The Office of the National Coordinator for Health Information Technology

Structured Data Capture (SDC)

The Use of Structured Data Capture for Clinical Research

July 2015

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HHS/ONC Sponsor: Farrah Darbouze

Putting the I in HealthIT
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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

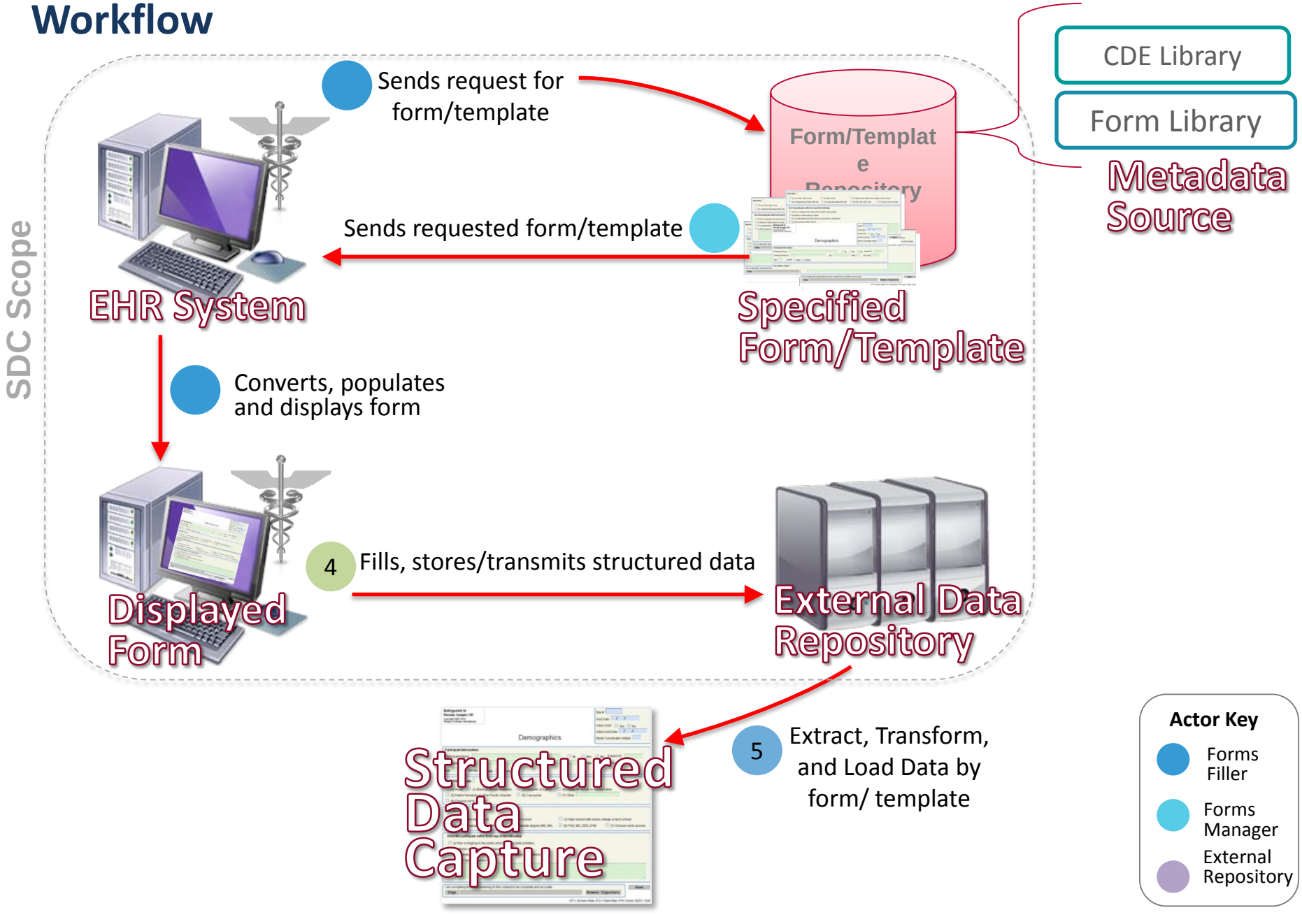
SDC Initiative has adopted and enhanced existing standards for:

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



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
- 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

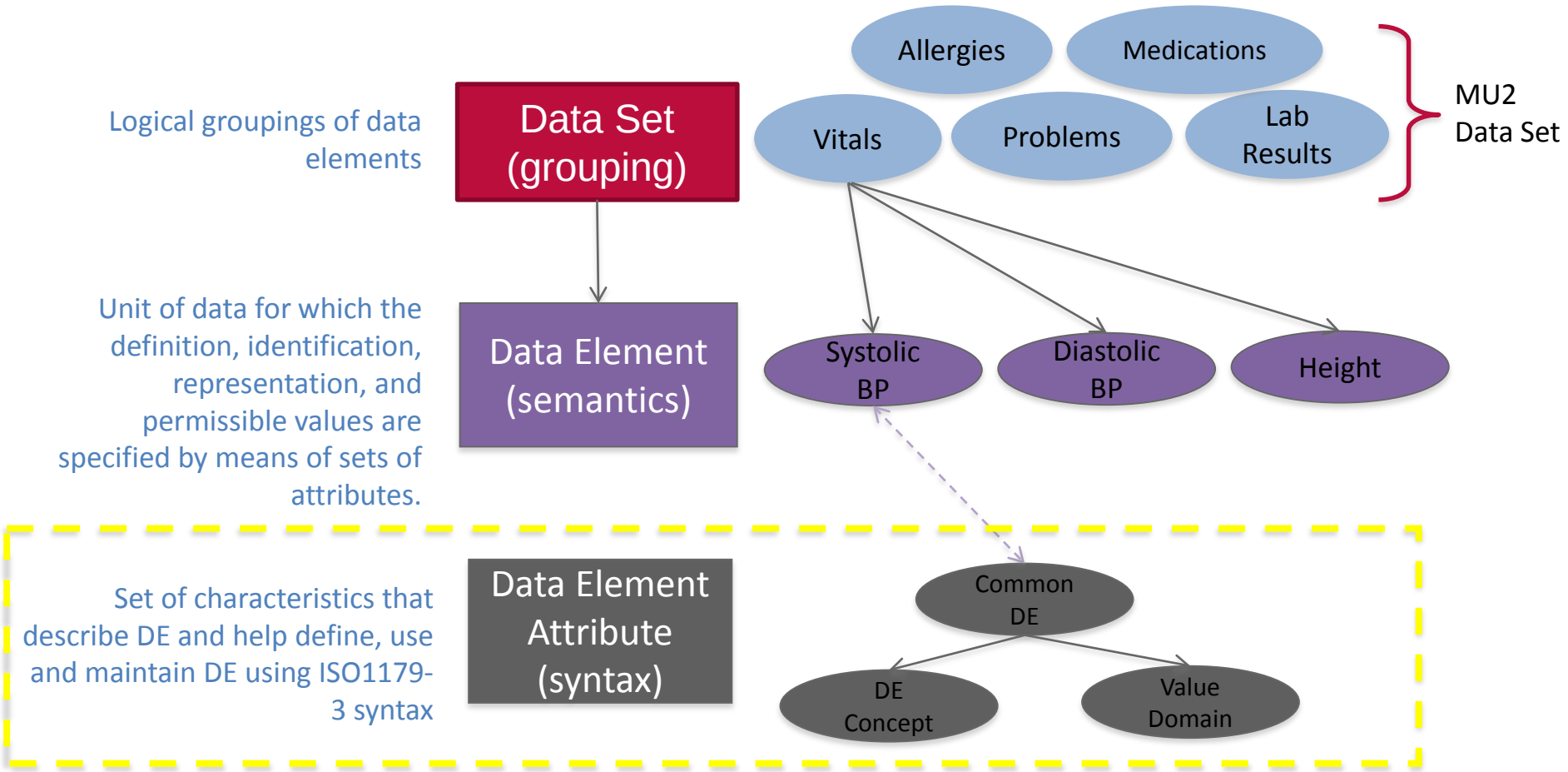
- SDC FHIR Profile is based on the HL7 FHIR Standard.
- SDC FHIR Profile was balloted through HL7 in **April 2015** and is currently in comment reconciliation. The expected publication date is September 2015
  - http://hl7.org/fhir/2015May/iglist.html
- SDC FHIR Profile is intended to support clinical 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.

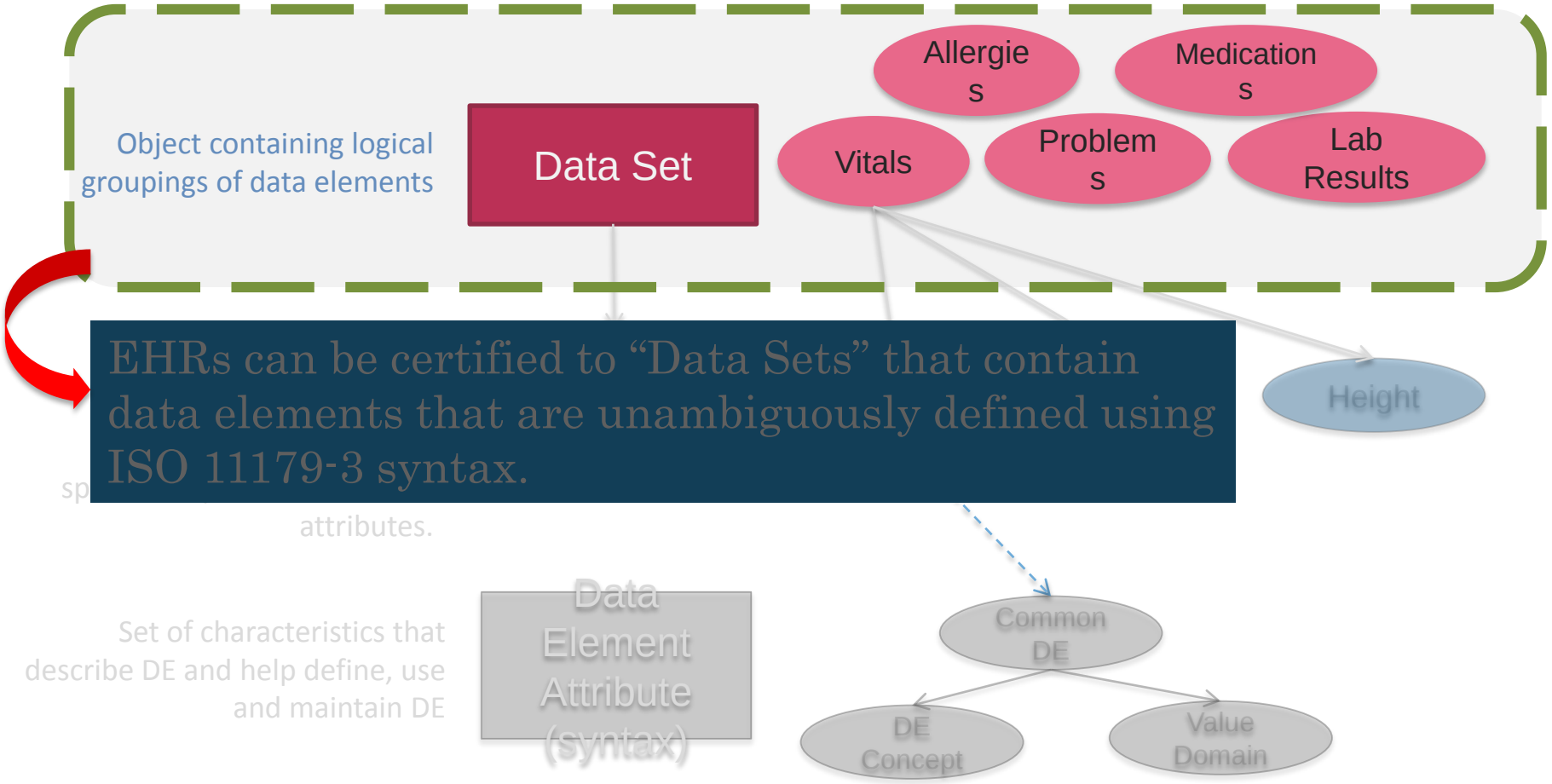
SDC Data Element Definition Framework

SDC Data Element Definition Framework



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.

SDC Data Element Definition Framework



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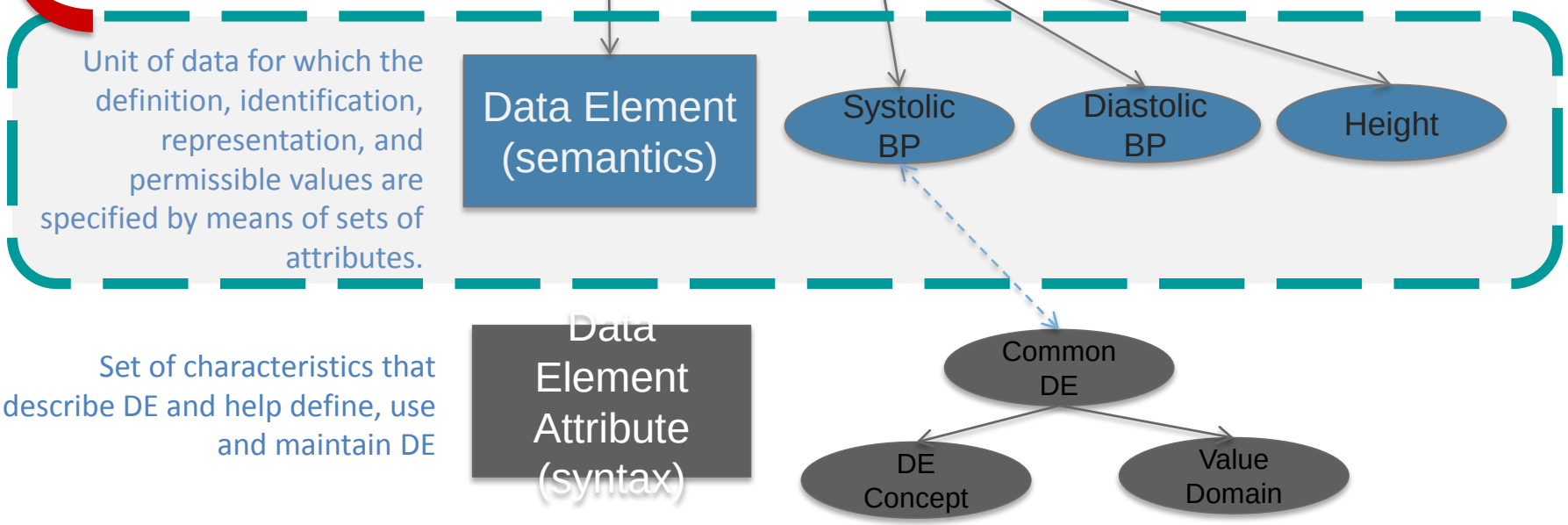
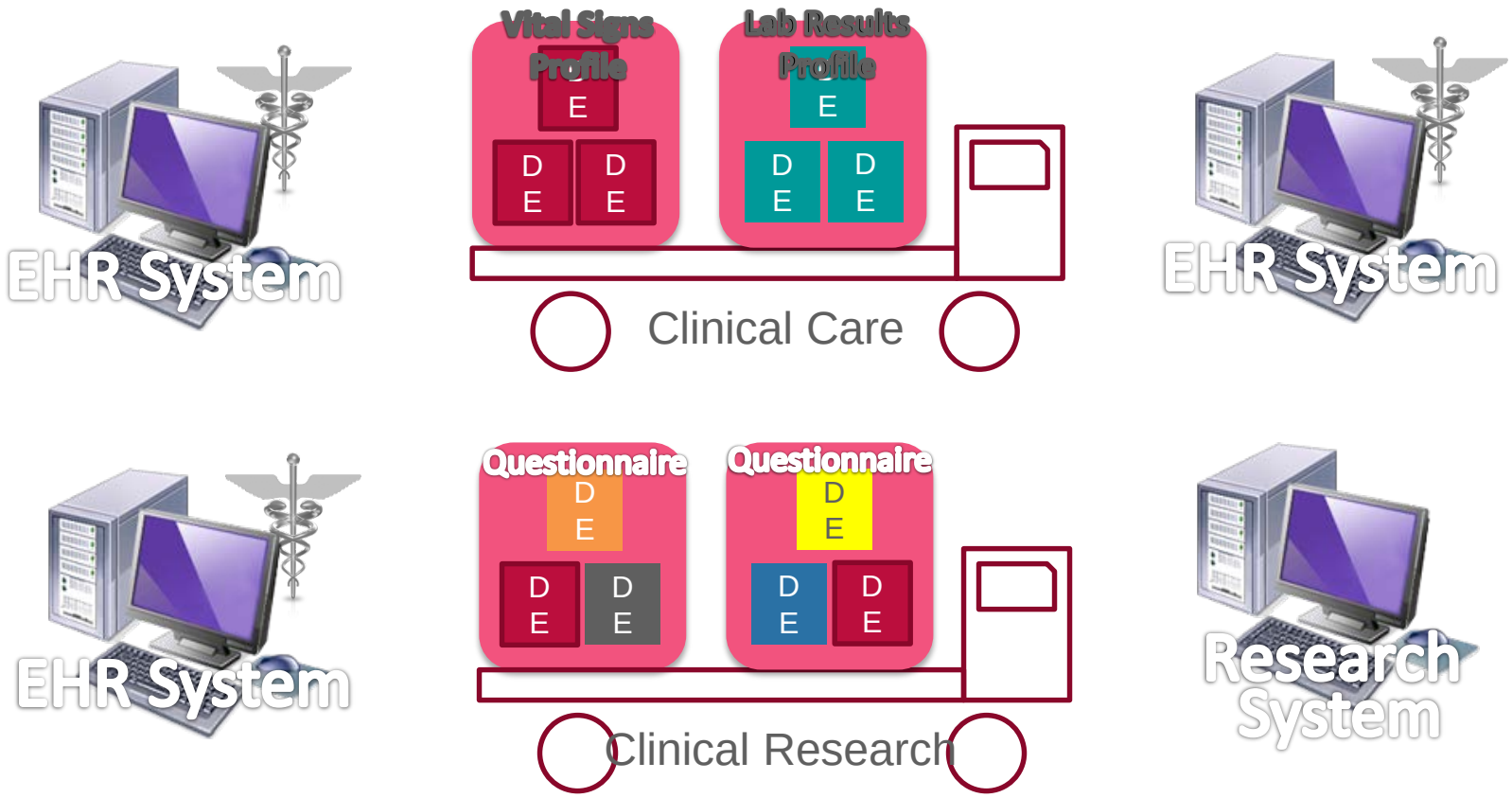
SDC Data Element Definition Framework

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

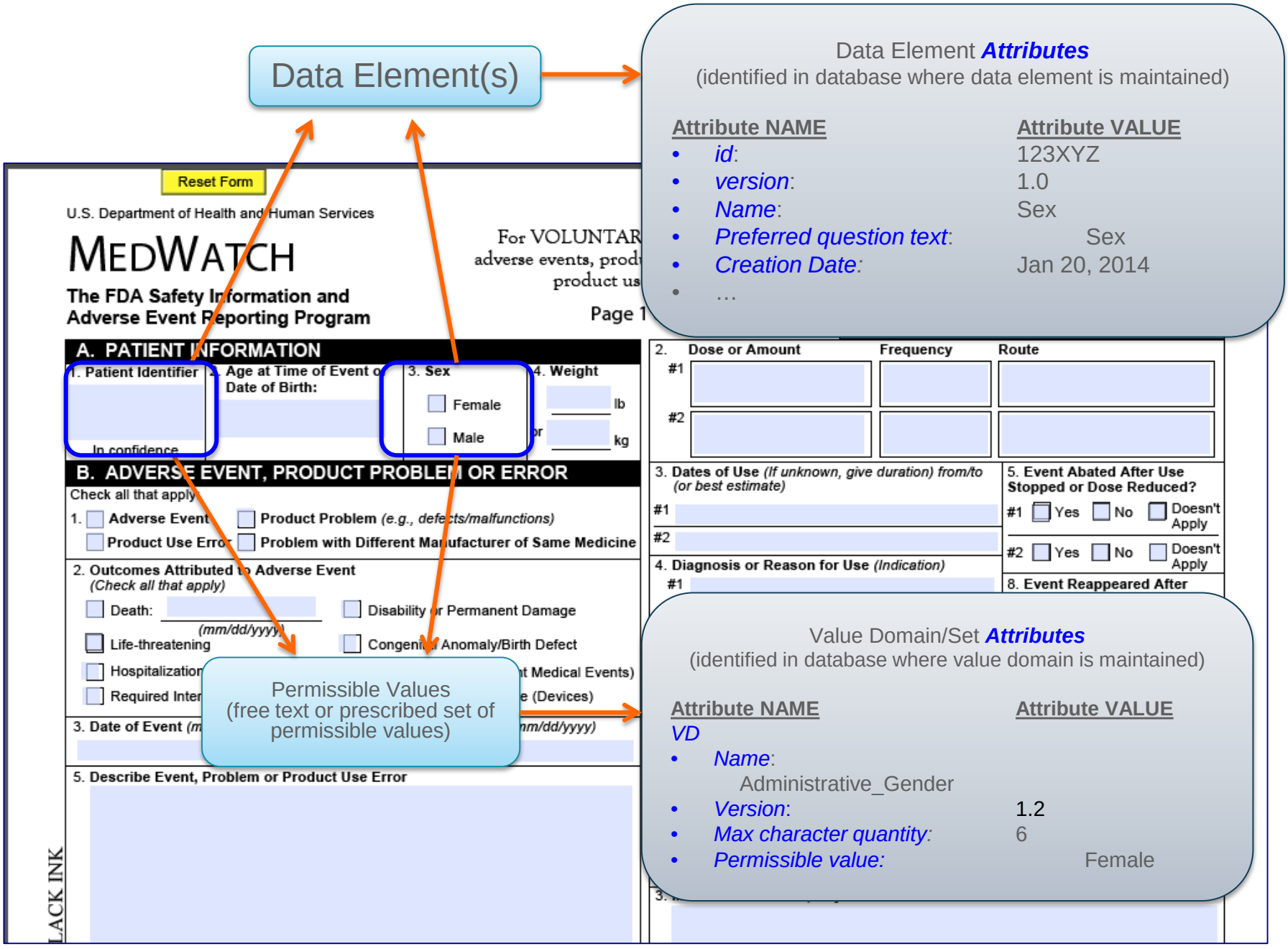


Common Data Elements (CDEs) form bridge between clinical 'Profile' perspective and the research 'Questionnaire' perspective

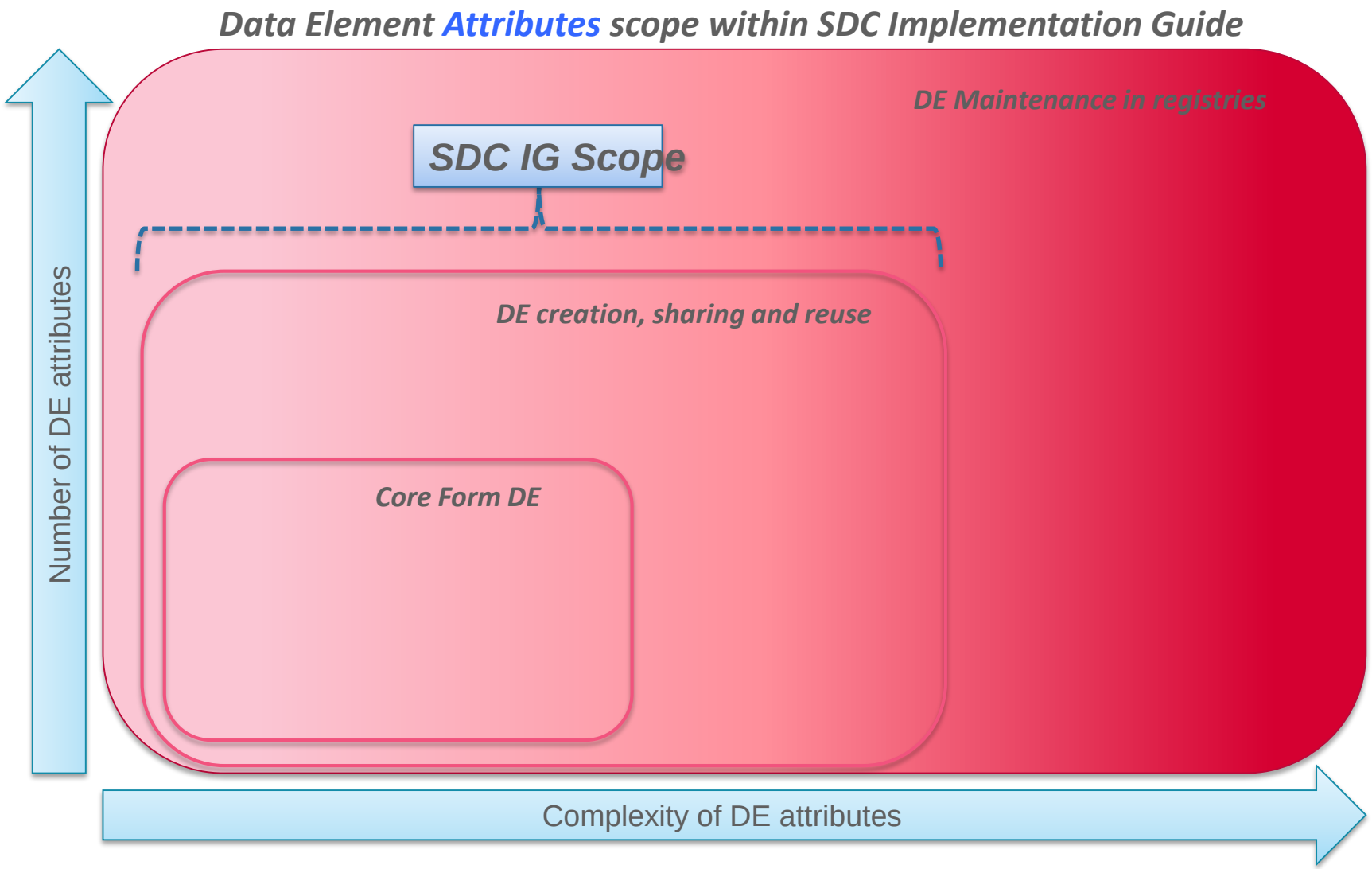
SDC Data Element Attributes

Common Data Element Attribute

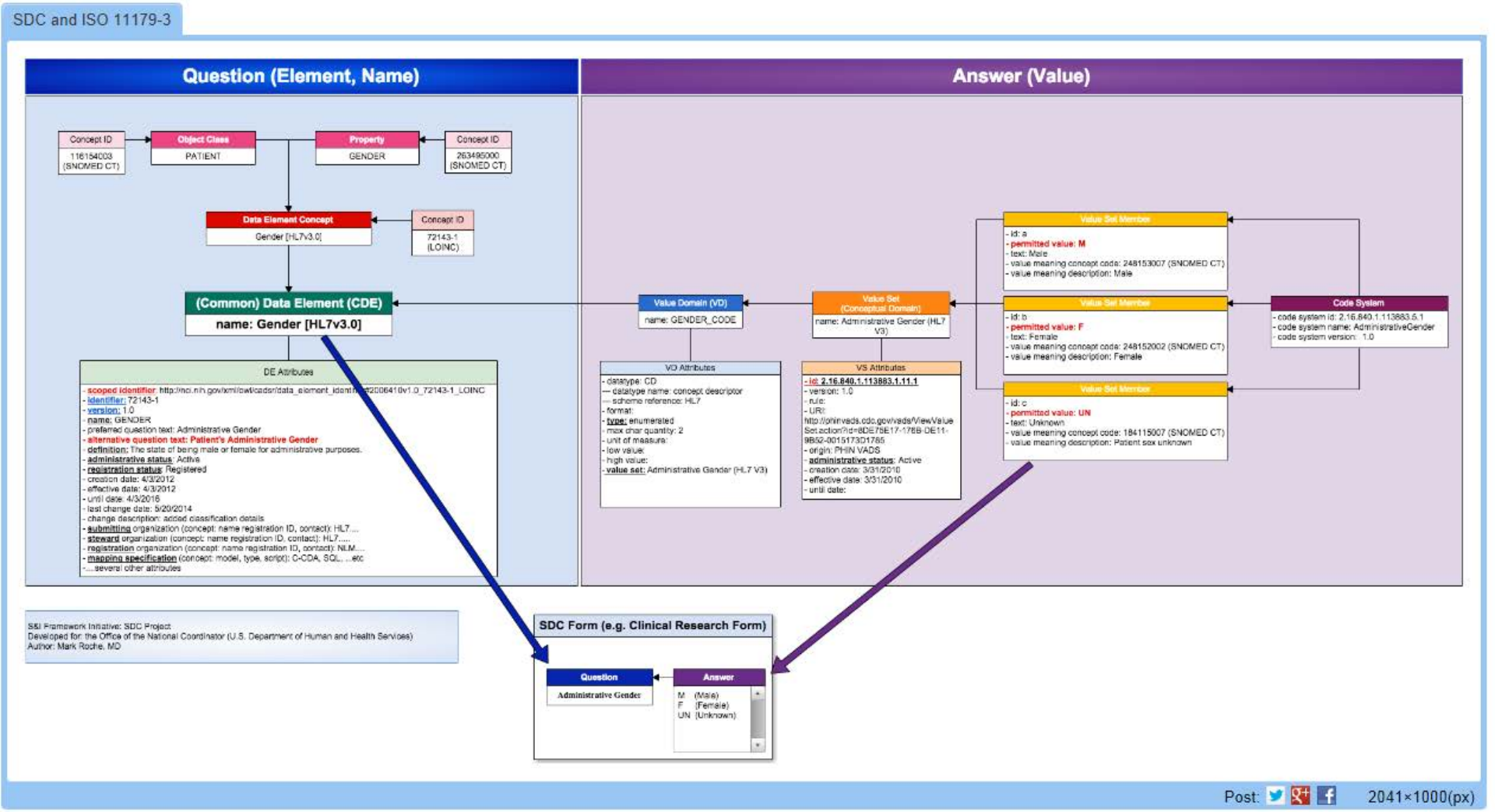
- Data Element (DE)
  - A data element is a unit of data for which the definition, identification, representation, and permissible values are specified by means of a set of attributes.
- *Common* Data Elements (CDEs)
  - CDEs are data elements that are developed, maintained and used based on *commonly 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(s)
Data Element Attributes
(identified in database where data element is maintained)
Attribute NAME
Attribute VALUE
id: 123XYZ
version: 1.0
Name: Sex
Preferred question text: Sex
Creation Date: Jan 20, 2014
…
Reset Form
U.S. Department of Health and Human Services
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program
Page 1
A. PATIENT INFORMATION
1. Patient Identifier
In confidence
3. Sex
Female
Male
4. Weight
lb
kg
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply
1. Adverse Event
Product Problem (e.g., defects/malfunctions)
Product Use Error
Problem with Different Manufacturer of Same Medicine
2. Outcomes Attributed to Adverse Event
(Check all that apply)
Death:
(mm/dd/yyyy)
Disability or Permanent Damage
Life-threatening
Congenital Anomaly/Birth Defect
Hospitalization
Medical Events)
Required Inter
(Devices)
3. Date of Event
mm/dd/yyyy)
5. Describe Event, Problem or Product Use Error
2. Dose or Amount
Frequency
Route
#1
#2
3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1
#2
4. Diagnosis or Reason for Use (Indication)
#1
5. Event Abated After Use Stopped or Dose Reduced?
#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply
8. Event Reappeared After
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
VD
Name: Administrative_Gender
Version: 1.2
Max character quantity: 6
Permissible value: Female

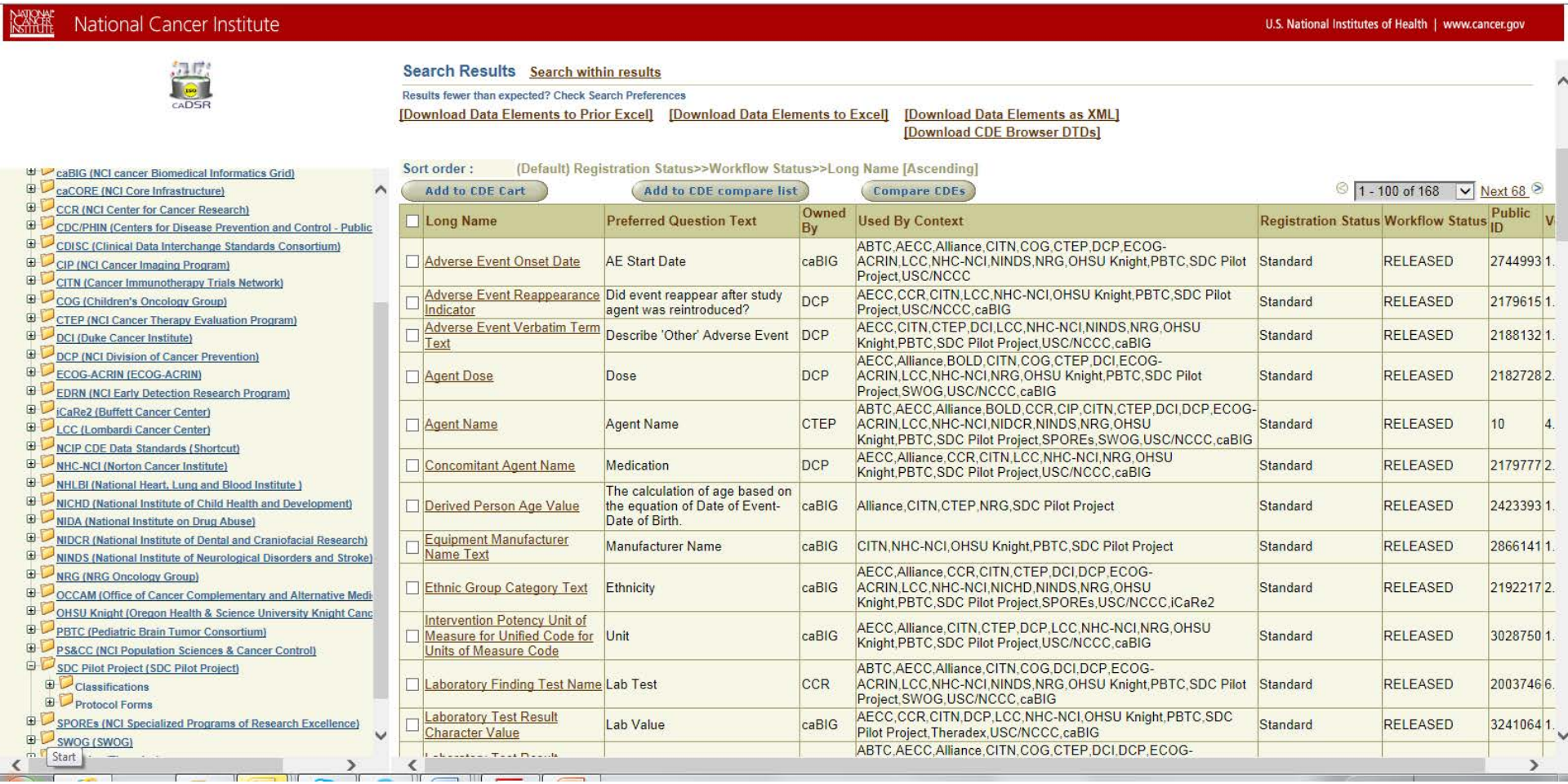
SDC Data Element Attributes Scope



SDC CDE Model



SDC DE Example



Long Name	Preferred Question Text	Owned By	Used By Context	Registration Status	Workflow Status	Public ID	V
Adverse Event Onset Date	AE Start Date	caBIG	ABTC,AECC,Alliance,CITN,COG,CTEP,DCP,ECOG-ACRIN,LCC,NHC-NCI,NINDS,NRG,OHSU Knight,PBTC,SDC Pilot Project,USC/NCCC	Standard	RELEASED	2744993	1.
Adverse Event Reappearance Indicator	Did event reappear after study agent was reintroduced?	DCP	AECC,CCR,CITN,LCC,NHC-NCI,OHSU Knight,PBTC,SDC Pilot Project,USC/NCCC,caBIG	Standard	RELEASED	2179615	1.
Adverse Event Verbatim Term Text	Describe 'Other' Adverse Event	DCP	AECC,CITN,CTEP,DCI,LCC,NHC-NCI,NINDS,NRG,OHSU Knight,PBTC,SDC Pilot Project,USC/NCCC,caBIG	Standard	RELEASED	2188132	1.
Agent Dose	Dose	DCP	AECC,Alliance,BOLD,CITN,COG,CTEP,DCI,ECOG-ACRIN,LCC,NHC-NCI,NRG,OHSU Knight,PBTC,SDC Pilot Project,SWOG,USC/NCCC,caBIG	Standard	RELEASED	2182728	2.
Agent Name	Agent Name	CTEP	ABTC,AECC,Alliance,BOLD,CCR,CIP,CITN,CTEP,DCI,DCP,ECOG-ACRIN,LCC,NHC-NCI,NIDCR,NINDS,NRG,OHSU Knight,PBTC,SDC Pilot Project,SPOREs,SWOG,USC/NCCC,caBIG	Standard	RELEASED	10	4.
Concomitant Agent Name	Medication	DCP	AECC,Alliance,CCR,CITN,LCC,NHC-NCI,NRG,OHSU Knight,PBTC,SDC Pilot Project,USC/NCCC,caBIG	Standard	RELEASED	2179777	2.
Derived Person Age Value	The calculation of age based on the equation of Date of Event-Date of Birth.	caBIG	Alliance,CITN,CTEP,NRG,SDC Pilot Project	Standard	RELEASED	2423393	1.
Equipment Manufacturer Name Text	Manufacturer Name	caBIG	CITN,NHC-NCI,OHSU Knight,PBTC,SDC Pilot Project	Standard	RELEASED	2866141	1.
Ethnic Group Category Text	Ethnicity	caBIG	AECC,Alliance,CCR,CITN,CTEP,DCI,DCP,ECOG-ACRIN,LCC,NHC-NCI,NICHD,NINDS,NRG,OHSU Knight,PBTC,SDC Pilot Project,SPOREs,USC/NCCC,iCaRe2	Standard	RELEASED	2192217	2.
Intervention Potency Unit of Measure for Unified Code for Units of Measure Code	Unit	caBIG	AECC,Alliance,CITN,CTEP,DCP,LCC,NHC-NCI,NRG,OHSU Knight,PBTC,SDC Pilot Project,USC/NCCC,caBIG	Standard	RELEASED	3028750	1.
Laboratory Finding Test Name	Lab Test	CCR	ABTC,AECC,Alliance,CITN,COG,DCI,DCP,ECOG-ACRIN,LCC,NHC-NCI,NINDS,NRG,OHSU Knight,PBTC,SDC Pilot Project,SWOG,USC/NCCC,caBIG	Standard	RELEASED	2003746	6.
Laboratory Test Result Character Value	Lab Value	caBIG	AECC,CCR,CITN,DCP,LCC,NHC-NCI,OHSU Knight,PBTC,SDC Pilot Project,Theradex,USC/NCCC,caBIG	Standard	RELEASED	3241064	1.
			ABTC,AECC,Alliance,CITN,COG,CTEP,DCI,DCP,ECOG-				

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

The Office of the National Coordinator for Health Information Technology

Thank you!

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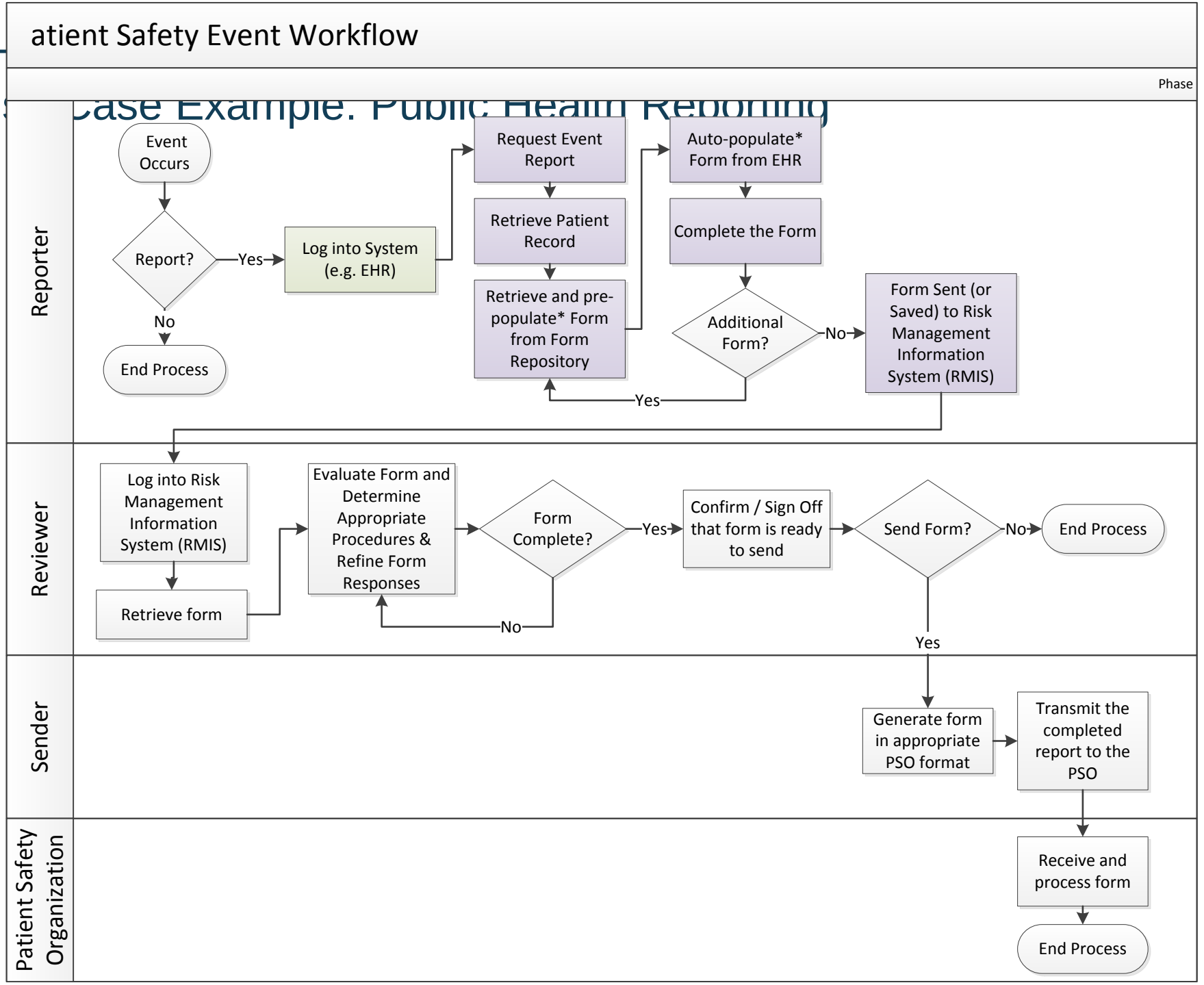
Appendix

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

IH
Us Case Example: Public Health Reporting

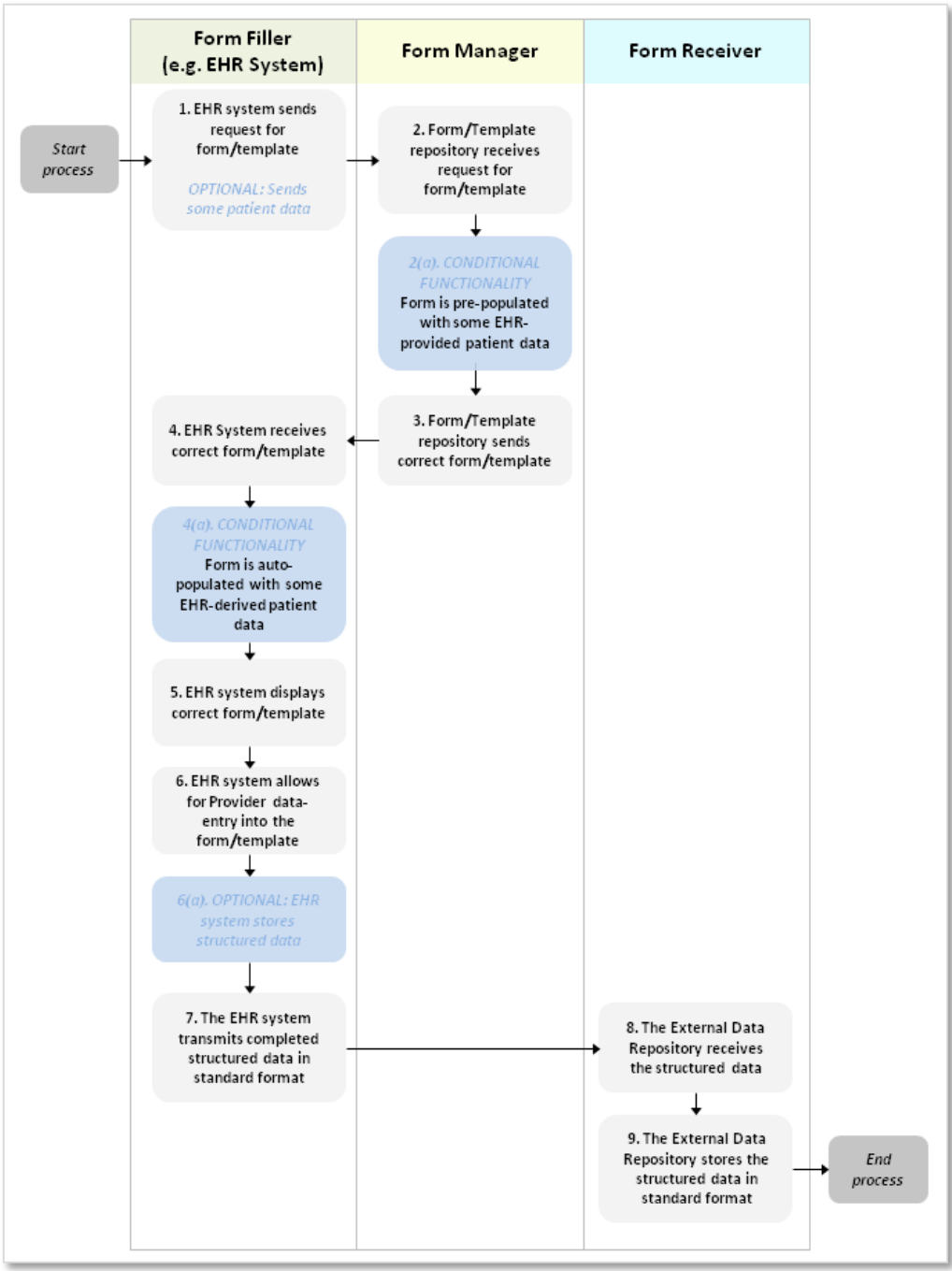


IHE SDC Profile
Roles and Descriptions

IHE Profile Role	Description
Form Filler	Retrieves forms from a Form Manager as and when required. When requesting a form, the Form Filler can optionally provider EHR context information by providing pre-population xml data in the request for use by the Form Manager.
Form Manager	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.
Form Receiver	Receives and processes completed or partially completed forms instance data from a Form Filler.

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.

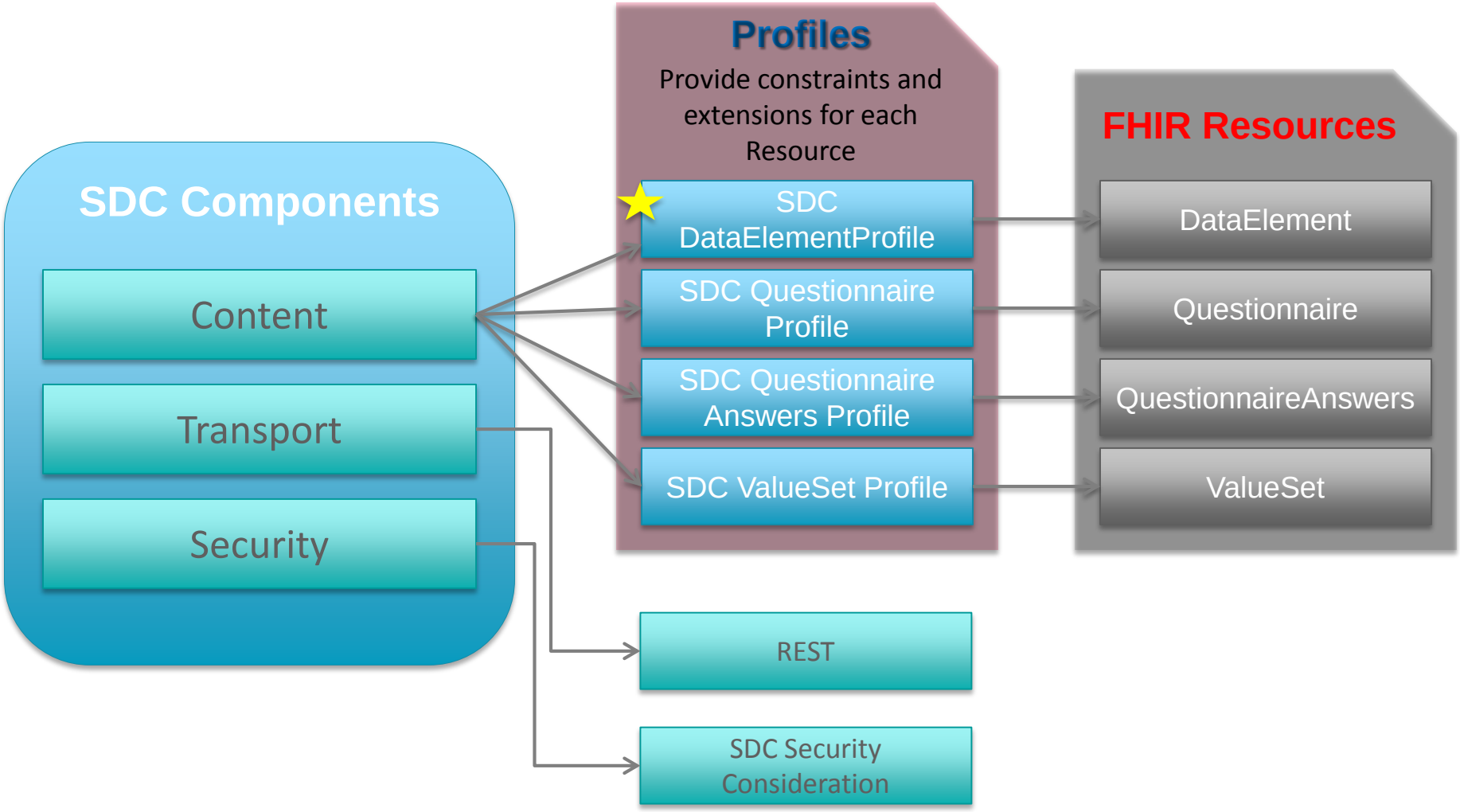


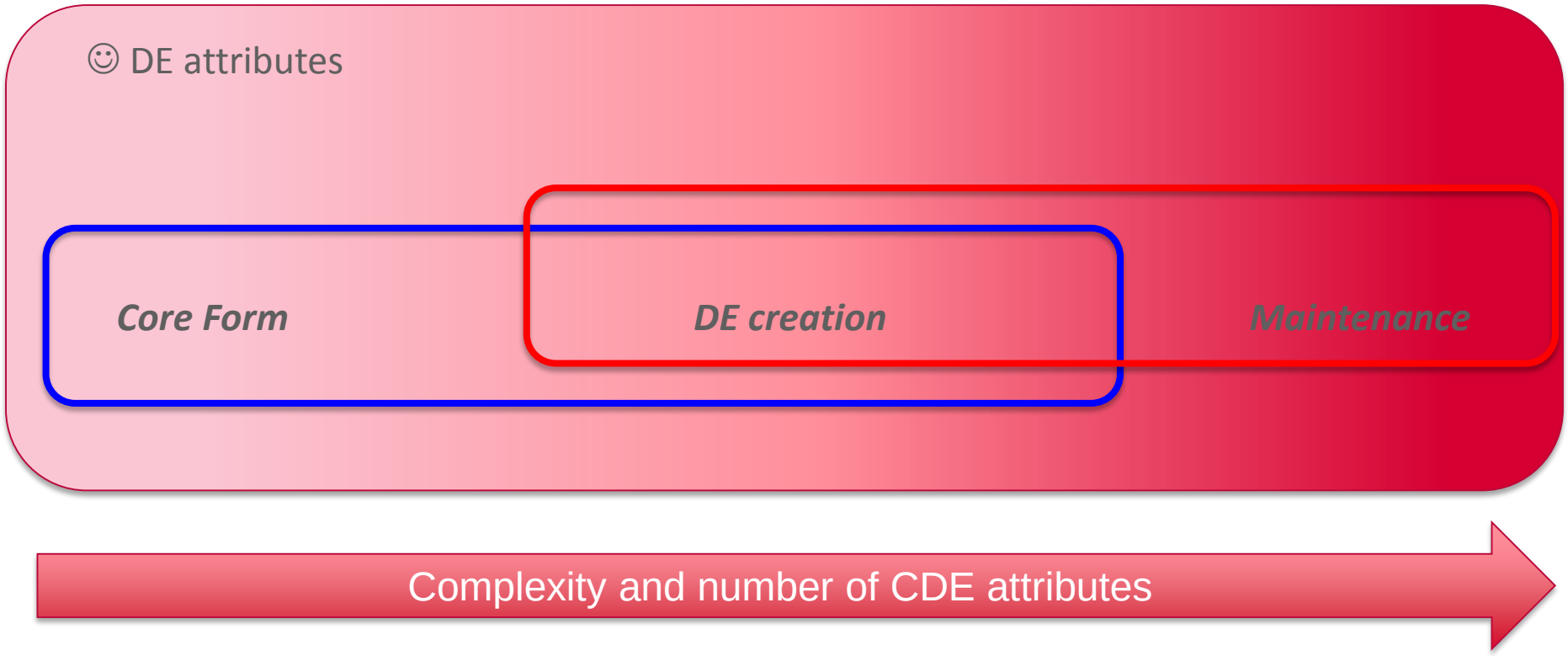
SDC FHIR Implementation Guide
How SDC Leverages FHIR Resources

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



★ SDC FHIR Data Element Profile serves as the **Logical Model**

SDC Data Elements Scope