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CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

The CDISC Vision is to Inform Patient Care & Safety
Through Higher Quality Medical Research

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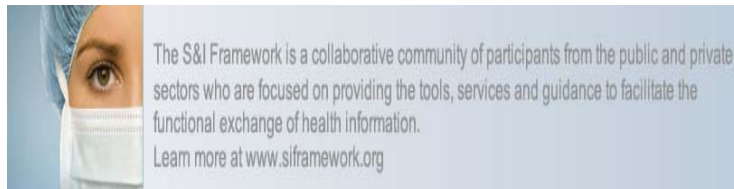# Structured Data Capture Initiative

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Structured Data Capture - Context

- The Office of the National Coordinator for Health Information Technology (ONC), an office of the U.S. Department of Health and Human Services, launched a program called the Standards and Interoperability Framework in 2011:

The S&I Framework is a collaborative community of participants from the public and private sectors who are focused on providing the tools, services and guidance to facilitate the functional exchange of health information.
Learn more at www.siframework.org

Structured Data Capture

- Within the S&I framework, the Structured Data Capture initiative is particularly relevant to re-use of EHR data for research
- The Structured Data Capture (SDC) initiative will develop and validate a standards-based data architecture so that a structured set of data can be accessed from EHRs and be stored for merger with comparable data for other relevant purposes to include:
The **electronic Case Report Form** (eCRF) used for clinical research including clinical trials or comparative effectiveness research

Structured Data Capture Workflow
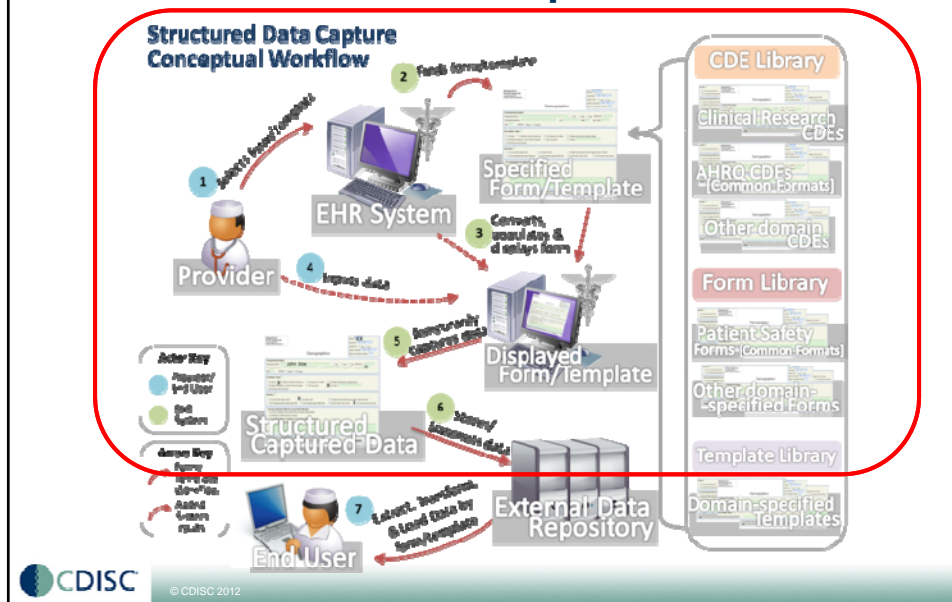
Common Data Elements

- Various independent initiatives to standardize data collection across projects in their domains in order to maximize the utility of the resulting datasets for subsequent research
  - **Develop common definitions and representations of data elements**
  - 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 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.

SDC Planned Deliverables

- A standard for how EHRs interact with the form or template

Structured Data Capture – Standards Overlay
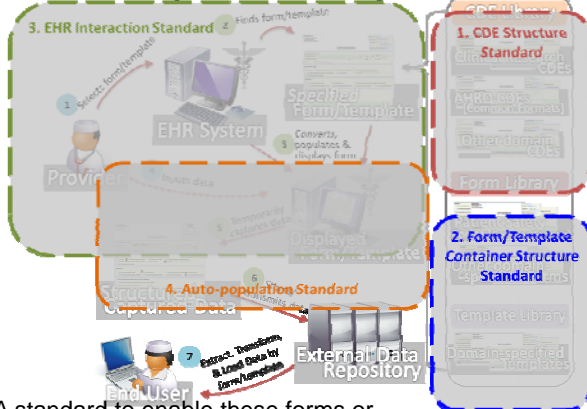
- A standard for the CDEs that will be used to fill the specified forms or templates;

- A standard for the structure or design of the form or template (container);

- A standard to enable these forms or templates to auto-populate with data extracted from the existing EHR.

SDC Planned Deliverables

The proposed infrastructure will consist of four new standards that will enable EHRs to capture and store structured data.

1. A standard for the CDEs that will be used to fill the specified forms or templates;
2. A standard for the structure or design of the form or template (container);
3. A standard for how EHRs interact with the form or template;
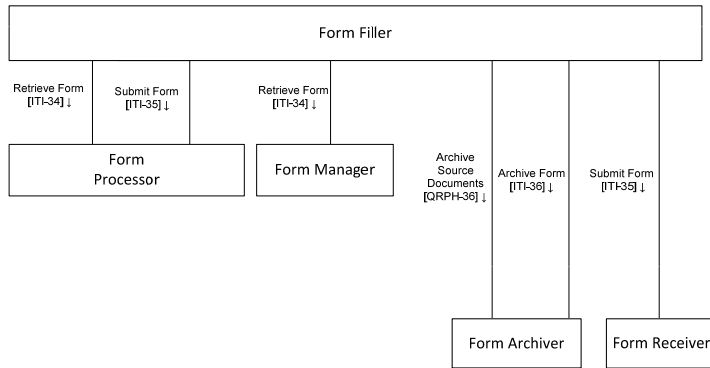4. A standard to enable these forms or templates to auto-populate with data extracted from the existing EHR.

SDC Actual Deliverables

- The ONC SDC Implementation Guide
- The IHE QRPH Structured Data Capture profile. http://wiki.siframework.org/file/detail/IHE_QRPH_Suppl_SDC_Rev1.0_resolution_20140730.docx
- An HL7 FHIR Implementation Guide

IHE QRPH SDC Profile

- The SDC profile employs the well-known mechanism of Retrieve Form for Data Capture (RFD) to define the necessary transactions for EHR pre-population

- SDC adds the concept of a forms repository and the option of persistent forms based on the emerging ISO/IEC 19763-13 Meta-model for Framework Interoperability (MFI) form compliance model.

- ISO-IEC 11179 Metadata Registries for the Definition of Common Data Elements

- This profile also supports optional use IHE Data Element Exchange (DEX) Profile for auto-populating and prepopulating forms.

SDC Profile Actor Diagram

```
                            Form Filler
  ┌──────────────────────────────────────────────────────────────────────┐
  └──┬──────────┬──────────────────┬─────────────┬──────────────┬─────────┘
     │          │                  │             │              │
Retrieve Form  Submit Form    Retrieve Form    Archive        Archive Form   Submit Form
[ITI-34]↓     [ITI-35]↓      [ITI-34]↓        Source         [ITI-36]↓      [ITI-35]↓
                                              Documents
                                              [QRPH-36]↓
  ┌──────────────────┐      ┌──────────────┐
  │      Form        │      │ Form Manager │
  │    Processor     │      │              │
  └──────────────────┘      └──────────────┘

                                            ┌──────────────┐  ┌──────────────┐
                                            │Form Archiver │  │Form Receiver │
                                            └──────────────┘  └──────────────┘
```

SDC Profile Process – RFD Version
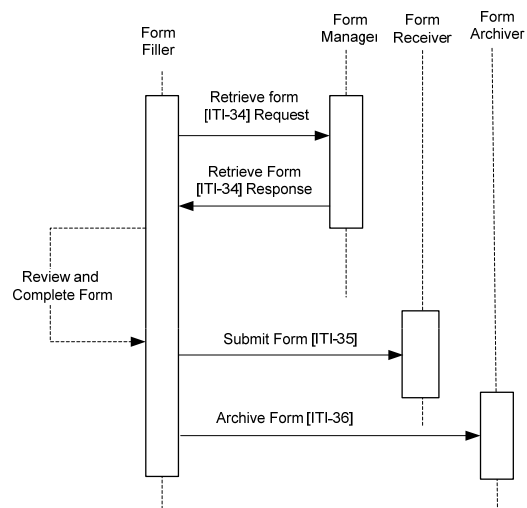
SDC Profiles Supports Two Form Completion from EHR Data

- In traditional RFD, form **pre-population** is done by a Form Manager system, such as a research electronic data capture (EDC) system, using data exported from the EHR.
- The IHE SDC profile introduces a second mode called of **auto-population**, where the EHR applies data directly to the form. In this approach, the data element definitions within the form would be interpreted by the EHR system, and corresponding instance data would be retrieved from the EHR database and applied to the form.

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MFI 13 based SDC Form Definition

Name	Relative Location	Card	Comments
Question	/section/base_question		
@initial state	@initial_state		Of type 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
Question number	/question_number	0..1	Of type Number
Question instruction	/question_instruction	0..1	Of type Text Element
Additional instruction	/additional_instruction	0..N	Of type Text Element
Text_field	/text_field	0..1	Of type Text Field
List_field	/list_field	0..1	Of type List Field
Lookup field	/lookup_field	0..1	Of type Lookup Field
Text after question	/text_after_question	0..1	Of type Text Element
Question order	/question_order	0..1	Of type String
Question ID	/question_identitifier	0..1	Of type Identifier
Next relevant element ID	/next_relevant_element	0..1	Of type Identifier
Section ID	/section_identifier	0..1	Of type Identifier

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DEX Mapping

- DEX enables to query a metadata repository to retrieve the metadata of a Data Element
  - Including the extraction specification from a given Content Model

```
<dex:mappingSpecification>
    <dex:contentModel>
        <dex:id>2.16.840.1.113883.10.20.1</dex:id>
        <dex:name>HL7 CCD</dex:name>
    </dex:contentModel>
    <dex:type>XPATH</dex:type>
    <dex:mappingScript>./ClinicalDocument/recordTarget/patientRole/patient/ethnicGroupCode</dex:mappingScript>
</dex:mappingSpecification>
                </dex:DataElement>
            </dex:RetrieveMetadataResponse>
        </soap:Body>
    </soap:Envelope>
```


SDC 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

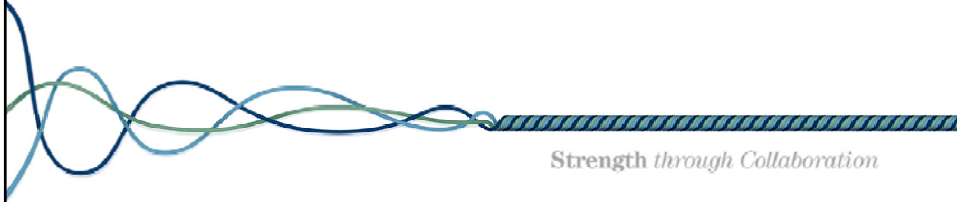## SDC Profile Process Flow with DEX Option

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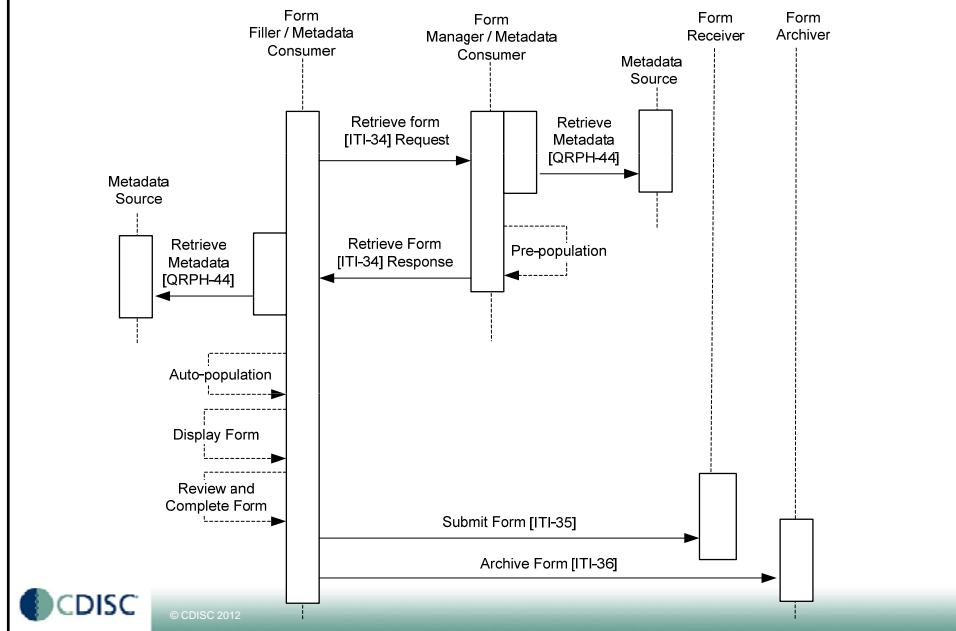
Summary

The ONC Structured Data Capture initiative puts another arrow in the quiver of researchers who seek to re-use EHR data.

The IHE Structured Data Capture profile provides an accessible specification using existing standards and technologies.

Thank you..

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