• Background & Overview
• SDC Timeline
• SDC Accomplishments To-Date
• SDC Candidate Standards List
• NIH/NLM Common Data Element Activities
• SDC Expected Outcomes & Deliverables
Background

• One of 10 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)
Community Participation

• Strong public & private community participation
  • Over 280+ individuals participated in the Initiative Launch Webinar
  • ~200 Registered Community Members; 50+ regularly participate in weekly meetings

• In addition to the NIH and AHRQ, strong federal partner engagement and participation:
  • FDA (CDER/CDHR)
  • CMS (esMD)
  • CDC
  • SAMSHA
Community Participation

- Federal/State/Local Agencies: 29.50%
- Provider/Provider Organizations: 21.40%
- SDOs/Analytics/Research: 11.80%
- Intermediaries: 3.30%
- Commercial Payer: 2.20%
- HIT/EHR, Vendors/PHR and Associations: 20.70%
- Other: 11.10%
Why Focus on Structured Data Capture?

- Exponential growth in volume and detail of information captured by healthcare organizations and payers
- Strong public and private interest in leveraging clinical data captured in the health record during episodes of care (EOC) and using this data to supplement data collected for other purposes including: research, patient safety event reporting, and public health reporting
- Eventually, such data could be used to enhance EHR data collected during EOC. Enhanced data would be valuable for:
  - Quality and performance improvement
  - Determination of Coverage

Aggregated and analyzed EHR data can be used to identify trends, predict outcomes and influence patient care, drug development and therapy choices.
The utility of EHR data for supplemental purposes has been limited due to a lack of uniformity in the terminology and definitions of data elements across EHRs. This limitation is compounded by the fact that clinician workflow often records patient information in unstructured free-text data well after the episodes of care.

- EHRs are recognized as the data source with the highest potential to provide timely and relevant data in a form that is quickly usable for quality and safety improvement, population health, and research.

- Linking EHR data with other data in a uniform and structured way could accelerate the utility of EHR data for supplemental purposes.
The Value of SDC within EHRs

Advances MU3 Learning Health System
- Will enable patient information to flow securely from EHRs to other systems: research consortia, registries, bio repositories, and public health systems

Reduces Data Collection Burden
- Will enable secure, single-point data entry that populates to multiple systems

Improves Comparability of Data
- Aggregated patient data is more comparable
- Will better inform research, quality reporting and ultimately, influence patient care

Reduces need for site-specific EHR enhancements
- Will enable EHR systems to participate in important reporting and research activities

Limits barriers to volunteer adverse event reporting
- Will improve workflow of reporting to public health agencies leading to improvements in population health
Scope of Work

• 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 new 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

• Standards will facilitate the collection of data so that any researcher, clinical trial sponsor, reporting and/or oversight entity can access and interpret the data in electronic format
• Will leverage existing standards such as XML and CDISC Retrieve Form for Data Capture (RFD)
Structured Data Capture - Conceptual Workflow

1. Selects form/template
2. Finds form/template
3. Converts, populates & displays form
4. Inputs data
5. Caches data
6. Stores/transmits data
7. Extract, Transform, & Load Data by form/template
Structured Data Capture - Standards Overlay

1. CDE Structure Standard
   - Clinical Research CDEs
   - AHRQ CDEs [Common Formats]
   - Other Domain CDEs

2. Form/Template Structure Standard
   - Other domain-specified Forms

3. EHR Interaction Standard: Find, display, cache, store/transmit

4. Auto-populate Standard

Actors:
- Actor Key
- Provider/End User
- EHR System

Processes:
1. Select form/template
2. EHR System
3. Specified Form/Template
4. Inputs data
5. Structured Captured Data
6. Caches data
7. Extract, Transform, & Load Data by form/template

End User

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

- Pre-Planning
- Pre-Discovery
- Use Case & Functional Requirements
  - SDC All-Hands WG
  - Use Case WG
- Standards & Harmonization
  - Standards & Harmonization WG
  - Form SWG
    1. CDE Structure Standard
    2. Form/Template Structure Standard
  - Standards SWG
    3. EHR Interaction Standard
    4. Auto-populate standard
- Technical Work stream
- Content Work stream
  - Common Formats SWG...
    AHRQ Lead
  - PCOR Content SWG...
    NLM Lead

Initiative Kick Off: 1/23/13
Pilots & Evaluation after September
Pilots & Testing
Evaluation

We are here!
SDC Accomplishments to-date

• Achieved Project Charter Consensus.
  – Strong community involvement in review and in voting of final Project Charter

• Kicked-off Use Case (UC) Development Phase
  – Completed presentation and review of User Stories, Base Flow and Activity Diagram
  – UC on schedule to go through consensus voting before end of May 2013

• Continued Stakeholder Outreach Activities:
  – HIMSS
  – Public Health Organizations (PHRI, JPHIT)
  – Learning Health System
  – SDOs (CDISC, IHE, HL7)
  – EHR/ PSO Vendors
Structured Data Capture – Use Case Scope

1. Selects form/template
2. Finds form/template
3. Converts, populates & displays form
4. Inputs data
5. Caches data
6. Stores/transmits data
7. Extract, Transform, & Load Data by form/template

CDE Library
- Clinical Research CDEs
- AHRQ CDEs [Common Formats]
- Other Domain CDEs

Form Library
- Patient Safety Forms [Common Formats]
- Other domain-specified Forms

Template Library
- Domain-specified Templates
Kicked-off series of presentations to SDC Community on relevant SDC-related Initiatives

- Federal Interagency Traumatic Brain Injury Research (FITBIR) (31JAN13)
- AHRQ Common Formats (14FEB13)
- National Human Genome Research Institute (NHGRI) PhenX (21FEB13)
- KB Core-Purple Button for Patient Event Reporting (28MAR13)
- FDA ASTER-D Demonstration (04APR13)
- S&I Candidate Standards Overview (11APR13)
- NIH Patient Reported Outcomes Measurement Information System (PROMIS) (25APR13)
- AHRQ USHIK (09MAY13)
- Duke Clinical Research Institute (DCRI) (16MAY13)
- Clinical Information Model Initiative (CIMI) (JUN13)

And we welcome consideration of other efforts suggested by the community
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<td>SNODENT, CDT</td>
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And we welcome consideration of other standards suggested by the community.
CIMI aims to improve the interoperability of healthcare systems through shared implementable clinical information models.

CIMI will use a single formalism, common set of base data types, formal bindings of its models to standard coded terminologies, and operate at no cost to users.

To create a new paradigm, a standard set of detailed clinical data models should be coupled with:

- Standard coded terminology
- Standard APIs for healthcare related services
- Open sharing of models, coded terms and APIs
- Sharing of decision logic and applications

### Selected CIMI Participants

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<th>Netherlands/ISO Standard CEN 13606</th>
<th>openEHR Foundation</th>
<th>Intermountain Healthcare</th>
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NIH Common Data Element (CDE) Resource Portal

http://cde.nih.gov

- Version 1.0 launched in January 2013
- Provides single point-of-entry for information about NIH-supported CDE initiatives and CDE tools & resources
- Enables browsing of descriptive summaries of the CDE initiatives and of the subject areas to which they apply
- Links out to repositories containing the data elements themselves.
- Contains information on 16 NIH-supported initiatives
- Future enhancements: additional NIH and HHS initiatives, improved navigation
Repository of CDEs and PAIs
(under development)

• NLM, working with NIH and others, working towards developing a means of providing easy access and searching capability for standardized representations of CDEs and PAIs that have been specified using consensus data standards and terminologies

• Approach will capitalize on attributes, capabilities of existing distribution systems, such as FITBR, CaDSR, NLM Value Set Authority Center and others

• Resulting repository will serve as a resource for efforts to further standardize and harmonize CDEs and PAIs

• Initial development: 2013
Structured Data Capture Immediate & Long-Term Outcomes

1. Use Case(s) and Functional Requirements
2. Identification of National standards for the structure of CDEs, structure for forms used to capture those CDEs and standardized functions for how EHRs interact with those standards and forms
3. Implementation guidance to assist researchers, patient safety personnel, software vendors and others in apply technical requirements for the customized use of structured forms/ templates
4. Pilots to evaluate use of the specified form standard for CER and patient safety event reporting
5. Proliferation and use of NIH-identified and curated CDEs for PCOR and AHRQ ‘Common Formats’ for patient safety event reporting
6. Alignment and integration to other health IT infrastructure to support effective maintenance, distribution, and use of specified forms or templates
7. Enhancement of patient care through improvements in quality and safety interventions, population health and research
8. Improvement in provider experience and workflow when using EHRs for patient care and other purposes
Structured Data Capture Initiative
Resources and Questions

- ONC Leads
  - Doug Fridsma (doug.fridsma@hhs.gov)
  - Farrah Darbouze (farrah.darbouze@hhs.gov)

- Teaming Partner Leads
  - Lisa Lang (langl@mail.nlm.nih.gov)
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- Initiative Coordinator
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- Use Case & Functional Requirements Development
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  - Jennifer T. Sisto (jennifer.t.sisto@accenturefederal.com)

- Standards Development Support
  - Caryn K. Just (caryn.k.just@accenturefederal.com)

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