SDO

Standards Development Organization

CDISC

Paul Houston

An Overview of CDISC

16 March 2018

Possble calls and call areas

- TOPIC : Data integration and data-driven in-silico models for enabling personalised medicine - a European standardization framework
- Calls where data standards or domain models are essential in achieving interoperability or FAIR data
- Calls where therapeutic areas standards need developing to specifically aid research reproducibility and interoperability
- Calls to solidify and triangulate research and real world data in the persuit of personalized medicine

CDISC Members Around the Globe

Membership Represents:

- Pharmaceutical
- Clinical Research Orgs
- Government
- Academic Researchers
- Healthcare Systems
- BioTech
- Nonprofit Organizations
- Medical Device Companies
- Nutrition Companies

CDISC Standards required for submission in the by the
*United States FDA
*Japan by PMDA
*Suggested by European IMI & EMA

What is CDISC?

- >435 organizational members
- Community consensus standards development for clinical & translational research

- Ongoing global research support in the Americas, Europe, Japan, China, India, Korea and other regions
  - Standards downloaded in 90+ countries

www.cdisc.org

CDISC Standards Required for Regulated Research in the US and Japan

Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

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)

December 2014
Electronic Submissions

Providing Regulatory Submissions In Electronic Format — Standardized Study Data

Guidance for Industry

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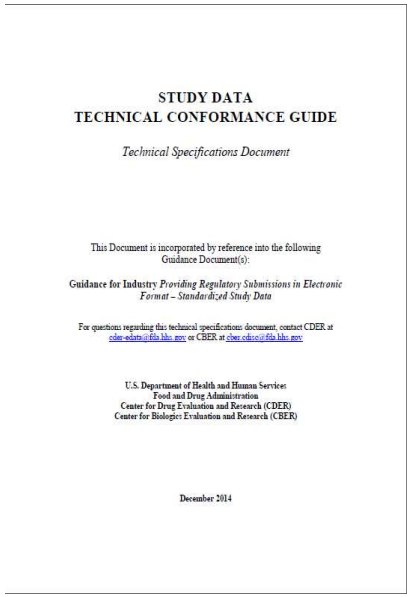
December 2014
Electronic Submissions



STUDY DATA TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

This Document is incorporated by reference into the following Guidance Document(s):

Guidance for Industry *Providing Regulatory Submissions in Electronic Format – Standardized Study Data*

For questions regarding this technical specifications document, contact CDER at cder-edata@fda.hhs.gov or CBER at cber-edoc@fda.hhs.gov

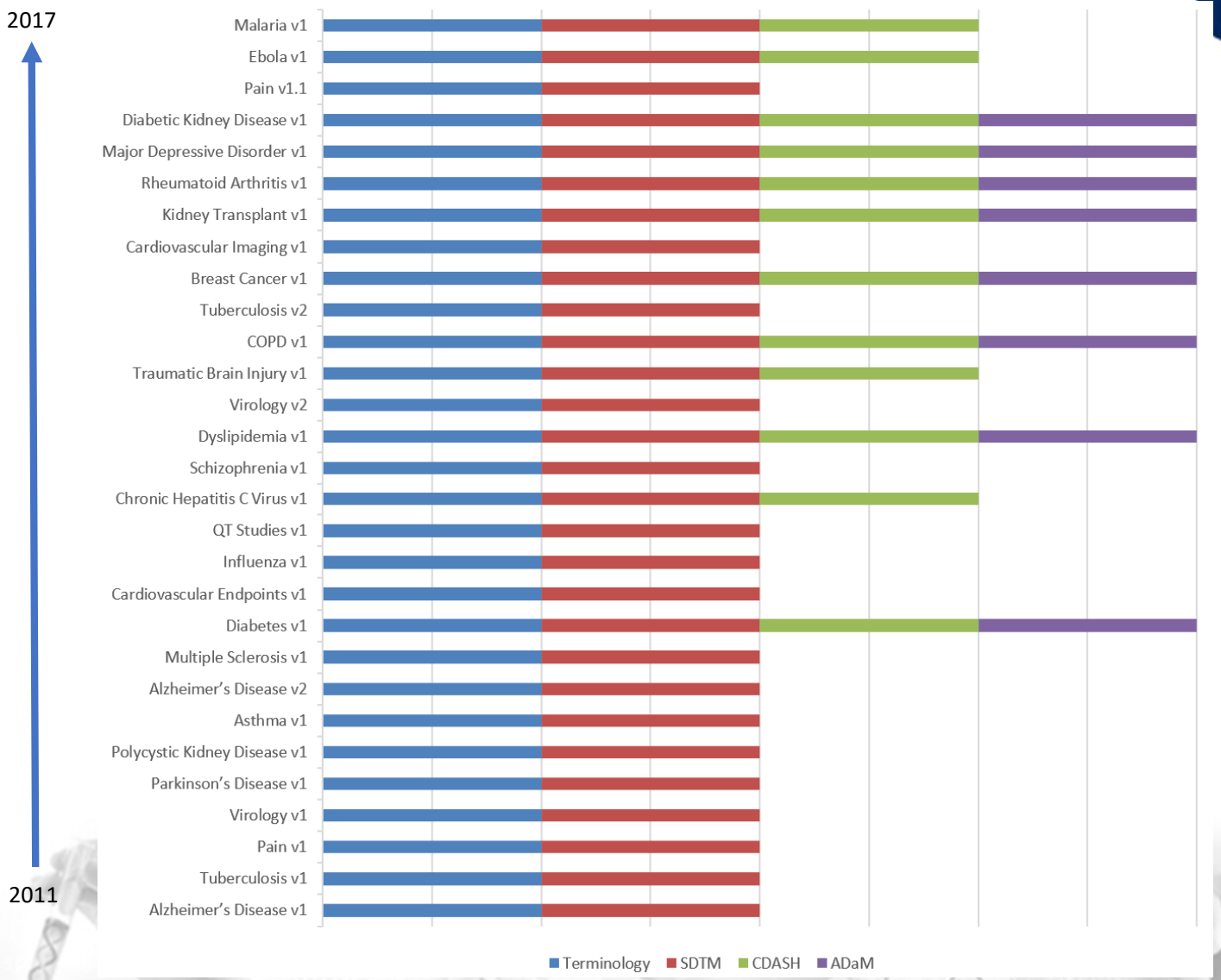
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2014

BINDING DOCUMENTS

US FDA & Japan's PMDA Require CDISC Standards, China's CFDA and EMA Recommend CDISC Standards

What We Have Done



Why Standards are Needed

(the Pillars of Misunderstanding)

Homonyms

If you *misunderstand the meaning of clinical concepts* you can't merge or make any meaningful connections or conclusions.

Definitions

If you *have different definitions for clinical concepts* you can't merge or make meaningful connections or conclusions.

<< 5 companies oncol project ex.>>

Terminology

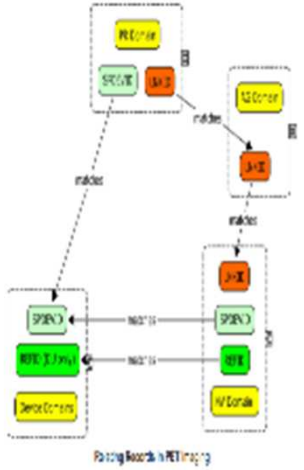
If you *can't agree on the naming conventions and where to use them*, you can't merge or make meaningful connections or conclusions.

SUBJ ID	SEX
0001	M
0002	F
0003	F
0004	M
0005	F

USUBID	SEX
0001	0
0002	1
0003	1
0004	0
0005	1

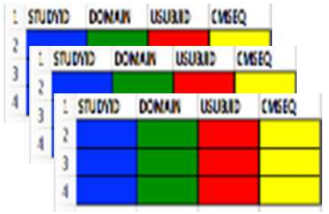
Relationships

If you *don't see the relationships* between and amongst you create variability in how standards implemented.



Organization

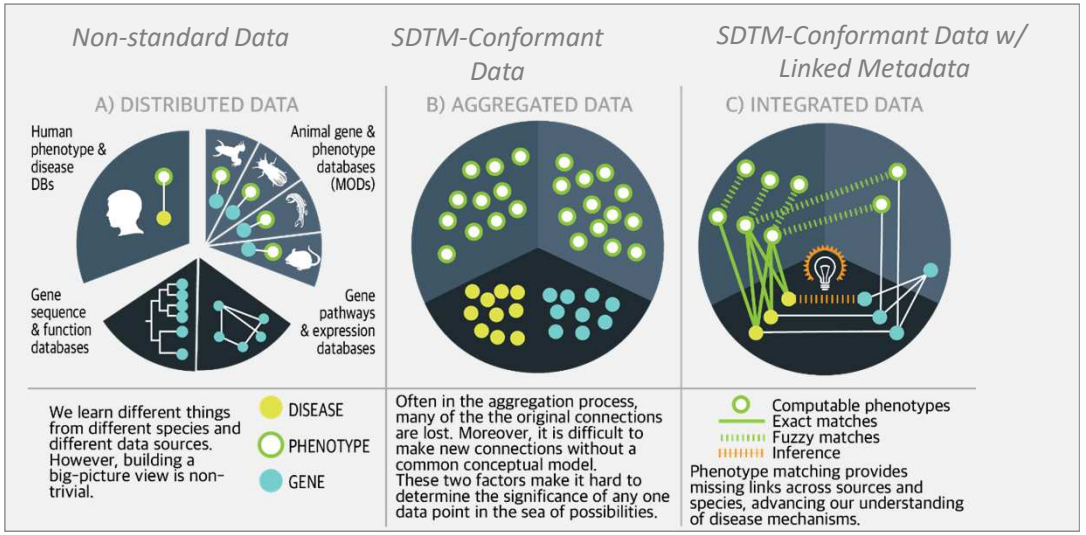
If you *can't find the data* you waste time and resource.



Data Sharing

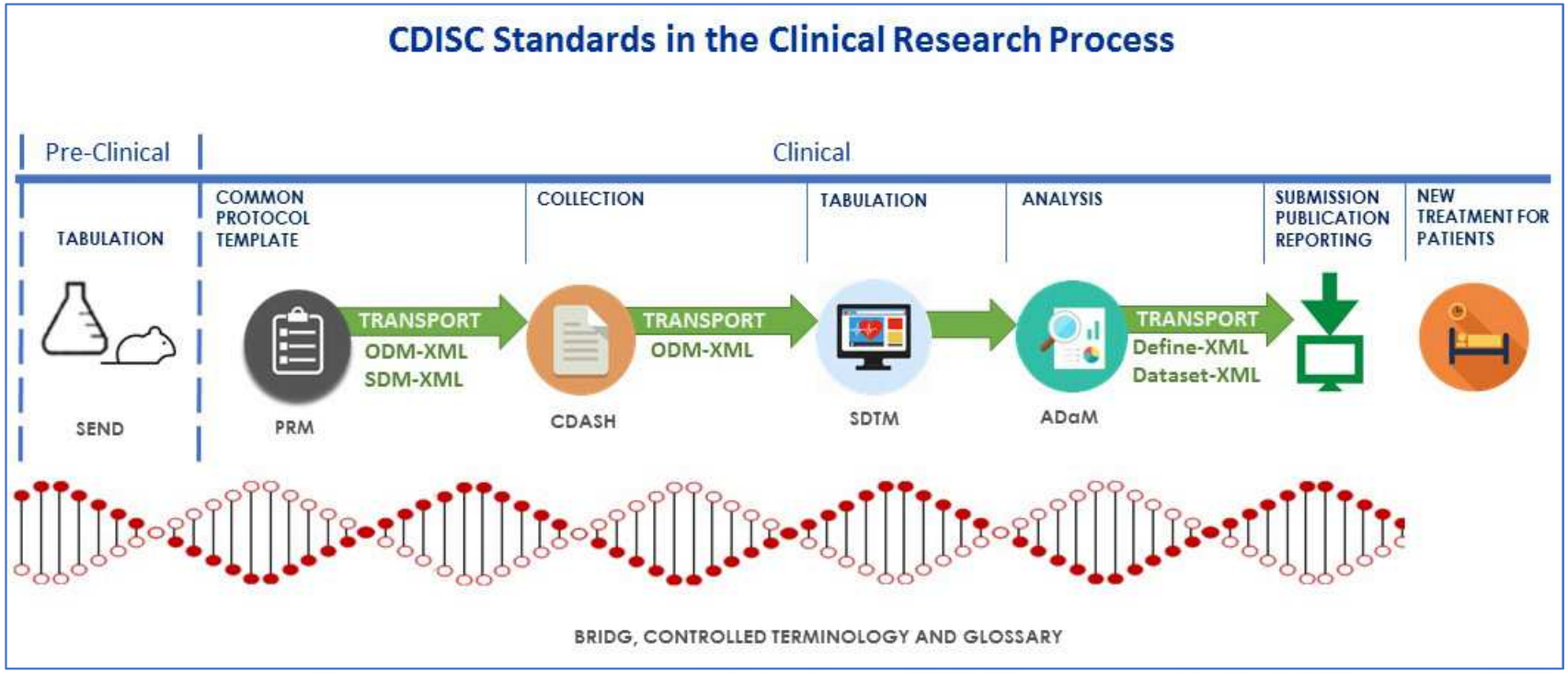
You *can't share data* in a meaningful and efficient way without addressing each of the above aspects.

Biomedical Concepts & Ontologies Can Drive Big Data Analyses



From Haendel, M. http://www.scidatacon.org/2016/sessions/14/paper/315/

CDISC Standards Do NOT Dictate Research Questions or Conduct



…And Used for Non-Regulated Research in the EU

Vaccines Standard Training on collection, modeling and aggregation standards for interoperability

TRANSFoRm

Mobile patient reported outcomes (PRO)

eTRIKS

Standards Starter Pack Curation pipeline to TransMART

CORBEL

Data sharing recommendations

EHR4CR

Use of standardized data for research sourced from multiple EHRs

UNIVERSITY OF OXFORD

Infectious Diseases - field research data collection and aggregation support

Only with good data management and clinical and preclinical standards as a foundation can successful precision medicine programs be achieved