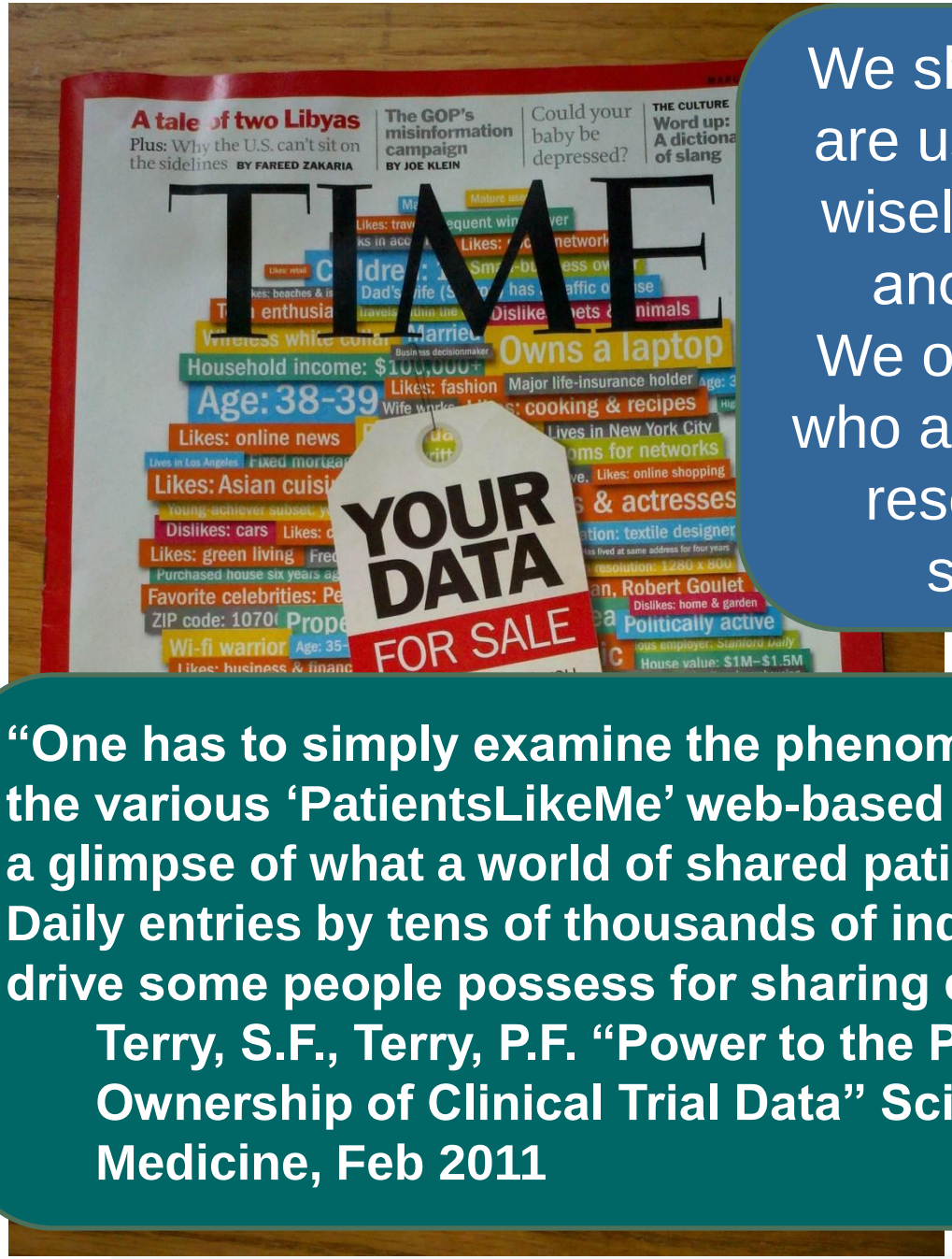
Institute of Medicine Workshop
Clinical Data Sharing
4-5 October 2012

"CDISC Efforts to Support Clinical Research"

Rebecca Kush, PhD
President and CEO, CDISC

Strength *through Collaboration*



We should make sure we are using the information wisely, that it is accurate and we can find it….
We owe it to the patients who agree to participate in research studies and share their data.

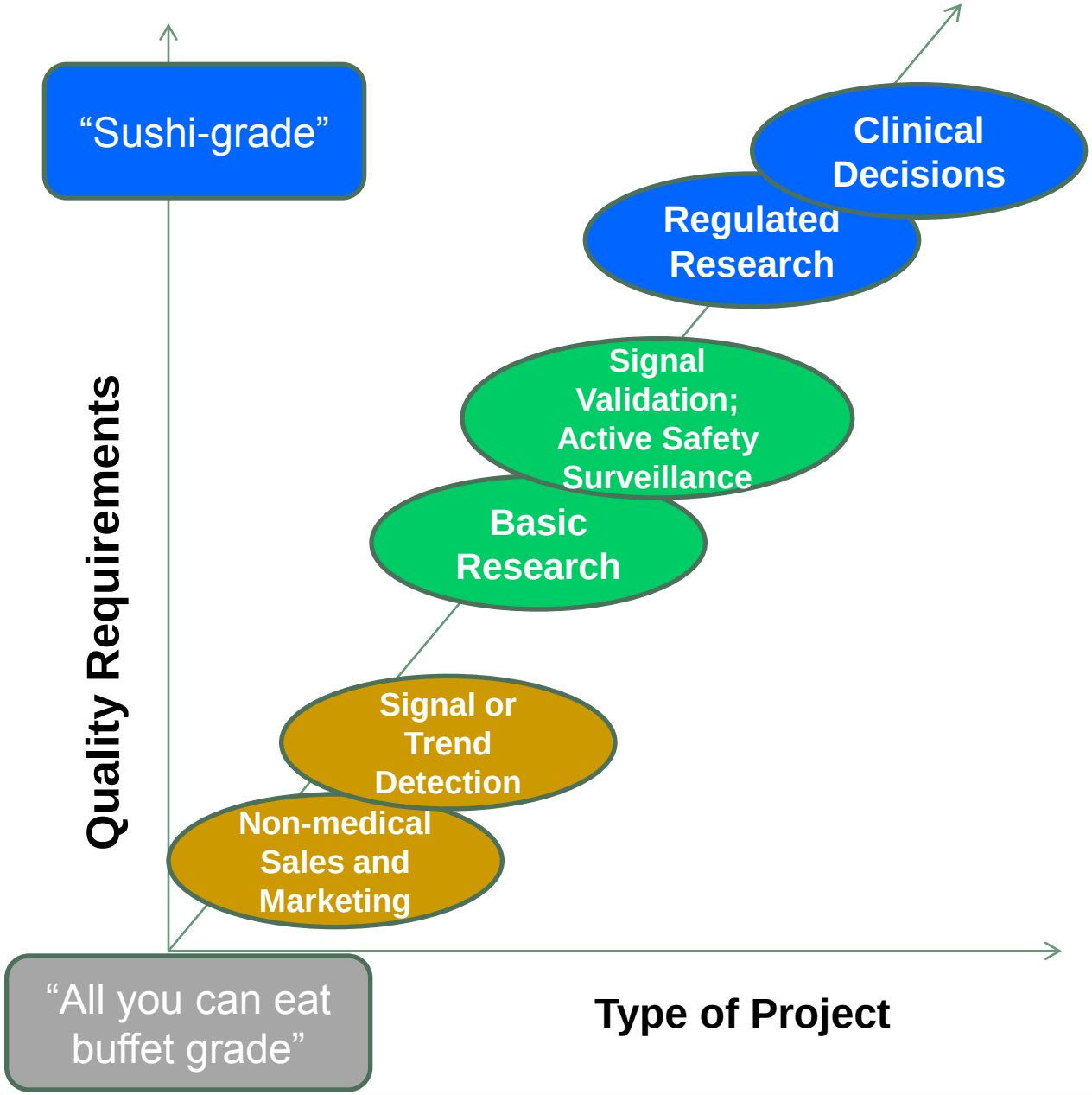
"One has to simply examine the phenomenon taking place in the various 'PatientsLikeMe' web-based communities to gain a glimpse of what a world of shared patient data looks like. Daily entries by tens of thousands of individuals indicate the drive some people possess for sharing data with others."

Terry, S.F., Terry, P.F. "Power to the People: Participant Ownership of Clinical Trial Data" Science Translational Medicine, Feb 2011

JPMA Presentation – Data Quality for Clinical Research

SPECULATION

by R.D. Kush



Road to Clinical Quality

- Build quality into the system – up front
- Train and educate research teams/sites/reviewers
- Collect only the data that are needed
- Clearly define the data and specify requirements
- Standardize! (data structures, processes)
- Reduce the number of times data are “handled”
- Plan data quality throughout lifecycle

Anticipated ‘by-products’ of these steps will be to improve quality, increase efficiency and lower costs

Source: Assuring Data Quality and Validity in Clinical Trials for Regulatory Decision-making: Workshop Report, 2000

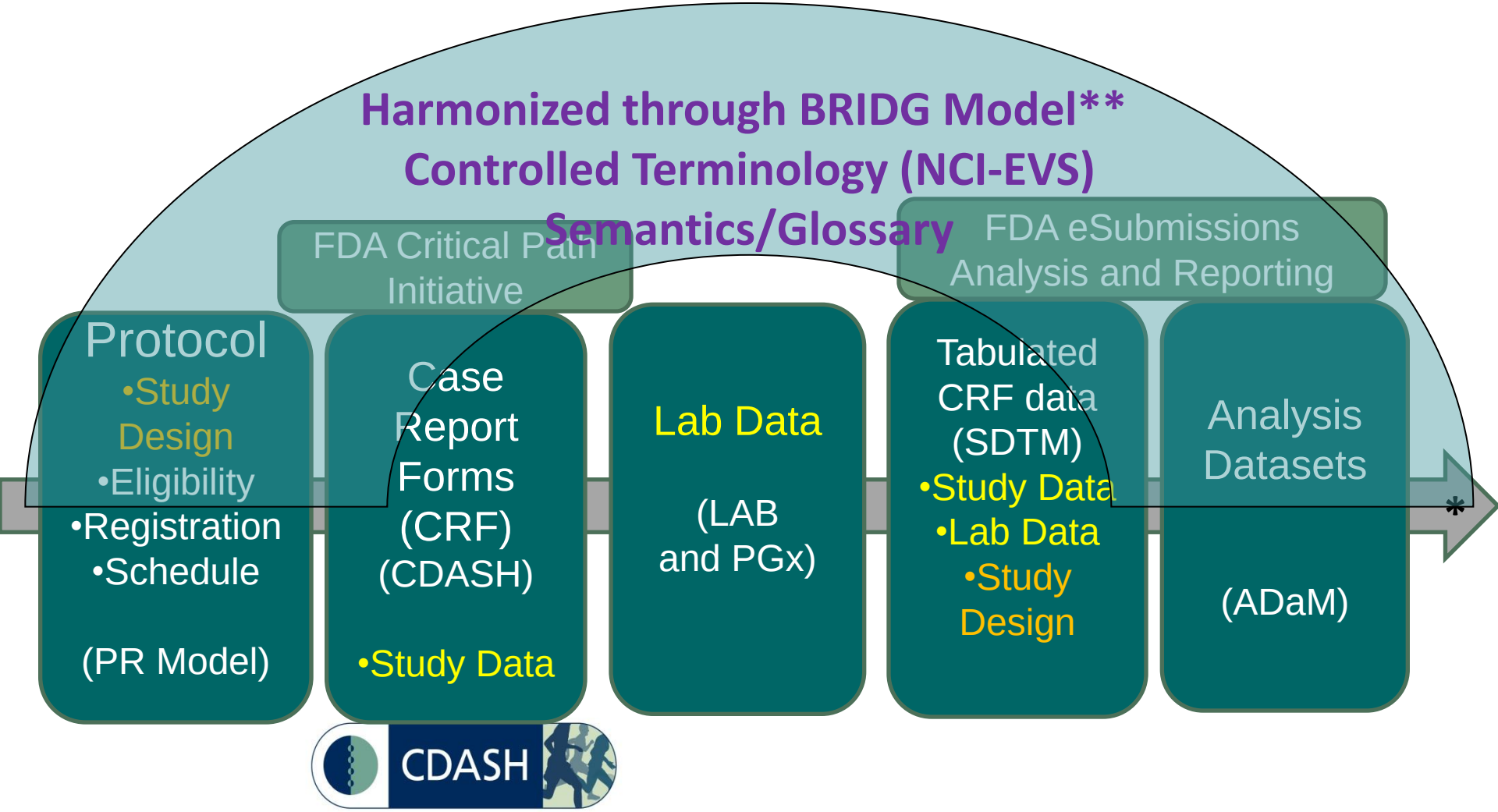
CDISC Snapshot

- Global, open, multi-disciplinary, vendor-neutral, non-profit standards developing organization (SDO)
- 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, Korea
- >> 90 countries in participant database and/or downloading CDISC standards

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

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

Global Content Standards for Clinical Research (Protocol-driven Research; Protocol →Reporting)



** CDISC, HL7 Standard→ ISO/CEN

**Transport: CDISC ODM, SASXPT (and/or HL7)*

Demographics (dmg, demog, dmgph, adx): Is it Gender or Sex?

Study #1 – demog.xpt

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

Study #2 – dmg.xpt

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

Study #3 – axd222.xpt

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

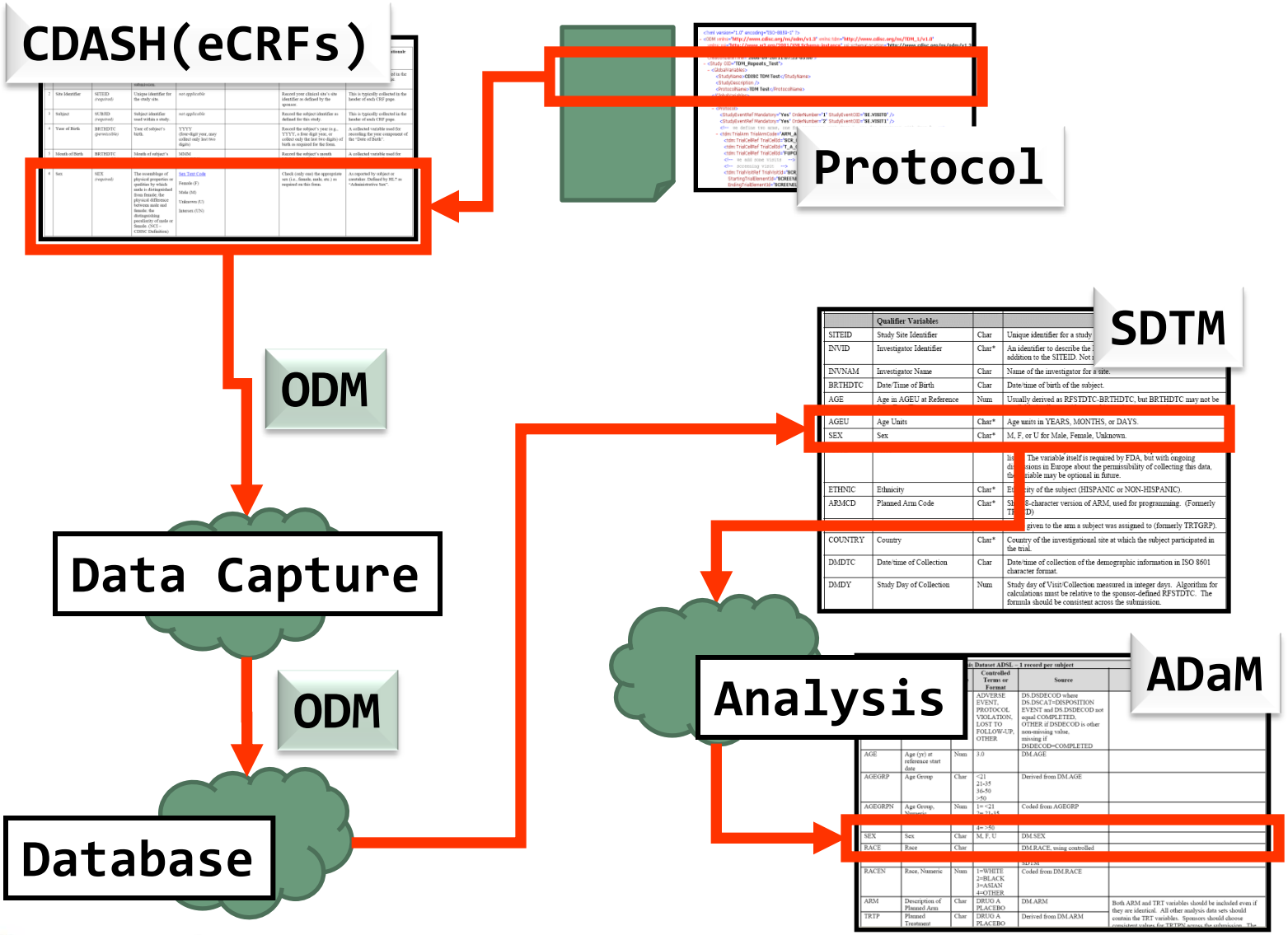
Study #4 – dmgph.xpt

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

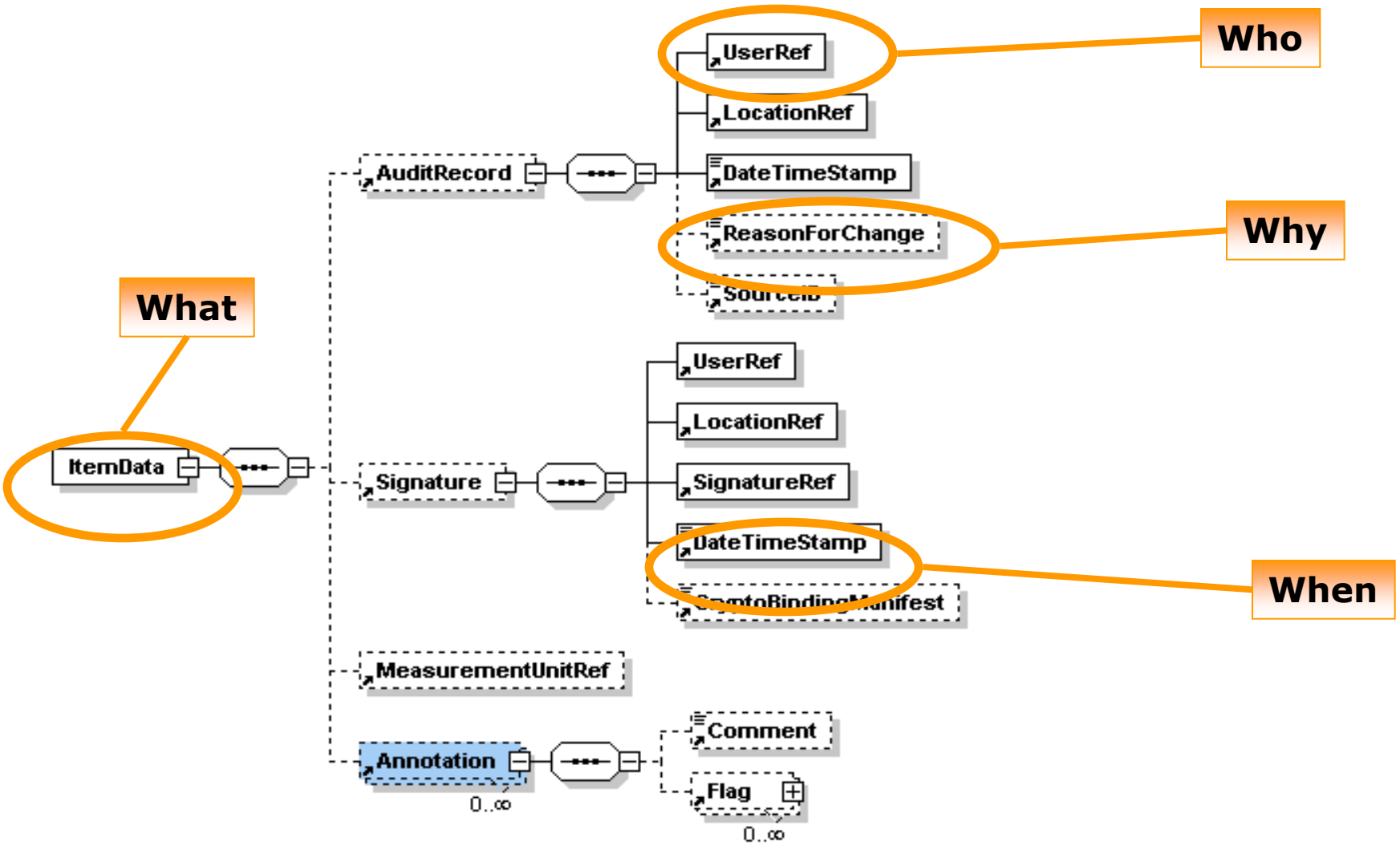
HITSP – 4 options

HL7 - 15 options for this field

CDISC – End to End



ODM & Audit Trail



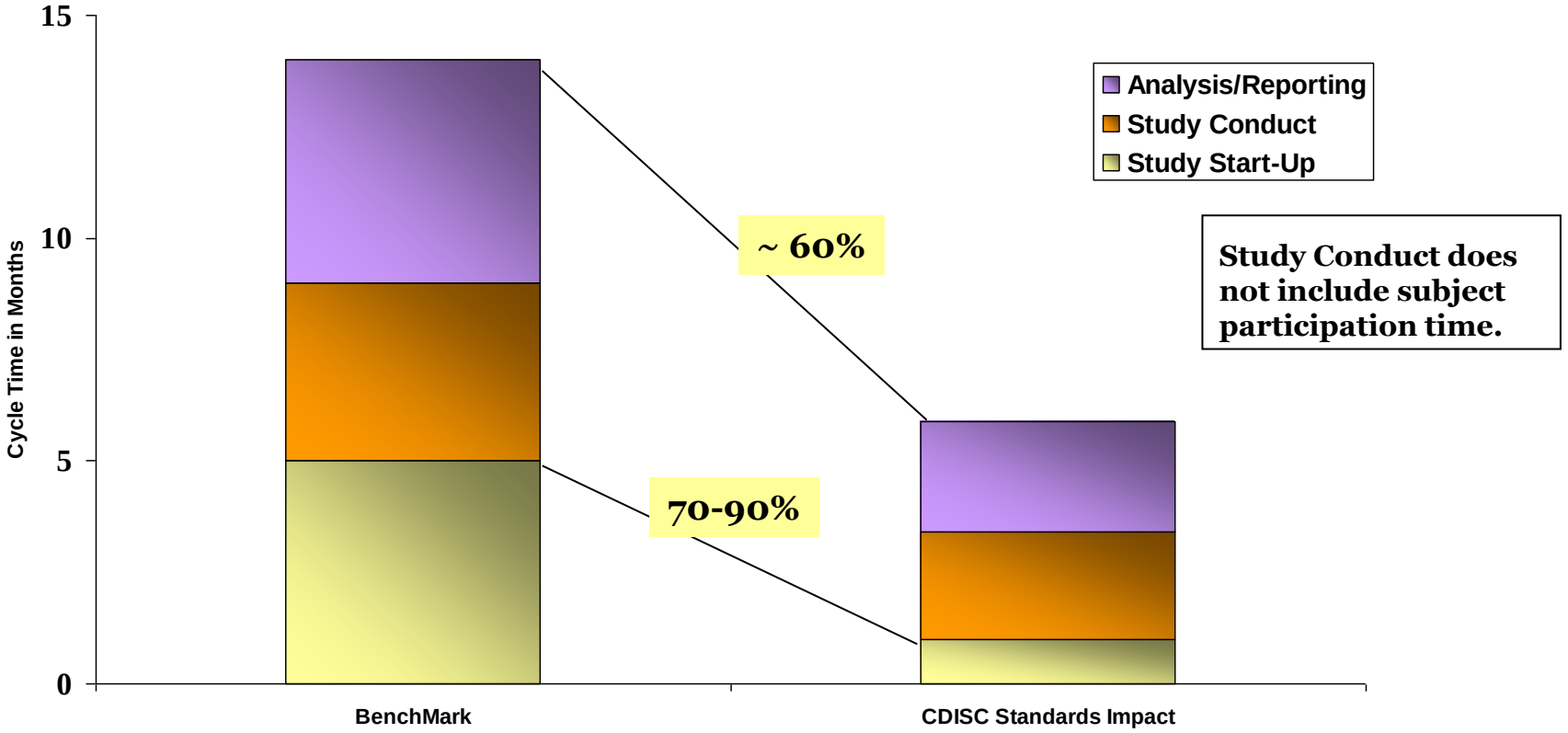
Gartner-PhRMA-CDISC Project

- Business Case for using CDISC standards
- 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
    - Increased data quality
    - Data Integration / enhanced re-usability
    - Facilitates data exchange with partners
    - Enable software tools
    - Improve team communication
    - Facilitate regulatory reviews and audits

Opportunity Value: Do More With Less

Quantifying the Value of Standards

- Cycle Time (and Cost) Savings -



Note: Figures are benchmarks based on aggregate data; study-specific cycle times and cost metrics will vary.

Figure: K. Getz, Tufts CSDD

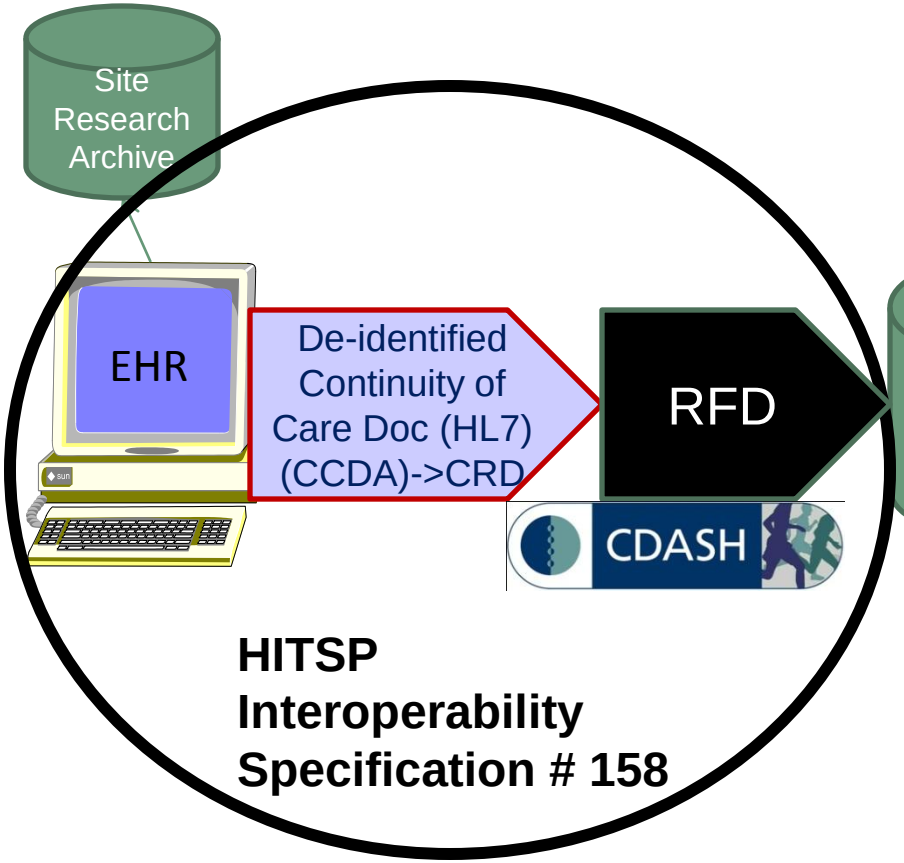
BRIDG (Biomedical Integrated Domain Group Model)

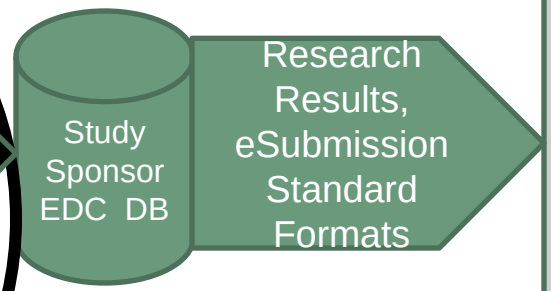
- **BRIDG Purpose:**
  A collaborative effort to produce a shared view of the semantics that collectively define a shared domain-of-interest, i.e. protocol-driven research
  - Harmonizes the CDISC standards and other similar standards
  - Links research and healthcare

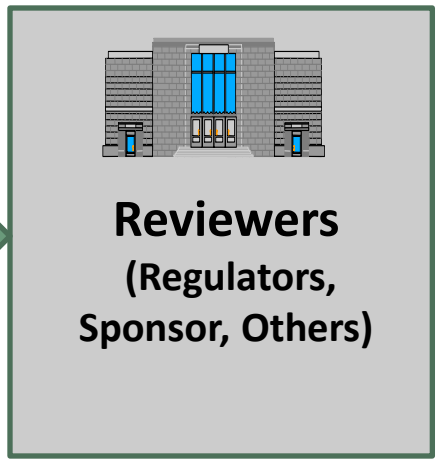
- **Core Stakeholders:**

- **Global Standard**: Currently, CDISC and HL7 Standard, on the path to becoming an ISO/CEN Standard through Joint Initiative Council for Global Harmonization of Standards (JIC)

Patient Value:
Quality of Healthcare, Safety







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

ASTER (AE Reporting from EHRs)

30 Ambulatory care physicians at Harvard and Brigham and Women's

with Pfizer, CDISC, CRIX

Nov 08 – Jun 09, > 200 Reports Sent to FDA

Physician Reporting:

*91% of participating physicians had submitted no ADE reports in the prior year

**During the study, participants reported an average of approximately 5 reports in a 3 month time period*

*All participants reported at least 1 AD

* Process: *Time to report decreased from ~35 min to* ***< 1 min***

Source: Michael Ibara, Pfizer

CDISC – Key Partnerships/Collaborations (Examples)

National Cancer Institute

EVS Enterprise Vocabulary Services

Controlled Terminology

Critical Path Institute
collaborate · innovate · accelerate

CAMD (AD, PD)
CPTR (TB)
…TA Standards

CFAST Coalition For Accelerating Standards and Therapies

Duke Medicine

DCRI
CTRI

CV, TB, HL7 CIC Workgroup

TRI

Translational Research Informatics Institute (TRI) Kobe, Japan

Use of CDISC in research projects by academia funded by TRI.

imi Innovative Medicines Initiative

IMI = European Union and EFPIA; > 250 IMI consortia academics/SMEs are CDISC Members. Default is for IMI projects to use CDISC if available, If not, partner in developing new standard.

Strength *through Collaboration*

CDISC is known for bringing together the expertise of thousands of individuals from around the world toward productive collaboration to develop clinical research standards.

CDISC

TransCelerate Biopharma, Inc.

Drug Makers Join Efforts in Research

- New York Times, Published: September 19, 2012

"Ten of the world's largest pharmaceutical companies said on Wednesday that they would cooperate on research aimed at accelerating drug development, starting with streamlining clinical trials……."

"TransCelerate said it would work with other organizations. At least two nonprofit organizations, each with pharmaceutical company participation, are already working on accelerating clinical trials and standardizing data. Just last week, those two organizations — the **Clinical Data Interchange Standards Consortium** and the Critical Path Institute — announced that they would form the Coalition for Accelerating Standards and Therapies."

Standards and 'Tools' Needed

- A global, accessible electronic library, which through advanced technology, enables precise and standardised data element definitions (including value sets) that can be used in applications and studies to improve biomedical research and its link with healthcare (e.g. SHARE = Shared Health and Research Electronic Library)

Key purposes:
a) Develop therapeutic area standards & others faster
b) Make current standards more accessible and useful

Desired Criteria for Standards to Facilitate Clinical Research

- **Fit for Purpose (MU)**
- **Global**
- Based upon Good Clinical Practices (GCP), ICH Guidelines, and applicable Regulations
- Harmonized and semantically consistent
- Developed through a recognized standards development process (by SDO)
- Consensus-based (multidisciplinary contributions)
  - not proprietary or redundant
  - not 'right' or 'wrong', but widely adopted
- Platform-independent; **encourage innovation**
- Support interoperability/link with healthcare

Quality Improvement

Enablers

CDISC is more than Standards!

Speed

Process Redesign

Workflow Integration

Standards-inspired Innovation

Resource Savings

Strength through collaboration

CDISC®

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

Thank you!

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

www.cdisc.org

Strength *through Collaboration*