The Office of the National Coordinator for
Health Information Technology

Structured Data Capture (SDC)

HITSC Overview

April 17, 2013

Doug Fridsma, MD, PhD, FACP, FACMI
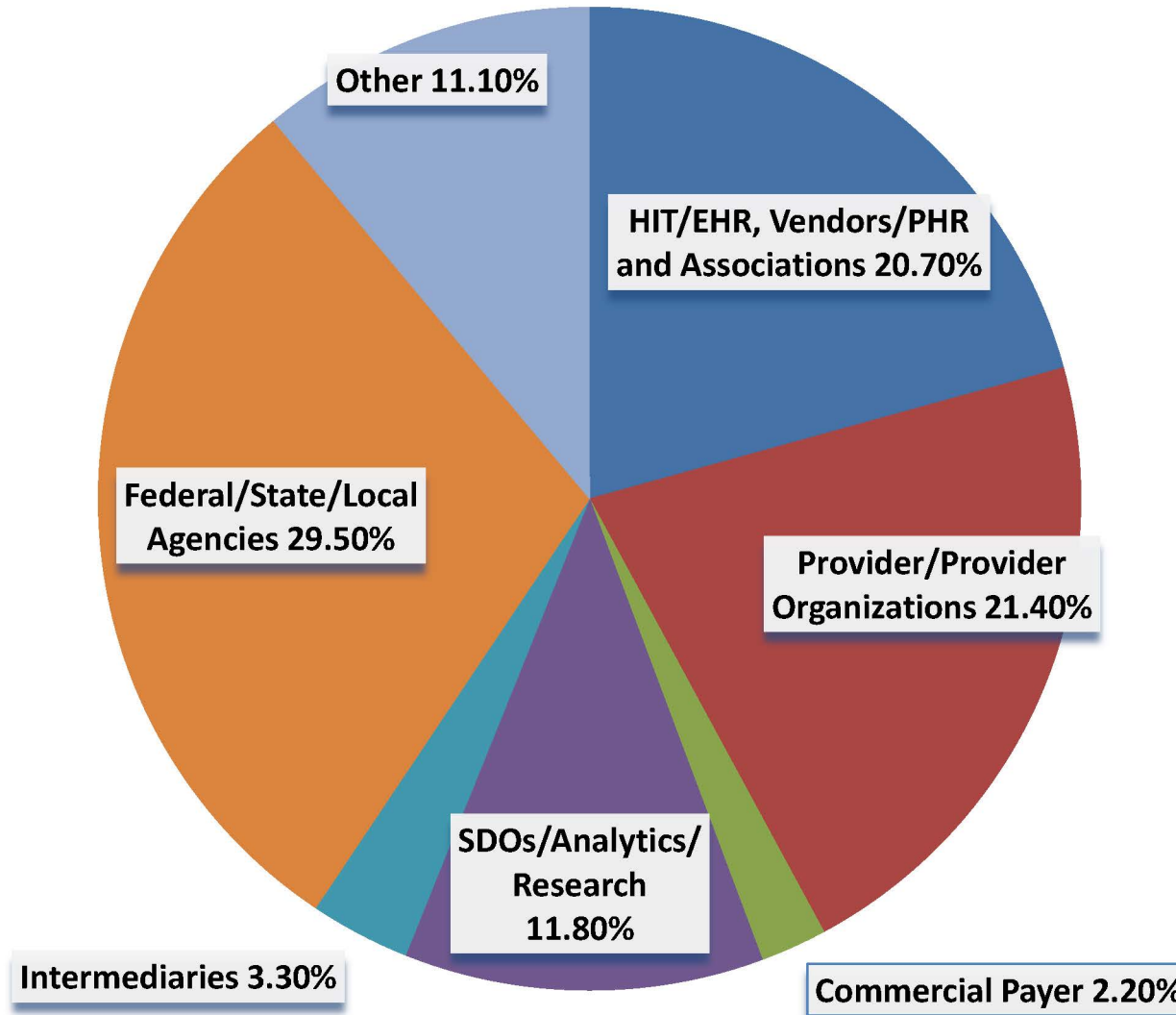Chief Science Officer & Director, Office of Science & Technology

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Agenda

- Background & Overview

- SDC Timeline

- SDC Accomplishments To-Date

- SDC Candidate Standards List

- NIH/NLM Common Data Element Activities

- SDC Expected Outcomes & Deliverables

- 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

- Other 11.10%
- HIT/EHR, Vendors/PHR and Associations 20.70%
- Provider/Provider Organizations 21.40%
- Commercial Payer 2.20%
- SDOs/Analytics/Research 11.80%
- Intermediaries 3.30%
- Federal/State/Local Agencies 29.50%

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.

Challenge & Opportunity of Using EHRs

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

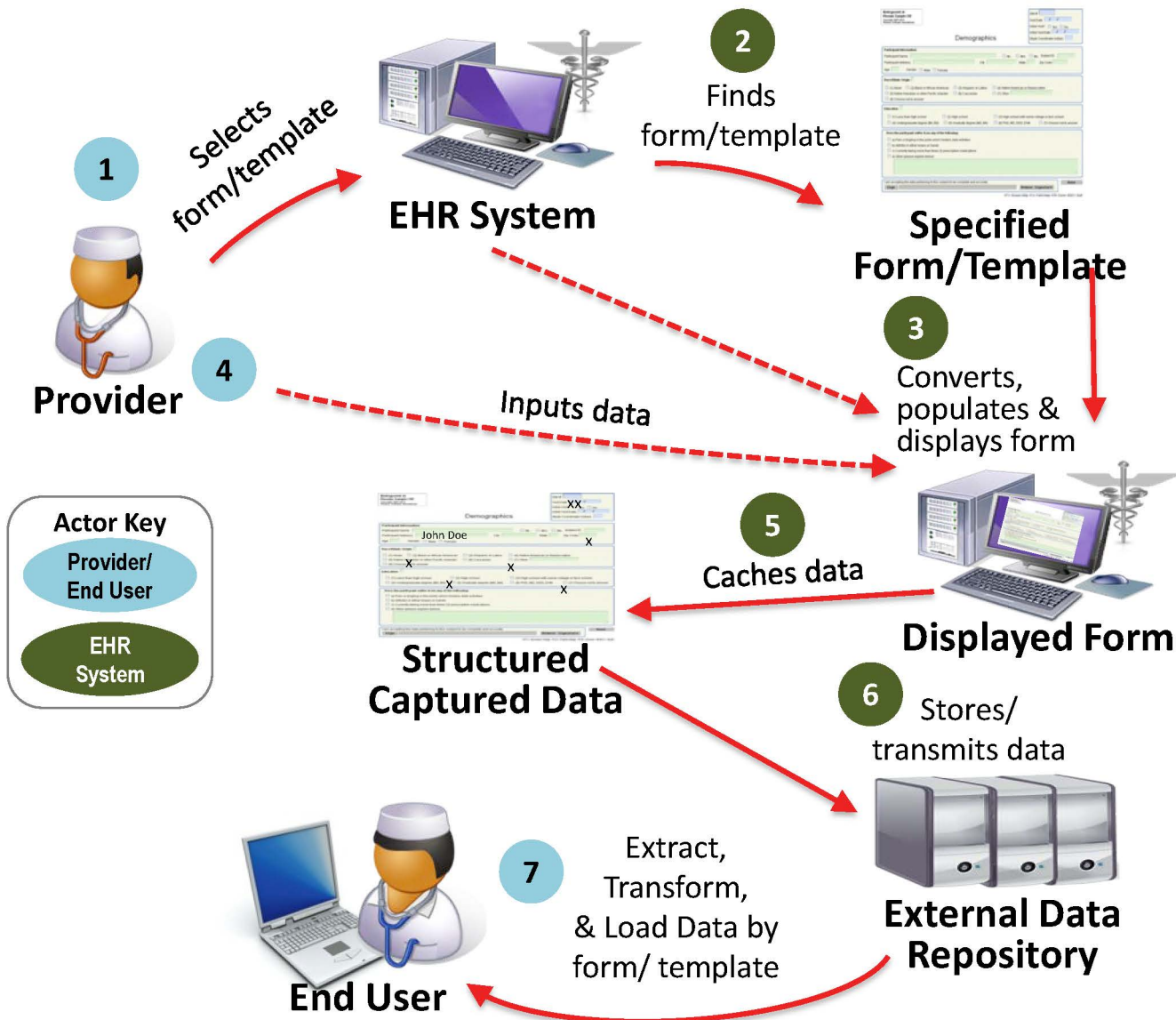|	
Advances MU3 Learning Health System	• Will enable patient information to flow securely from EHRs to other systems: research consortia, registries, bio repositories, and public health systems
Reduces Data Collection Burden	• Will enable secure, single-point data entry that populates to multiple systems
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 Standards Focus and Success Metrics

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

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1 Provider → **Selects form/template** → **EHR System**

2 Finds form/template → **Specified Form/Template**

3 Converts, populates & displays form

4 Inputs data

5 Caches data → **Displayed Form**

Structured Captured Data

6 Stores/ transmits data → **External Data Repository**

7 Extract, Transform, & Load Data by form/ template → **End User**

Actor Key
- Provider/ End User
- EHR System

John Doe
XX

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**

Structured Data Capture - Standards Overlay

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

1

Select a form/template

EHR System

2

Enable form/template

Specified Form/Template

3

Converts, populates & displays form

4

Inputs data

5

Caches data

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4. Auto-populate Standard

6

Stores/ transmits data

7

Extract, Transform, & Load Data by form/ template

End User

External Data Repository
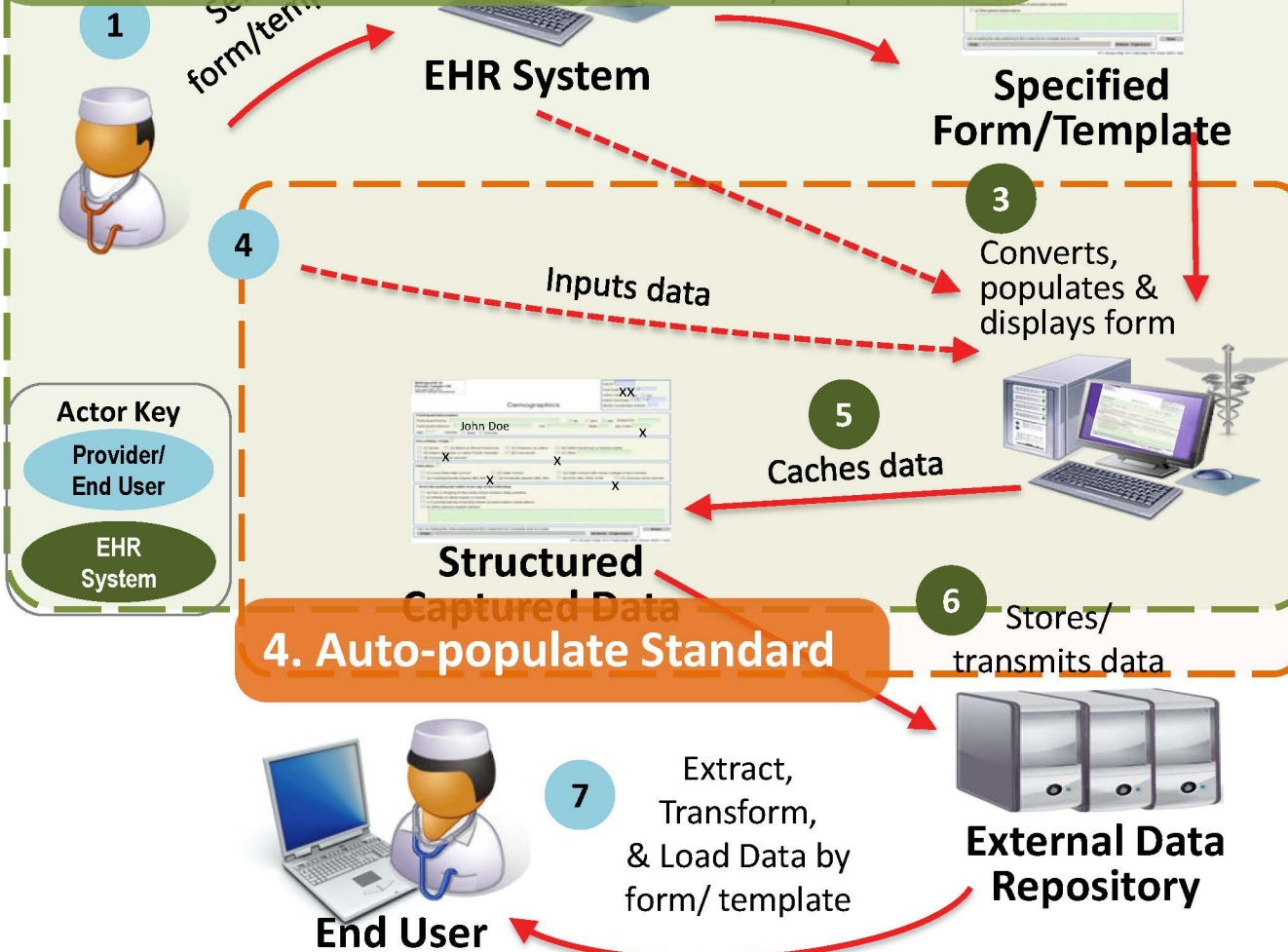
1. CDE Structure Standard

CDE Library

Clinical Research CDEs

AHRQ CDEs [Common Formats]

Other Domain CDEs

Form Library

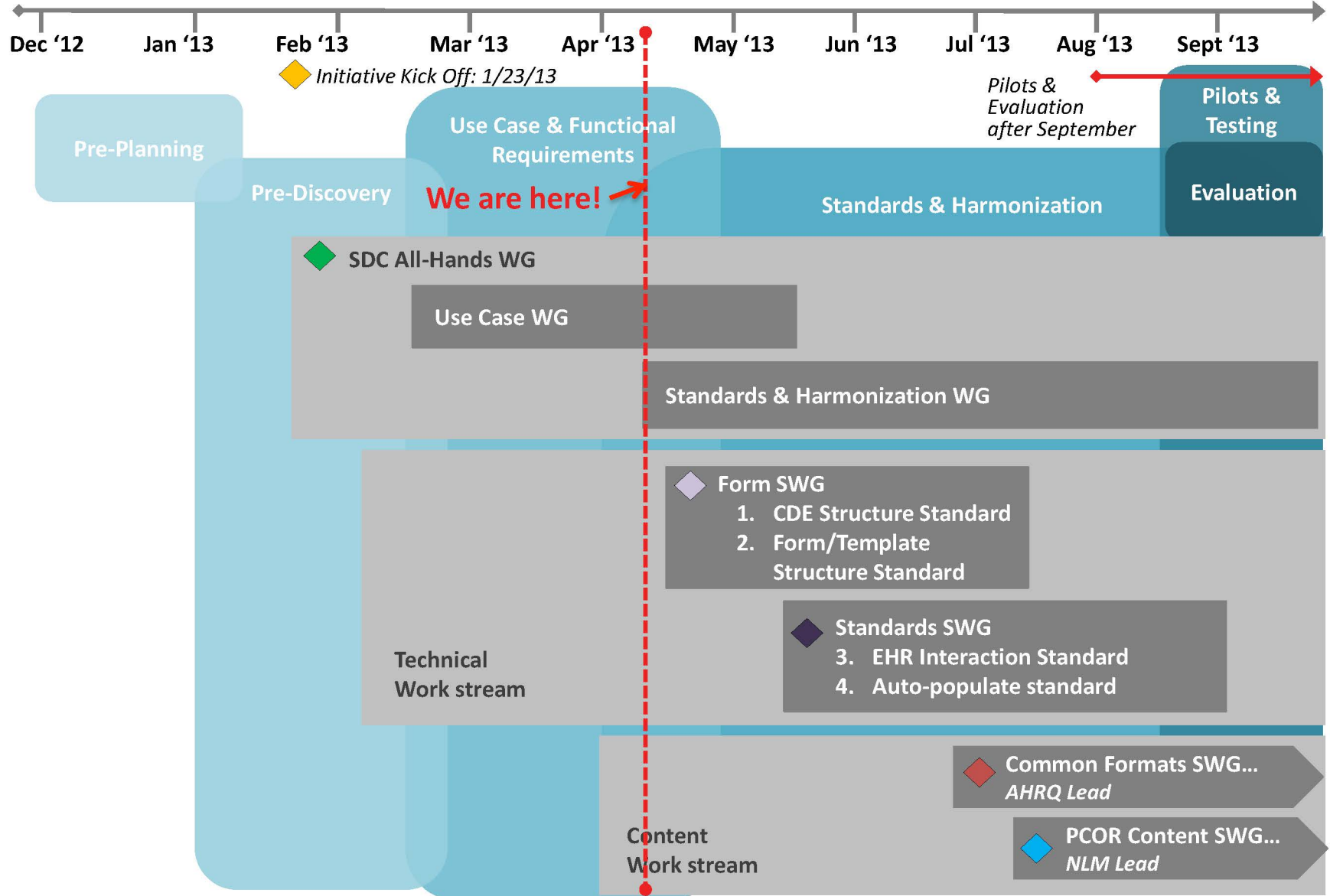**2. Form/Template Structure Standard**

Patient Safety Forms [Common Formats]

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Template Library

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

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Timeline: Dec '12 | Jan '13 | Feb '13 | Mar '13 | Apr '13 | May '13 | Jun '13 | Jul '13 | Aug '13 | Sept '13

Initiative Kick Off: 1/23/13

Pilots & Evaluation after September

Pilots & Testing

Pre-Planning

Pre-Discovery

Use Case & Functional Requirements

We are here!

Standards & Harmonization

Evaluation

SDC All-Hands WG

Use Case WG

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

Common Formats SWG...
AHRQ Lead

PCOR Content SWG...
NLM Lead

Content Work stream

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
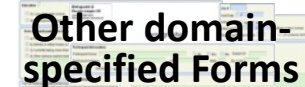
Structured Data Capture – Use Case Scope

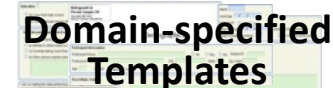Putting the **I** in Health**IT**
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Use Case Scope

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SDC Concert Series Presentations

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

SDC Candidate Standards List

Candidate
Standards List

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Category	Standards Organization	Standards
Vocabulary and Code Set	ADA	SNODENT, CDT
	AHRQ	Common Formats
	AMA	CPT
	APA	DSM-IV
	CDC	CVX, PHIN-VADS
	CMS	HCPCS
	First Databank	Multilex DDF
	IHTSDO	SNOMED-CT, IDNT
	ISO	3166-1, 26324, 639-2
	Medicomp Systems	MEDCIN
	NCI	NCI Thesaurus
	NIST	FIPS 5-2
	NLM	UMLS, RxNorm, VSAC
	Northrop Grumman/ICH/IFPMA	MedDRA
	NQF	NQF
	Regenstrief	LOINC, UCUM
	WHO	ICD-10-PCS, ICD-9-CM, ICD-10-CM, INCP

SDC Candidate Standards List (cont'd)

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Category	Standards Organization	Standards
Content and Structure	ASTM	CCR, GEM
	HITSP/HL7	C32
	HL7	CCD, Arden Markup Language, CRS, CDA R2, C-CDA, CTS2, Decision Support Service, Green CDA, HL7 v2.x, HL7 v3, WRDA, HQMF, vMR
	IHE	Shared Value Services, DEC, RFD, CRD, RPE
	ISO	ISO 11179
Transport and Security	HITSP	T24, C25
	IETF	HTTPS, SSL, TLS
	IHE	ATNA, XUA, BPPC
	ITU-T	X.509
	OASIS	SAML, XSPA XACML
	OMG	hData REST Binding for RLUS
	ONC	Direct
	W3C	SOAP
Other/ Information Models		CIMI/CEMs, FHIM, CDASH, BRIDG, FHIR

And we welcome consideration of other standards suggested by the community

Candidate Standard: CIMI

- 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
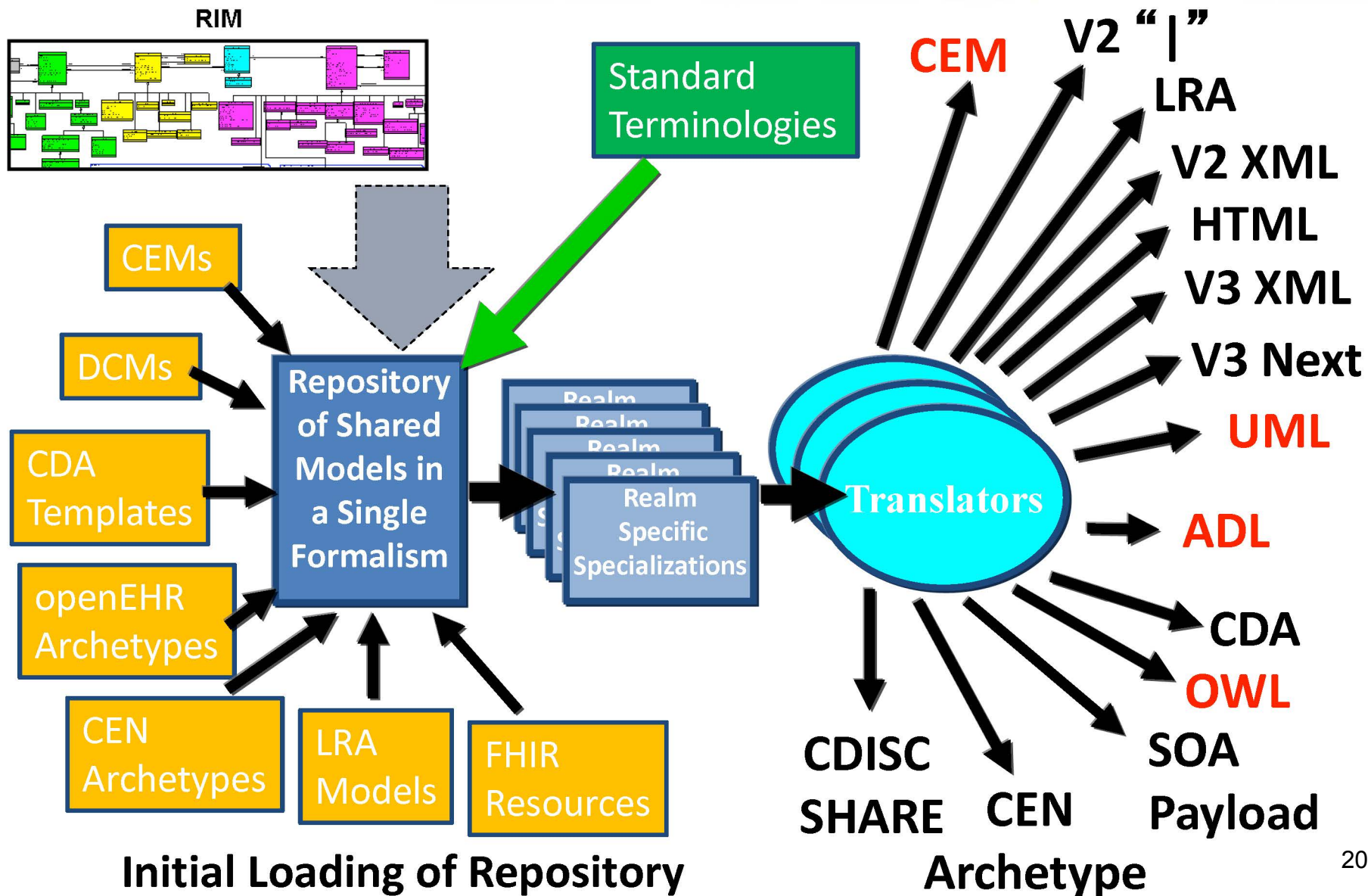 - Sharing of decision logic and applications

Selected CIMI Participants		
Netherlands/ISO Standard CEN 13606	openEHR Foundation	Intermountain Healthcare
United Kingdom – NHS	Canada	Mayo Clinic
Singapore	US Department of Veterans Affairs	HL7
Sweden	US Department of Defense	Tolven
Australia		CDISC
		Korea

CIMI Information Model Ideas

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

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

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