The Future of CDISC

PharmaSUG Workshop
La Jolla, CA
13 September 2013

Rebecca Kush, PhD
President, CDISC

Strength *through Collaboration*

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Themes for the Future of CDISC

- Develop global research standards faster and better
  - CDISC Teams and CFAST
- Make the standards readily accessible
  - SHARE
- Support the global trends in healthcare
  - Healthcare Link

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What is CDISC?

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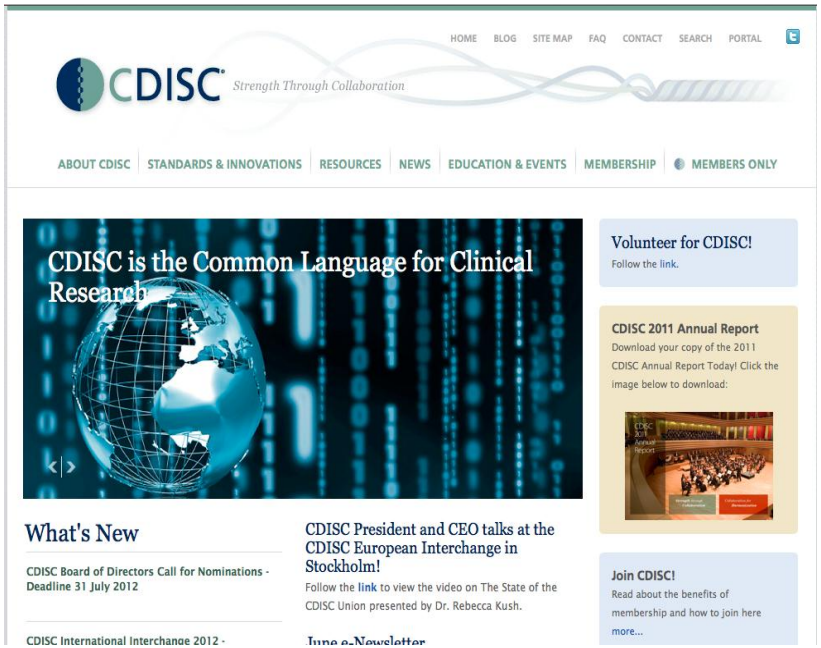
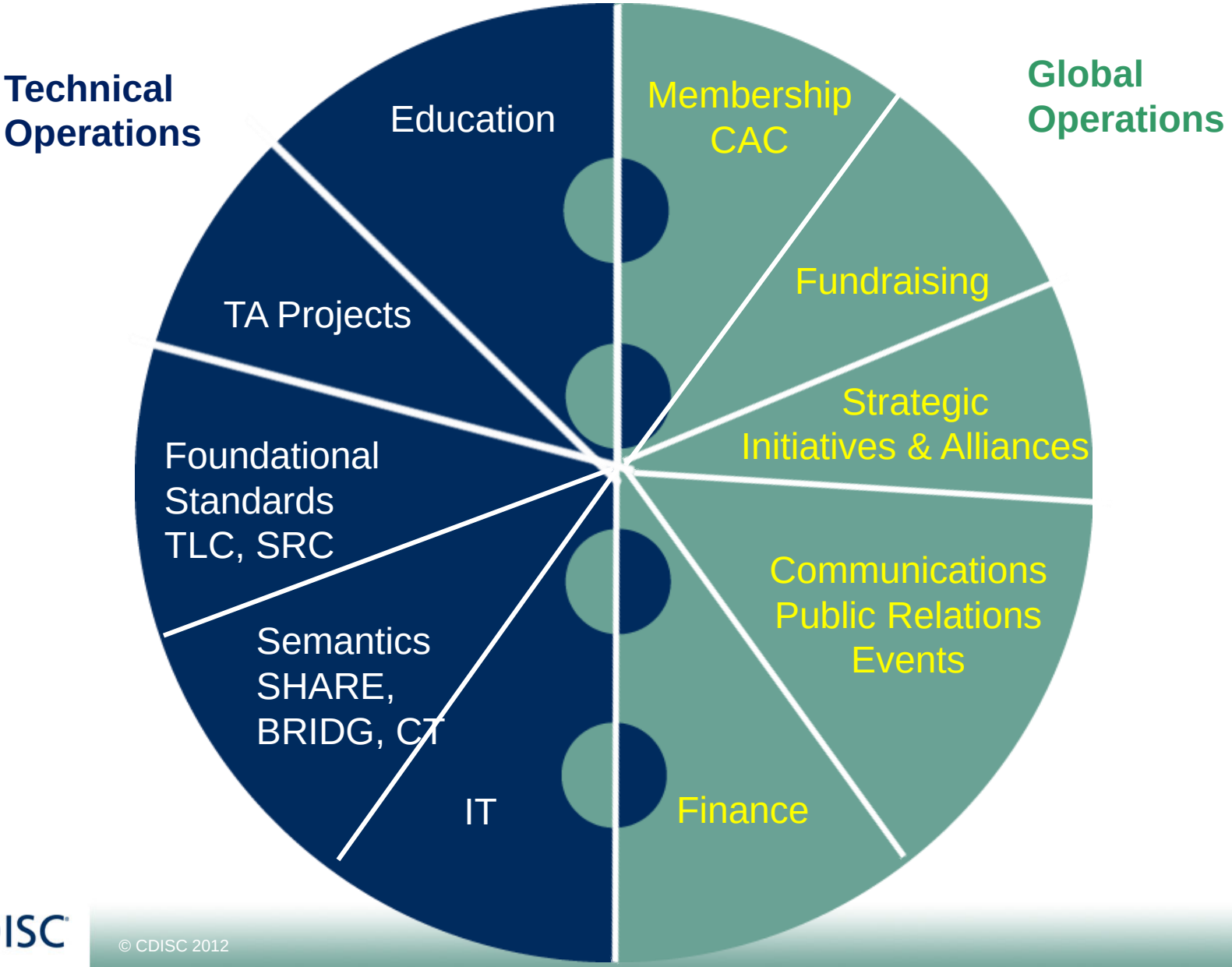
Clinical Data Interchange Standards Consortium (CDISC)

- Global, open, multi-disciplinary, vendor-neutral, non-profit standards developing organization (SDO), a 501c3
- Founded 1997, incorporated 2000
- Member-supported (> 300 member organizations: academia, biopharma, service and technology providers and others)
- Liaison A Status with ISO TC 215
- Charter agreement with HL7 (2001->)
- Leadership of Joint Initiative Council (JIC) for Global Harmonization of Standards
- Member of ANSI-led ISO TAG
- Active Coordinating Committees (3C)
  - Europe, Japan, China
- >> 90 countries (18,0000 individuals) in participant/contact database



CDISC Standards are freely available via the website www.cdisc.org

CDISC Operations



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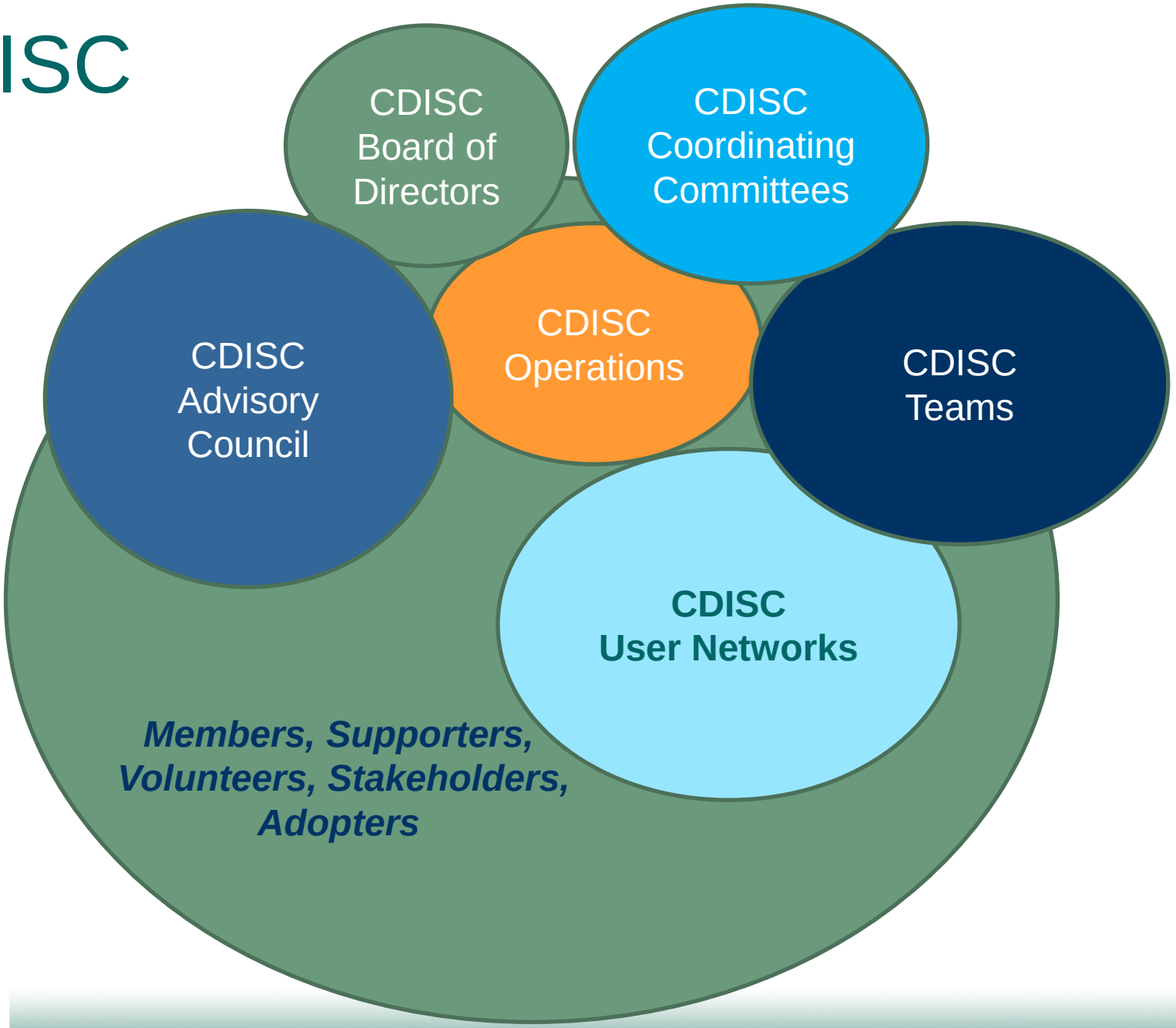
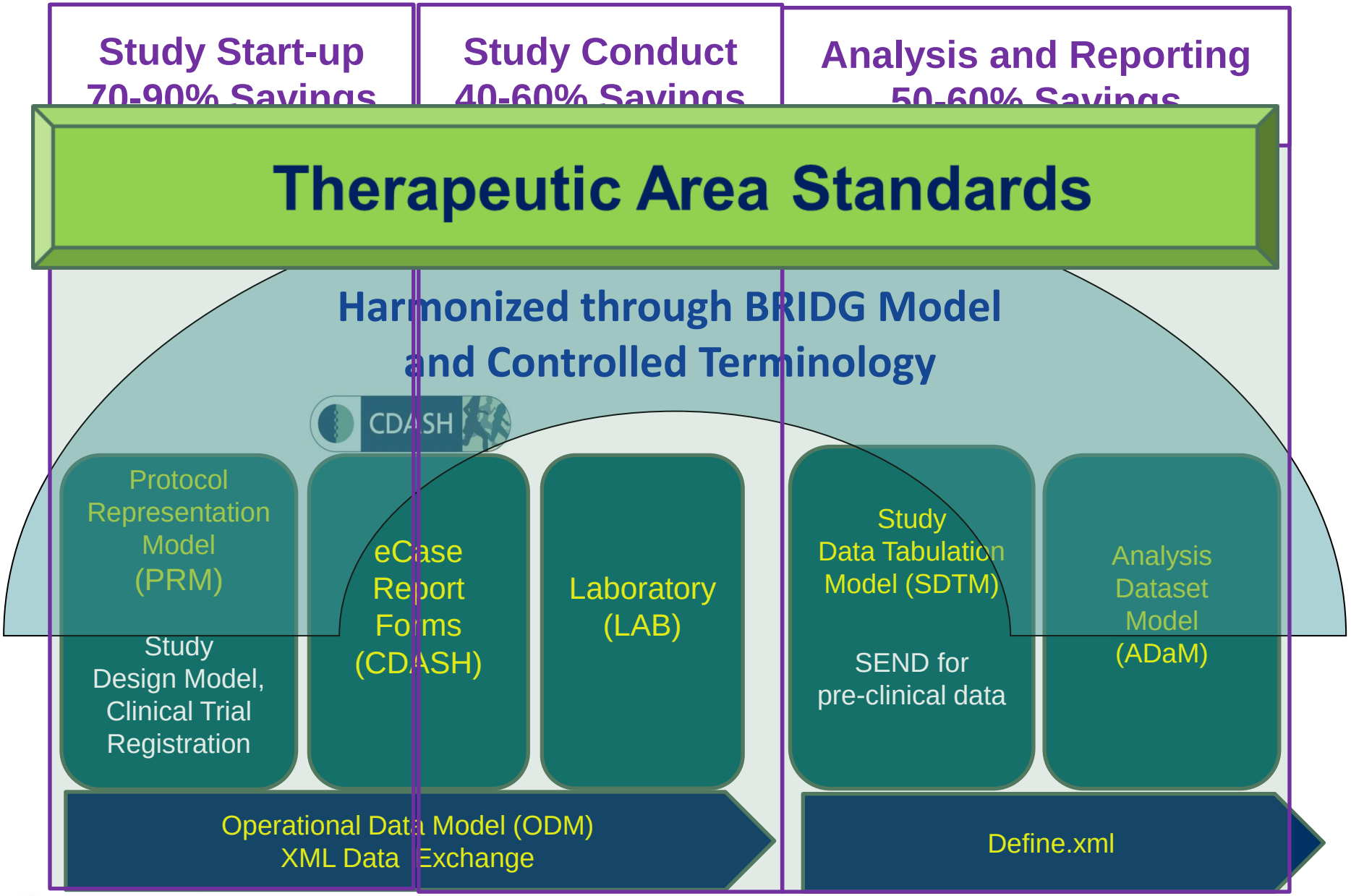

CDISC Board of Directors
CDISC Coordinating Committees
CDISC Advisory Council
CDISC Operations
CDISC Teams
CDISC User Networks
Members, Supporters, Volunteers, Stakeholders, Adopters

Global Clinical Research Standards End-to-End



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TA Standards Development - Hx

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TB and CV (ACS) elements through NIH Roadmap Grants w/ Duke

Polycystic Kidney Disease w/ Tufts

Pain w/ Rochester through FDA Grant

Virology through NIH/FDA Grant

CRITICAL PATH INSTITUTE
collaborate · innovate · accelerate

Alzheimer's Disease w/ C-Path / CAMD

Parkinson's Disease w/ C-Path / NIH-NINDS

TB with C-Path/CPTR, TB Alliance, Gates Foundation, IMI…
MS with C-Path

2008 → Present

NATIONAL CANCER INSTITUTE EVS ENTERPRISE VOCABULARY SERVICES

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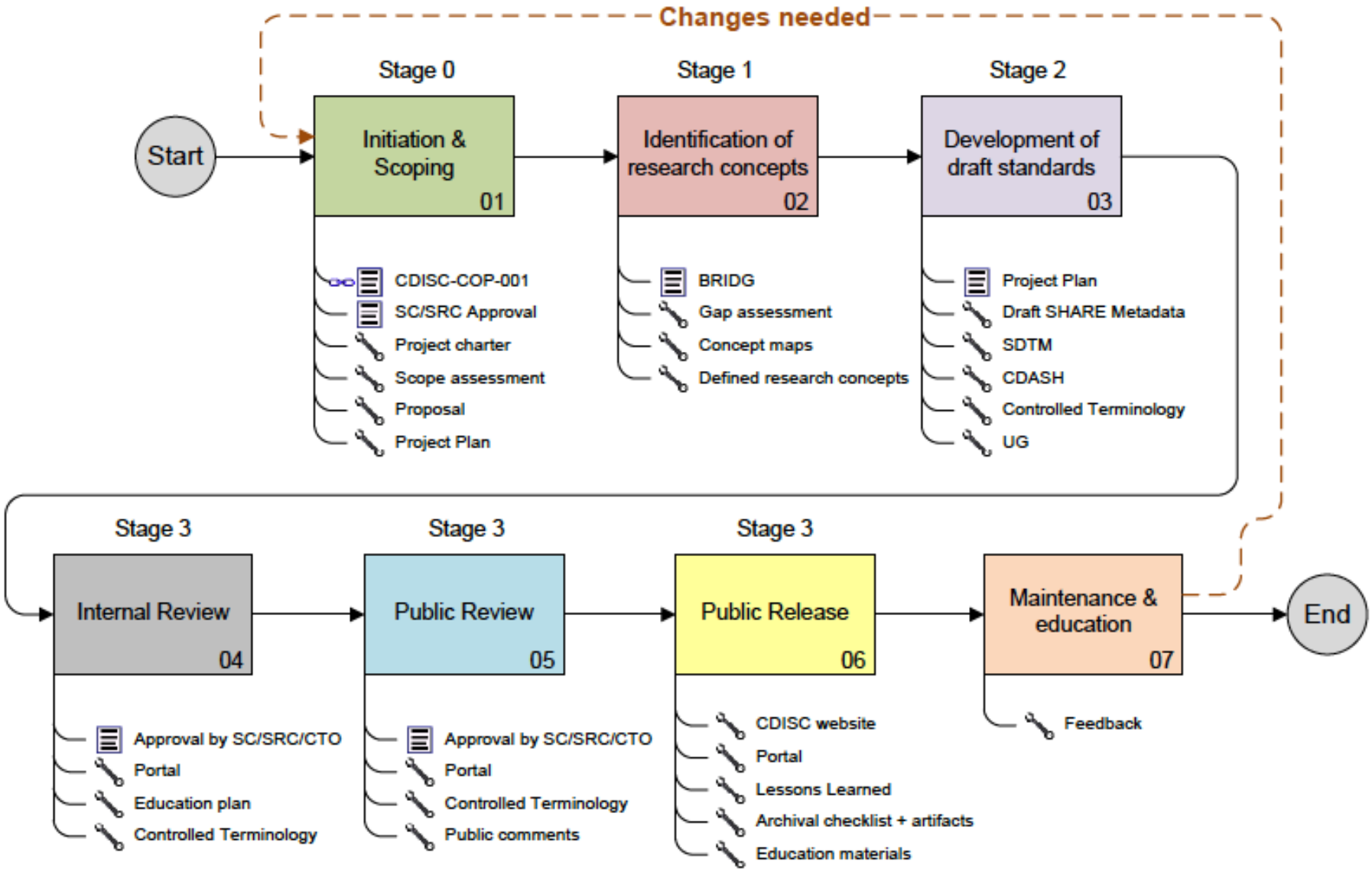
A New Process



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Target Timelines Under New Process

Stage 0	Stage 1	Stage 2	Stage 3		
Scoping, Inputs, Planning	Concept Definition and Modeling	Standards Development (Metadata, Terminology, User Guide, Examples)	Internal Review	Public Review	Publication
Months <1-2	Months 2-4	Months 3-6	Months 6-10+		

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Coalition for Accelerating Standards & Therapies

- In response to CDISC member value surveys and PDUFA V (with the FDA's statement of need for therapeutic area data standards), C-Path and CDISC established CFAST

- CFAST is an **initiative** to accelerate clinical research and medical product development by creating and maintaining data standards, tools and methods for conducting research in therapeutic areas that are important to public health

- Now contributing to CFAST: FDA, TransCelerate Biopharma, NCI EVS, ACRO and IMI

Therapeutic Area Standards Governance

CFAST SAC
Scientific Advisory Committee

- Provides Scientific Advice to TAPSC
- Identifies Risks and Opportunities
- Identifies/Engages Relevant Partners

CFAST TAPSC
Therapeutic Area Program Steering Committee

- Prioritizes/Approves Proposals
- Approves Projects & Charters
- Resources & Oversees Projects

CDISC TA Standards Project Teams

Project Leader +

Clinical leads (SMEs), BRIDG Modeler, Concept Creators, Terminologists, Metadata Analysts, Stats Consultants, Writers, Communications

CDISC Research Community

Ongoing Maintenance & Enhancement of Foundational CDISC Standards

CDISC Research Community

CFAST Program Overview

Therapeutic Area Standards Under Development

	Coordinating Organization(s)	Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c
	Project Manager	Scoping & Input	Concept Modeling	Standards Development	Internal Review	Public Review	Publication
Alzheimer's V1.1	CPATH/CDISC Jon Neville	Jan	Mar	Jun	*Jul*	*Sep*	*Q313*
Asthma V1	CDISC Rhonda Facile	Jan	Mar	Jun	Jul	*Sep*	*Q413*
Cardiovascular Endpoints V1	CDISC/DCRI Amy Palmer	Jun	*Jul*	*Aug*			*Q114*
Multiple Sclerosis V1	CPATH/CDISC Bess Leroy	May	*Aug*	*Jul*			*Q114*
Diabetes V1	TCB/CDISC Rachael Zirkle	Mar	*Jun*	Aug	*Sep*		*Q114*
QT Studies V1	TCB/CDISC John Owen	*Jul*	*Sep*				*Q214*
Traumatic Brain Injury V1	CDISC TBD	*Sep*					*Q214*
Hepatitis C V1	TBD	*Sep*					*Q314*
Schizophrenia V1	CDISC/DCRI Amy Palmer	*Oct*					*Q314*
Oncology	TBD	*Oct*					

Project Status: Stage ongoing Stage completed *Italics = Projected*

Published Therapeutic Area Standards

Alzheimer's Disease V 1 - Final	Polycystic Kidney Disease V1- Provisional
Pain V1 - Provisional	Tuberculosis V1 - Provisional
Parkinson's Disease V1 - Provisional	Virology V1 - Provisional

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IMI-CDISC-FDA Synergies

IMI Therapeutic Area projects

- *Alzheimer's Disease - EMIF
- *Asthma (Severe) – U-BIOPRED
- Autism
- *Cancer (Breast, Colon, Lung and Prostate Cancer)
- *Chronic Pain – EUROPAIN
- *Diabetes Type II – DIRECT
- *Neurodegenerative Diseases – Pharma-Cog
- *Rheumatoid Arthritis – 2 IMI projects
- *Tuberculosis – PredictTB
- Other US-EU project synergies e.g. TBI, PTSD

* = FDA Therapeutic Area Priority as well

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CDISC SHARE

A global, accessible electronic metadata library, which through advanced technology, enables precise and standardized data element definitions **and richer metadata** that can be used in applications and studies to improve biomedical research and its link with healthcare.

http://www.cdisc.org/cdisc-share

- ***Accelerates standards development***
- ***Improves standards accessibility***

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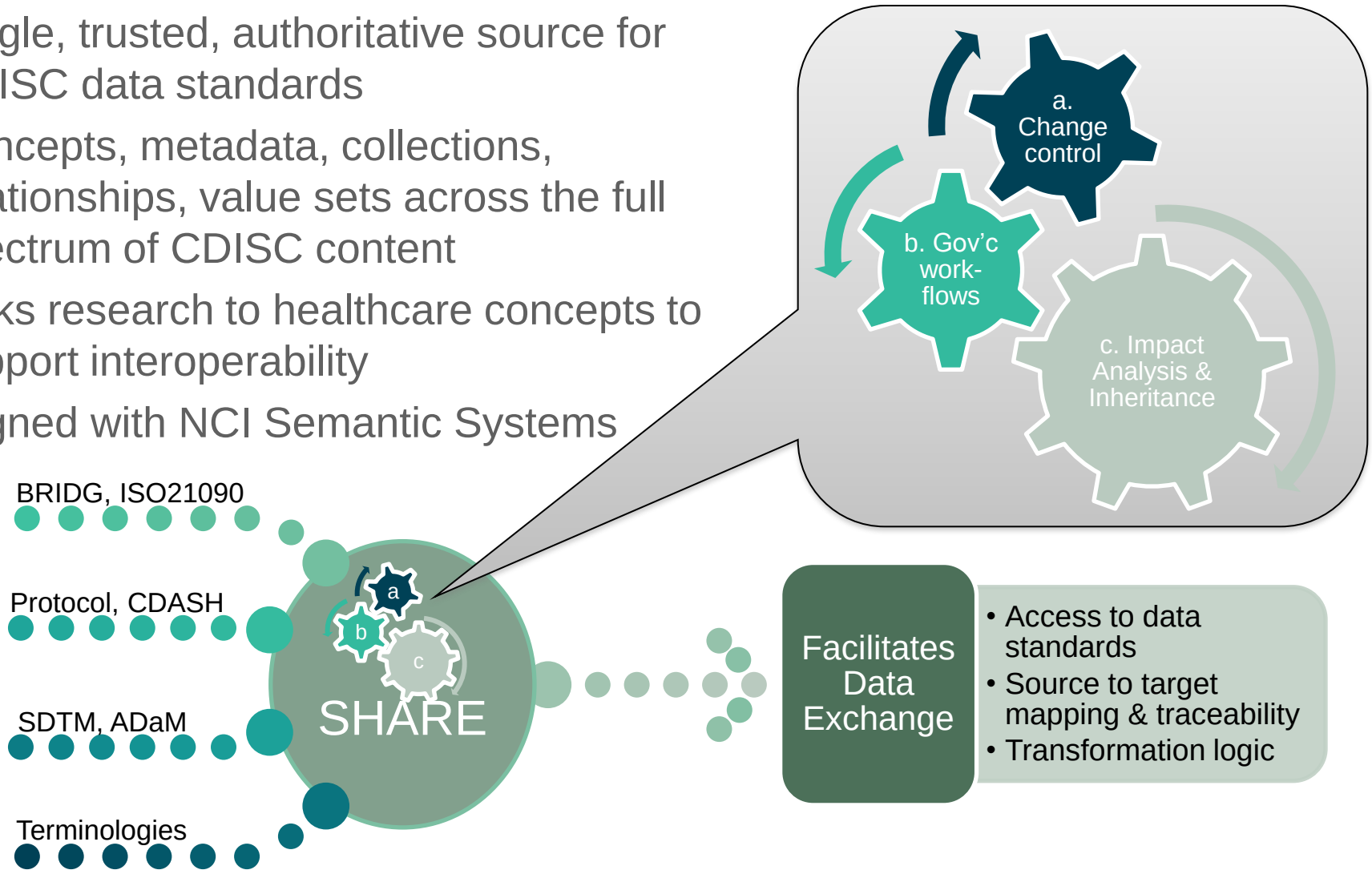
CDISC SHARE

SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC LIBRARY

- Single, trusted, authoritative source for CDISC data standards
- Concepts, metadata, collections, relationships, value sets across the full spectrum of CDISC content
- Links research to healthcare concepts to support interoperability
- Aligned with NCI Semantic Systems



Adapted from Source by Sue Dubman, Sanofi (Genzyme)

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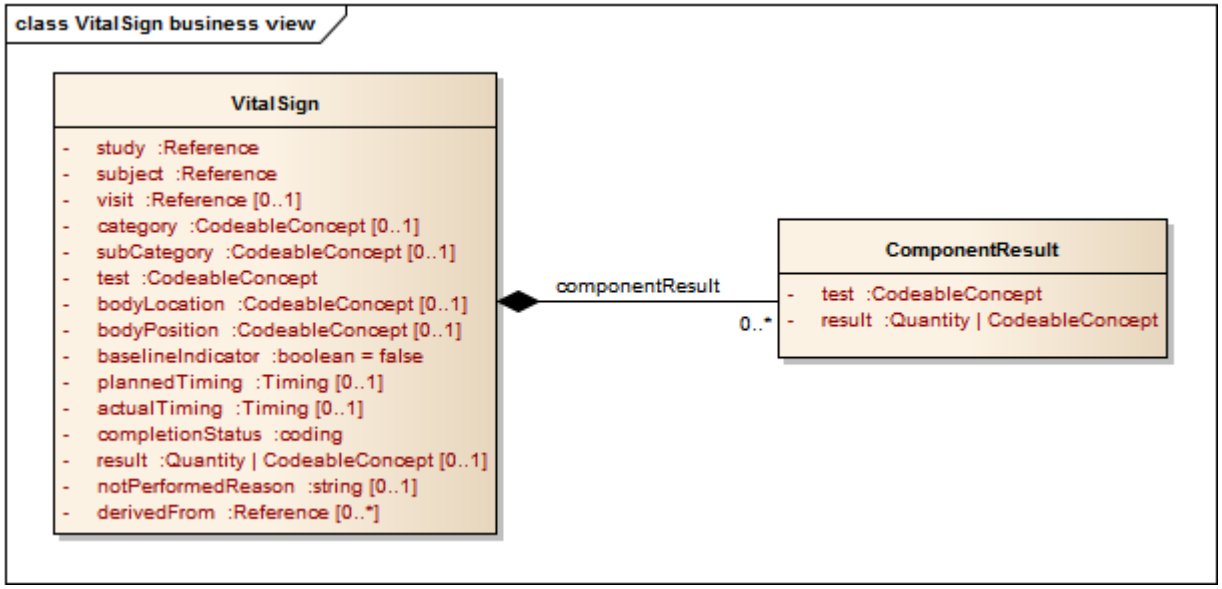
Future Standards will be Built in SHARE: SHARE Business Template Example



- In SHARE:
  - Each variable is a unique object, assembled into metadata sets, domains and standards
  - Each terminology value is an object, assembled into value sets and codelists
  - SHARE templates will reuse component objects, assembling new metadata for new versions of standards and new therapeutic areas
  - Object-level repository will also improve ease of translation

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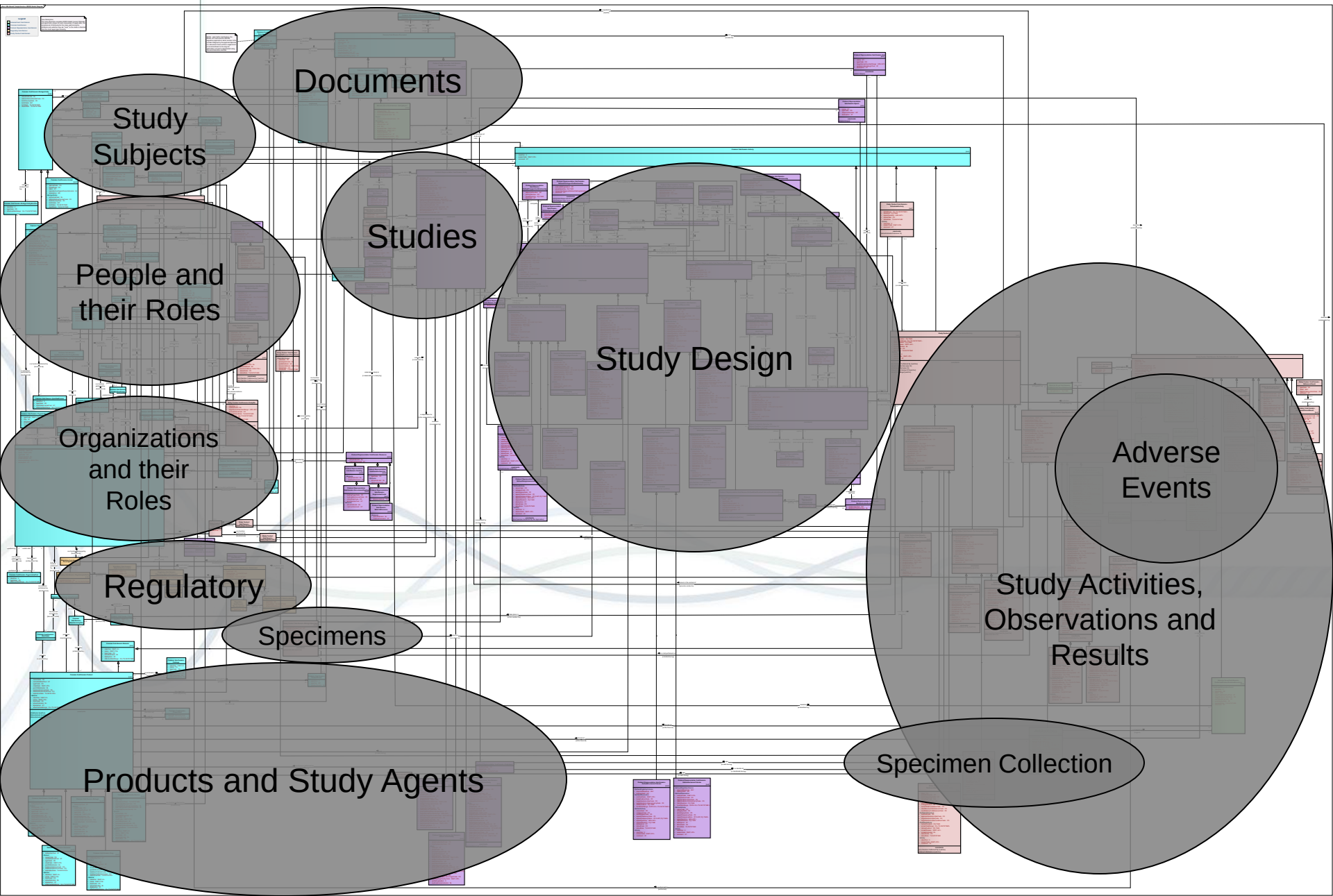
BRIDG Model Content (Layer 2)



Information from healthcare (private, aggregated) to enable research

Healthcare

- Quality healthcare
- Informed decisions
- Personalized medicine
- Patient safety and privacy
- Public health
- Improved therapies
- Efficiencies/reduced costs

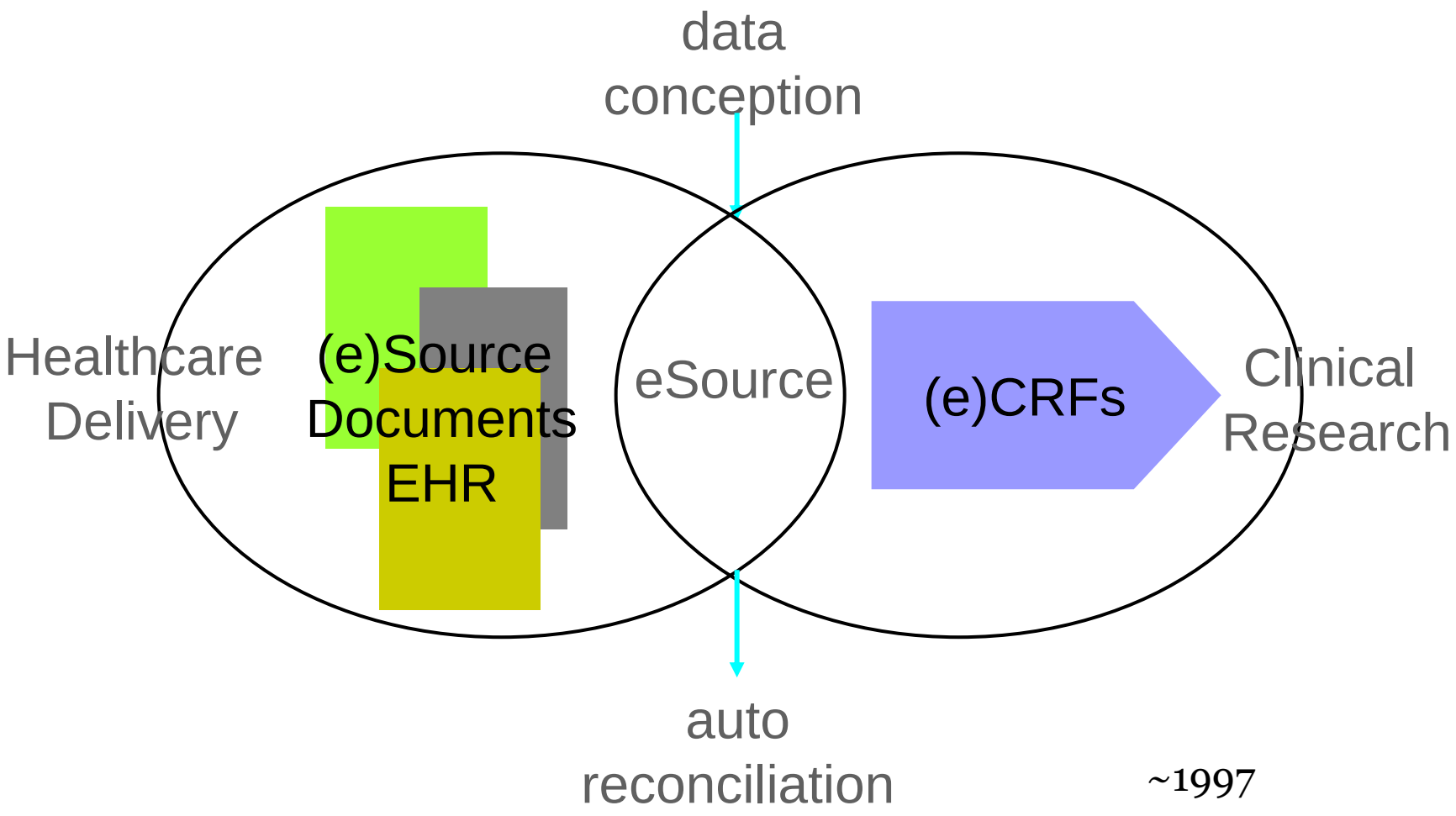
Research

- Discovery of new therapies
- Understanding diseases
- Testing/comparing therapies (CER)
- Assessing efficacy
- Monitoring safety
- Understanding responses (genomics, biomarkers)
- Public health/quality evaluations
- Post-marketing surveillance

Research findings to inform healthcare decisions

Photos courtesy of Women's Clinic of Lincoln, NE

Goal: Optimize the Process



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eSource Data Interchange (eSDI) Initiative

- **Purpose:** FDA initiative to facilitate the use of electronic technology in the context of existing regulations for the collection of eSource data in clinical research

Note: eSource pertains to collecting data electronically initially through eDiaries, ePatient Reported Outcomes, eData Collection, EHRs

- **Overarching Goals:**
  - To make it easier for physicians to conduct clinical research,
  - Collect data only once in an industry standard format for multiple downstream uses, and thereby
  - Improve data quality and patient safety
- **Product from multidisciplinary team:**
  - **eSDI Document**
  - **12 requirements for eSource**
  - **Available at www.cdisc.org/eSDI-document**
  - **Formed the basis for the Retrieve Form for Data Capture (RFD) Integration Profile**

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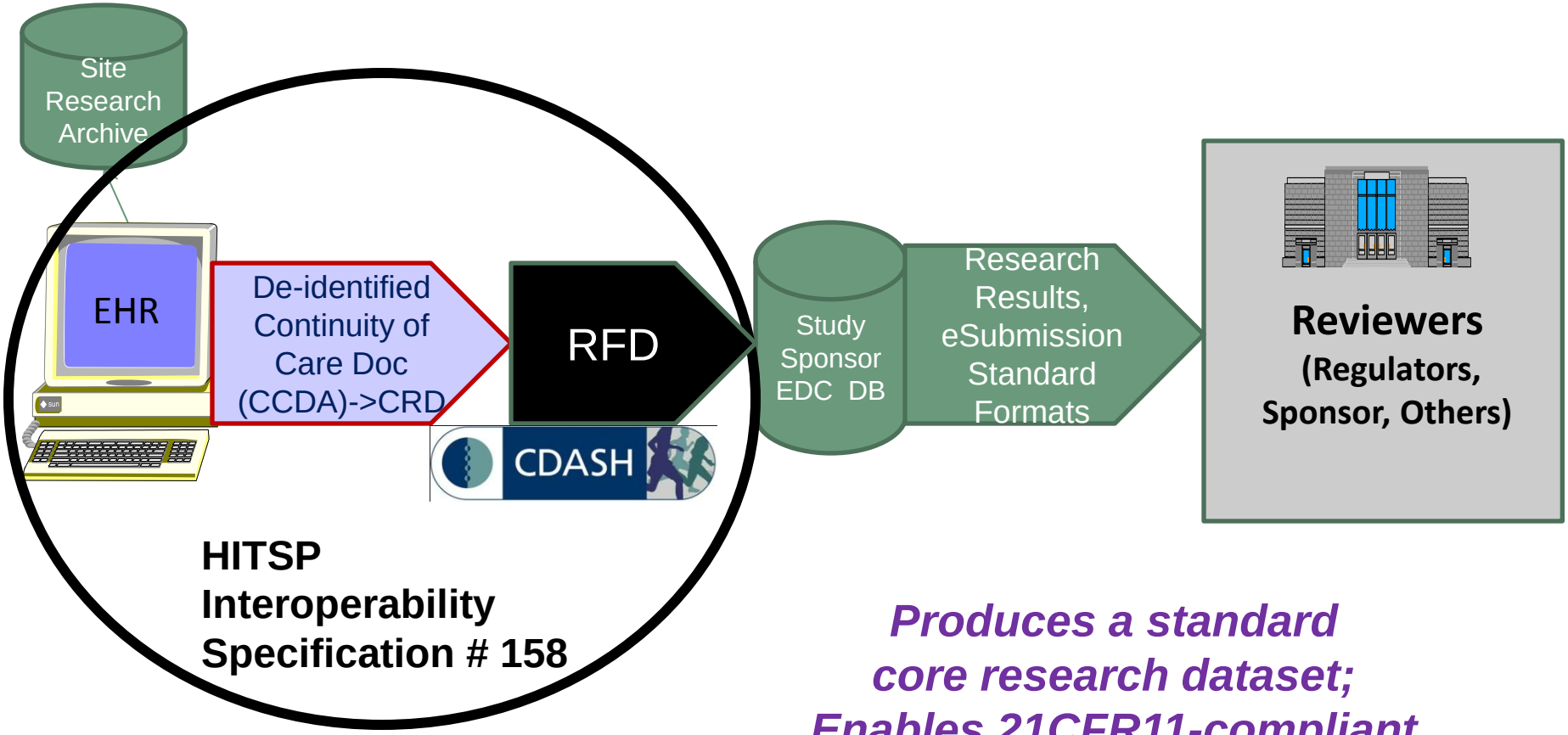
Patient Value:
Quality of Healthcare, Safety



Produces a standard core research dataset; Enables 21CFR11-compliant interoperability and eSource

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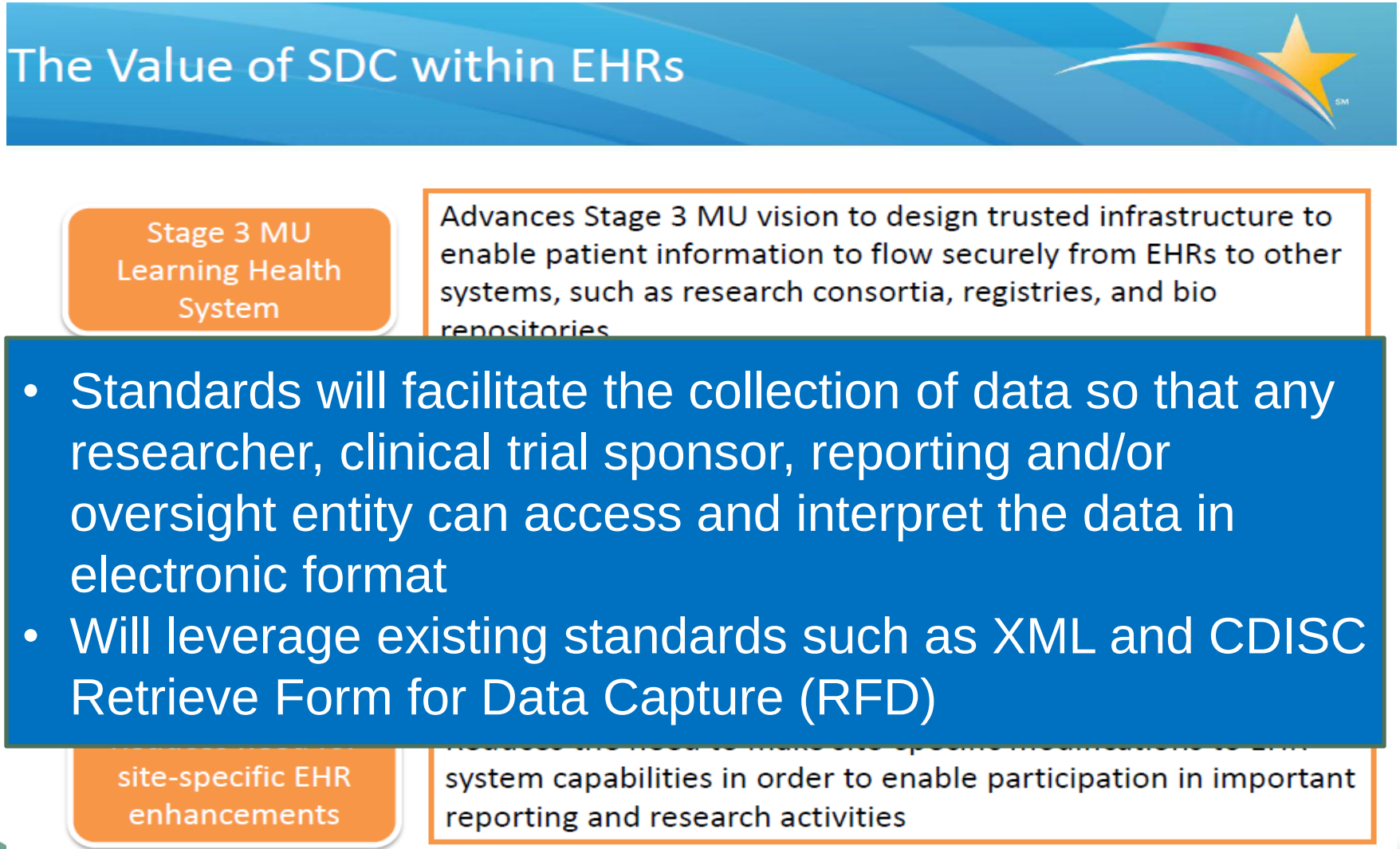
HHS/ONC (U.S. Dept. Health and Human Services Office of the National Coordinator of Health Information Technology) Structured Data Capture Initiative, Launched 23 Jan 2012



- 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)

Source: HHS/ONC SDC Launch Presentation

CDISC- IHE Profiles for EHR-enabled Research

- *make the connection*
  - Retrieve Form for Data-capture (RFD)
- *auto-populate the eCRF*
  - Clinical Research Data (CRD)
  - Drug Safety Content (DSC)
  - Redaction Services
  - Data Element Exchange (DEX)
- *automate collaborative business processes*
  - Retrieve Process for Execution (RPE)
  - Clinical Research Process Content (CRPC)
  - Research Matching (RM)

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Capabilities with Available (Core) Data Standards and Integration Profiles/Interoperability Specifications (Standards-inspired Innovation)

- Dramatic reduction in time and effort to report core data for safety, research, public health
- Can accommodate eDiaries, patient-entered data
- Improved data quality
- Data can be more readily aggregated and analyzed or queried
- Extensible; paves the way for more complex research and clinical genomics for personalized healthcare
- RFD is easily implemented by vendors; endorsed by EHRA

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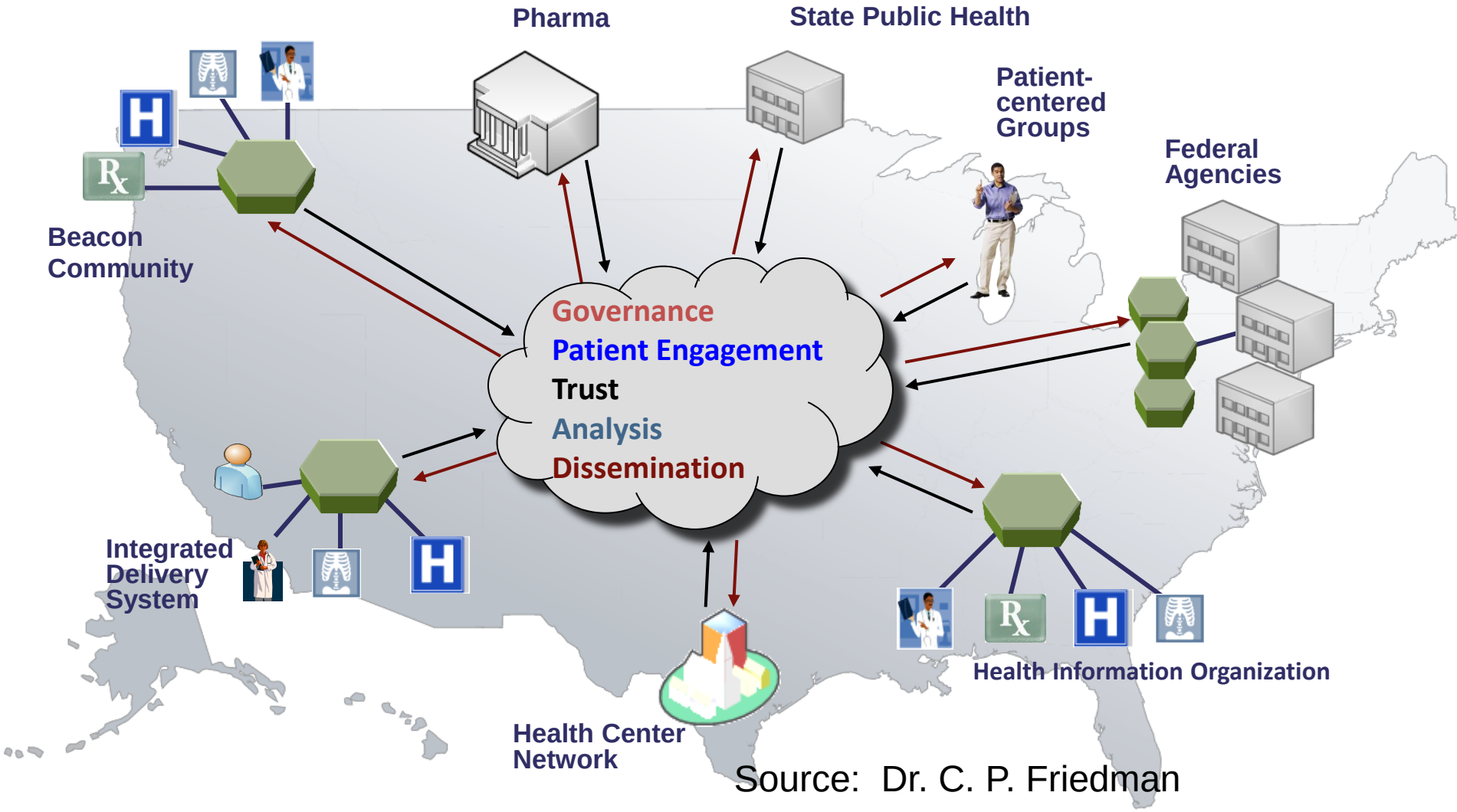
A National-Scale Learning Health System



Source: Dr. C. P. Friedman

CDISC Leading ESTEL = Essential Standards to Enable Learning

Regulatory Agencies and CDISC

- PMDA (Japan) – According to new J3C Chair, plan to adopt CDISC by 2016
  - PMDA leader met with CDISC, J3C and TRI leaders leaders at Japan Interchange 2012
  - PMDA recently announced a CDISC pilot
- CFDA (China) – Visiting U.S. in November; requested one-day training in CDISC in PA and half-day meeting with CDISC
  - In discussions with CDISC/C3C for several years

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EMA

From: Peter Van Reusel (Chair) to E3C

Subject: FW: EMA policy on publication and access to clinical-trial data released for public consultation

Dears,

FYI below, the EMA has released the draft policy for public review. The policy will come into effect on Jan 2014. Data standards are mentioned as follows:

242 Wherever technically possible, analysable, de-identified raw CT data shall be made available for
243 downloading in the format in which they have been analysed by the applicant, submitted and
244 evaluated. For the time being, this can be according to CDISC (Clinical Data Interchange Standards
245 Consortium) or other appropriate standard. In future, CDISC shall be the required standard, in line
246 with future guidance from the Agency. No conversion of formats is recommended, either by the
247 marketing-authorisation holder or the Agency.

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• Guidances & Notices in Process

eCTD Guidance	• Published January 3, 2013
eSource Guidance	• Publication November 20, 2012 • Comment Review Completed • Final Guidance in Clearance
eStudy Data Guidance	• Revised Draft Completed • New Draft in Clearance
Therapeutic Area Project Plan	• Plan in Clearance

- **Federal Register Notices**
  - SDTM 3.1.1 retirement date
  - Data Standards Strategy and Action Plan

How can you and your companies benefit from CDISC?

Participate in the Interchange - 6-7 November, Bethesda, MD
Keynoters: Drs. Mark McClellan, Dr. Lisa LaVange (FDA Statistics)

- ✓ Join a team; attend the INTRAchanges
- ✓ Comment on the standards during public reviews
- ✓ Use the standards from the start – CDASH (and Protocol)
- ✓ Participate in the Tuft's CSDD Study
- ✓ Take authorized CDISC training courses
- ✓ Make sure your organization is a member of CDISC and you are on the mailing list; participate in the CDISC Advisory Council

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Communication is Essential

CDISC eNewsletter

- Hot Topics
- Success Stories
- Technical News
- FAQs
- Blogs and Press Releases
- 3C and User Networks
- Membership
- Education
- Networking Events

CDISC Annual Report

Sign up online to our e-mail list!

“All too many observations lie isolated and forgotten on personal hard drives and CDs, trapped by technical, legal and cultural barriers.”

Nature, September 2009

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Quality Improvement

Enablers

CDISC is more than Standards!

Speed

Process Redesign

Workflow Integration

Standards-inspired Innovation

Resource Savings

Strength through collaboration