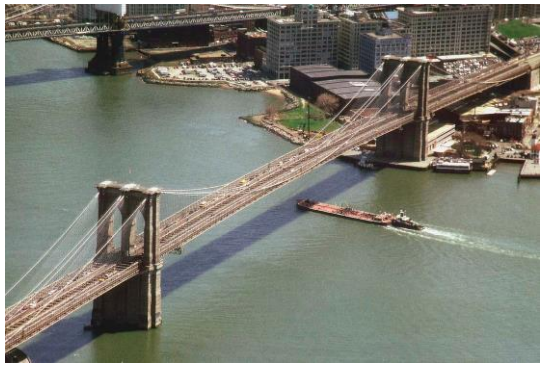
Learning Health Community

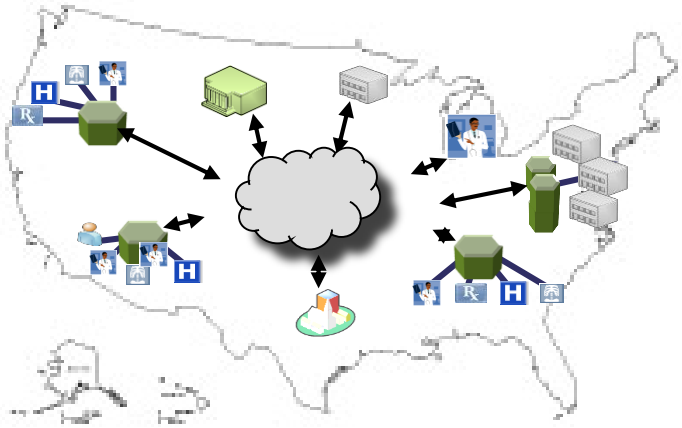
Essential Standards to Enable Learning (ESTEL) Initiative

17-18 April 2014
AHRQ, Rockville, MD

The National LHS: *One Infrastructure* that Supports

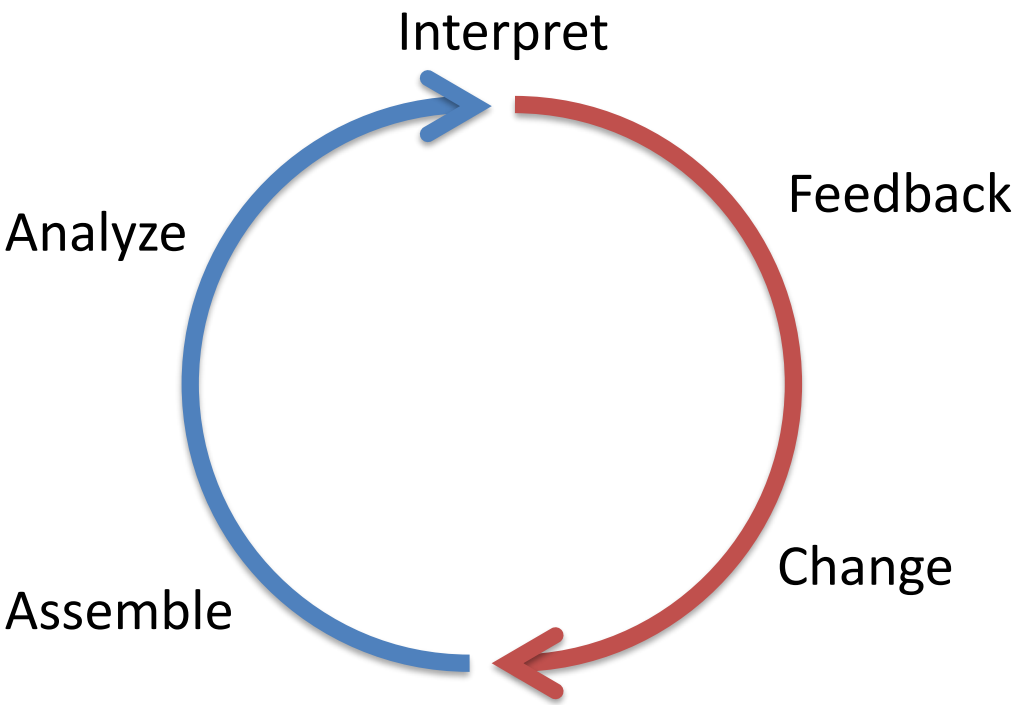


- Research
  - Clinical
  - Comparative effectiveness
  - Translational
- Public Health
  - Surveillance
  - Situational Awareness
- Quality Improvement
  - Health process and outcomes research
  - Best practice dissemination
- Consumer Engagement
  - Knowledge-driven decision making



What Infrastructure Can Enable

- A needed virtuous cycle of study, learning and improvement
- This requires assembly of data, analysis, and feedback



Learning Health System *Core Values*

1. Person-Focused
2. Privacy
3. Inclusiveness
4. Transparency
5. Accessibility
6. Adaptability
7. Governance
8. Cooperative and Participatory Leadership
9. Scientific Integrity
10. Value

54 Endorsements of the LHS *Core Values** (As of 5/8/2013)

NCHICA
North Carolina Healthcare Information and Communications Alliance, Inc.

Lewin and Associates LLC
Ursus Technologies (SDVOSB)

patientslikeme

Minnesota e-Health

ACP
American College of Physicians
Internal Medicine | Doctors for Adults®

MedDATA FOUNDATION

MINNESOTA MDH DEPARTMENT OF HEALTH

SANOFI

GEISINGER HEALTH SYSTEM

Peachy
SecureHealthHub, LLC

JOHNS HOPKINS MEDICINE

INHS
Inland Northwest Health Services

Biovista
To seek - To know - To act

ANA
AMERICAN NURSES ASSOCIATION

GPII
Global Patient Identifiers Inc.

AZZLY®
One Click Patient Care Management™

VUHID
Voluntary Universal Healthcare Identifier

Open Health Tools

SIEMENS
Siemens Health Services

THE CDI GROUP®

Intermountain Healthcare

NorthShore University HealthSystem

HealthCore

WELLPOINT

AMIA
INFORMATICS PROFESSIONALS. LEADING THE WAY.

galileo analytics

ALTARUM INSTITUTE
SYSTEMS RESEARCH FOR BETTER HEALTH

CDISC

National eHealth Collaborative

KANTER HEALTH
JOSEPH H. KANTER FAMILY FOUNDATION

CRITICAL PATH INSTITUTE

Rhode Island Quality Institute

Open mHealth

oz systems

Duke Clinical Research Institute
DUKE UNIVERSITY MEDICAL CENTER

The Center for Learning Health Care

Memorial Sloan-Kettering Cancer Center
Established 1884

e-Patient Dave
A Voice of Patient Engagement

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Genetic Alliance

HL7 INTERNATIONAL

MOSAICA PARTNERS™

COUNT US IN

Harvard Pilgrim Health Care

2311 LLC

DANA-FARBER CANCER INSTITUTE

gsk GlaxoSmithKline

ASCO®

ONS Oncology Nursing Society

GE Healthcare IT

ANI

sas

HEALTH

HIMSS®
transforming healthcare through IT

University of Pittsburgh
School of Dental Medicine
Center for Dental Informatics

Diogenec Group
Seek Truth. Question Convention®

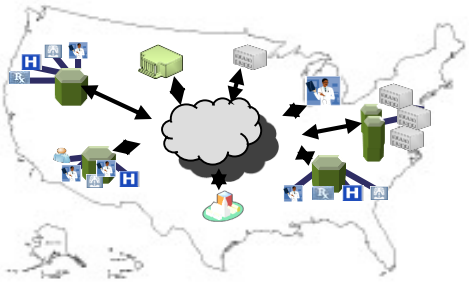
*To be included on a Learning Health Community public website that will list all organizations that have endorsed the LHS *Core Values*.

Medical Advocacy Mural Project

Let's change the "face" of healthcare.

The Learning Health Community

- Grew out of the 2012 “Summit”
- A self-organizing, multi-stakeholder coalition of the willing
- 54 “endorsers” plus ~ 600 others expressing interest
- “Summit” Planning Committee became the Community’s Coordinating Committee
- Catalyzing, leading, and participating in initiatives to realize a Learning Health System
  - Standards (ESTEL)
  - Governance
  - Technology



Agenda – 17 April 2014

12:30 -1:00	Call to Order, Introductions of Participants	Becky Kush
1:00 - 1:30	Background and Setting the Stage for this LHC ESTEL Meeting	Chuck Friedman Ken Pool and Landen Bain
1:30 – 3:00	**Current Projects-** ***Updates, specifically focusing on the use of standards as enablers in these projects/initiatives and how they fit into the 'narrow neck' categories*** • HHS/ONC – Doug Fridsma • ONC Structured Data Capture Initiative – Ken Pool • PCORI and Standards – Jeff Brown • IOM – Digital Learning Collaborative – Claudia Grossman • BRIDG, SHARE, CFAST - Bron Kisler • Research Match and keyCRF – Landen Bain • FDA Regulatory Guidances and HIT Plans – Ron Fitzmartin • TRANSFoRm – Theodoros Arvanitis	Facilitator: Becky Kush
3:00-3:30	Break	
3:30-5:30	Preparation for Breakout Groups on Wednesday • Definitions/descriptions of the three areas to address at the Narrow Neck of the Hourglass • Descriptions of three exemplars of learning cycles: research, public health, quality	Landen Bain, Ken Pool

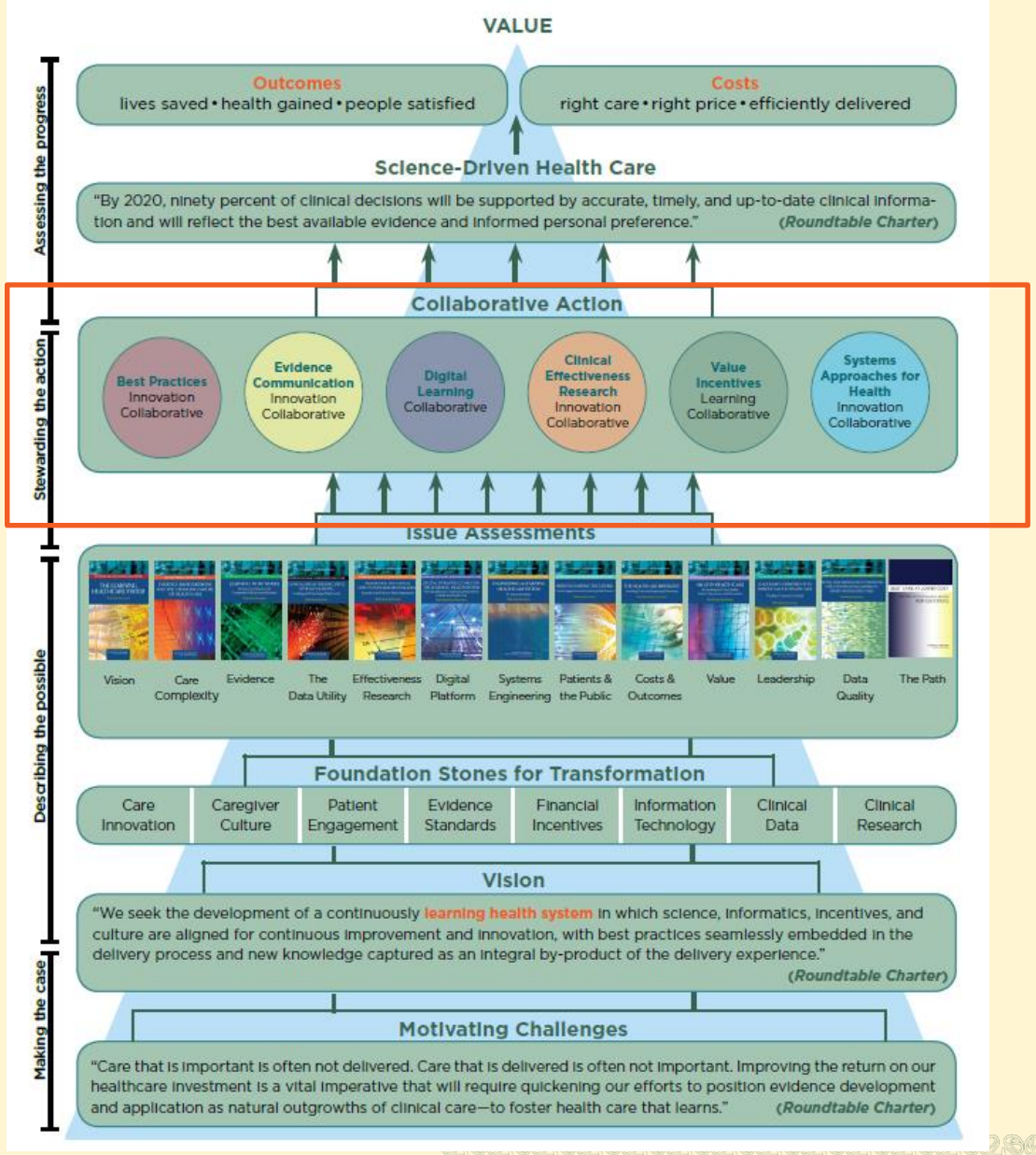
IOM Roundtable on Value & Science-Driven Health Care

Claudia Grossmann PhD
Senior Program Officer

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES
Advising the nation • Improving health

Roundtable Charter

"We seek the development of a learning health system in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation—with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience."



INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

Advising the nation • Improving health

“Digital health data are the lifeblood of a continuous learning health system…The totality of available health data is a crucial resource that should be considered an invaluable public asset in the pursuit of better care, improved health, and lower health care costs.”

- IOM, 2012

Value: *Transparency & Continuous Improvement*

Value Incentives

2014 plans under way & under consideration

- Pilot analytic project identifying and assessing cost disparities
- Strategy framework for health care administrative simplification
- An expert vision paper on core expectations for accountable care
- Additional NGA-IOM Governor's retreats for value innovation

Science: *Evidence & Continuous Learning*

Clinical Effectiveness Research

Digital Learning

2014 plans under way & under consideration

- An expert vision paper on the future of clinical research
- Convening CEO & executive leaders on continuous learning
- A case study of a test-bed for real-time digitally-facilitated research
- An expert vision paper on academic medical center leadership for continuous learning

2013 deliverables

- Workshop: *Large simple trials for clinical research* (Sep report)
- Workshop: *Observational studies in CER* (Sep report)
- IOM paper: *The Common Rule and continuous learning* (Aug hearing)
- Workshop: *Data harmonization across networks* (Oct meeting)
- IOM paper: *Return on information systems investments* (Jan release)
- Workshop: *Improving data quality* (Feb dissemination)
- IOM paper: *Making the case for clinical data use* (Apr release)

- IOM paper: *Making the case for clinical data use* (Apr release)

Culture: *People & Continuous Engagement*

Best Practices

Evidence Communication

2014 plans under way & under consideration

- Formalize national network of patient-family advisory leadership
- Vision and strategy piece on practice models for clinician-patient partnership
- Build the inventory of case studies on clinical data & care improvement
- An expert vision paper and meeting on decision-making tool validation

2013 deliverables

- Workshop/Video: *Partnering with Patients* (Aug release)
- IOM paper: *Team-based care principles and values* (Jan dissemination)
- Patient interviews: *Patients' roles as team members* (paper in draft)
- Survey: *Patients views on clinical data sharing* (Jan dissemination)
- Meeting: *Patient and family leader partnership* (Nov meeting)

Digital Learning Collaborative

The Digital Learning Collaborative (DLC) was created to provide a venue for joint activities that can accelerate progress towards the digital infrastructure necessary for continuous improvement and innovation in health and health care.

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Advising the nation • Improving health

Roundtable on Value & Science-Driven Health Care

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES
Advising the nation • Improving health

Digital Learning Collaborative

Advancing the digital infrastructure for the learning health system

Issue. With more components—testing, diagnosis, records, and patient-clinician communication—shifting to digital platforms, there exists enormous potential for increasing the efficiency, convenience, and effectiveness of health care. Digitalizing health care processes and information provides the foundation necessary to drive a continuously improving health system in which knowledge from past events is used to guide decisions. A health information technology infrastructure that supports a continuously improving, learning health care system requires consideration of the capabilities, technical and policy approaches, and operating principles needed to allow data from multiple areas of clinical health care, population health, clinical, biomedical, and translational research to be leveraged while protecting patients' privacy. In 2010, the IOM, with support from the Office of the National Coordinator for Health Information Technology, held a series of workshops to explore the current efforts and opportunities to accelerate progress in improving health and health care with information technology. The resulting report—*Digital Infrastructure for the Learning Health System: The Foundation for Continuous Improvement in Health and Health Care*—highlighted several areas for follow up activities in developing the digital infrastructure such as data stewardship, quality monitoring, research capabilities, and coordinating requirements around leadership, policies, and sustainability.

Collaborative. Formerly the Electronic Health Records Innovation Collaborative (EHRIC), the Digital Learning Collaborative (DLC) is an *ad hoc* convening activity under the auspices of the IOM Roundtable on Value & Science-Drive Health Care. It was created to provide a venue for joint activities that can accelerate progress towards the digital infrastructure necessary for continuous improvement and innovation in health and health care. This includes fostering a new culture of collaborative action among participants in the learning process—e.g. patients, clinicians, researchers, and product developers.

CO-CHAIRS

Jonathan B. Perlin, M.D., Ph.D.
Chief Medical Officer
HCA, Inc.
"DLC participants work on the projects necessary to ensure that the staggering advances in health IT translate to improved health."

Reed Tuckson, M.D.
Chief of Medical Affairs
UnitedHealth Group
"A smarter digital infrastructure is essential for using clinical data to make better health decisions."

STAFF CONTACT
Claudia Grossmann, Ph.D,
Program Officer / 202-334-3867
cgrossmann@nas.edu

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

IOM Roundtable on Value & Science-Driven Health Care

❖

Digital Learning Collaborative

❖

May 30, 2014
National Academy of Sciences Building
Room 120
2101 Constitution Ave NW
Washington DC

Meeting goals

1. Together with the Learning Healthcare Community's Essential Standards to Enable Learning (ESTEL) working group, convene essential stakeholders, including standards groups, federal agencies, academic health systems (AHSs), and electronic health record (EHR) and research technology vendors around the issue of the implementing standards-based EHR-enabled research.
2. Describe approaches to EHR-enabled research, including those based on the ONC Structured Data Capture (SDC) Initiative, CDISC Healthcare Link, IHE Quality, Research and Public Health, and FDA eSource Guidance and identify how to realize available opportunities.
3. Identify opportunities for vendors, interested AHSs, and research sponsors to accelerate progress towards more widely implemented EHR-enable research

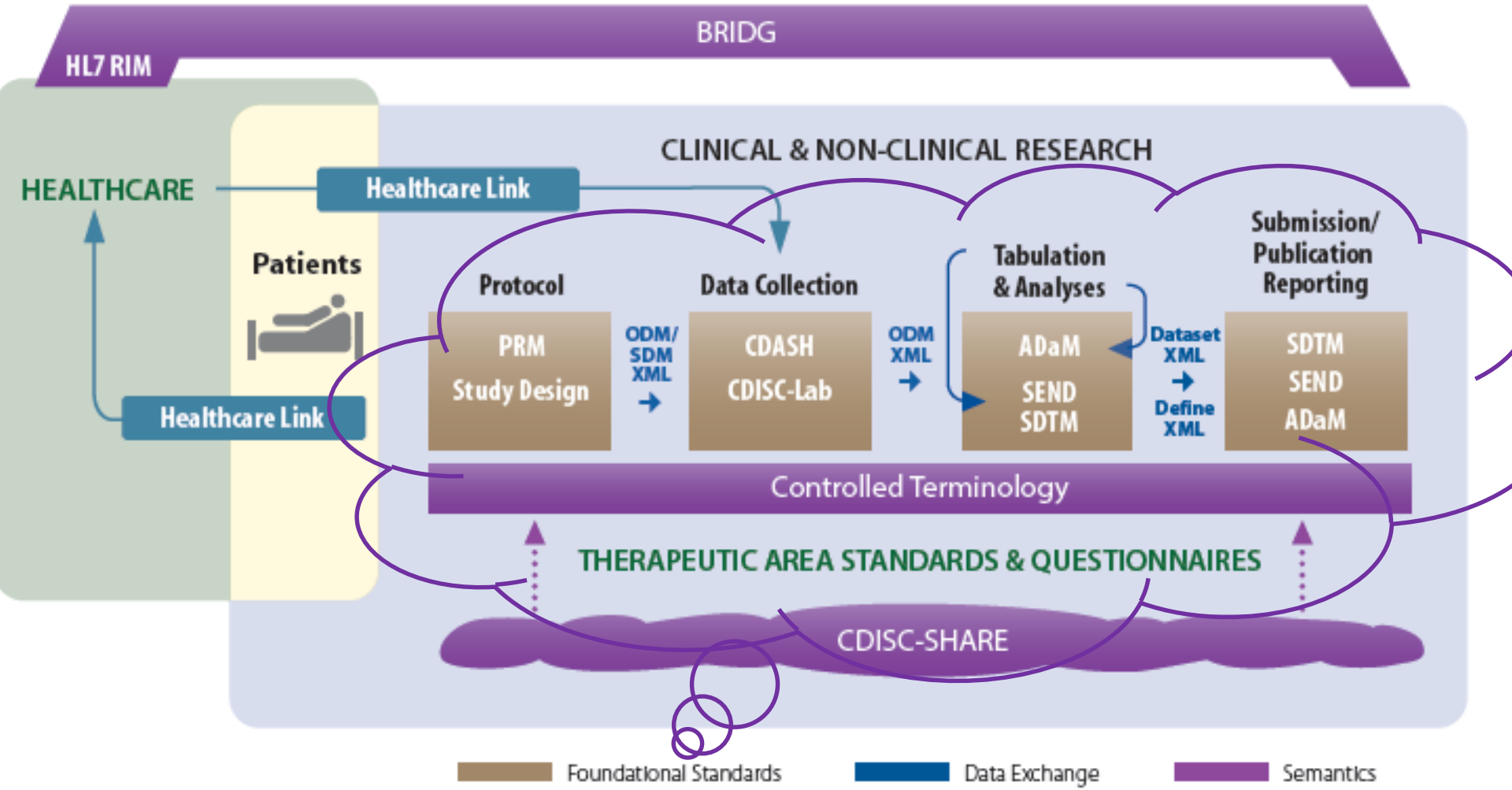
BRIDG, SHARE, CFAST

Bron Kisler, VP, Strategic Alliances, CDISC

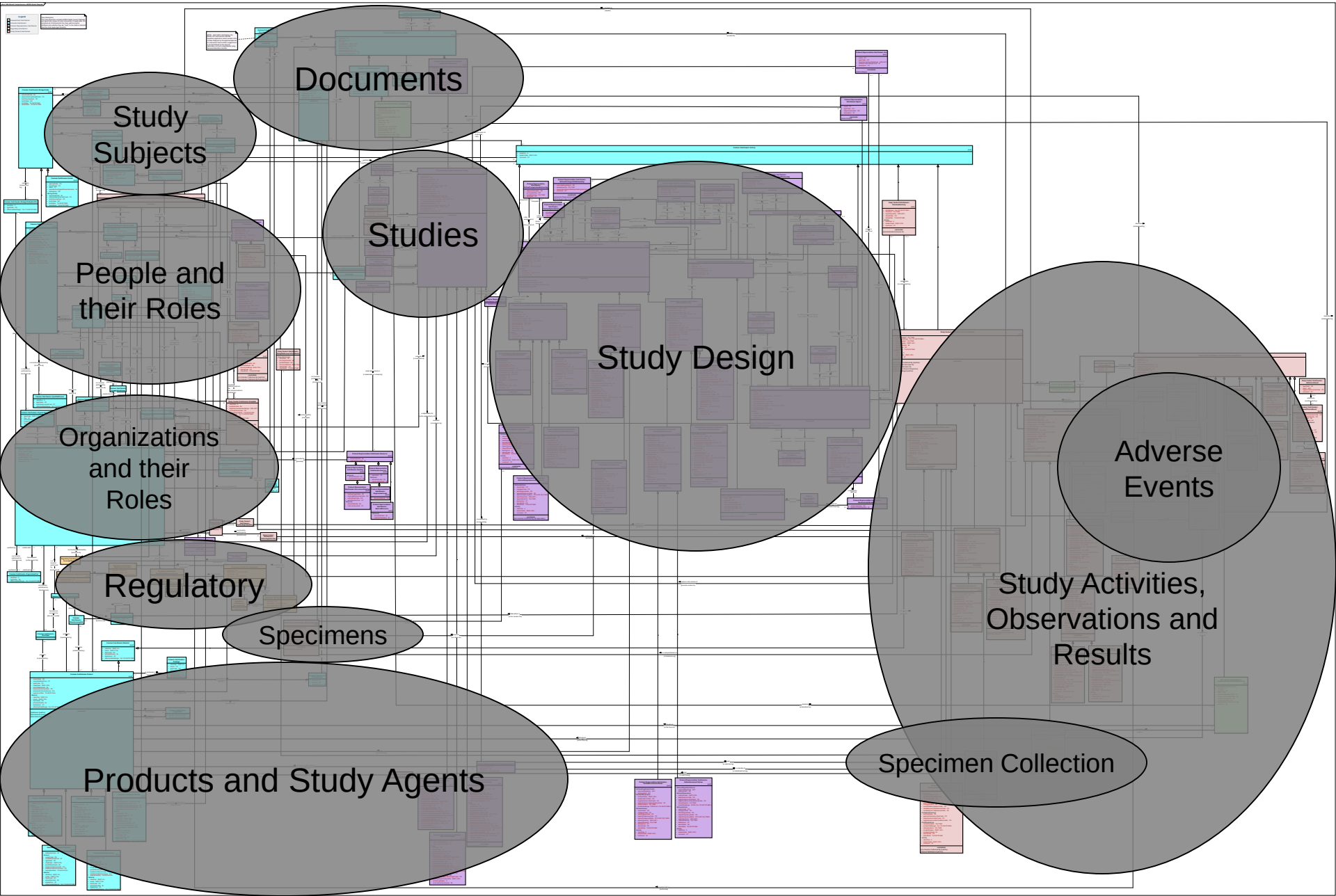
Strength *through Collaboration*

© CDISC 2014

Achieving Interoperability



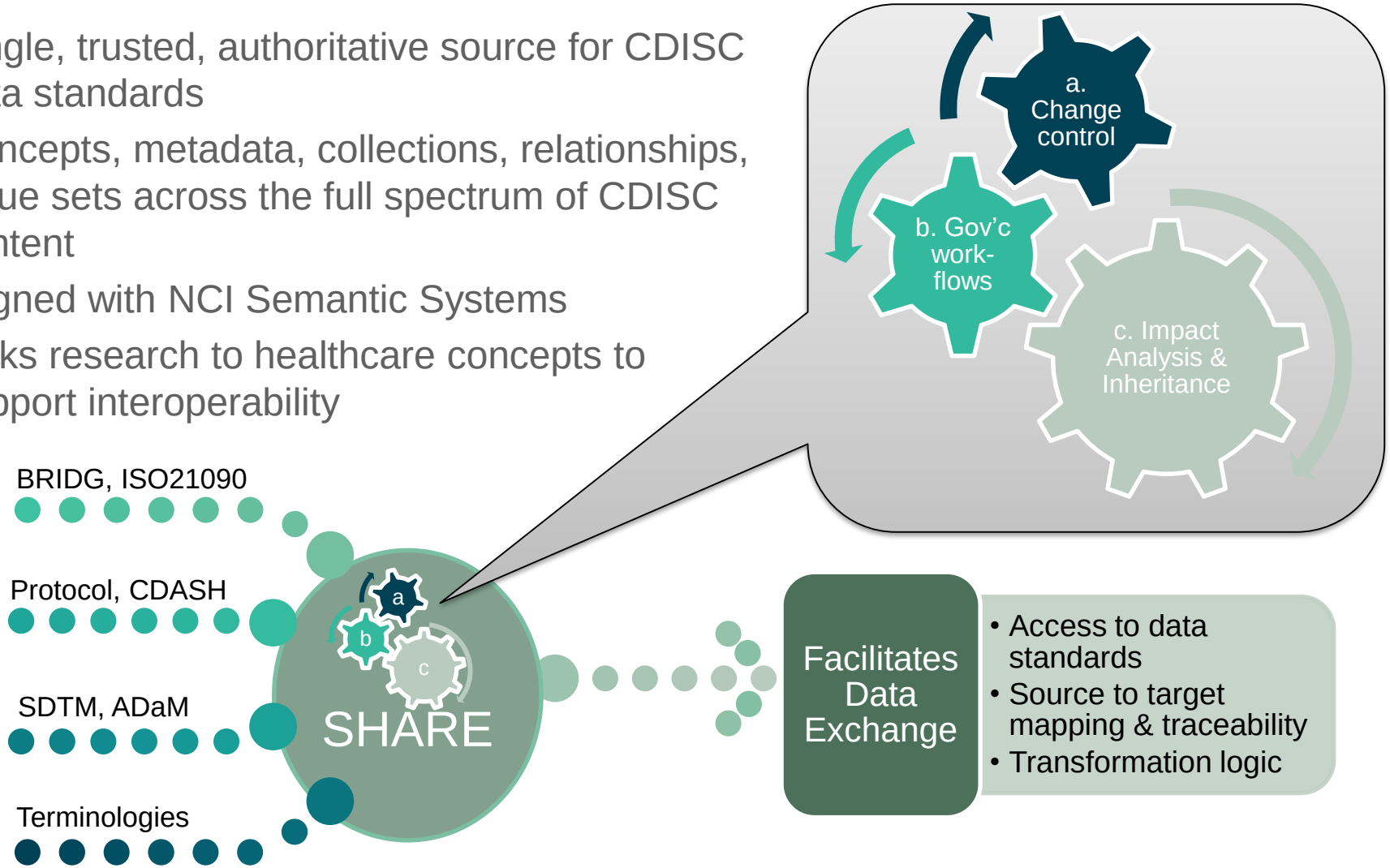
BRIDG Model Content (Layer 2)



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
- Aligned with NCI Semantic Systems
- Links research to healthcare concepts to support interoperability



Adapted from Source by Sue Dubman, Sanofi-Aventis

© CDISC 2013

SHARE MDR Framework

A Versioned Standard is comprised of a set of Operational Collections and associated variables and rules for a specific use case (e.g., SDTM, CDASH)

An Operational Collection is a grouping of Research Concepts. There may be additional rules between objects within the Operational Collection. An Operational Collection may be analogous with a SDTM Domain, a CRF, an ADaM data set, or a similar level of operational structure.

Basic elements that are the foundation for the content described in the SHARE repository. A Research Concept defines one or more related pieces of clinical data, which is developed using an Integrated BRIDG / ISO 21090 Template.

Integrated BRIDG / ISO 21090 Templates use BRIDG classes and relationships to fashion small re-usable patterns that are commonly needed in clinical research

BRIDG is the foundation model for SHARE that provides classes, attributes and associations use to creates core building blocks.

Source: Sam Hume, VP SHARE Development

© CDISC 2013

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

Research Community

Ongoing Maintenance & Enhancement of Foundational CDISC Standards

Research Community

Data Standards in Regulated Clinical Research and FDA Review

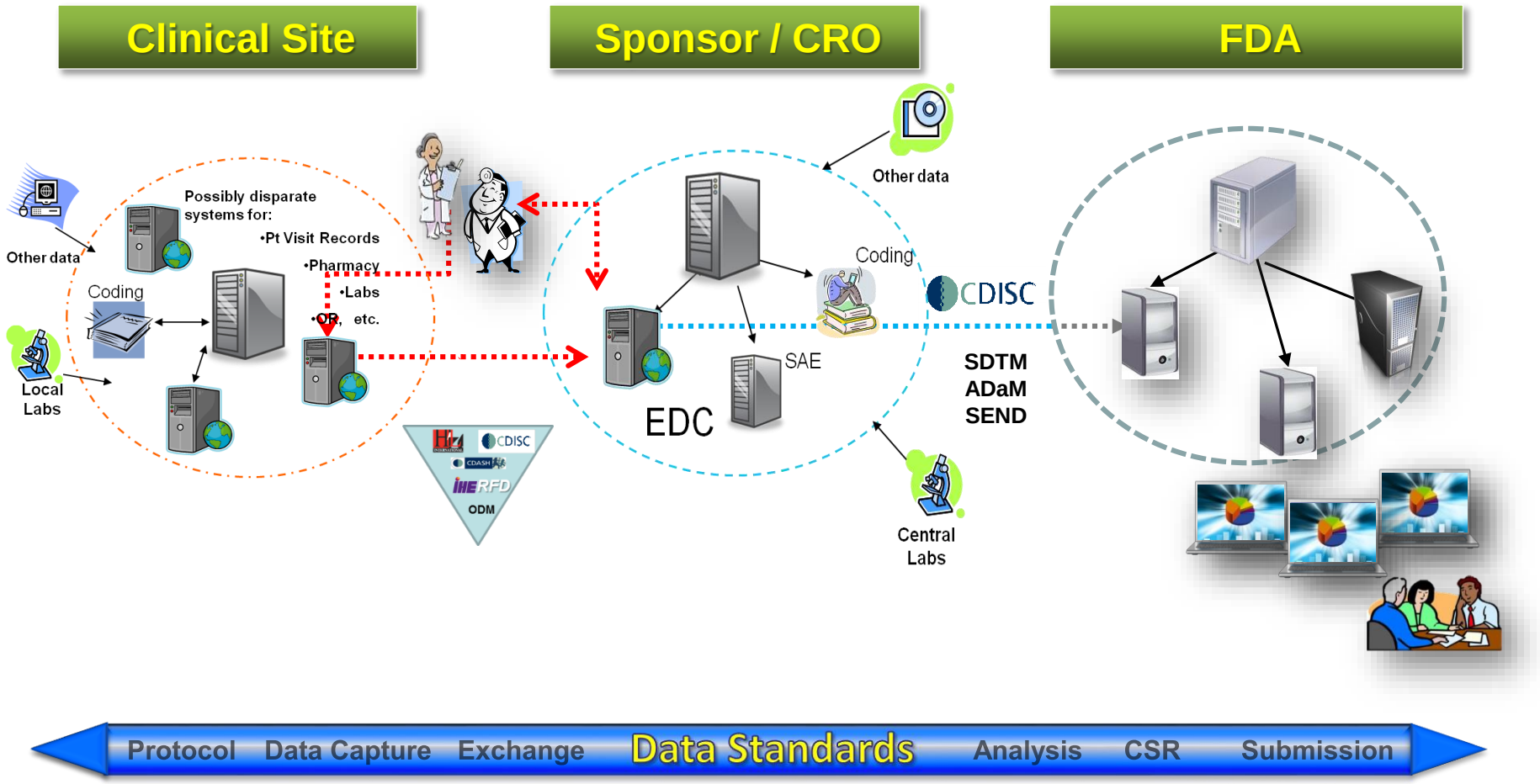
Ron Fitzmartin, PhD, MBA
Sr. Advisor
Data Standards Program
Office of Strategic Programs
Center for Drug Evaluation and Research
Food and Drug Administration

ESTEL Meeting
Rockville, MD
April 17, 2014

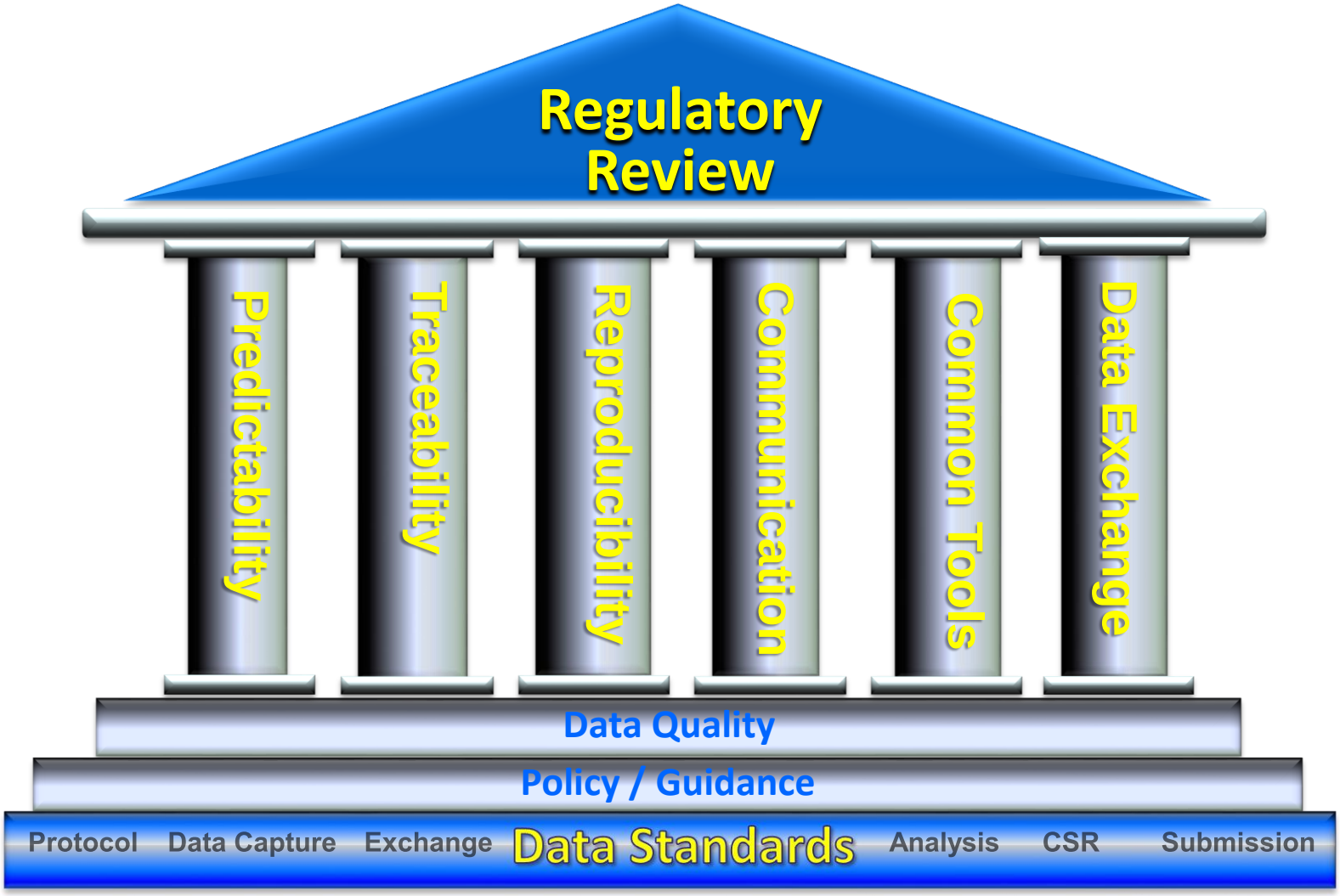
Disclaimer

The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the Food and Drug Administration.

Regulated Clinical Research



Data Standards @ the Foundation of Regulatory Review



Guidance & *Binding* Guidance to Industry

Guidance for Industry

Electronic Source Data in Clinical Investigations

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

September 2013
Procedural

Guidance for Industry

Providing Regulatory Submissions in Electronic Format — Standardized Study Data

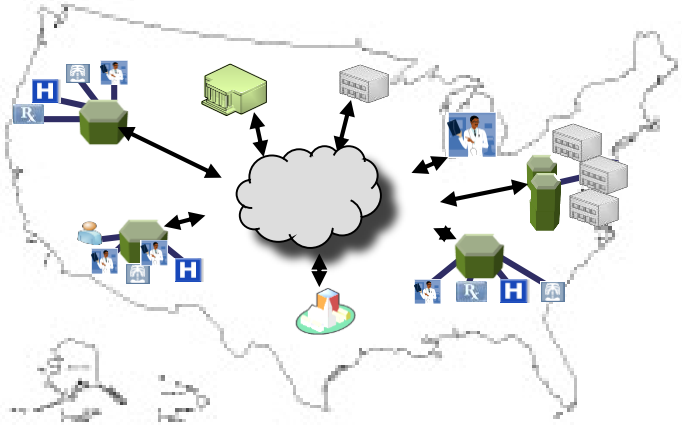
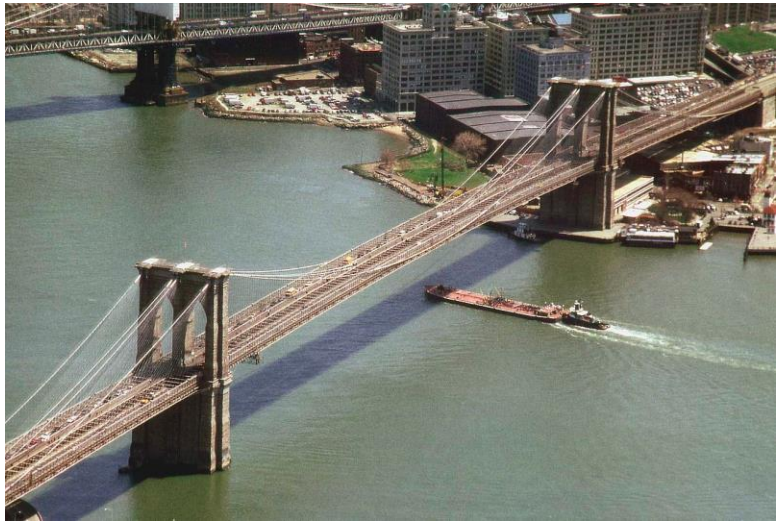
DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Ron Fitzmartin at 301-796-5333, (CBER) Office of Communication, Outreach and Development (OCOD) at 301-827-1800 or 1-800-835-4709.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

February 2014
Electronic Submissions
Revision 1

Thanks