SDC Overview

- Launched in 2013 in collaboration with NIH (NLM, NCI), AHRQ, FDA, CMS and CDC
- Uses the structured data within EHRs to supplement data collected for other purposes, such as:
  - Clinical research (Patient Centered Outcomes Research/Comparative Effectiveness Research) (NLM)
  - Patient safety event reporting (AHRQ) & Adverse Event Reporting (FDA)
  - Public Health Reporting (CDC)
  - Determination of Coverage (CMS)
Value and Benefits

- Reduce data collection burden on health care providers
- Improve comparability of data to better inform research, quality reporting and ultimately, influence patient care
- Contribute to the Public Health, Patient Safety and Adverse Event Reporting, and Clinical Research communities
SDC Standards Focus
SDC Implementation Guidance

SDC Initiative has adopted and enhanced existing standards for:
1. Forms (also called templates)
2. Data Elements on those forms
3. Pre-population / Auto-population of the forms
4. Transport (how EHRs exchange forms)

These standards/guidelines are explained in two Implementation Guides:
1. IHE SDC Profile (current technology)
2. FHIR SDC Profile (emerging technology)
Structured Data Capture Workflow

1. Sends request for form/template

2. Sends requested form/template

3. Converts, populates and displays form

4. Fills, stores/transmits structured data

5. Extract, Transform, and Load Data by form/template

Actor Key:
- Forms Filler
- Forms Manager
- External Repository

Metadata Source:
- CDE Library
- Form Library
SDC Form Transaction Options

There are 3 Form Transaction Options:

- **Blank Form**
  - EHR System sends a request for a blank form/template to the Form/Template Repository
  - Form/Template Repository sends requested blank form back to the EHR System

- **Partially Completed Form**
  - EHR System sends a request for the form/template with relevant patient data to the Form/Template Repository
  - Form/Template Repository sends the form/template with pre-populated patient data back to the EHR system

- **Completed Form**
  - EHR System sends a completed form/template to an External Data Repository
IHE SDC Profile

- Published in Sept 2014
  - [http://wiki.siframework.org/IHE+SDC+Profile](http://wiki.siframework.org/IHE+SDC+Profile)
- Provides specifications to enable an Electronic Health Record (EHR) system to retrieve a form, populate it with existing data, add additional data, then submit the completed form.
- IHE SDC Profile uses the following standards:

**Content & Structure**
- CDA Consent Directives
- ISO/IEC 11179
- ISO/IEC 19763-13

**Transport, Security & Authentication**
- IHE RFD
- IHE ATNA
- SOAP
- TLS v1.0 or higher
- SAML
SDC FHIR Profile

- SDC FHIR Profile is based on the HL7 FHIR Standard.
- SDC FHIR Profile was balloted through HL7 in April 2015 and is currently in comment reconciliation. The expected publication date is September 2015
- SDC FHIR Profile is intended to support clinical systems in the creation and population of forms with patient-specific data.
- SDC FHIR Profile defines a mechanism for linking questions in forms to pre-defined data elements and enables systems to automatically populate portions of the form based on existing data (from an EHR or other system).
Pilot and Demonstration Activities

- **IHE Connectathon (Jan 2015)**
  - Convened a group of 13 organizations to demonstrate and evaluate the recently published IHE SDC Profile
  - Successfully tested both the form definitions, responses and transactions between systems for 5 forms.

- **HIMSS 2015 (Mar 2015)**
  - Convened a subset of the group who participated in the IHE Connectathon to successfully demonstrate the IHE SDC Profile capabilities during the HIMSS Interoperability Showcase scenario.

- **FHIR SDC Virtual Connectathon (April 2015)**
  - Convened a group of organizations to test the FHIR SDC Implementation Guides in a virtual meeting environment.

- **ASCO 2015 (June 2015)**
  - Convened a subset of the group who participated in the IHE Connectathon to successfully demonstrate the IHE SDC Profile capabilities during the 1st ASCO Interoperability Showcase scenario.
SDC Data Element Definition Framework
**SDC Data Element Definition Framework**

Data Set (grouping)

- Vitals
- Allergies
- Problems
- Lab Results
- Medications

Data Element (semantics)

- Systolic BP
- Diastolic BP
- Height

Data Element Attribute (syntax)

- Common DE
- DE Concept
- Value Domain

**Common Data Elements (CDEs)** are those DEs that are developed, maintained and used based on commonly agreed upon principles by the user community. CDEs are reusable across a variety of clinical and non-clinical domains.
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EHRs can be certified to “Data Sets” that contain data elements that are unambiguously defined using ISO 11179-3 syntax.

Object containing logical groupings of data elements

Data Set

- Vitals
- Problems
- Lab Results

Common Data Elements (CDEs) are those DEs that are developed, maintained and used based on commonly agreed upon principles by the user community. CDEs are reusable across a variety of clinical and non-clinical domains.
Data Elements that are unambiguously defined enable access to and sharing of health information across spectrum of clinical and clinical research domains (“Free-flow” of information between EHRs and research information systems).

Common Data Elements (CDEs) are those DEs that are developed, maintained and used based on commonly agreed upon principles by the user community. CDEs are reusable across a variety of clinical and non-clinical domains.
Clinical Care vs. Clinical Research
Interoperability on FHIR

Common Data Elements (CDEs) form bridge between clinical ‘Profile’ perspective and the research ‘Questionnaire’ perspective.
SDC Data Element Attributes
Common Data Element Attribute

- **Data Element (DE)**
  - A data element is a unit of data for which the definition, identification, representation, and permissible values are specified by means of a set of attributes.

- **Common Data Elements (CDEs)**
  - CDEs are data elements that are developed, maintained and used based on *commonly agreed upon* principles by the user community.
  - Another characteristics of CDEs is their *reusability across* a variety of forms and clinical domain that in turn provides a *consistent* way to *aggregate and analyze* data *across* clinical trials and clinical domains.

- **(Common) Data Element attribute**
  - Attributes are a set of characteristics that *describe* CDE and help defined, use and maintain CDE.
Data Element Attributes
(identified in database where data element is maintained)

Attribute NAME | Attribute VALUE
--- | ---
\text{id}: | 123XYZ
\text{version}: | 1.0
\text{Name}: | Sex
\text{Preferred question text}: | Sex
\text{Creation Date}: | Jan 20, 2014

Permissible Values
(free text or prescribed set of permissible values)

Value Domain/Set Attributes
(identified in database where value domain is maintained)

Attribute NAME | Attribute VALUE
--- | ---
\text{Name}: | Administrative_Gender
\text{Version}: | 1.2
\text{Max character quantity}: | 6
\text{Permissible value}: | Female
SDC Data Element Attributes Scope

Data Element Attributes scope within SDC Implementation Guide

- **SDC IG Scope**
- DE Maintenance in registries
- DE creation, sharing and reuse
- Core Form DE
- Number of DE attributes
- Complexity of DE attributes
SDC CDE Model

SDC and ISO 11179-3

Question (Element, Name)

Data Element Concept

(Common) Data Element (CDE)
name: Gender [IL7y3:0]

Value Domain (VD)
name: GENDER_CODE

Value Set (Conceptual Domain)
name: Administrative Gender [IL7y3:0]

SDC Form (e.g. Clinical Research Form)

Answer (Value)

Value Set Member

- value: M
  - permitted value: M
  - role meaning concept code: 24815/2002 (SNOMED CT)
  - role meaning description: Male

Value Set Member

- value: F
  - permitted value: F
  - role meaning concept code: 24815/2002 (SNOMED CT)
  - role meaning description: Female

Value Set Member

- value: U
  - permitted value: U
  - role meaning concept code: 109112007 (SNOMED CT)
  - role meaning description: Unknown
### SDC DE Example

![Image of a webpage displaying search results for Data Elements (DEs) with columns for Long Name, Preferred Question Text, Owned By, Used By Context, Registration Status, and more.](image-url)
Contact Information

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- Harmonization Support: Perry Smith (perri.smith@accenturefederal.com)
- Subject Matter Expert: Dr. Mark Roche (mrochemd@gmail.com)

SDC Wiki Page:
http://wiki.siframework.org/Structured+Data+Capture+Initiative

Weekly All-Hands Meeting Info (Thursdays):
- **Time:** 3:25pm – 4:30Ppm Eastern
- **URL:** https://siframework1.webex.com/
- **Dial-In Number:** 1-650-479-3208
- **Access Code:** 663 397 496
Thank you!
Appendix
IHE SDC Profile
Workflow Example

1. Provider identifies a patient with a reportable condition.

2. Provider logs in to the EHR and requests an appropriate form.

3. EHR system (acting as the Form Filler) requests and retrieves the appropriate form from the Form Repository (acting as the Form Manager).

4. EHR populates the form with any available data.

5. Provider verifies the pre- and auto-populated data, adds any missing data, and then submits the completed, structured form to the Public Health Organization.

6. Public Health Organization receives the form.

7. Provider receives a response confirming the form was received.
Patient Safety Event Workflow

**Case Example: Public Health Reporting**

**Reporter**
- Event Occurs
- Report? Yes → Log into System (e.g. EHR)
- No → End Process

**Reviewer**
- Log into Risk Management Information System (RMIS)
- Retrieve form
- Evaluate Form and Determine Appropriate Procedures & Refine Form Responses
- Form Complete? Yes → Confirm / Sign Off that form is ready to send
- No → End Process

**Sender**
- Confirm / Sign Off that form is ready to send
- Send Form? Yes → Send Form
- No → End Process

**Patient Safety Organization**
- Receive and process form
- End Process

*Auto-populate* Form from EHR
*Retrieve and pre-populate* Form from Form Repository
*Generate form in appropriate PSO format*
## IHE SDC Profile
### Roles and Descriptions

<table>
<thead>
<tr>
<th>IHE Profile Role</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form Filler</td>
<td>Retrieves forms from a Form Manager as and when required. When requesting a form, the Form Filler can optionally provide EHR context information by providing pre-population xml data in the request for use by the Form Manager.</td>
</tr>
<tr>
<td>Form Manager</td>
<td>Supplies forms to Form Fillers based upon form retrieval requests. In some cases, may return a form whereas in other cases the returned form may be selected or constructed based upon context information supplied in the form retrieval request.</td>
</tr>
<tr>
<td>Form Receiver</td>
<td>Receives and processes completed or partially completed forms instance data from a Form Filler.</td>
</tr>
</tbody>
</table>
SDC FHIR Profile Workflow Example

1. EHR system requests the form.
2. Form Template Repository receives the request, pre-populates the form with some EHR-provided patient data, and sends the form back to the EHR.
3. EHR receives the form, auto-populates the form with additional EHR-derived patient data, and displays the form to the provider.
4. Provider adds additional data to the form (as needed) and completes the form.
5. EHR system transmits the completed structured form, in a standard format, to the Form Receiver.
SDC FHIR Implementation Guide
How SDC Leverages FHIR Resources

SDC FHIR Profile makes use of the following FHIR Resources:

- **DataElement**: is used to define data elements that can be referenced in questionnaires, and can be used to auto-populate form data.

- **Questionnaire**: is used to define form definitions that may be downloaded for manual and/or automatic population.

- **QuestionnaireAnswers**: is used to share instance data captured using questionnaire forms.

- **ValueSet**: is used to define allowed values for
SDC FHIR Implementation Guide
How SDC Leverages FHIR Resources

Profiles
Provide constraints and extensions for each Resource

SDC DataElementProfile
SDC Questionnaire Profile
SDC QuestionnaireAnswers Profile
SDC ValueSet Profile

FHIR Resources
DataElement
Questionnaire
QuestionnaireAnswers
ValueSet

REST
SDC Security Consideration

SDC FHIR Data Element Profile serves as the Logical Model
SDC Data Elements Scope

Core Form  DE creation  Maintenance

 Complexity and number of CDE attributes