



The Office of the National Coordinator for
Health Information Technology



Structured Data Capture (SDC)

Overview for Digital Learning Collaborative

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Putting the **I** in Health **IT**
www.HealthIT.gov



- SDC Background & Scope
- SDC Conceptual Workflow
- SDC Solution Plan & Implementation Guide Outline
- Next Steps

- One of 11 active Initiatives under the ONC S&I Framework
- Launched on January 23, 2013 in partnership with NIH NLM and AHRQ
- Key area of focus is enabling the collection of structured data within EHRs to supplement data collected for other purposes specific to:
 - Clinical research (Patient Centered Outcomes Research/ Comparative Effectiveness Research) (NLM FOCUS)
 - Patient safety event reporting (AHRQ FOCUS) & Adverse Event Reporting (FDA FOCUS)

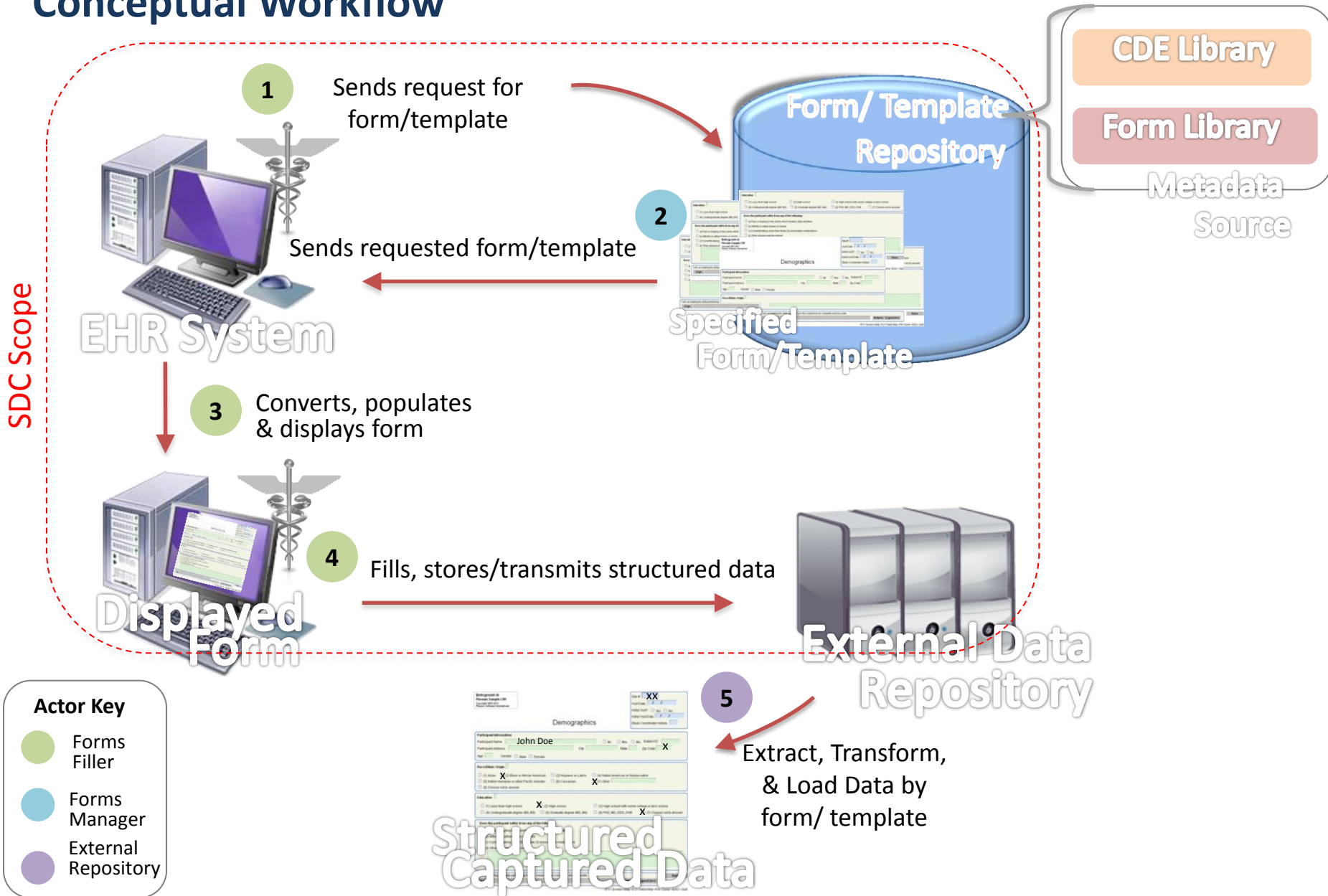
- Develop and validate a standards-based data architecture so that a structured set of data can be accessed from EHRs and be stored for merger with comparable data for other relevant purposes to include:
 - The **electronic Case Report Form (eCRF)** used for clinical research including PCOR
 - The **Incident Report** used for patient safety reporting leveraging AHRQ ‘Common Formats’ and FDA form 3500/3500a
 - The **Surveillance Case Report Form** used for public health reporting of infectious diseases
 - The collection of patient information used for **Determination of Coverage**, as resources permit

SDC will identify, evaluate and harmonize **four** *standards that will enable EHRs to capture and store structured data:

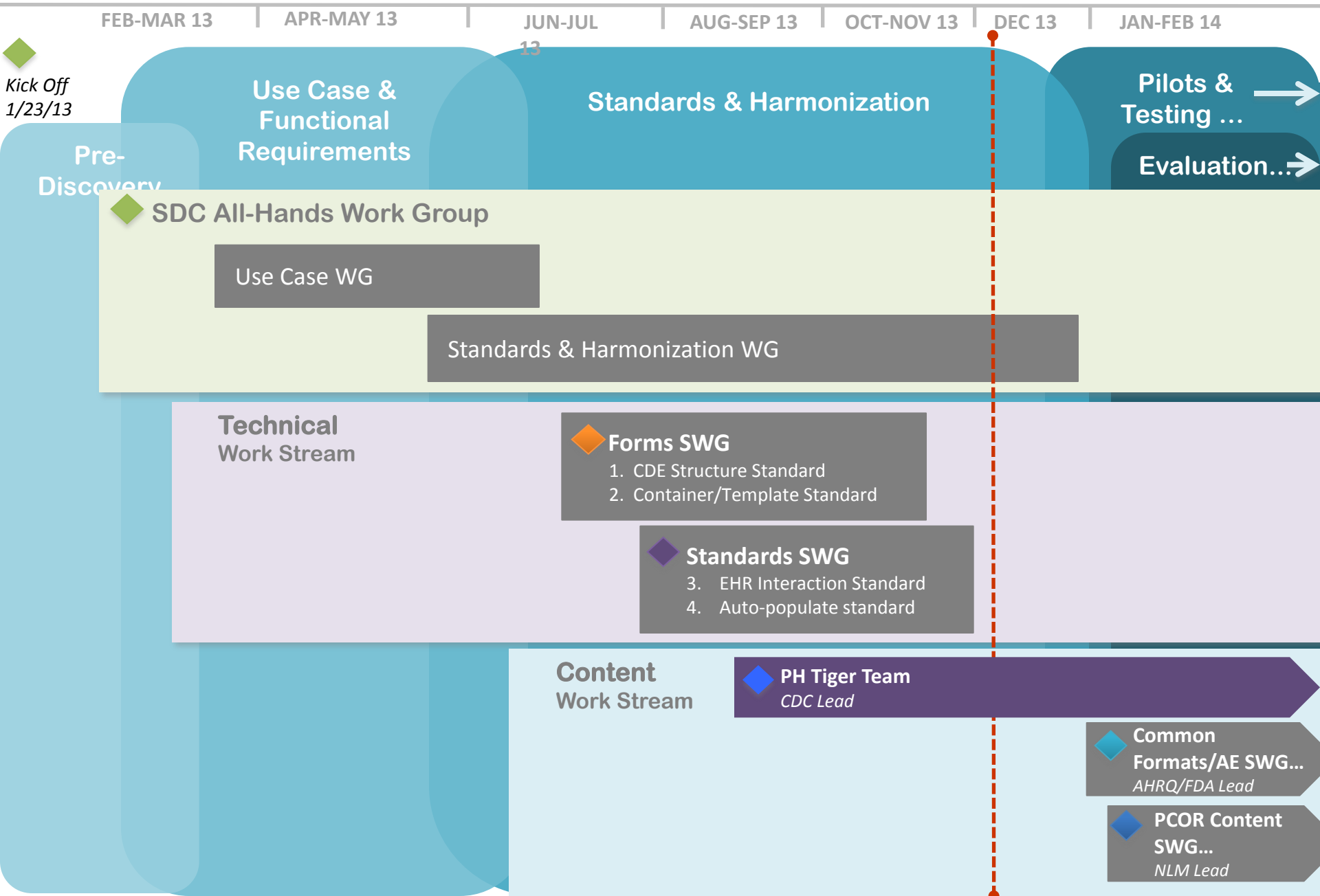
1. Standard for the structure of the CDEs that will be used to fill the specified forms or templates
2. Standard for the structure or design of the form or template (container)
3. Standard for how EHRs interact with the form or template
4. Standard to auto-populate form or template

* SDC standards identified are not 'new'; most are mature standards being used across industry to meet specific interoperability specifications

Structured Data Capture Conceptual Workflow



Structured Data Capture (SDC) Initiative: Standards & Harmonization WGs and Timeline



FEB-MAR 13

APR-MAY 13

JUN-JUL 13

AUG-SEP 13

OCT-NOV 13

DEC 13

JAN-FEB 14

Kick Off
1/23/13

Pre-Discovery

Use Case & Functional Requirements

Standards & Harmonization

Pilots & Testing ...

Evaluation...→

SDC All-Hands Work Group

Use Case WG

Standards & Harmonization WG

Technical Work Stream

Forms SWG

- 1. CDE Structure Standard
- 2. Container/Template Standard

Standards SWG

- 3. EHR Interaction Standard
- 4. Auto-populate standard

Content Work Stream

PH Tiger Team
CDC Lead

Common Formats/AE SWG...
AHRQ/FDA Lead

PCOR Content SWG...
NLM Lead

SDC Information Interchange (II) requirements defined in terms of 5 Transactions:

- **II01:** EHR System sends request for empty form/template to Form/Template Repository
- **II02:** EHR System sends request for form/template with relevant patient data to Form/Template Repository
- **II03:** Form/Template Repository sends empty form/template to EHR System
- **II04:** Form/Template Repository sends form/template with pre-populated patient data to EHR System
- **II05:** EHR System sends completed form/template to External Data Repository

- Content and Structure
 - [CDA Consent Directives](#)
 - [ISO/IEC 11179](#)
 - [ISO/IEC 19763-13](#)
 - [IHE DEX](#)
- Transport, Security, and Authentication
 - [IHE RFD](#)
 - [IHE ATNA](#)
 - [SOAP](#)
 - [TLS v1.0 or higher](#)
 - [SAML](#)

Phase 1 (DEC 13)

- **SOAP/SAML Ballot Package**
- **Base Standard Document**
 - EHR Interaction guidance
 - Information interchange transactions
 - System requirements
 - Form Standard/Definition
 - CDE Definition
 - Introduction to Schema
 - Instance document
- **XML Schema**

Phase 2 (MAR 2014)

- **REST/OAuth Ballot Package**
- **Base Standard Document**
 - EHR Interaction guidance
 - Information interchange transactions
 - System requirements
 - Form Standard/Definition
 - CDE Definition
 - Introduction to Schema
 - Instance document
- **XML Schema**

- **JAN 14:** Publish SDC SOAP/SAML Implementation Guide
- **JAN 14:** Submit SDC IHE Profile Vol. 1
- **JAN/FEB 2014:** Test implementations for SDC Content Profile U.S. Connectathon & Interoperability Showcase
- **FEB 14:** Launch PSE/AE & PCOR Content Workstreams & Pilots
- **FEB 14:** Begin Public Health Pilots
- **APR 14:** Submit SDC IHE Profile Vol. 2 & 3
- **MAY 14:** Publish SDC REST/OAuth Implementation Guide & submit HL7 Project Scope Statement
- **JUNE 14:** Publish SDC IHE Profile for public comment supplements
- **AUG 14:** Publish SDC IHE Profile Trial Implementation Supplements and Final Text Technical Framework
- **SEP 14:** Submit SDC HL7 Ballot Package

In addition to NIH/NLM and AHRQ participation in the SDC Initiative, other key stakeholders include:

- FDA
- CMS
- CDC
- DoD/VA IPO
- ASPE
- PCORi
- CDISC
- HL7
- Vendors: Allscripts, McKesson, Cerner, Greenway, Oz Systems, KBCore

SDC Leads Contact Information

- Initiative Coordinator: Evelyn Gallego (evelyn.gallego@siframework.org)
- Federal Lead: Farrah Darbouze (farrah.darbouze@hhs.gov)
- Project Manager: Jenny Brush (jenny.brush@esacinc.com)
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- Harmonization Support: Hector Cintron (hector.cintron@accenture.com)
- Harmonization Lead: Vijay Shah (vshah@jbsinternational.com)

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

Weekly All-Hands Meeting Info (Thursdays):

- **Time:** 3:25pm - 5:00pm Eastern
- **URL:** <https://siframework1.webex.com/>
- **Dial-In Number:** 1-650-479-3208
- **Access Code:** 663 397 496