerSerial, X509SKI, X509SubjectName, X509Certificate, X509CRL | Any X509IssuerSerial, X5099SKI, and X509SubjectName elements that appear MUST refer to the certificate or certificates containing the validation key. |
| Object | R | [1..\*] | Parent element to all XAdES extension elements, which are added on to the base XMLDSIG core element (detailed in the rows above). | While the Object element may be repeated for purposes other than XAdES, such use is out of scope for this guide. |
| QualifyingProperties | R | [1..1] | Acts as a container element for all the qualifying information that should be added to an XML signature. QualifyingProperties are split into properties that are cryptographically bound to (i.e. signed by) the XML signature (SignedProperties), and properties that are not cryptographically bound to the XML signature (UnsignedProperties). | The SignedProperties MUST be covered by a ds:Reference element of the XML signature. |
| SignedProperties | R | [1..1] | Properties that are cryptographically bound (i.e., signed) to the XML signature |  |
| SignedSignatureProperties | R | [1..1] | Contains properties that qualify the XML signature that has been specified with the Target attribute of the QualifyingProperties container element. | The optional Id attribute can be used to make a reference to the UnsignedProperties element. |
| SigningTime | R | [1..1] | Specifies the time at which the signer (purportedly) performed the digital signature process. | This element is optional within the XAdES specification, but required for the purposes of this guide. |
| SigningCertificate | R | [1..1] | Contains references to certificates and digest values computed on them. The certificate used to verify the signature SHALL be identified in the sequence. The signature policy MAY mandate other certificates be present, that MAY include all the certificates up to the point of trust. | This element is optional within the XAdES specification, but required for the purposes of this guide.  This element contains the sequence of certificate identifiers and digests computed on the certificates. This information is further elaborated within the Cert elements CertDigest and IssuerSerial (listed below). |
| CertDigest | R | [1..1] | Contains the digest of one of the certificates referenced in the sequence. It contains two elements: ds:DigestMethod indicates the digest algorithm, and ds:DigestValue contains the value of the digest. | The optional URI attribute serves to indicate where the referenced certificate can be found. |
| IssuerSerial | R | [1..1] | Contains the identifier of one of the certificates referenced in the sequence. Should the ds:X509IssuerSerial element appear in the signature to denote the same certificate, its value MUST be consistent with the corresponding IssuerSerial element. |  |
| SignaturePolicyIdentifier | R | [1..1] | Contains elements that specify ways to identify the set of rules governing the creation and validation of the digital signature. | Must contain exactly one of the following: SignaturePolicyID or SignaturePolicyImplied |
| SignaturePolicyID | RE | [0..1] | Appears when the signature policy contains an explicit and unambiguous identifier of a signature policy together with a hash value of the signature policy, so it can be verified that the policy selected by the signer is the one being used by the verifier. An explicit signature policy has a globally unique reference which is bound to a digital signature by the signer as part of the signature calculation. In these cases, for a given explicit signature policy there shall be one definitive form that has a unique binary encoded value. | The SigPolicyId element contains an identifier that uniquely identifies a specific version of the signature policy. The SigPolicyHash element contains the identifier of the hash algorithm and the hash value of the signature policy. The SigPolicyQualifier element can contain additional information qualifying the signature policy identifier. |
| SignaturePolicyImplied | O | [0..1] | Appears when the digital signature can avoid the inclusion of the aforementioned identifier and hash value. This will be possible when the signature policy can be unambiguously derived from the semantics of the type of data object(s) being signed, and some other information, e.g. national laws or private contractual agreements, that mention that a given signature policy MUST be used for this type of data content. In such cases, the signature will contain a specific empty element indicating that this implied way to identify the signature policy is used instead the identifier and hash value. | Use of this field is based on signature policy that is agreed to by both the signer and the intended recipient. Details of such a policy are out-of-scope of this document. |
| SignatureProductionPlace | O | [0..1] | In some transactions the purported place where the signer was at the time of signature creation MAY need to be indicated. This element specifies an address associated with the signer at a particular geographical (e.g. city) location. | Must contain no more than one of each of the following elements: City, StateorProvince, PostalCode, CountryName. |
| SignerRole | R | [1..5] | Property that contains a sequence of roles that the signer can play. | This element is optional within the XAdES specification, but required for the purposes of this guide. It must contain at least one of the two elements: ClaimedRoles, CertifiedRoles. |
| ClaimedRoles | R | [1..1] | Contains a sequence of roles (using ClaimedRole element(s)) claimed by the signer but not certified. Additional contents types MAY be defined on a domain application basis and be part of this element. | From Healthcare Taxonomy Data Set |
| CertifiedRoles | O | [0..1] | Contains one or more wrapped DER-encoded attribute certificates for the signer (using CertifiedRole elements). | Not required for this implementation guide |
| SignaturePurpose | R | [1..1] | Contains a signature purpose claimed by the signer. | From ASTM E 1762-95 |
| SignedDataObjectProperties | O | [0..1] | Contains properties that qualify some of the signed data objects. | May include any of the following elements: DataObjectFormat, CommitmentTypeIndication, AllDataObjectsTimeStamp, IndividualDataObjectsTimeStamp |
| DataObjectFormat | O | [0..\*] | Provides information that describes the format of the signed data object. This element SHOULD be present when the signed data is to be presented to human users on verification if the presentation format is not implicit within the data that has been signed.  Must include the ObjectReference attribute, which must reference the ds:Reference element of the ds:Signature corresponding with the data object qualified by this property. | If used, this element must include at least one of any the following elements: Description, ObjectIdentifier, MineType, Encoding. These properties may not be repeated within the DataObjectFormat element. |
| CommitmentTypeIndication | O | [0..\*] | Identifies the type of commitment made by the digital signer by either explicitly using a commitment type indication in the digital signature, or by implicitly or explicitly using the semantics of the signed data object. A commitment type definition includes the object identifier for the commitment as well as a sequence of qualifiers. | Must contain exactly one CommitmentTypeId element.  Must contain either AllSignedDataObjects element, or ObjectReference element(s). May contain CommittmentTypeQualifiers element. |
| CommitmentTypeId | O | [0..1] | Unequivocally identifies the type of commitment made by the signer.  Required if CommitmentTypeIndication element is used. | Must include exactly one Identifier element (which indicates URI of commitment).  May include no more than one of each of the following elements: Description and DocumentationReferences. |
| AllDataObjectsTimeStamp | O | [0..\*] | Contains the time-stamp computed before the signature production, over the sequence formed by ALL the ds:Reference elements within the ds:SignedInfo referencing whatever the signer wants to sign except the SignedProperties element.  The application MUST compose the Include elements to refer to all the ds:Reference elements except the one referencing the SignedProperties element. Their corresponding referencedData attribute MUST be present and set to "true." | May contain more than one Include element.  May contain no more than 1 CanonicalizationMethod elements.  Must contain at least one of the following two elements: EncapsulatedTimeStamp or XMLTimeStamp. |
| IndividualDataObjectsTimeStamp | O | [0..\*] | Contains the time-stamp computed before the signature production, over a sequence formed by SOME ds:Reference elements within the ds:SignedInfo. Note that this sequence cannot contain a ds:Reference computed on the SignedProperties element.  The application MUST compose the Include elements to refer to those ds:Reference elements that are to be time-stamped. Their corresponding referencedData attribute MUST be present and set to "true." | May contain more than one Include element.  May contain no more than 1 CanonicalizationMethod elements.  Must contain at least one of the following two elements: EncapsulatedTimeStamp or XMLTimeStamp. |
| UnsignedProperties | R | [1..1] | Contains properties that are not bound/signed by the digital signature. | May contain at most one of each of the following elements: UnsignedSignatureProperties, UnsignedDataObjectProperties |
| UnsignedSignatureProperties | R | [1..1] | Contains properties that qualify the XML signature that has been specified with the Target attribute of the QualifyingProperties container element. | The optional Id attribute can be used to make a reference to the UnsignedProperties element. |
| CounterSignature | O | [0..\*] | Provides support for multiple embedded signatures.  Each counter-signature is carried in one CounterSignature element added to the Signature element to which the counter-signature is applied. | In a qualified Signature the contents of the CounterSignature element are one or more signatures (i.e. ds:Signature elements) of the SignatureValue in the qualified Signature.  A counter-signature can itself be qualified by a CounterSignature property. |
| SignatureTimeStamp | O | [0..\*] | A container for a time-stamp token over the ds:SignatureValue element to protect against repudiation in case of a key compromise. | The application MUST compose one Include element with an URI referencing the ds:SignatureValue element. The input for the time-stamp has is, in consequence, the ds:SignatureValue element. |
| AttributeCertificateRefs | 0 | [0..1] | Contains the references to the full set of Attribute Authorities certificates that have been used to validate the attribute certificate.  This property MAY be used only when a user attribute certificate is present within the digital signature. | Must contain exactly one CertRefs element. |

Code Sets

Table : Code Sets

| Data Element | Usage | Cardinality | Code Set | Additional Notes |
| --- | --- | --- | --- | --- |
| Role | R | [1..1] | Healthcare Taxonomy Data Set | Healthcare Provider Taxonomy (HIPAA) 2.16.840.1.114222.4.11.1066 |
| Signature Purpose | R | [1..1] | ASTM E 1762-95 |  |
| Delegation of Rights Assertion Action | R | [1..1] | ‘Authorized Signer’ |  |

Example

The following XML examples present an XAdES Signature.

XAdES Digital Signature

<ds:Signature>

<ds:SignedInfo>

<ds:CanonicalizationMethod Algorithm=**"http://www.w3.org/2001/10/xml-exc-c14n#"**/>

<ds:SignatureMethod Algorithm=**"http://www.w3.org/2001/04/xmldsig-more#rsa-sha512"**/>

<ds:Reference>

<ds:DigestMethod Algorithm=**"http://www.w3.org/2001/04/xmlenc#sha512"**/>

<ds:DigestValue>**2c2dc2c30d3dd3fca22e3ccf02ca0f4db8a5d6494b6319df28b70fb76c7b246fed13840ca913be70802e2345c6dd3a6087ab00c41f64e80e61e2c6bc24d105fe**</ds:DigestValue>

</ds:Reference>

</ds:SignedInfo>

<ds:SignatureValue>**oRrea2fzFswyLeE+a36P2C/xQB4BMk6LJPAyym873qgjS1loqR3fbZLYvm/yJ6iGCANc9+mbP4U/**

**kwIyn63QQhjhIST/i3Z9bwwo6QV9EewHGybkNEFvK+7C5lJI88bNR9pihp/3Y5AfP9+a0o566fKX**

**HNnksd5a5cSytqfPTYoiZq5LQdLYkjzLSyCy0YhGDiG6DKk0uBjAdkNit1Z7GtaP2XhpcKQ1x3XI**

**n1S8T1HjBqKNw6ZIz64+8GtA+kwwayXOVpdYL1r6M6iq1HrbLlSqGFY1+RQCe0+9qjSTHQRgg+eT**

**y7K2x1Rg9zMg3tLkAtdUyLOsP/jNa7RU5HwC/Q==**</ds:SignatureValue>

<ds:Object>

<QualifyingProperties>

<SignedProperties>

<SignedSignatureProperties>

<SigningTime>**2012-04-26T16:04:56Z**</SigningTime>

<SigningCertificate>

<Cert URI=**"http://www.example.com/"**>

<CertDigest>

<ds:DigestMethod Algorithm=**"http://www.w3.org/2001/04/xmldsig-more#rsa-sha512"**/>

<ds:DigestValue xmlns=**"http://www.w3.org/2000/09/xmldsig#"**>**bJrQQeyoztdAPO6nsoRQ5oX5oAg=**</ds:DigestValue>

</CertDigest>

<IssuerSerial>

<X509IssuerName>**X.509 distinguished name of certificate**</X509IssuerName>

<X509SerialNumber>**certificate serial number**</X509SerialNumber>

</IssuerSerial>

</Cert>

</SigningCertificate>

<SignaturePolicyIdentifier>**...**</SignaturePolicyIdentifier>

<SignatureProductionPlace>

<City>**City**</City>

<State>**State**</State>

<PostalCode>**Zip**</PostalCode>

<CountryName>**Country**</CountryName>

</SignatureProductionPlace>

<SignerRole>

<ClaimedRoles>

<ClaimedRole>**Any text**</ClaimedRole>

</ClaimedRoles>

<CertifiedRoles>

<CertifiedRole>**EncapsulatedPKIDataType**</CertifiedRole>

</CertifiedRoles>

</SignerRole>

</SignedSignatureProperties>

<SignedDataObjectProperties>

<DataObjectFormat>

<Description>**string**</Description>

<ObjectIdentifier>

<Identifier>**http://www.example.com/**</Identifier>

<Description>**string**</Description>

<DocumentationReferences>

<DocumentationReference>**http://www.example.com/**</DocumentationReference>

</DocumentationReferences>

</ObjectIdentifier>

<MimeType>**string**</MimeType>

<Encoding>**http://www.example.com/**</Encoding>

</DataObjectFormat>

<CommitmentTypeIndication>

<CommitmentTypeId>

<Identifier>**http://www.example.com/**</Identifier>

<Description>**string**</Description>

<DocumentationReferences>

<DocumentationReference>**http://www.example.com/**</DocumentationReference>

</DocumentationReferences>

</CommitmentTypeId>

<ObjectReference>**http://www.example.com/**</ObjectReference>

<CommitmentTypeQualifiers>

<CommitmentTypeQualifier>**text**</CommitmentTypeQualifier>

</CommitmentTypeQualifiers>

</CommitmentTypeIndication>

<AllDataObjectsTimeStamp>

<Include URI=**"http://www.example.com/"**/>

<CanonicalizationMethod Algorithm=**"http://www.example.com/"**>**text**</CanonicalizationMethod>

<EncapsulatedTimeStamp>**EncapsulatedPKIDataType**</EncapsulatedTimeStamp>

</AllDataObjectsTimeStamp>

<IndividualDataObjectsTimeStamp>

<Include URI=**"http://www.example.com/"**/>

<CanonicalizationMethod Algorithm=**"http://www.example.com/"**>**text**</CanonicalizationMethod>

<EncapsulatedTimeStamp>**EncapsulatedPKIDataType**</EncapsulatedTimeStamp>

</IndividualDataObjectsTimeStamp>

</SignedDataObjectProperties>

</SignedProperties>

<UnsignedProperties>

</UnsignedProperties>

</QualifyingProperties>

</ds:Object>

</ds:Signature>

Glossary

| Term | Definition |
| --- | --- |
| Certificate Authority | (NIST). An authority trusted by one or more users to issue and manage X.509 Public Key Certificates and CARLs or CRLs. |
| Digest | The result of applying a hash function to a message. Also known as “hash value.” A hash function is a function that maps a bit string of arbitrary length to a fixed length bit string. Approved hash functions are specified in FIPS 180-3 and are designed to satisfy the following properties: (1) (One-way) it is computationally infeasible to find any input that maps to any new pre-specified output, and (2) (Collision resistant) it is computationally infeasible to find any two distinct inputs that map to the same output. |
| Digital Signature | (NIST). The result of a transformation of a message by means of a cryptographic system using keys such that a Relying Party can determine: (1) whether the transformation was created using the private key that corresponds to the public key in the signer’s digital certificate; and (2) whether the message has been altered since the transformation was made.  The use of the terms “Digital Signature,” “Digitally Signed,” “Signed” and other variations are used in the context as described in this document. |
| Entity | An “entity” is an organization or a person that fulfills a role, e.g., Signer, Payer, or Provider. |
| Non-repudiation | (NIST). A service that is used to provide assurance of the integrity and origin of data in such a way that the integrity and origin can be verified by a third party. This service prevents an entity from successfully denying involvement in a previous action. |
| Registration Authority | (NIST). An entity that is responsible for identification and authentication of certificate subjects, but that does not sign or issue certificates (i.e., a Registration Authority is delegated certain tasks on behalf of an authorized CA). |
| Signer | The use of the term “Signer” indicates the entity that has applied a Digital Signature to a SDC transaction as described in this implementation guide. All other participants who may otherwise sign a document are out of scope. |

Appendix D

SDC Data Element Attributes

Attributes in Appendix D are organized in following columns:

* **Attribute Scope**: This column indicates attributes that are required by SDC form only versus those that are required for describing data elements outside of form. Based on graphics shown above, note that all attributes required for SDC are also considered to be attributes required for DE creation, sharing and reuse (vice versa does not apply).
* **Attribute Category**: describes main groups of attributes: those describing Data Elements, Value Domains, Value Sets, Value Set Members, Code Systems, Mapping Specification and Content Model. This classification helps user focus on specific set of attributes of interest.
* **Attribute Type**: classifies attributes based on attribute’s intended purpose such as: Definitional, Referential, Classification, Contextual, Administrative, and Associations. This classification is also intended to help user focus on specific set of attributes of interest.
* **Attribute Name**: This column is focal point of SDC Implementation guide; it provides list of explicit attribute names.
* **Data Type**: describes datatype associated with each attribute.
* **Cardinality**: describes the permissible number of occurrences of each attribute.
* **Optionality**: determines whether attribute is required, optional or conditionally required.
* **Definition**: provides definition for each attribute.
* **Constraints**: list vocabulary or formatting constraints associated with an attribute. For example, an attribute may have values drawn from a specific value set. These constraints are meant to improve syntactical uniformity in how attributes are defined, which in turn improves exchange and reuse of data elements across registries.
* **Examples**: list examples of values for an attribute.
* **IHE DEX Attributes**: Provides mapping between SDC Attributes and Attributes defined within IHE DEX profile.

| Attribute Scope | Attribute Category | Attribute Type | Attribute Name | Data type | Card | Optionality | Definition | Constraints | Example | IHE DEX Attribute Name |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Core Form DE Attribute | Data Element | Definitional | **scoped identifier** | String | 1..1 | Mandatory | A globally unique identifier for a metadata item within a specific namespace  It is usually composed of the DE Identifier, DE Version, and either the full\_expansion OR shorthand\_expansion associated with the namespace. If a Data Element repository does not use DE Verstion, then the scoped\_identifier may not include a version number. It is up to the owner of the data element to determine what the scoped\_identifier value should be. |  | http://nci.nih.gov/xml/owl/cadsr/data\_element\_identifier#2006410v3.0 46552-6\_LOINC | id |
| Core form DE Attribute | Data Element | Definitional | **Identifier** | String | 1..1 | Mandatory | String used to unambiguously denote an Identified\_Item within the scope of a specified Namespace | SHOULD be LOINC\_NUM selected from LOINCDB, bound DYNAMIC, binding strength CWE LOINC OID: 2.16.840.1.113883.6.1  SHOULD be CONCEPT ID selected from SNOMED CT, bound DYNAMIC, binding strength CWE SNOMED CT OID: 2.16.840.1.113883.6.96  SHOULD be RXCUI selected from RxNorm, bound DYNAMIC, binding strength CWE RxNorm OID: 2.16.840.1.113883.6.88 | |  |  | | --- | --- | | 2006410 46552-6 | id | | id |
| Attribute for creating, sharing and reuse of DE | Data Element | Definitional | **version** | String | 1..1 | Mandatory | The unique version identifier of the metadata item. |  | 3 | version |
| Core Form DE Attribute | Data Element | Definitional | **name** | String | 1..\* | Mandatory | The designation of an object by a linguistic expression; The primary means of identification of objects and concepts. A name by which a metadata item is known within a specific context. | MAY be "LONG\_COMMON\_NAME" selected from LOINCDB, bound DYNAMIC, binding strength CWE  LOINC OID: 2.16.840.1.113883.6.1  MAY be "term" selected from SNOMED CT, bound DYNAMIC, binding strength CWE  SNOMED CT OID: 2.16.840.1.113883.6.96  MAY be "long description" selected from ICD-9, bound DYNAMIC, binding strength CWE  ICD-9 OID: 2.16.840.1.113883.6.42  MAY be "long description" selected from ICD-10, bound DYNAMIC, binding strength CWE  ICD-10 OID: 2.16.840.1.113883.6.3 | Person Body Mass Index Value |  |
| Core Form DE Attribute | Data Element | Definitional | **preferred question text** | String | 1..1 | Mandatory | The preferred text used to express the data element as a question. | MAY be "LONG\_COMMON\_NAME" selected from LOINCDB, bound DYNAMIC, binding strength CWE  LOINC OID: 2.16.840.1.113883.6.1  MAY be "term" selected from SNOMED CT, bound DYNAMIC, binding strength CWE  SNOMED CT OID: 2.16.840.1.113883.6.96  MAY be "long description" selected from ICD-9, bound DYNAMIC, binding strength CWE  ICD-9 OID: 2.16.840.1.113883.6.42  MAY be "long description" selected from ICD-10, bound DYNAMIC, binding strength CWE  ICD-10 OID: 2.16.840.1.113883.6.3 | Body Mass Index (BMI) | displayName |
| Core Form DE Attribute | Data Element | Definitional | **alternative question text** | String | 1..\* | Optional | Alternative expressions of the question text that have been approved for use this is data element. | MAY be "LONG\_COMMON\_NAME" selected from LOINCDB, bound DYNAMIC, binding strength CWE  LOINC OID: 2.16.840.1.113883.6.1  MAY be "term" selected from SNOMED CT, bound DYNAMIC, binding strength CWE  SNOMED CT OID: 2.16.840.1.113883.6.96  MAY be "long description" selected from ICD-9, bound DYNAMIC, binding strength CWE  ICD-9 OID: 2.16.840.1.113883.6.42  MAY be "long description" selected from ICD-10, bound DYNAMIC, binding strength CWE  ICD-10 OID: 2.16.840.1.113883.6.3 | Body Mass Index |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Definitional | **definition** | Text | 1..\* | Mandatory | Representation of a concept by a descriptive statement which serves to differentiate it from related concepts. A statement that expresses the essential nature of a data element and its differentiation from all other data element. |  | A calculated numerical quantity that represents an individual's weight to height ratio. [Manually-curated] | Definition |
| Core Form DE Attribute | Data Element Concept | Definitional | **concept** | String | 1..1 | Conditional |  | SHOULD be "survey\_quest\_text" selected from LOINCDB, bound DYNAMIC, binding strength CWE LOINC OID: 2.16.840.1.113883.6.1  MAY be "LONG\_COMMON\_NAME" selected from LOINCDB, bound DYNAMIC, binding strength CWE LOINC OID: 2.16.840.1.113883.6.1  SHOULD be "term" selected from SNOMED CT, bound DYNAMIC, binding strength CWE SNOMED CT OID: 2.16.840.1.113883.6.96  SHOULD be "term" selected from RxNorm, bound DYNAMIC, binding strength CWE RxNorm OID: 2.16.840.1.113883.6.88  AND/OR(!)  SHOULD be "LOINC\_NUM" selected from LOINCDB, bound DYNAMIC, binding strength CWE LOINC OID: 2.16.840.1.113883.6.1  SHOULD be "CONCEPT ID" selected from SNOMED CT, bound DYNAMIC, binding strength CWE SNOMED CT OID: 2.16.840.1.113883.6.96  SHOULD be "RxCUI" selected from RxNorm, bound DYNAMIC, binding strength CWE RxNorm OID: 2.16.840.1.113883.6.88  At least DEC name must be specified in addition to DE specifications - ISO 1179-3 Clause 12 conformance.  Ideally, both concept ID AND associated ddescription from the same code system should be used - ISO 1179-3 Clause 11 conformance. | Patient\_height |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Definitional | **object Class** | String | 0..1 | Optional | The object that is a part of this data element definition. An objectClass represents a set of ideas, abstractions, or things in the real world that are identified with explicit boundaries and meaning and whose properties and behaviour follow the same rules. Each data element is composed of an objectClass, a property term and a valueDomain triple. See informative appendix for further description. | MAY be "LONG\_COMMON\_NAME" selected from LOINCDB, bound DYNAMIC, binding strength CWE  LOINC OID: 2.16.840.1.113883.6.1  MAY be "term" selected from SNOMED CT, bound DYNAMIC, binding strength CWE  SNOMED CT OID: 2.16.840.1.113883.6.96  MAY be "long description" selected from ICD-9, bound DYNAMIC, binding strength CWE  ICD-9 OID: 2.16.840.1.113883.6.42  MAY be "long description" selected from ICD-10, bound DYNAMIC, binding strength CWE  ICD-10 OID: 2.16.840.1.113883.6.3 |  | objectClass |
| Core Form DE Attribute | Data Element Concept | Definitional | **property** | String | 0..1 | Optional | The name of the property term which is a part of this data element definition. A property is a characteristic common to all members of an object Class. Each data element is composed of an objectClass, a property term and a valueDomain triple. | MAY be "LONG\_COMMON\_NAME" selected from LOINCDB, bound DYNAMIC, binding strength CWE LOINC OID: 2.16.840.1.113883.6.1  MAY be "term" selected from SNOMED CT, bound DYNAMIC, binding strength CWE  SNOMED CT OID: 2.16.840.1.113883.6.96  MAY be "long description" selected from ICD-9, bound DYNAMIC, binding strength CWE  ICD-9 OID: 2.16.840.1.113883.6.42  MAY be "long description" selected from ICD-10, bound DYNAMIC, binding strength CWE  ICD-10 OID: 2.16.840.1.113883.6.3 |  | property |
| Attribute for creating, sharing and reuse of DE | Data Element | Referential | **reference** | Reference Document | 0..1\* | Optional | Additional information about the data element, can be a reference document, protocol text, instructions, guidelines, etc. |  | If more than one type of blood product was administered to the patient and you are unable to assign involvement in the event to a single product type, select 'Other' and specify all potentially-involved product types in the space provided. |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Referential | **identifier** | String | 1..1 | Mandatory | identifier for the Reference\_Document |  |  |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Referential | **title** | Text | 0..1 | Optional | title of the Reference Document. |  |  |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Referential | **uri** | String | 0..1 | Optional | uri for Reference Document. |  |  |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Classificational | **classification scheme** | Classification Scheme Item | 0..\* | Optional | Classification mechanism: taxonomies, categories or controlled terminology that is used to organize data elements into collection for specific usage or to express the concept of the data element. A classification scheme may be a taxonomy, a network, an ontology, or any other terminological system. The classification may also be just a list of controlled vocabulary of property words (or terms). The list might be taken from the "leaf level" of a taxonomy. OWL or RDF can also be used. |  | Demographics, Family History |  |
| Attribute for creating, sharing and reuse of DE |  | Classificational | **item name** | String | 0..1 | Optional | name of a Classification Scheme Item | MAY be SNOMED CT code, bound DYNAMIC, binding strength CWE  SNOMED CT: 2.16.840.1.113883.6.96‎ | Type of Condition |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Contextual | **context** | Context | 1..\* | Mandatory | A universe of discourse in which data element name or definition is used. In SDC, context is used to represent the intended purpose or use for which data element is intended for. Context is assigned to data element name and definition |  | Meaningful Use Stage 2, Clinical Quality Measure, Safety Report, etc | contextualDomain |
| Attribute for creating, sharing and reuse of DE | Data Element | Contextual | **name** | String | 1..1 | Mandatory | Context short name (=sign in ISO terminology) |  | NCI, CDISC, FDA, NLM |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Contextual | **definition text** | String | 1..1 | Mandatory | Full description of the name of context |  | National Cancer Institute, National Library of Medicine |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **administrative status** | String | 1..1 | Mandatory | Status of data element in the administrative process of a Registration\_Authority | MAY be a value selected from FHIR ValueSetStatus Value Set, bound DYNAMIC, binding strength CWE. OID: 1.13.2.1.178.; available at http://hl7.org/implement/standards/fhir/valueset-status.html | final |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **registration status** | String | 1..1 | Mandatory | A designation of the status of data element in the registration life-cycle. | SHOULD be a value selected from the following list of permissible values drawn from ISO 11179-6 Section, B.3: Incomplete, Candidate, Recorded, Qualified, Standard, Preferred Standard, Retired, Superseded, Historical, Application | final |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **creation date** | Datetime | 0..1 | Optional | The date when data element was created. | SHALL be specific to DAY. If time is needed, SHALL be specific to SECONDS and time zone offset MUST be specified  SHALL comply with HL7 v3 format for TS | 20070303 | creationDate |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **effective date** | Datetime | 0..1 | Optional | The date when data element becomes effective. | SHALL be specific to DAY. If time is needed, SHALL be specific to SECONDS and time zone offset MUST be specified  SHALL comply with HL7 v3 format for TS | 20070304 | effectiveDate |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **until date** | Datetime | 0..1 | Optional | The date when data element ceases to be effective. | SHALL be specific to DAY. If time is needed, SHALL be specific to SECONDS and time zone offset MUST be specified  SHALL comply with HL7 v3 format for TS | 20130304100000-0600 | expirationDate |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **last change date** | Datetime | 1..1 | Mandatory | The date when data element was last changed. | SHALL be specific to DAY. If time is needed, SHALL be specific to SECONDS and time zone offset MUST be specified  SHALL comply with HL7 v3 format for TS  When the item is first created "last change date" is equivalent to item's "created date". Thereon, "last change date" will be updated whenever item information is updated. | 20120504120000-0500 | revisionDate |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **change description** | String | 0..1 | Optional | The description of what has changed in the data element since the prior version of the data element |  |  | revisionNote |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **origin** | Text | 0..1 | Optional | The source (e.g. document, project, discipline or model) of data element | SHOULD be a value selected from "SOURCE" attribute from LOINCDB, bound DYNAMIC, binding strength CWE  LOINC OID: 2.16.840.1.113883.6.1 | caDSR |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **submitting organization** | Organization | 1..1 | Mandatory | The organization or unit within an organization that has submitted the data element for addition, change or cancellation/withdrawal in a metadata registry. |  | Agency for Healthcare Research and Quality (AHRQ) |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **organization name** | String | 1..1 | Mandatory | A designation for the Organization |  | HL7 |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **organization mail address** | String | 0..1 | Optional | The physical, postal or delivery address of the Organization |  | 123 Elm Ave, Washington DC, 20009, USA |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **contact name** | String | 1..1 | Mandatory | The name of the Contact |  | John Applebee |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **contact information** | String | 1..1 | Mandatory | Information to enable a Contact to be located or communicated with |  | JohnA@myemail.com |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **steward organization** | Organization | 1..1 | Mandatory | The organization or unit within an organization that is responsible for the contents of the mandatory attributes by which the data element is specified. |  | Agency for Healthcare Research and Quality (AHRQ) |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **organization name** | String | 1..1 | Mandatory | A designation for the Organization |  | HL7 |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **organization mail address** | String | 0..1 | Optional | The physical, postal or delivery address of the Organization |  | 123 Elm Ave, Washington DC, 20009, USA |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **contact name** | String | 1..1 | Mandatory | The name of the Contact |  | John Applebee |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **contact information** | String | 1..1 | Mandatory | Information to enable a Contact to be located or communicated with |  | JohnA@myemail.com |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **registration organization** | Organization | 1..1 | Mandatory | Metadata registry/repository (or "local" organization) that is maintaining the content of this data element (e.g. changing name, definition, etc.) | SHOULD be a value selected from "SOURCE" attribute from LOINCDB, bound DYNAMIC, binding strength CWE  LOINC OID: 2.16.840.1.113883.6.1 | USHIK | registrationAuthority |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **international code designator** | String | 1..1 | Mandatory | the identifier of an organization identification scheme |  | 2.16.840.1.113883 |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **organization id** | String | 0..1 | Optional | the identifier assigned to an Organization within an organization identification scheme, and unique within that scheme |  |  |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Administrative | **organization name** | String | 1..1 | Mandatory | a designation for the Organization |  | HL7 |  |
| Attribute for creating, sharing and reuse of DE | Data Element | Associations | **value domain** | Value Domain | 1..1 | Mandatory | The description of the permissible set of values for the property of the data element definition. |  |  | valueDomain |
| Attribute for creating, sharing and reuse of DE | Data Element | Associations | **mapping Specification** | Mapping Specification | 1..1 | Required | The exact specification to locate the Data Element in a Content Model. If there are multiple mapping specifications, each specification is returned as a separate mappingSpecification. |  |  |  |
| Core Form DE Attribute | Value Domain | Definitional | **datatype** | Datatype | 1..1 | Mandatory | A designation for the datatype | SHALL be a value selected from HL7 Data Types R2 specification (which is itself based on the implementable specification of ISO 21090 data types). | string, coded value | dataType |
| Attribute for creating, sharing and reuse of DE | Value Domain | Definitional | **Name** | String | 1..1 | Mandatory | designation for the Datatype |  | PQ, ST, etc |  |
| Attribute for creating, sharing and reuse of DE | Value Domain | Definitional | **scheme reference** | Reference Document | 1..1 | Mandatory | reference identifying the source of the Datatype specification |  | HL7 v3 |  |
| Core Form DE Attribute | Value Domain | Definitional | **Format** | String | 0..1 | Optional | template for the structure of the presentation of the value(s) |  | YYYY-MM-DD for a date |  |
| Attribute for creating, sharing and reuse of DE | Value Domain | Definitional | **type** | String | 1..1 | Mandatory | Type of value domain. This field is a derived and its purpose is to facilitated search and retrieval of value domains based on their type. | The value SHALL be derived based on a following criteria: non-enumerated, enumerated (extensional), described (intensional or Criteria-based) | non-enumerated, extensional |  |
| Core Form DE Attribute | Value Domain | Definitional | **maximum character quantity** | Integer | 0..1 | Optional | Maximum number of characters available to represent the Data\_Element value |  | 4 |  |
| Core Form DE Attribute | Value Domain | Definitional | **unit of measure** | Unit of Measure | 1..1 | Conditional | The name of a unit of measure. | If datatype is Physical Quantity type then "unit of measure" attribute SHALL be supplied.  SHALL be UCUM code from value set below bound DYNAMIC, binding strength CNE  "Table of Example UCUM Codes for Electronic Messaging - Version 1.1 (xlsx)" available at http://loinc.org/usage/units | mmHg | unitOfMeasure |
| Attribute for creating, sharing and reuse of DE | Value Domain | Definitional | **low value** | String | 0..1 | Optional | Low end of data range | If value set is non-enumerated, then low value MAY be provided. Enumerated value domains SHALL NOT have low value | 80 |  |
| Attribute for creating, sharing and reuse of DE | Value Domain | Definitional | **high value** | String | 0..1 | Optional | High end of data range | If value set is non-enumerated, then high value MAY be provided. Enumerated value domains SHALL NOT have high value | 120 |  |
| Core Form DE Attribute | Value Domain | Representational | **permissible value** | Value | 1..1 | Mandatory | The actual data value |  | Hgb Bld-mCnc |  |
| Attribute for creating, sharing and reuse of DE | Value Domain | Associations | **value set** | value set | 1..1 | Conditional | If a value domain draws its values from a value set, then value set must be associated with the value domain, and value set members must be made available as permissible values. |  |  | valueSet |
| Attribute for creating, sharing and reuse of DE | Value Set | Definitional | **id** | String | 1..1 | Mandatory | The unique identifier of the value set. Value Set must be identified with OID. | SHALL be OID | 2.16.840.1.113883.1.11.1 | id/ Identifier |
| Attribute for creating, sharing and reuse of DE | Value Set | Definitional | **name** | String | 1..1 | Mandatory | The textual representation of the name of the value set. |  | Administrative Gender (HL7 V3) | displayName/ Name |
| Attribute for creating, sharing and reuse of DE | Value Set | Definitional | **version** | String | 0..1 | Conditional | The version of the value set in question. | If Value Set version is available, it SHALL be provided. | 1.0 | version |
| Attribute for creating, sharing and reuse of DE | Value Set | Definitional | **rule** | String | 0..1 | Conditional | Value Set specification by description or rule or procedure or range. |  | example of intentional statement for Value set intensionally defined from RXNORM (OID: 2.16.840.1.113883.6.88):  Intersection(FilterOnProperty(PRESCRIBABLE,Y),  Union(FilterOnProperty(TTY,SCDG),  FilterOnProperty(TTY,SCDF),  FilterOnProperty(TTY,SCD),  ilterOnProperty(TTY,GPCK),  ),  ) | Definition |
| Attribute for creating, sharing and reuse of DE | Value Set | Referential | **URI** | String | 0..1 | Optional | A link to the web resource of the value set (e.g. PHIN VADS) |  | https://phinvads.cdc.gov/vads/ViewValueSet.action?id=8DE75E17-176B-DE11-9B52-0015173D1785 | Source URI |
| Attribute for creating, sharing and reuse of DE | Value Set | Administrative | **origin** | Text | 0..1 | Optional | The source (e.g. document, project, discipline or model) of value set | SHOULD be a value selected from "SOURCE" attribute from LOINCDB, bound DYNAMIC, binding strength CWE  LOINC OID: 2.16.840.1.113883.6.1 | HL7 | Source |
| Attribute for creating, sharing and reuse of DE | Value Set | Administrative | **administrative status** | String | 1..1 | Mandatory | Status of value set in the administrative process of a Registration Authority | MAY be a value selected from FHIR ValueSetStatus Value Set, bound DYNAMIC, binding strength CWE. OID: 1.13.2.1.178.; available at http://hl7.org/implement/standards/fhir/valueset-status.html | final | Status |
| Attribute for creating, sharing and reuse of DE | Value Set | Administrative | **creation date** | Datetime | 0..1 | Optional | The date when value set was created. | SHALL be specific to DAY. If time is needed, SHALL be specific to SECONDS and time zone offset MUST be specified  SHALL comply with HL7 v3 format for TS | 20070303 | creationDate |
| Attribute for creating, sharing and reuse of DE | Value Set | Administrative | **effective date** | Datetime | 0..1 | Optional | The date when value set becomes effective. | SHALL be specific to DAY. If time is needed, SHALL be specific to SECONDS and time zone offset MUST be specified  SHALL comply with HL7 v3 format for TS | 20070304 | effectiveDate |
| Attribute for creating, sharing and reuse of DE | Value Set | Administrative | **until date** | Datetime | 0..1 | Optional | The date when value set ceases to be effective. | SHALL be specific to DAY. If time is needed, SHALL be specific to SECONDS and time zone offset MUST be specified  SHALL comply with HL7 v3 format for TS | 20130304100000-0600 | expirationDate |
| Attribute for creating, sharing and reuse of DE | Value Set | Administrative | **last change date** | Datetime | 1..1 | Mandatory | The date when value set was last changed. | SHALL be specific to DAY. If time is needed, SHALL be specific to SECONDS and time zone offset MUST be specified  SHALL comply with HL7 v3 format for TS  When the item is first created "last change date" is equivalent to item's "created date." Thereon, "last change date" will be updated whenever item information is updated. | 20120504120000-0500 | revisionDate |
| Attribute for creating, sharing and reuse of DE | Value Set Member | Definional | **id** | String | 1..1 | Mandatory | Unique Identifier or code for the value within a Value Set or code for the value within a value set. | SHOULD be CONCEPT ID selected from SNOMED CT, bound DYNAMIC, binding strength CWE SNOMED CT OID: 2.16.840.1.113883.6.96  SHOULD be RXCUI selected from RxNorm, bound DYNAMIC, binding strength CWE RxNorm OID: 2.16.840.1.113883.6.88  SHOULD be 'code' selected from ICD-9, bound DYNAMIC, binding strength CWE ICD-9 OID: 2.16.840.1.113883.6.42  SHOULD be 'code' selected from ICD-10, bound DYNAMIC, binding strength CWE ICD-10 OID: 2.16.840.1.113883.6.3 | 718-7 |  |
| Attribute for creating, sharing and reuse of DE | Value Set Member | Definional | **text** | String | 1..1 | Mandatory | The preferred name or display for this code from the standard terminology | SHOULD be 'term' selected from SNOMED CT, bound DYNAMIC, binding strength CWE SNOMED CT OID: 2.16.840.1.113883.6.96  SHOULD be STR selected from RxNorm, bound DYNAMIC, binding strength CWE RxNorm OID: 2.16.840.1.113883.6.88  SHOULD be 'long description' selected from ICD-9, bound DYNAMIC, binding strength CWE ICD-9 OID: 2.16.840.1.113883.6.42  SHOULD be 'long description' selected from ICD-10, bound DYNAMIC, binding strength CWE ICD-10 OID: 2.16.840.1.113883.6.3 | Hemoglobin [Mass/volume] in Blood |  |
| Attribute for creating, sharing and reuse of DE | Value Set Member | Definional | **value meaning concept code** | String | 0..1 | Optional | The preffered standard terminology code for the value set member. | SHOULD be CONCEPT ID selected from SNOMED CT, bound DYNAMIC, binding strength CWE SNOMED CT OID: 2.16.840.1.113883.6.96  MAY be DESCRIPTION ID selected from SNOMED CT, bound DYNAMIC, binding strength CWE SNOMED CT OID: 2.16.840.1.113883.6.96  SHOULD be RXCUI selected from RxNorm, bound DYNAMIC, binding strength CWE RxNorm OID: 2.16.840.1.113883.6.88  SHOULD be 'code' selected from ICD-9, bound DYNAMIC, binding strength CWE ICD-9 OID: 2.16.840.1.113883.6.42  SHOULD be 'code' selected from ICD-10, bound DYNAMIC, binding strength CWE ICD-10 OID: 2.16.840.1.113883.6.3 |  |  |
| Core Form DE Attribute | Value Set Member | Definional | **value meaning description** | String | 0..1 | Optional | The exact text for the meaning of the permitted value | SHOULD be 'term' selected from SNOMED CT, bound DYNAMIC, binding strength CWE SNOMED CT OID: 2.16.840.1.113883.6.96  SHOULD be STR selected from RxNorm, bound DYNAMIC, binding strength CWE RxNorm OID: 2.16.840.1.113883.6.88  SHOULD be 'long description' selected from ICD-9, bound DYNAMIC, binding strength CWE ICD-9 OID: 2.16.840.1.113883.6.42  SHOULD be 'long description' selected from ICD-10, bound DYNAMIC, binding strength CWE ICD-10 OID: 2.16.840.1.113883.6.3 | The substance inside red blood cells that binds to oxygen in the lungs and carries it the tissues. |  |
| Attribute for creating, sharing and reuse of DE | Code System | Definional | **code system id** | Concept System (referenced\_concept\_system or importing\_concept\_system?) | 1..1 | Conditional | unique identifier for the code system | SHALL be OID  If value member codes originate from specific coding system then coding system id SHALL be provided. | 2.16.840.1.113883.6.1 |  |
| Attribute for creating, sharing and reuse of DE | Code System | Definional | **code system name** | Concept System (referenced\_concept\_system or importing\_concept\_system?) | 1..1 | Conditional | name of the code system | If value member codes originate from specific coding system then coding system name SHALL be provided | LOINC |  |
| Attribute for creating, sharing and reuse of DE | Code System | Definional | **code system version** | Concept System (referenced\_concept\_system or importing\_concept\_system?) | 1..1 | Conditional | version of the code system | If value member codes originate from specific coding system then coding system version SHALL be provided | 2.43 |  |
| Core Form DE Attribute | Mapping Specification | Associations | **content Model** | content Model | 0..1 | Optional | The Content Model that the Data Element is interrelated with. |  |  |  |
| Core Form DE Attribute | Mapping Specification | Definional | **mapping type** | String | 0..1 | Optional | Type of the mappingSpecification. The type shall be selected from Mapping Specification Type Value Set (1.3.6.1.4.1.19376.1.7.3.1.1.22.1). | Value SHALL be selected from IHE DEX Profile, Mapping Specification Type Value Set. OID: 1.3.6.1.4.1.19376.1.7.3.1.1.22.1 | XPATH Scripts, SPARQL or SQL queries |  |
| Core Form DE Attribute | Mapping Specification | Definional | **mapping script** | String | 0..1 | Optional | The exact specification to locate the Data Element in a Content Model (Example: XPATH Scripts, SPARQL or SQL query). |  | select \* from table\_name |  |
| Core Form DE Attribute | Content Model | Definional | **Id** | String | 0..1 | Optional | Identifier for the contentModel. This is the OID of the contentModel. |  | 2.16.840.1.113883.10.20.1 (for ASTM/HL7 CCD) |  |
| Core Form DE Attribute | Content Model | Definional | **Name** | String | 0..1 | Optional | Name of the contentModel. |  | ASTM/HL7 CCD |  |
| Core Form DE Attribute | Value Set Member | Representational | **permitted value** | Value | 1..1 | Mandatory | The actual data value |  |  |  |

Appendix E

List of SDC Form Elements and Attributes Inherited from ISO/IEC 19763-13 and ISO/IEC 11179-3

###### *1. Organization*

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

Table 23: Organization Class

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Data Type |
| Organization | / Organization |  |  |
| Name | /name | 1..N | Sign |
| Mail address | /mail\_address | 0..1 | Postal\_Address |
| Email address | /email\_address | 0..N | String |
| Phone number | /phone\_number | 0..1 | Phone\_Number |
| URI | /uri | 0..1 | String |

###### *Reference Document*

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

Table 24: Reference Document

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Data Type |
| Reference Document | /reference\_document |  |  |
| ID | /identifier | 0..1 | String |
| Document Type | /document\_type | 0..1 | Document\_Type |
| Language | /language | 0..N | Language\_Identification |
| Notation | /notation | 0..1 | Notation |
| Title | /title | 0..1 | Text |
| Provider | /provider | 0..1 | Organization |
| URI | /uri | 0..1 | String |

###### *Document Type*

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

Table 25: Document\_Type

| Name | Relative Location | Card | Data Type |
| --- | --- | --- | --- |
| Document Type | /document\_type | 0..1 |  |
| ID | /identifier | 0..1 | String |
| Description | /description | 0..1 | Text |
| Scheme Reference | /scheme\_reference | 0..1 | Sign |

###### *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 26: Language

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Data Type |
| Language | /Language\_Identification |  |  |
| language identifier | /language identifier | 1..1 | String |
| script identifier | /script\_identifier | 0..1 | String |
| geopolitical territory | /geopolitical\_territory | 0..1 | String |
| variant identifier | /variant\_identifier | 0..N | String |
| extension identifier | /extension\_identifer | 1..N | String |
| private use qualifier | /private\_use\_qualifier | 0..1 | String |

###### *Interface*

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

Table 27: Interface

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Data Type |
| Interface | /interface |  |  |
| Identifier | / identifier | 0..1 | String |
| Name | / name | 0..1 | String |
| Description | / description | 0..1 | Text |
| URL | /URL | 0..1 | String |
| Version | / version | 0..1 | String |

###### *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 28: Designatable\_Item

| Name | Relative Location | Card | Data Type |
| --- | --- | --- | --- |
| Designatable Item | /designation | 1..1 |  |
| Designation | /designation | 1..N | Designation |
| Definition | /definition | 0..N | Definition |
| Text | /text | 1..1 | String |
| Language | /language | 0..1 | String |
| Source | /source | 0..1 | Identifier |
| Classifier | /classifier | 0..N | Classifiable\_Item |
| Type | @type |  | String |
| ID | @identifier |  | Identifier |

###### *Designation*

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

Table 29: Designation

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Data Type |
| Designation | /designation |  |  |
| Designation Context | /designation\_context | 1..1 | String |
| Sign | / sign | 1..1 | Sign |
| Language | / language | 0..1 | String |
| Namespace | / namespace | 0..N | Identifier |
| Convention | / convention | 0..N | Identifier |

###### *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 30: Individual

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name | Relative Location | Card | | Data Type |
| Individual | /contact | | 0..N |  |
| Name | /name | | 1..1 | Sign |
| Title | /title | | 0..1 | Sign |
| Mail address | /mail\_address | | 0..1 | Postal\_Address |
| Email address | /email\_address | | 0..N | String |
| Phone number | /phone\_number | | 0..1 | Phone\_Number |
| FHIR Mail Address | /fhir\_mail\_address | | 0..N | FHIR Mail Address |

###### *FHIR Mail Address*

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

Table 31: FHIR Mail Address Data Elements

| Name | Relative Location | Card | Data Type |
| --- | --- | --- | --- |
| **FHIR Address** | /fhir\_mail\_address |  |  |
| Use | /use | 0..1 | String |
| Text | /text | 0..N | String |
| Line | /line | 0..N | String |
| City | /city | 0..1 | String |
| State | /state | 0..N | String |
| ZIP | /zip | 0..1 | String |
| Country | /country | 0..1 | String |

###### *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 32: Role Data Elements

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Data Type |
| Role | /role |  |  |
| Title | /title | 0..1 | Sign |
| Mail address | /mail\_addresses | 0..1 | Postal\_Address |
| Email address | /email\_addresses | 0..1 | String |
| Phone number | /phone\_numbers | 0..1 | Phone\_Number |

* Each *Role* **MAY** contain zero or one *title* describing the name of the position of the individual
* Each *Role* **MAY** contain zero or one *mail addresses* which is the postal address by which you may reach the individual
* Each *Role* **MAY** contain zero or one *email addresses* which is the email address by which you may reach the individual
* Each *Role* **MAY** contain zero or one *phone numbers* which is the phone number by which you may reach the individual

###### *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 32: State Data Elements

| Name | Relative Location | Card | Data Type |
| --- | --- | --- | --- |
| State | /state |  |  |
| Registration status | / registration\_status | 1..1 | String |
| Effective date | /effective\_date | 1..1 | Datetime |
| Until date | /until\_date | 1..1 | Datetime |
| Administrative note | /administrative\_note | 1..1 | Text |
| Administrative status | /administrative\_status | 1..1 | String |
| Previous state | /previous\_state | 0..1 | Registration\_State |

###### *Initial State*

The SDC form package contains an Initial state is used across to indicate the initial behavior of an element. Its enumeration value may be set to enabled, which means that the element should be available for use. Alternatively, if its enumeration value is set to disabled, it means that the element should be unavailable for use.

###### *Administered Item*

Registered Item instantiated as an Administered Item. For additional details, reference: ISO/IEC 11179-3.

###### *Identifier*

Restriction Base is any URI. Contains any namespace and version

###### *MDR Association type*

MDR Association Type describes the type of association between a Question and an SDC Data Element that is in a metadata registry. It is restricted to “implements” to indicate that the creator of the mapping has asserted that the Form Design Element has been created from the specified MDR element without change. Note: implementation of a previously created MDR element in a Form Design naturally admits the potential for the narrowing of the meaning of the MDR element, as the form may have a narrower scope than the MDR element.

###### *Date*

A data type whose values are points in time to the resolution: year, month, and day. For additional details, reference: ISO/IEC 11179-3.

###### *Datetime*

A data type whose values are points in time to the resolution: year, month, day, hour, minute, second, and optionally fractions of seconds. For additional details, reference: ISO/IEC 11179-3.

###### *Natural Range*

Natural Range is a data type comprising a range of “natural numbers“, i.e. the positive integers, including zero. Any instance of Natural Range is one of: a constant non-negative Integer, a bounded range of non-negative Integers defined by a minimum and a (strictly larger) maximum value, an unbounded range defined by only a non-negative minimum (e.g., 0..\*, 1..\*, 2..\*).

NOTE Natural\_Range is used as the type of both multiplicity (an attribute of Relation Roles) and arity (an attribute of Relations) in the Concepts metamodel region, but this in no way constrains how it may be used by a Registration Authority. For additional details, reference: ISO/IEC 11179-3.

###### *Postal Address*

A postal address enables the unambiguous determination of an actual or potential delivery point, usually combined with the specification of an addressee and/or a mailee. For additional details, reference: ISO/IEC 11179-3.

###### *Identified Item*

Any metadata item that is to be retrieved directly (as opposed to indirectly through a related item), shall be an Identified Item), so the item can be referenced. An example of metadata items that might not be explicitly identified are the Permissible Values within a Value Domain. For additional details, reference: ISO/IEC 11179-3.

###### *Registered Item*

Any metadata item that is to be registered in the registry shall be a Registered Item. Registered Item is an abstract class, which means that each such item must be instantiated as one of the subclasses: Administered Item, or Attached Item. These subclasses are mutually exclusive and collectively exhaustive (mece). For additional details, reference: ISO/IEC 11179-3.

###### *Prompt*

Each instance of prompt represents textual elements used to introduce a Section Element, Question Element or List Item. For additional details, reference: ISO/IEC 19763-13.

###### *Number*

Number represents a number that is visible on the form for Section\_Element, Question\_Element or List\_Item. For additional details, reference: ISO/IEC 19763-13.

###### *Text Element*

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

###### *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 : Text Field

| Name | Relative Location | Card | Comments |
| --- | --- | --- | --- |
| Text Field | /section/base\_question/text\_field |  |  |
| Multiselect | /multiselect | 0..1 | Of type boolean |
| Default | /default\_value | 0..1 | Of type String  An optional default value for the input field when nothing is entered, where the maximum multiplicity is one. |
| Default value read only | /default\_value\_read\_only | 0..1 | Of type boolean  An optional indicator of whether the default value, if specified, can be edited, where the maximum multiplicity is one. |
| Maximum Character Quantity | /maximum\_character\_quantity | 0..1 | Of type String.  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. |
| Unit of Measure | /unit\_of\_measure | 0..1 | Of type 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. |
| @Schema Name | @schema\_name | 1..N | Of type String |
| Data type | /datatype | 0..1 | Of type String  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. |
| Format | /format | 0..1 | Of type [String](#_Number)  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. |
| Next Relevant Element | /next\_relevant\_element | 0..1 | Of type [Text Element](#_Text_Element)  an explicity reference to the next element to be shown in the form design |
| Default Element | /default\_element | 0..N | Of type [Text Element](#_Text_Element) |
| List Item ID | /list\_item\_identifier | 0..1 | Of type [Text Field](#_Text_Field) |
| Default | /default | 0..1 | Of type [List Field](#_List_Field) |
| Value | /value | 1..1 | Of type Sting |
| Default Prompt | /default\_prompt | 0..1 | Of type [Additional Text](#_Additional_Text) |
| @type | @type |  | Of type Text\_Type |
| @initial state | @initial\_state |  | Of type Initial State |
| Read Only | /read\_only | 1..1 | Of type Boolean  Default= “false” |
| Datatype | /datatype |  |  |
| String | /string |  |  |
| Regular expression | /reg\_ex | 0..1 |  |
| Pattern | /pattern | 0..1 |  |
| Minimum Characters | /minimum\_characters | 0..1 |  |
| Maximum Characters | /maximum\_characters | 0..1 |  |
| Integer | /integer |  |  |
| Minimum Value | /minimum\_value | 0..1 |  |
| Maximum Value | /maximum\_value | 0..1 |  |
| Decimal | /decimal |  |  |
| Minimum Value | /minimum\_value | 0..1 |  |
| Maximum Value | /maximum\_value | 0..1 |  |
| Fraction Digits | /fractiondigits | 0..1 |  |
| String Date | /string\_date |  | Comment: does sdc need a list of valid pattern types |
| Pattern | /pattern | 0..1 |  |
| International Date Time | /international\_dateTime |  | investigate date daatypes for accurate recordign of time for treatment administration |
| Pattern | /pattern |  |  |
| String Time | /string\_time |  | Possibly HH:MM:SS:ms am/pm 12/24 |
| Pattern | /pattern | 0..1 |  |
| Timezone | /timezone | 0..1 |  |
| Duration | /duration |  | investigate standard for duration, possibly w3c: "PnYn MnDTnH nMn S" investigate HL7 datatypes |
| File | /file |  | need a valid list of mime types check wikipedia |
| Mime Type | /mime\_Type | 0..1 |  |
| Max Size | /max\_Size | 0..1 |  |

###### *Additional Text*

Table : Additional Text

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Coments |
| Cardinality | /Cardinality | 0..1 |  |
| Minimum | /minimum | 1..1 | Of type Integer |
| Maximum | /maximum | 1..1 | Of type Integer |
| Rule | /Rule | 0..N |  |
| Expression | /expression | 1..N |  |
| Label | /label | 0..1 | Of type String  An optional name, label or identifier where the maximum multiplicity is one. |
| Style | /style | 0..N | Of type String  A optional set of statements in some style language about the element where the maximum multiplicity is unbounded. |

###### *List Field*

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

Table : List Field

| Name | Relative Location | Card | Comments |
| --- | --- | --- | --- |
| List Field | /section/base\_question/list\_field |  | List\_Field is a metaclass each instance of which represents a field in which only predefined answers are allowed. |
| Multiselect | /multiselect |  | Of type String |
| Default Element | /default |  |  |
| List Item ID | /list\_item\_identifier | 0..1 | Of type String |
| Default | /default | 0..1 |  |
| Value | /value | 0..1 | Of type String |
| Default Prompt | /default\_prompt | 0..1 | Of type Text Element |
| Read Only | /read\_only | 0..1 | Of type Boolean |
| Maximum Character Quantity | /maximum\_character\_quantity | 1..1 | Of type String |
| Unit of Measure | /unity\_of\_measure | 0..N |  |
| Schema Name | /schema\_name | 1..N | Of type String |
| Data type | /datatype | 0..1 | Of type [Prompt](#_Prompt) |
| Format | /format | 0..1 | Of type [Number](#_Number) |
| Next Relevant Element | /next\_relevant\_element | 0..1 | Of type [Text Element](#_Text_Element) |
| Ordered |  | 0..1 | Of type boolean  A flag that indicates if the order of child List\_Field instances is semantically significant, where the maximum multiplicity is one. |
| Fill\_in | /fill\_in | 0..1 | provide the ability to make a text entry instead of the items in the list selection. For example,”Other:” or “Specify:” |
| List\_item | /list\_item | 2..N | The set of pre-defined list items that are allowed answers to the question where the minimum multiplicity is two and the maximum multiplicity is unbounded. |
| Value | /value | 1..1 | Of type string |
| Item Number | /item\_number | 0..1 | Of type Number |
| Item Prompt | /item\_prompt | 0..1 | Of type Prompt |
| Additional Instruction | /additional\_instruction | 0..N | Of type Additional Text |
| Value Meaning | /value\_meaning | 0..N | Of type Additional Text |
| Fill in | /fill\_in | 0..1 | Of type boolean |
| Guard | /guard | 0..1 | Of type Guard\_Type |
| Item Prompt XHTML | /item\_prompt\_xhtml | 0..1 | A formatted prompt that includes html markup embedded in the element |
| Media | /media\_element | 0..N | Of type Media |
| List Item Order | /list\_item\_order | 0..1 | Of type Integer |
| List Item Identifier | /list\_item\_identifier | 0..1 | Of type String |

###### *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”,

Table : Guard

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Comments |
| Guard | /guard |  | Of type Guard |
| Guarded Element ID | /guarded\_element\_identifier | 0..N | Of type String |
| Guarded Element | /guarded\_element | 0..N |  |
| Section | /section | 0..N | Of type Section |
| Question | /question | 0..N | Of type Question |

###### *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 38: Lookup Field

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Relative Location | Card | Data Type |
| Lookup Field | /lookup\_field | 0..1 | Of type [Text Field](#_Text_Field) |
| End point | /end\_point | 0..N | Of type anyURI  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. |

Appendix F

Open Items

| Open Issue | Reported by | Reported Date |
| --- | --- | --- |
| Standardized Panels and Assessment Instruments: Critical element of PCOR-- how should reusable panels and assessment instruments should be represented (as reusable sections? Complex data elements?). Discussion of complex topic was deferred from first IG. | Lisa Lang (NLM) | 3/26/2014 |
| Identifiers: It is not clear from the IG whether identifiers should be URIs, “OIDs” (meaningless strings), or some sort of human-friendly schema that clearly identifies the registry, the form and the part of the form (e.g. Question, List Item, DE id, etc.) | Lisa Lang (NLM)/Denise Warzel (NCI) | 3/26/2014 |
| Association Type: IG currently limits association type to “implements.” Should other associations be allowed (such as“narrower\_than” or “broader\_than”) and how would the semantics be expressed? | Lisa Lang (NLM)/Denise Warzel (NCI) | 3/26/2014 |
| Versions vs Releases: IG does not provide guidance re versioning. Some DEs will have individual versions, others (especially terminologies or codesets) will update only as part of a general ‘release’ (version by release vs. version by term). How if at all should we distinguish these different types of ‘versions’? If the semantics of a data element stay the same but a new release issued, should the version number change in the data element identifier? Also linked to issue of static versus dynamic binding. | Lisa Lang (NLM)/Denise Warzel (NCI) | 3/26/2014 |

Appendix G

References

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2. <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm> [↑](#endnote-ref-2)
3. IHE RFD profile: http://wiki.ihe.net/index.php?title=Retrieve\_Form\_for\_Data\_Capture [↑](#endnote-ref-3)
4. ISO/IEC19763-13 (MFI-13) standard: http://metadata-standards.org/19763/ [↑](#endnote-ref-4)
5. Transport Layer Security (TLS) v1.0 security standard: http://datatracker.ietf.org/wg/tls/charter/ [↑](#endnote-ref-5)
6. Simple Object Access Protocol (SOAP) standard: http://www.w3.org/TR/soap12-part1/ [↑](#endnote-ref-6)
7. IHE ATNA profile: http://wiki.ihe.net/index.php?title=Audit\_Trail\_and\_Node\_Authentication [↑](#endnote-ref-7)
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15. Nationwide Health Information Network (NwHIN) resources: <http://www.healthit.gov/policy-researchers-implementers/health-information-network-tools> [↑](#endnote-ref-15)
16. IHE Clinical Research Data Capture (CRD) profile: http://wiki.ihe.net/index.php?title=Clinical\_Research\_Data\_Capture\_-\_%28CRD%29 [↑](#endnote-ref-16)
17. ISO/IEC. ISO/IEC 11179: Information Technology – Metadata Registries (MDR) Parts 1–6 (2nd Edition) [↑](#footnote-ref-1)
18. Source: <http://metadata-standards.org/11179/>; internet accessed on Feb 5, 2014 [↑](#footnote-ref-2)
19. Source: <http://www.ihe.net/Technical_Framework/upload/IHE_QRPH_Suppl_DEX_Rev1-0_PC_2013-06-03.pdf>; internet accessed on Feb 5, 2014. [↑](#footnote-ref-3)
20. http://wiki.siframework.org/share/view/47254038 [↑](#footnote-ref-4)