Opportunities and Challenges for adopting CDISC Standards Across Healthcare and the Life Sciences.

Frank W. Rockhold, PhD
Senior Vice President, GlaxoSmithKline
Past Chairman of the Board, CDISC

9th Annual SAS Health Care & Life Sciences Executive Conference
Cary, NC, May 2012

Strength *through Collaboration*

Information from healthcare (private, aggregated) to enable research

Healthcare

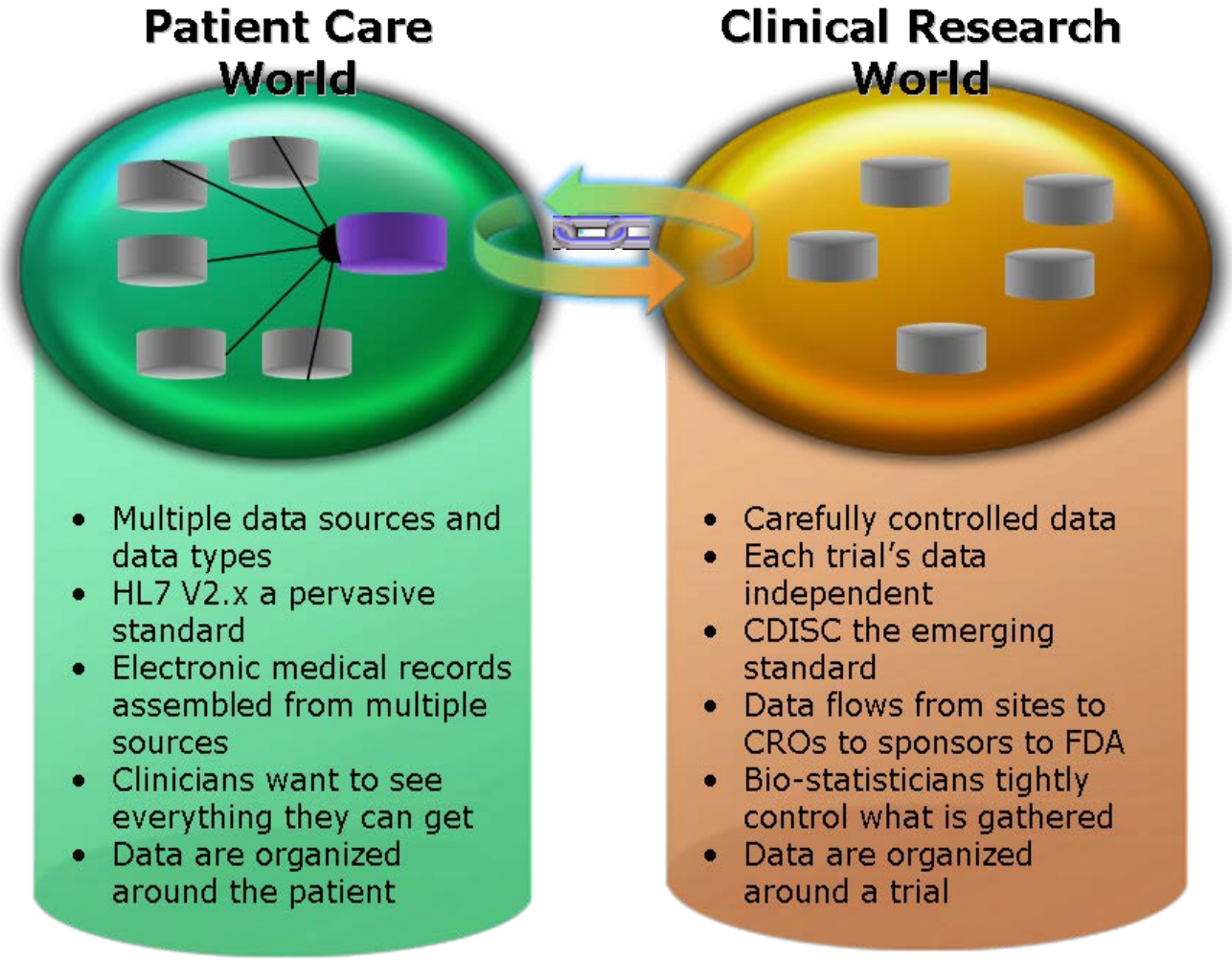
- Quality healthcare
- Informed decisions
- Personalized medicine
- Patient safety and privacy
- Public health
- Improved therapies
- Efficiencies/reduced costs

Research

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

Research findings to inform healthcare decisions

Healthcare and Clinical Research: Parallel Universes



Source: Landen Bain, CIO, DUMC ~ 2004

Standards, Who Needs Them?

Why Standards ?

Clinical Trials

What is the average age of patients enrolled in 11 industry trials for Alzheimer's Disease?

Clinical Trials Date of Birth

Jan. 15, 2011

January 15, 2011

1/15/11

1/15/2011

15/1/11

15 January 2011

15-1-11

2011-1-11

Study #2 – dmg.xpt

ID	GENDER
A1	Male
A2	Male
A3	Female
A4	Female
A5	Male

Study #1 – demog.xpt

SUBJID	SEX
0001	M
0002	F
0003	F
0004	M
0005	F

Study #3 – axd222.xpt

USUBID	SEX
00011	0
00012	1
00013	1
00014	0
00015	1

Study #4 – dmgph.xpt

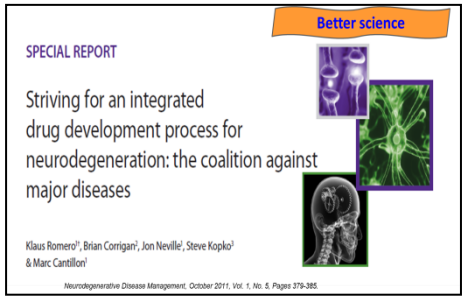
PTID	GENDER
0001	1
0002	1
0003	2
0004	2
0005	1

Lilliam Rosario, Ph.D.
Associate Director
Office of Critical Path Programs
Office of the Commissioner

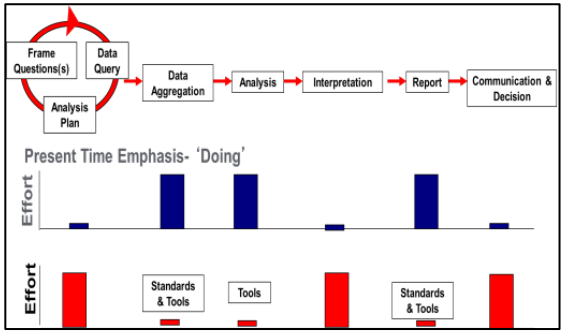
Why Standards ?

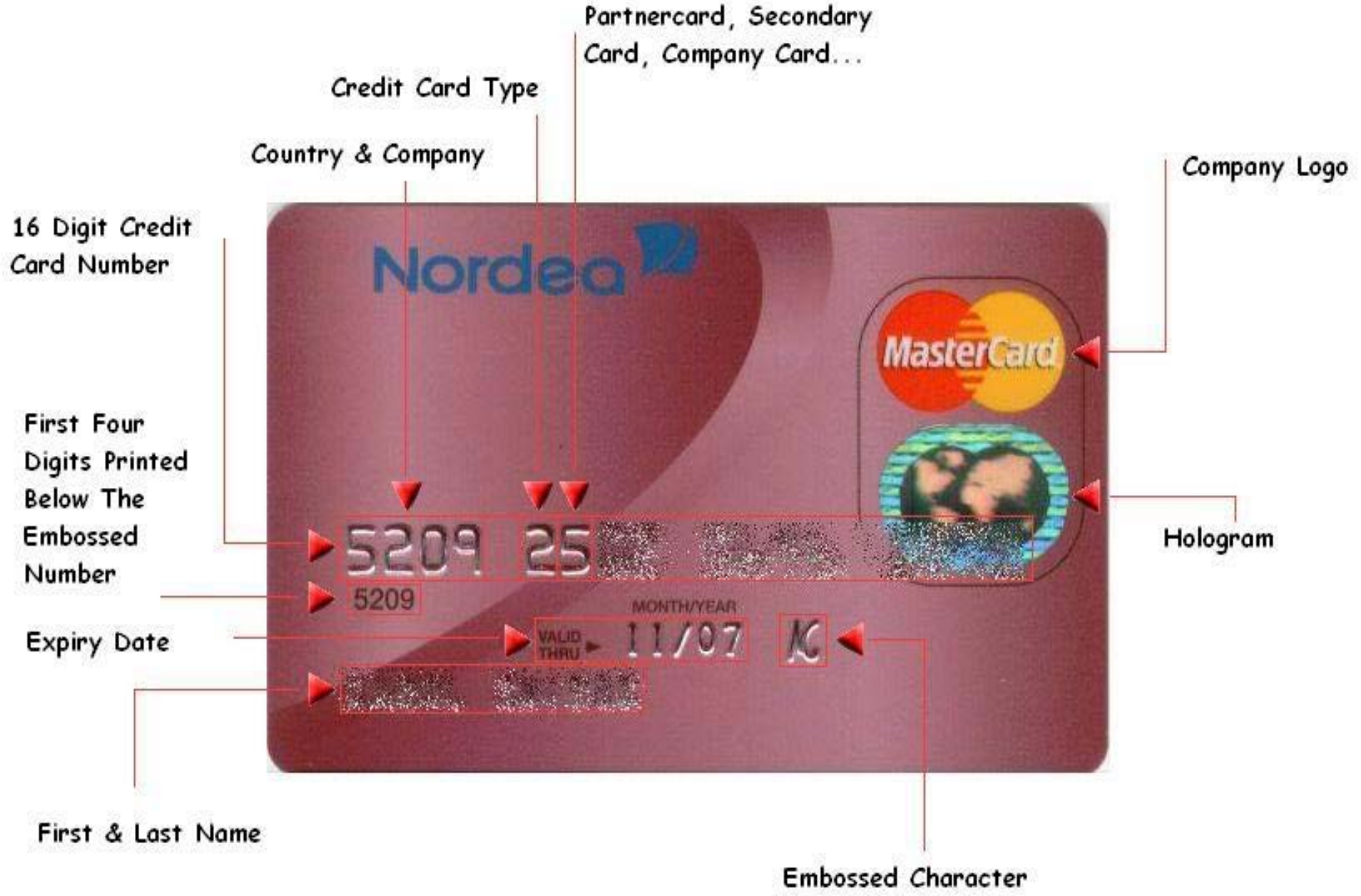
- Efficient collaboration

- Better science



- Regulatory efficiency




Partnercard, Secondary Card, Company Card...
Credit Card Type
Country & Company
Company Logo
16 Digit Credit Card Number
Nordea
MasterCard
First Four Digits Printed Below The Embossed Number
5209 25
5209
Hologram
MONTH/YEAR
Expiry Date
VALID THRU
11/07
First & Last Name
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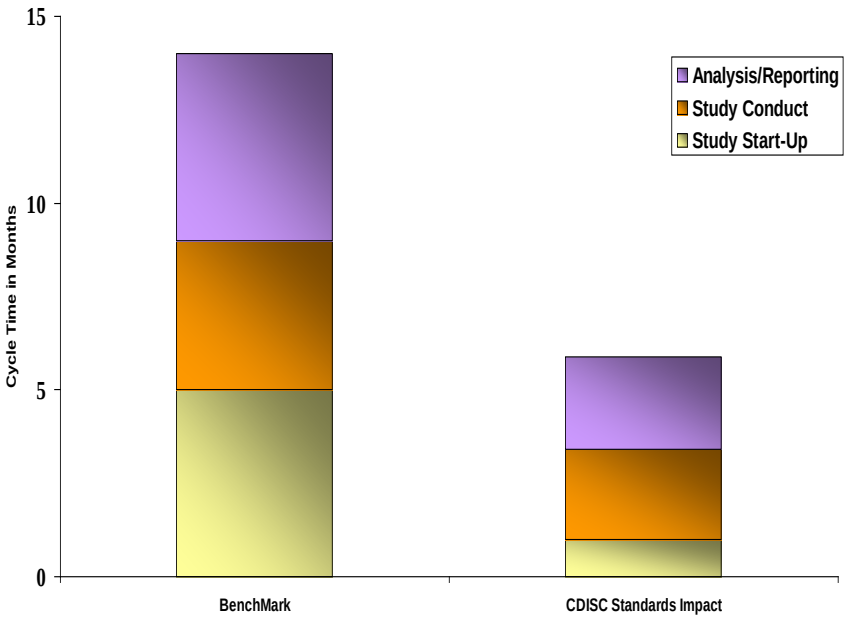
Gartner-PhRMA-CDISC: Business Case

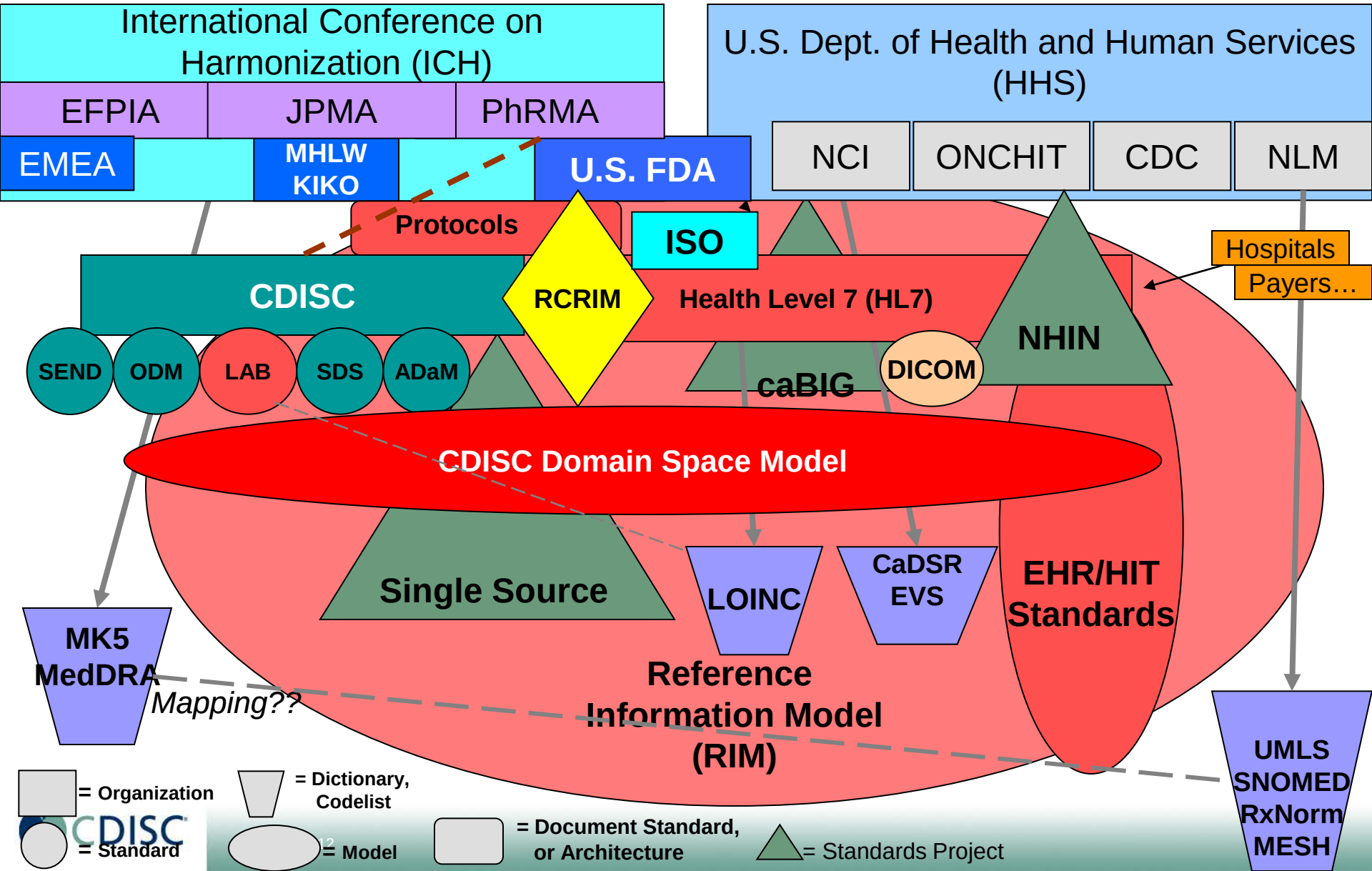


Resource (Time and Cost) Savings

- **Summary**
  - Using CDISC standards can save significant time and cost, especially when implemented in the early stages of the study
  - Opportunities for an additional impact on clinical research
    - **Increase data quality**
    - **Enable data integration; enhance re-usability**
    - **Facilitate data exchange with partners**
    - **Enable software tools**
    - **Improve team communication**
    - **Facilitate regulatory reviews and audits**

The "World of Standards"

Source: Adapted from CDISC



Clinical Data Interchange Standards Consortium

The CDISC Vision: informing patient care and safety through higher quality medical research.

- Standards Developing Organization (SDO)
- Global, open, multidisciplinary, vendor-neutral, non-profit
- Founded 1997, incorporated 2000
- Member-supported (>300 organizational members, e.g. academia, biopharma, service / technology providers)
- Additional revenue streams through education, certification, grants, contributions (now a 501c3 charitable non-profit)
- Active Coordinating Committees (3C)
  - Europe, Japan, China, Korea
- > 20 User Networks around the world
- > 90 countries in participant database (~ 11,000); downloading CDISC standards from website

CDISC Strategic Goals 2012-2015

- Achieve significant progress in the use of CDISC standards to allow scientifically sound **data aggregation** and support secondary uses of research data for the purposes of scientific investigation and comparative effectiveness.
- Achieve significant progress in enabling **interoperability between clinical care and clinical research**, and explore expansion from bench to bedside (**translational research**); accelerate the cycle through which healthcare informs research and research informs clinical decisions.
- Expedite the development and rollout of new **therapeutic-area or specialty standards**, **while continuing to refine, support and educate on existing/foundational standards**, to ensure consistency in data capture and analysis related to efficacy in addition to patient safety.

CDISC Strategic Goals 2012-2015

- Develop **CDISC SHARE (Shared Health And Research Electronic Library), a global, accessible, electronic library for CDISC content/semantics** that will enable precise and standardized data element definitions and richer metadata that can be reused within applications and across studies to improve biomedical research and its link with healthcare.
- Leverage our global, nonprofit, vendor neutral, independent status to forge **productive collaborations** with and provide **value** to key stakeholder communities.

The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare

Press Release: June 10, 2010

CDISC

CRITICAL PATH INSTITUTE

Initial database required mapping to a standard (CDISC); can now be leveraged to collect data using the standard

COALITION AGAINST MAJOR DISEASES

Public Announcement June 11, 2010

collaborate · innovate · accelerate

PUBLIC RELEASE OF ALZHEIMER'S CLINICAL TRIAL DATA BY PHARMACEUTICAL RESEARCHERS

First Combined Pharmaceutical Trial Data on Neuro-degenerative Diseases;

Shared Resource from Unique Public-Private Partnership Will Help Accelerate Alzheimer's, Parkinson's, and Other Brain Disease Research

Washington, DC – A new ...**ipated in 11 industry-sponsored cli**...**(CAMD). This is the first database of com**...**made available to qualified researchers arou**...

Strategic Goal #1:
Value of data aggregation made possible through CDISC standards

Conclusions from CAMD

CRITICAL PATH INSTITUTE
collaborate · innovate · accelerate

- Data from individual clinical trials of 200-400 patients with Alzheimer's Disease had limited power and frequently failed due to variability in outcome and small sub-groups.
- Mapping control arm data to a standard format for >6,000 patients in 20 trials **created a dataset with higher quality** (common methodology for ADAS-cog) and greater power to assess variables affecting progression
  - Severity and age at entry
  - ApoE4 genotype
- Data standards can
  1. Increase learning from clinical research study analysis
  2. Facilitate data sharing across research studies
  3. Create databases with which to design more informative and efficient research studies

NOTE: Data standards are most valuable (significantly reducing time and resources) when implemented from the beginning.

The CDISC vision is to inform patient care and safety through higher quality medical research.

Strategic Goal # 5:
Leverage global, non-profit, vendor neutral, independent status to forge productive collaborations

Strength through Collaboration

CDISC around the Globe

CDISC Therapeutic Area Projects: Engagement and Initiating Organizations

"Efficacy Standards"

Through Today

- Tuberculosis (Duke, NIH)
- Acute Coronary Syndrome (Duke, NIH)
- Polycystic Ki… Foundation, …
- Cardiovascu… ACC)
- Alzheimer's (C-Path, NINDS)
- Parkinson's Disease (NINDS)
- Pain & Analgesics (FDA, U. of Rochester)
- Virology (FDA/NIH)
- Oncology (CDISC, NCI, FDA)
- Diabetes (FDA, ScenPro)

2012 and Beyond

- Expand TB (C-Path, Gates, Global TB Alliance, IMI Europe)
- Other Neurological Disorders …BI, MS …cancers
- Medical Devices and Imaging (CDISC, NCI, FDA)
- Vaccines (IMI Europe)
- Pediatrics (NICHD)
- Other FDA TA priorities (55)

Strategic Goal #3:
Therapeutic Area standards for 'efficacy' data to augment safety data standards

PDUFA V

FDA's draft Performance Goals for PDUFA V

- Clinical data standards needed for therapeutic areas
- Use of data standards indicated for future applications.

E. *Clinical Terminology Standards: …FDA shall develop standardized clinical data terminology through open standards development organizations (i.e., ….CDISC) with the goal of completing clinical data terminology and …. implementation guides by FY 2017.*

1. *FDA shall develop a project plan for distinct therapeutic indications…. FDA shall publish a proposed project plan for stakeholder review and comment by June 30, 2013…..*

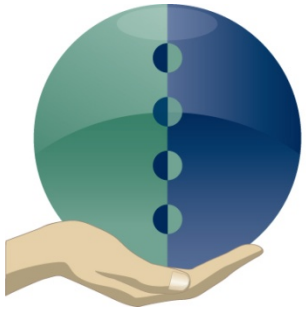
G. *FDA shall periodically publish final guidance specifying the completed data standards, formats, and terminologies that sponsors must use to submit data in applications…..*

http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf

FDA Priority Therapeutic Areas for Development

Tier 1		
Acne	Pain*	Schizophrenia
Alzheimer's Disease*	Parkinson's Disease*	Solid organ transplantation
Anti-diabetic agents*	Polycystic Kidney Disease* (added)	Treatment of Hepatitis C* (Virology)
Crohn's Disease	Prevention of pregnancy	Treatment of postmenopausal osteoporosis
Infections of skin and/or subcutaneous tissue	Psoriasis	Tuberculosis*
Cardiovascular and Cardiovascular Imaging*	QT Studies	Urinary tract infections
Oncology: time to efficacy event other than overall survival*	Rheumatoid arthritis	

Legend	2012	2013	2014	2015	2016	2017	*= in progress



CDISC SHARE

SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC LIBRARY

CDISC Terminology Collaboration

NATIONAL CANCER INSTITUTE

EVS ENTERPRISE VOCABULARY SERVICES

A global, accessible electronic library, which through advanced technology, en
el)
th
studies to improve biomedical research and its link with healthcare

Strategic Goal #4:
SHARE – Shared Health and Research Electronic library

Key purposes: Develop efficacy standards faster and make the CDISC standards more accessible.

*Biomedical Research Integrated Domain Group (BRIDG) Model

A clinical research domain analysis model (DAM) in UML
initiated by CDISC, BRIDGing

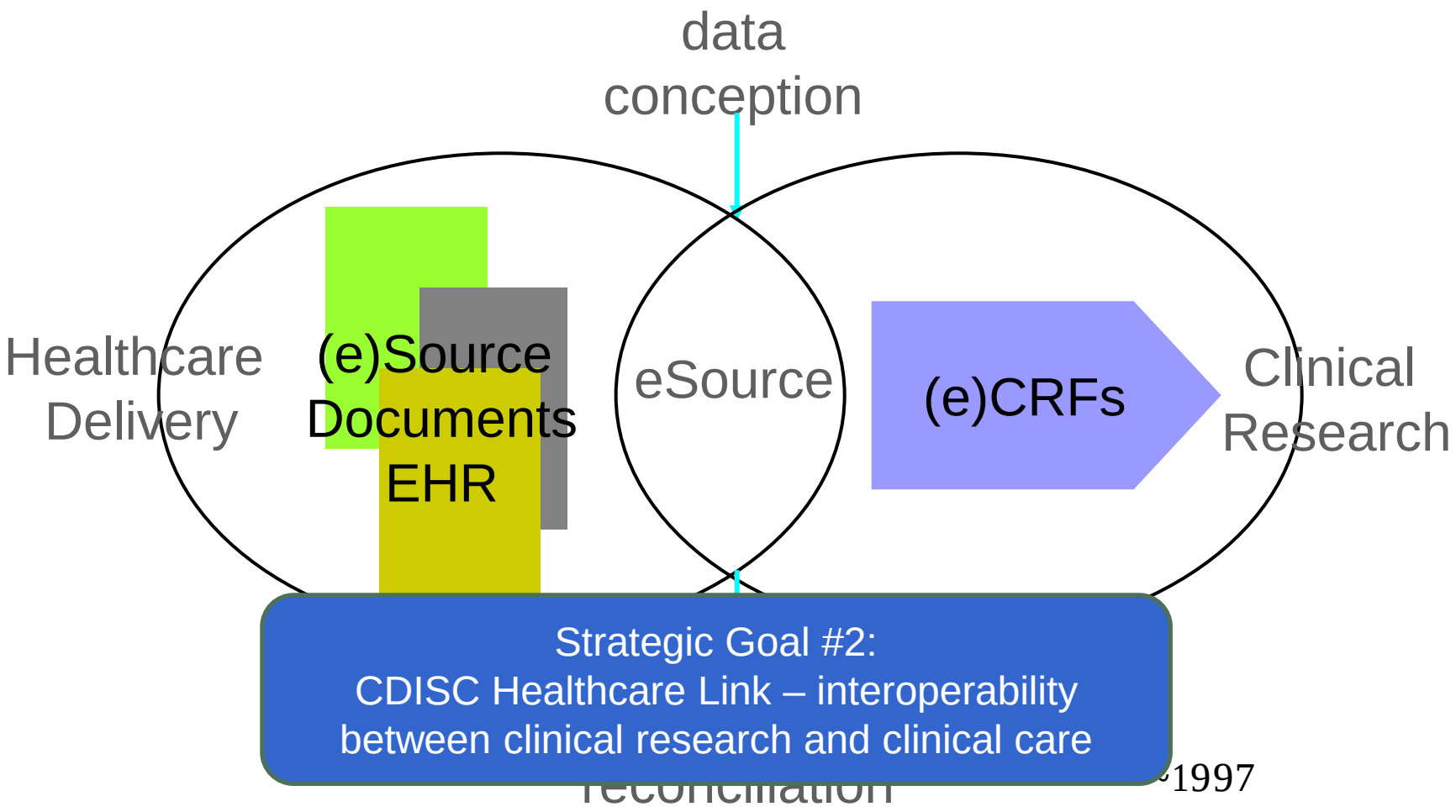
- *Organizations (CDISC, HL7, FDA, NCI)*
- *Standards*
- *Research and Healthcare*

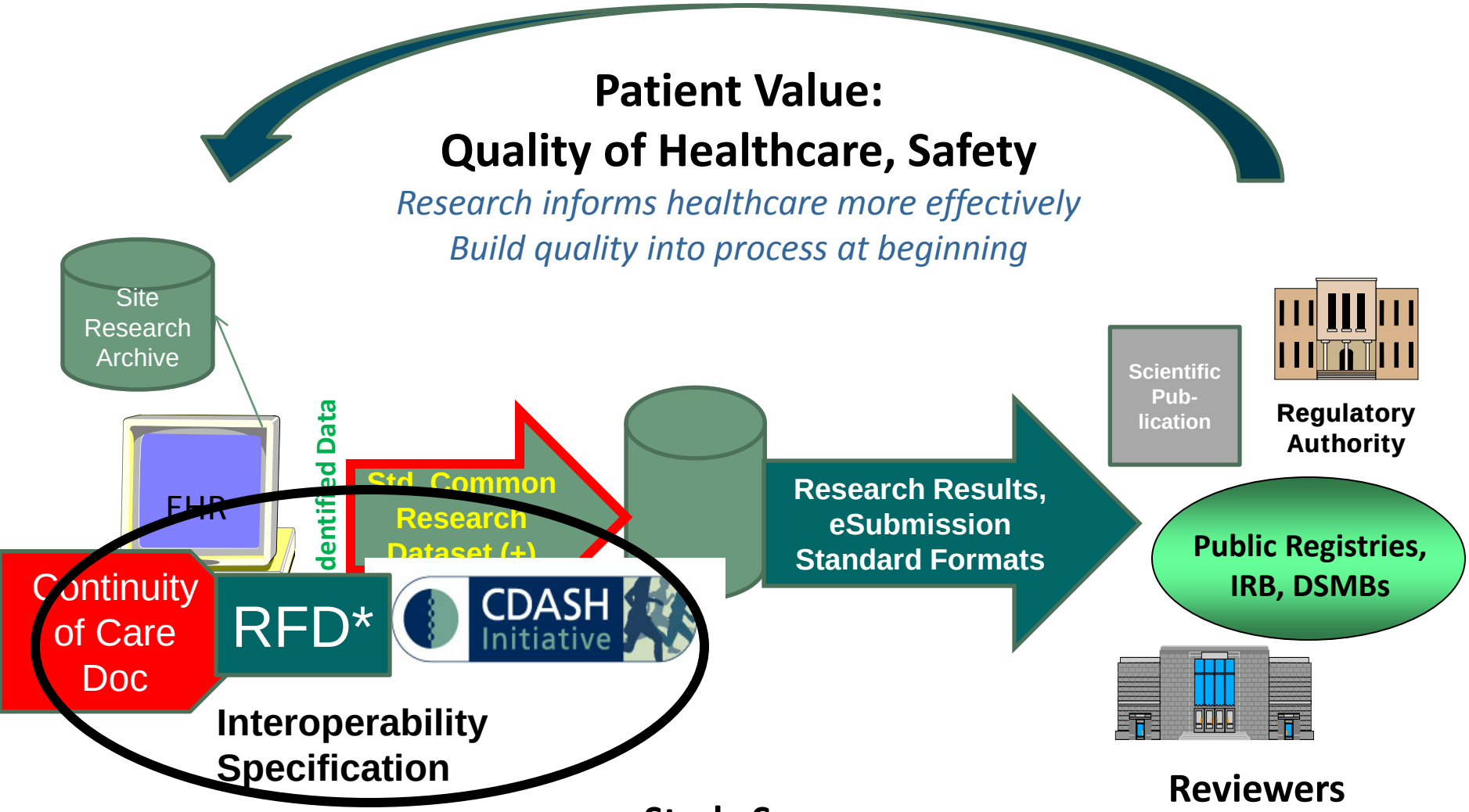
- ***Now exploring how to ensure alignment with NCI Life Sciences DAM and HL7-CDISC Clinical Genomics DAM***
- ***BRIDG is on the path to becoming an ISO/CEN standard through the JIC***

Open source ; Collaborative Project

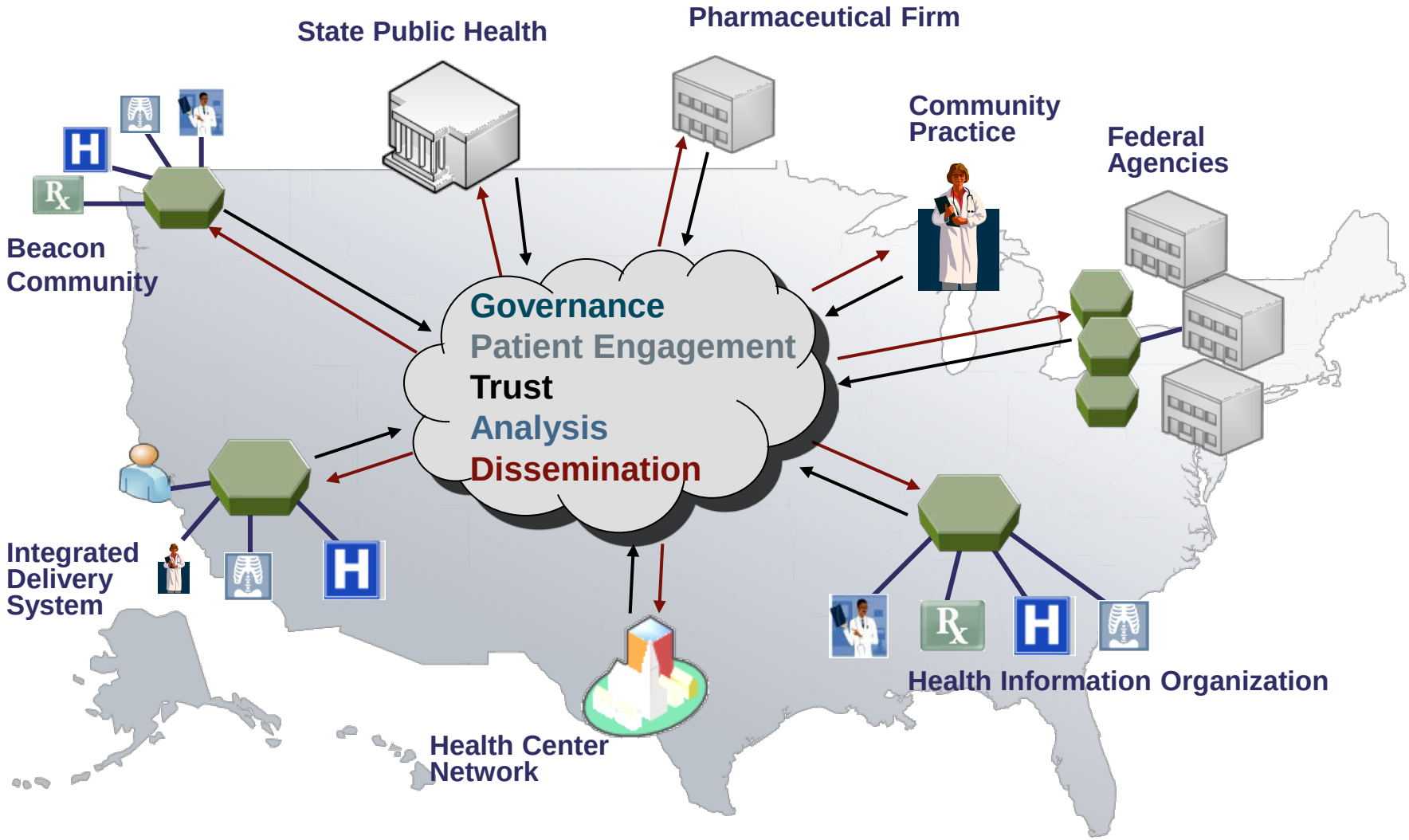
- *See BRIDG Model on CDISC website or www.bridgmodel.org*

Healthcare Link Goal: Optimize the Research Process





A Learning Health System for the Nation



Summit Planning Committee Members

- David Blumenthal, Partners HealthCare
- Adam Clark, MedTran Health Strategies
- Charles Friedman, University of Michigan (Chair)
- Claudia Grossman, Institute of Medicine
- Robert Kolodner, Open Health Tools
- Rebecca Kush, Clinical Data Interchange Standards Consortium
- Allen Lichter, American Society for Clinical Oncology
- Janet Marchibroda, Bipartisan Policy Center
- Michael McGinnis, Institute of Medicine
- Marc Overhage, Siemens Healthcare
- Frank Rockhold, GlaxoSmithKline
- Joshua Rubin, Joseph H. Kanter Family Foundation
- Jonathan Silverstein, NorthShore University HealthSystem
- Richard Tannen, University of Pennsylvania
- James Walker, Geisinger Health System
- *Joseph Kanter, ex officio*

Where is the Drug Safety Data?

- Clinical Trials
- Haelth Claims data
- Electronic Health records
  - OMOP
  - Mini Sentinel
  - IMI Protect
  - ….

Key Messages

- Research and Healthcare data are linked
- Building quality in from the beginning is ideal
  - ….adding in quality at the ‘back end’ (e.g. through mapping or normalization) can certainly be done but only at a high cost (time and resources)
- Data standards improve data quality
  - …..especially when implemented in the data collection steps at the beginning

Patients are motivated to have high quality data.

CDISC®

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

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

Strength *through Collaboration*

Backup Slides