CDISC

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

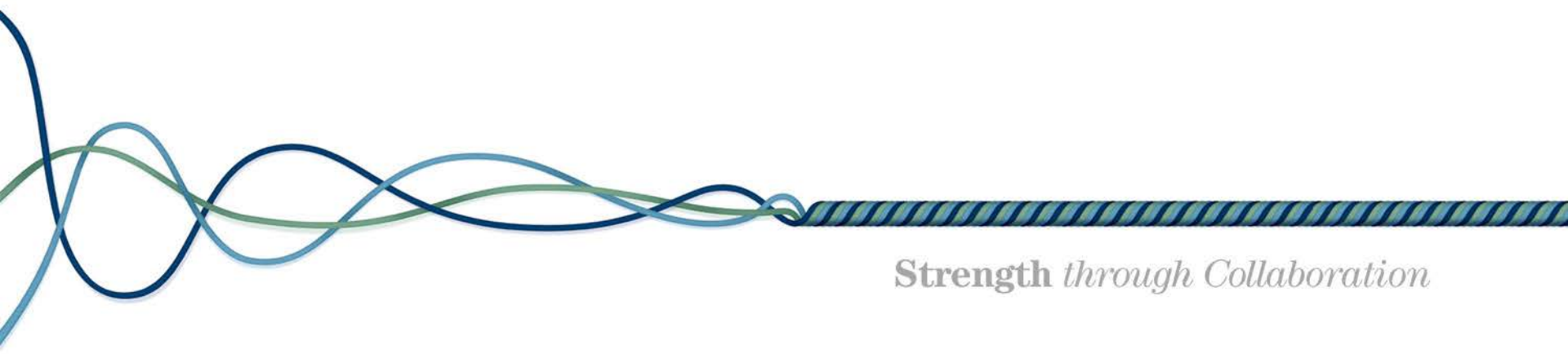
CAMD Mobile Devices

10 March 2017

Barrie Nelson

VP, Standards, Terminology and Technical Services

Introduction

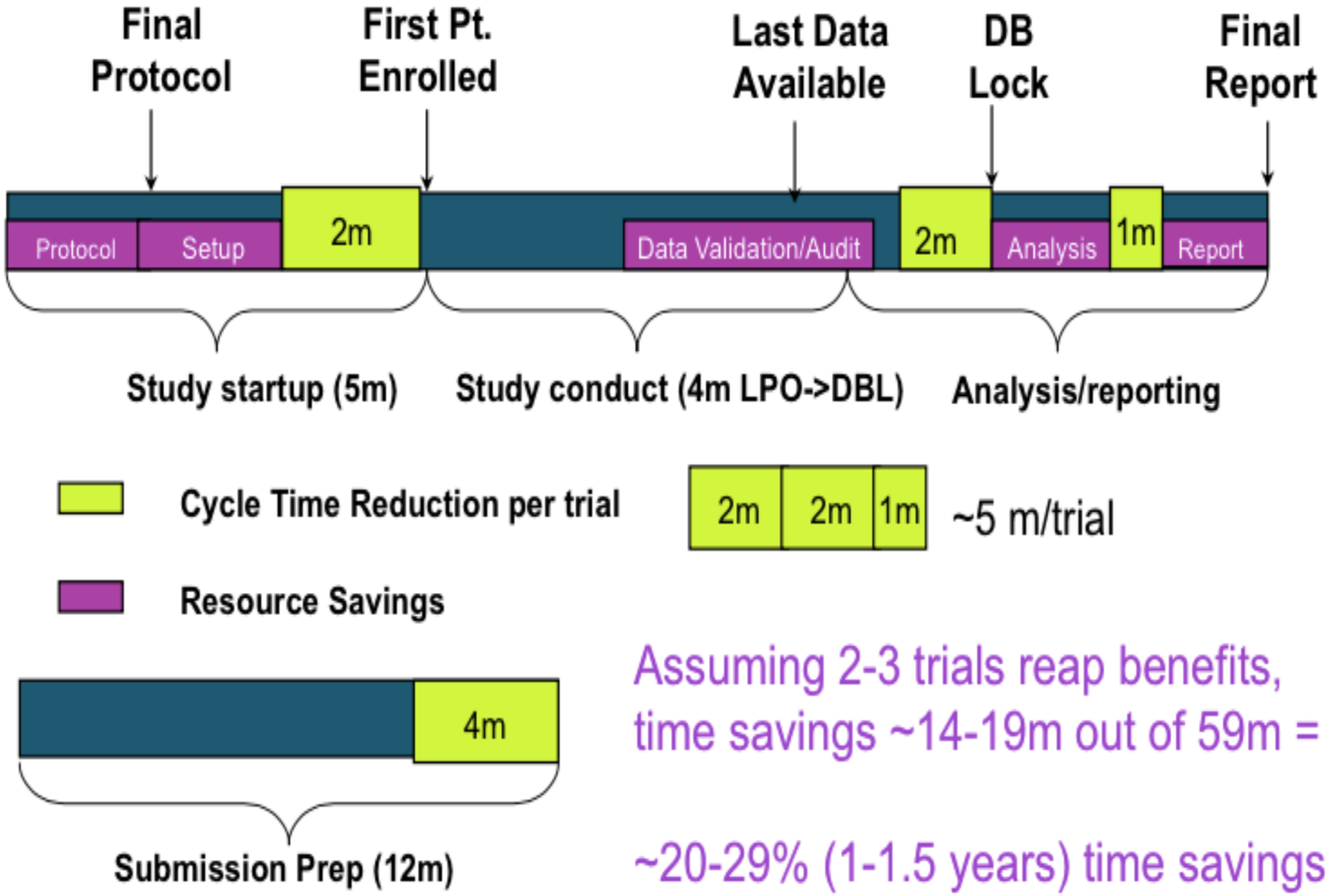


Clinical Data Interchange Standards Consortium, CDISC

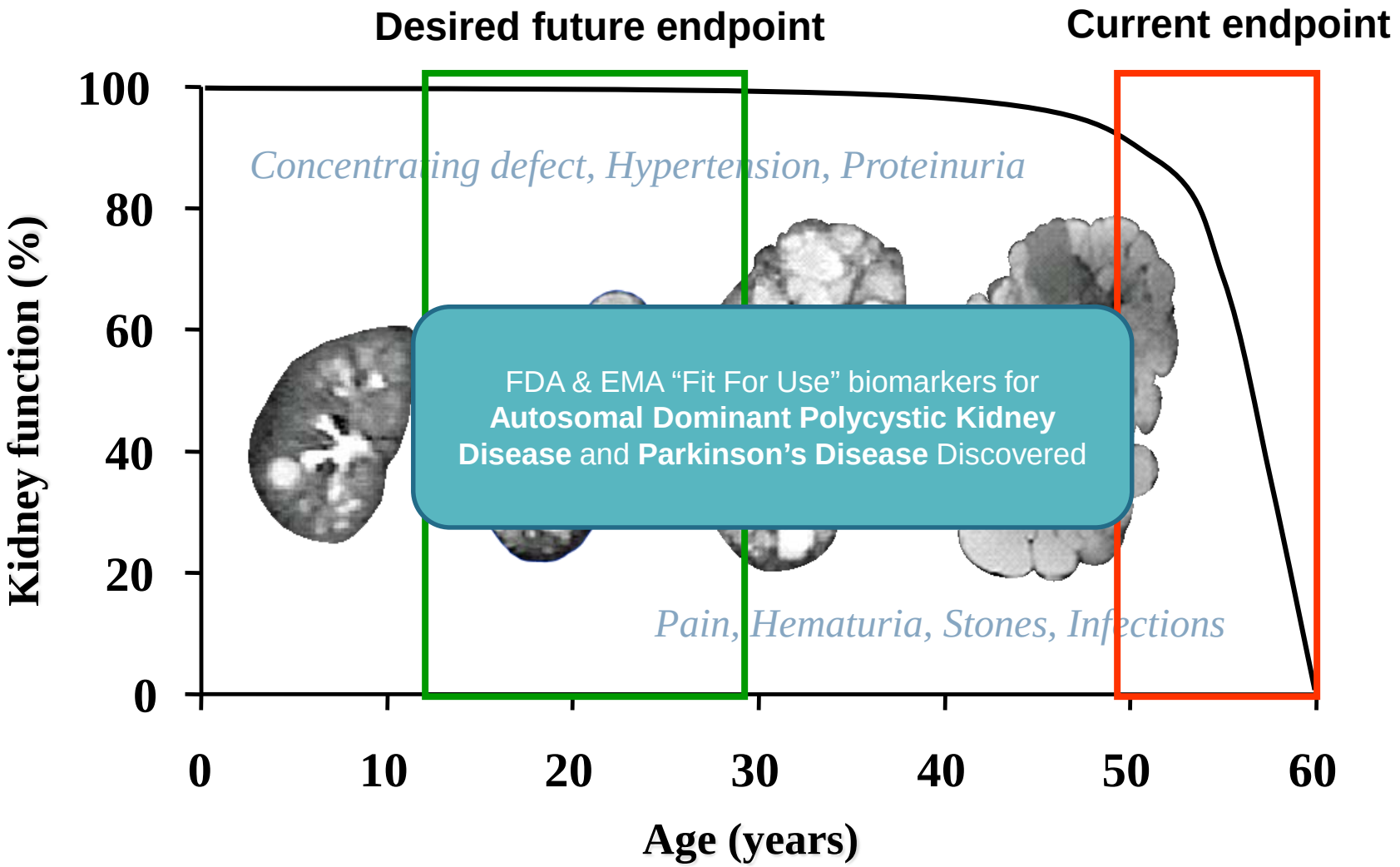
- Global, open, vendor-neutral, non-profit Standards Development Organization (SDO)
- Founded in 1997
- >400 organizational members (academia, biopharma, government & regulatory agencies, service & technology providers…)
- Supports community volunteers to develop **open, freely available** standards
- 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 Drive Prospective Research Efficiencies, …

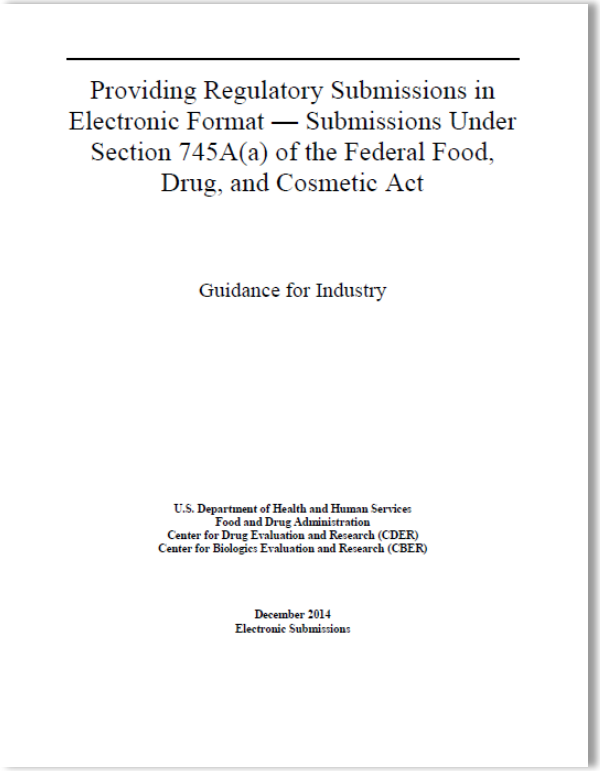


And Find Hidden Discoveries in Existing Datasets



Source: Dr. Ron Perrone PKD Foundation & Tufts Univ.

FDA & Japan's PMDA Require CDISC Standards

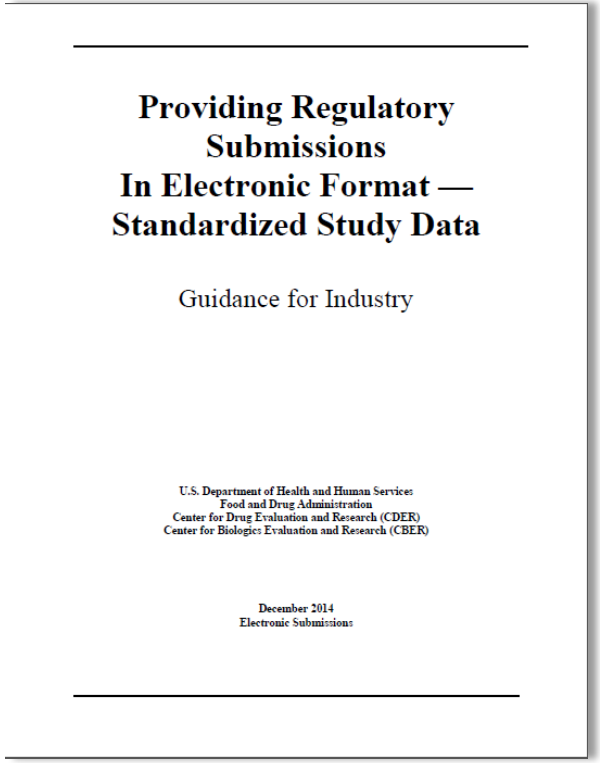


Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act

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

U.S. Department of Health and Human Services
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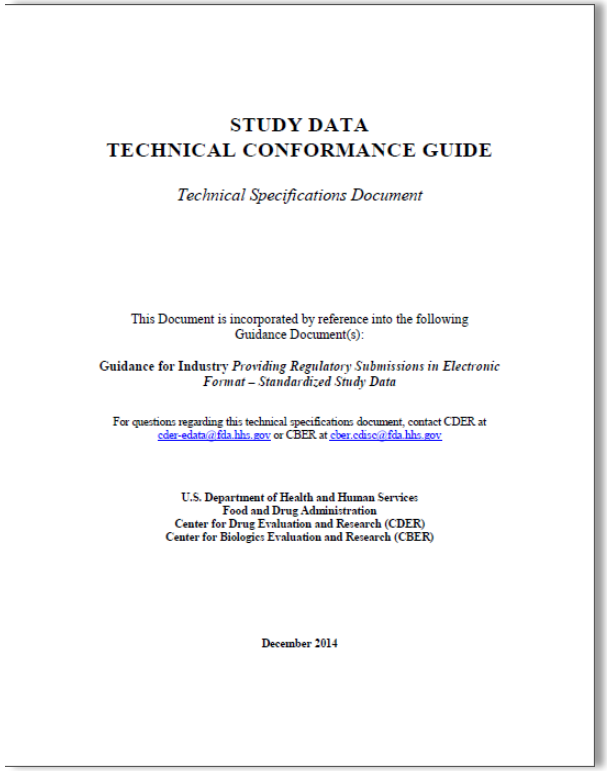
December 2014
Electronic Submissions



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*

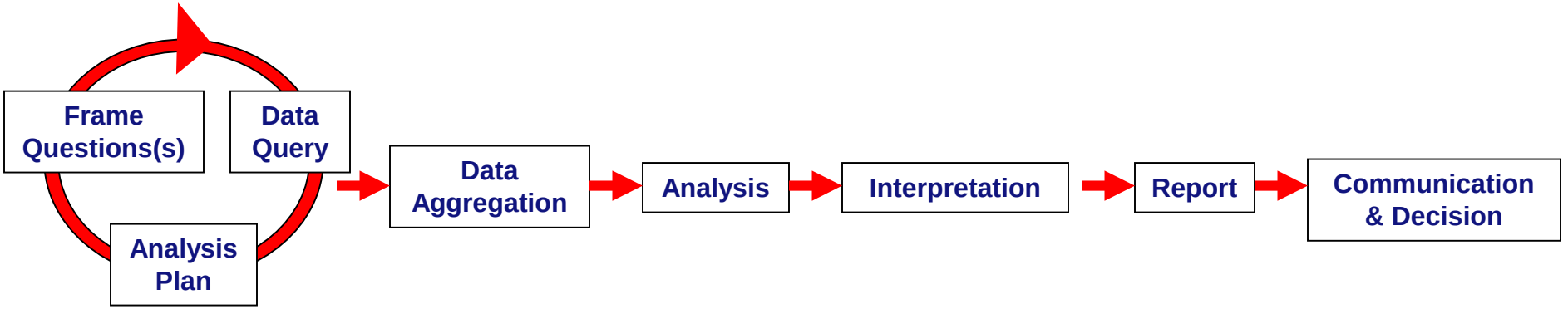
For questions regarding this technical specifications document, contact CDER at cder-edata@fda.hhs.gov or CBER at cber.edisc@fda.hhs.gov

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)

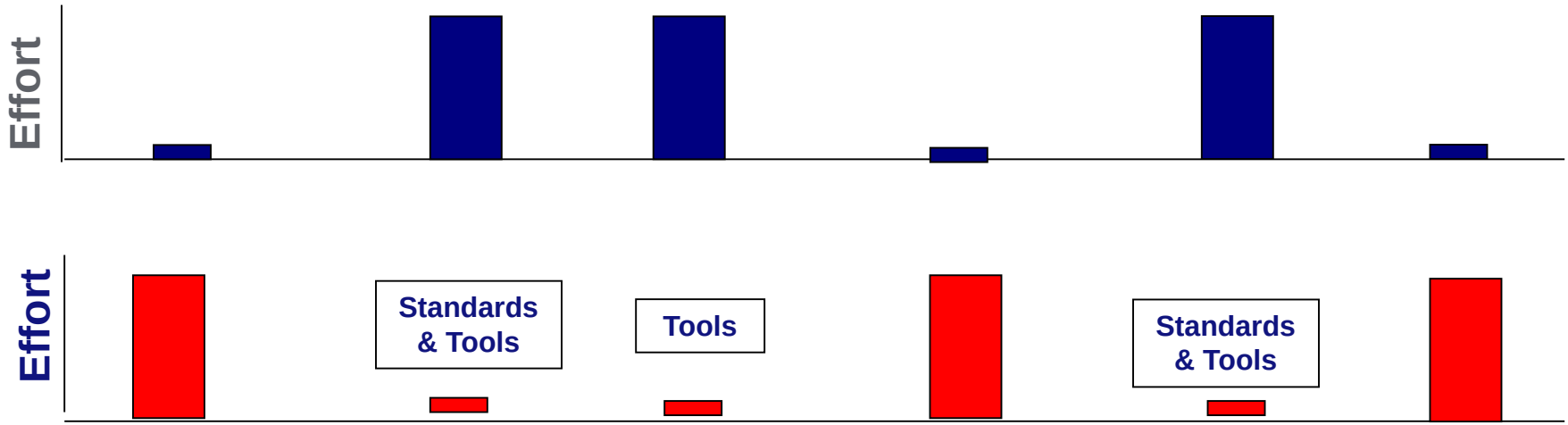
December 2014

CHINESE FDA AND EMA RECOMMEND CDISC STANDARDS. NON-REGULATED RESEARCHERS ALSO USE CDISC STANDARDS FOR DATA AGGREGATION, INTEGRATION AND ANALYSIS.

US FDA Goal: Reduce Time to Access / Analyze Data to Increase Time for Review

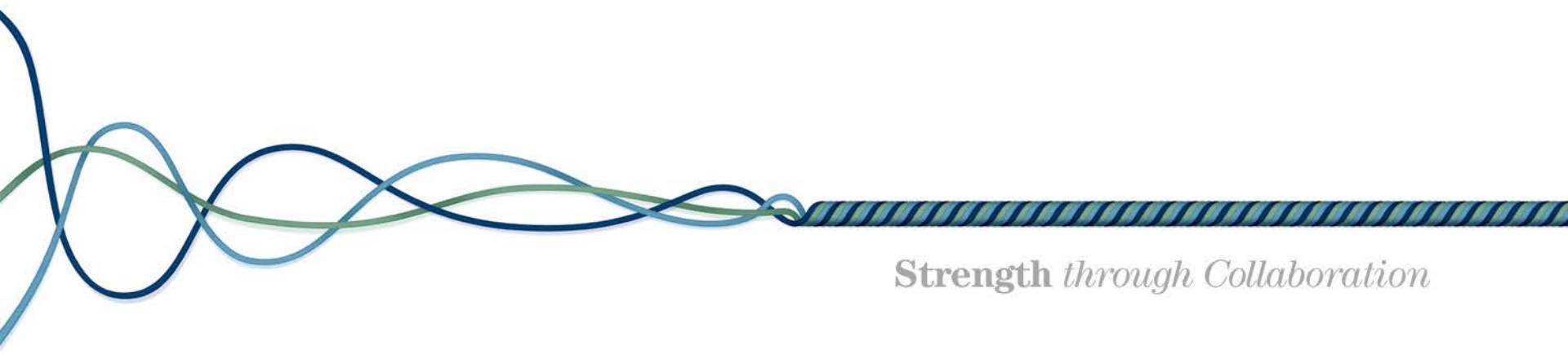


Present Time Emphasis- 'Doing'

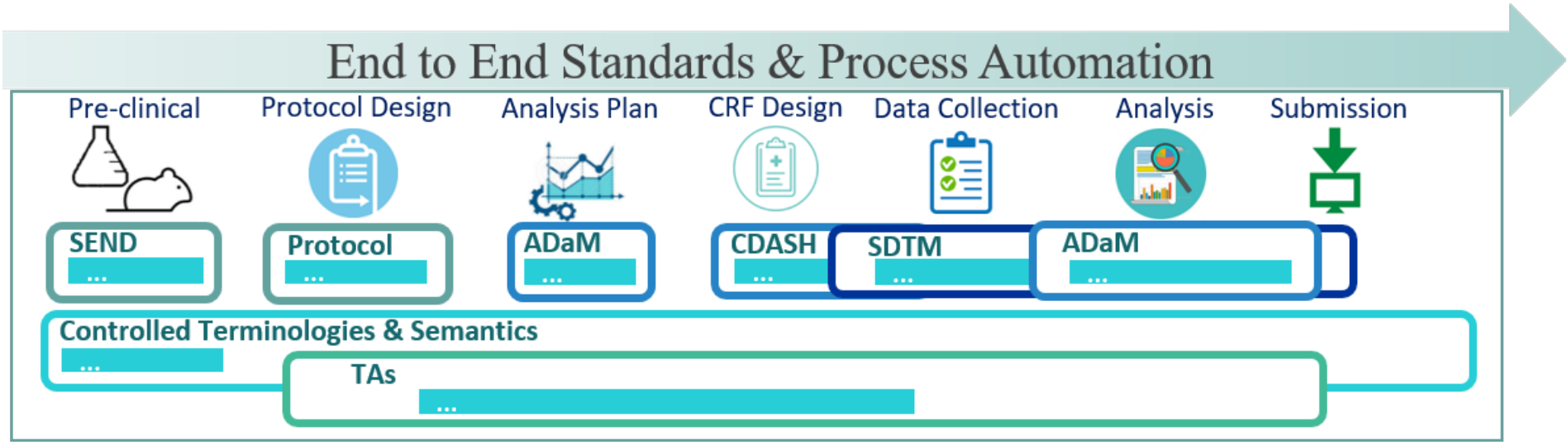


Source: Theresa Mullen, PhD, FDA CDER Associate Director

CDISC Standards in Clinical Development

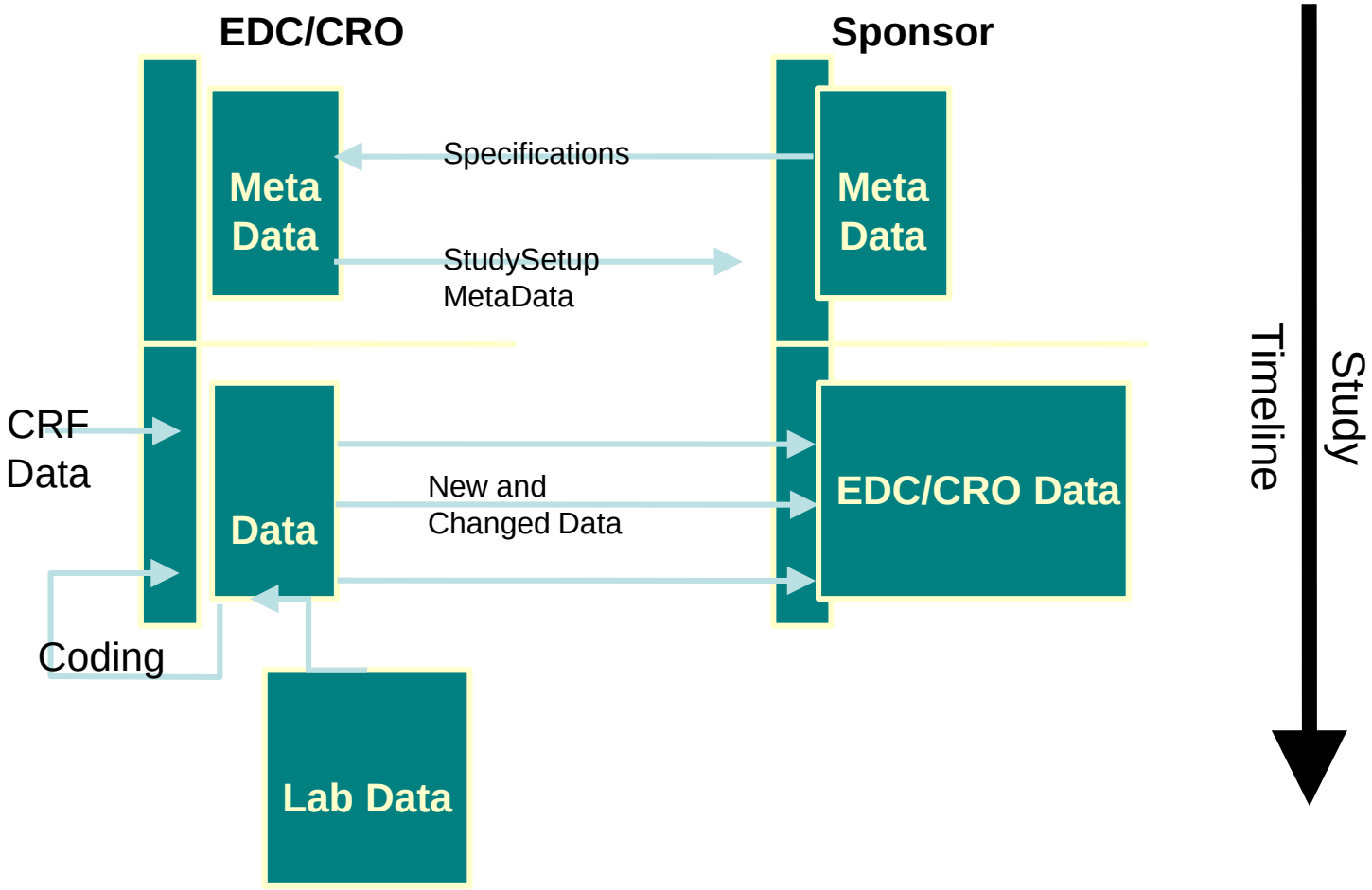


CDISC Standards Cover the Spectrum of Protocol-Driven Research



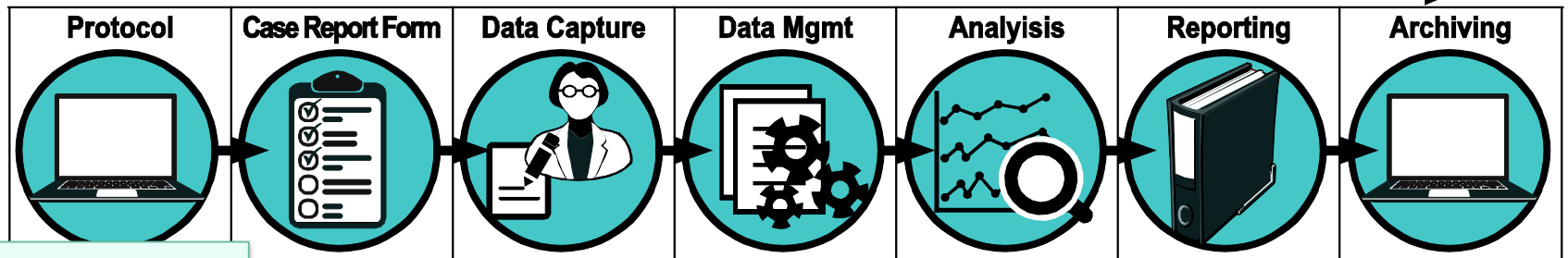
All standards available as PDFs on the CDISC website, **http://www.cdisc.org/**

…And Support Diverse Data Exchange



Clinical Research Process

CDISC Standards Include…



PRECLINICAL

Protocol Represent-ation Model **PRM**

Clinical Data Acquisition (CRF) Standards Harmonization **CDASH** Lab Model (core lab transfers) **Lab**

Study Data Tabulation Model **SDTM** for clinical studies, including medical devices

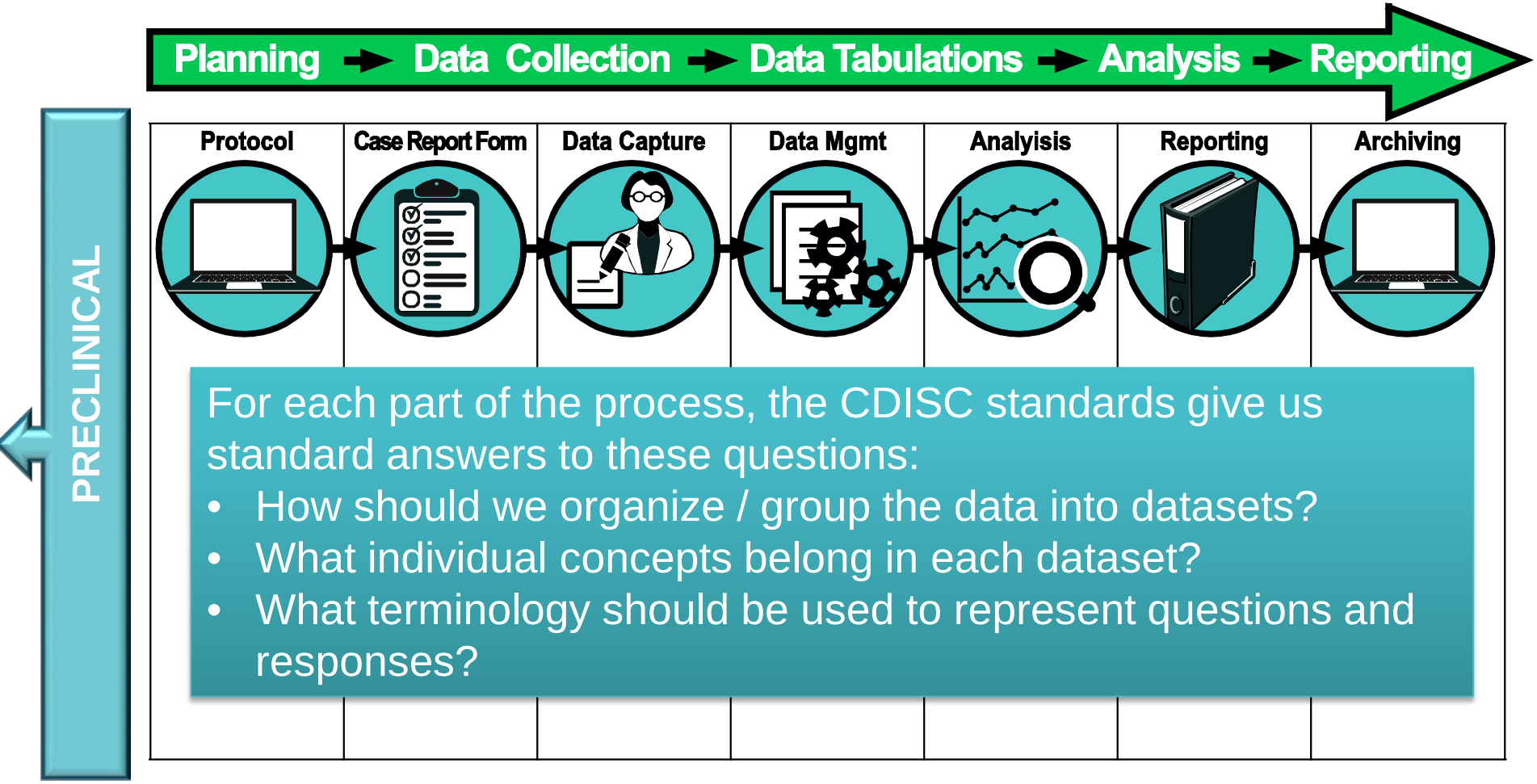
Analysis Data Model **ADaM**

Standard for the Exchange of Non-Clinical Data **SEND (**Based on **SDTM)**

Controlled Terminology **CT**

Operational Data Model (and extensions) **ODM**
Define-XML, SDM-XML, Dataset-XML

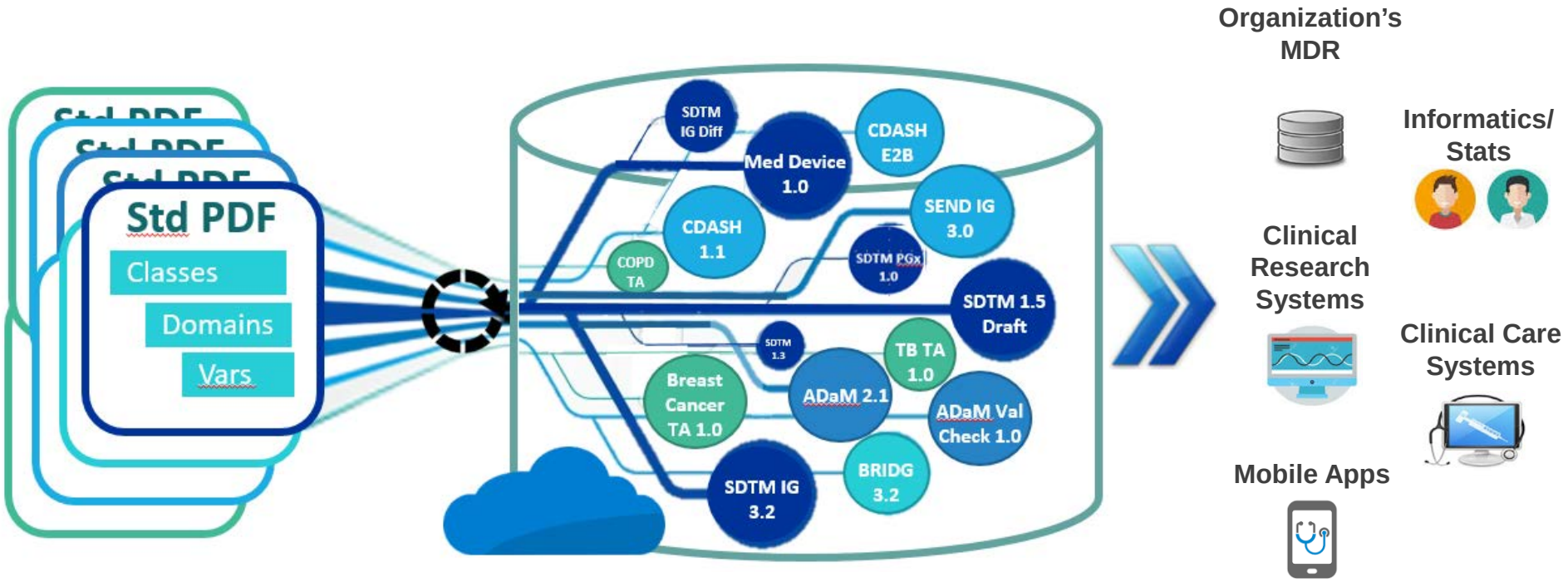
Clinical Research Process



For each part of the process, the CDISC standards give us standard answers to these questions:

- How should we organize / group the data into datasets?
- What individual concepts belong in each dataset?
- What terminology should be used to represent questions and responses?

SHARE Metadata Repository: Computable Standards



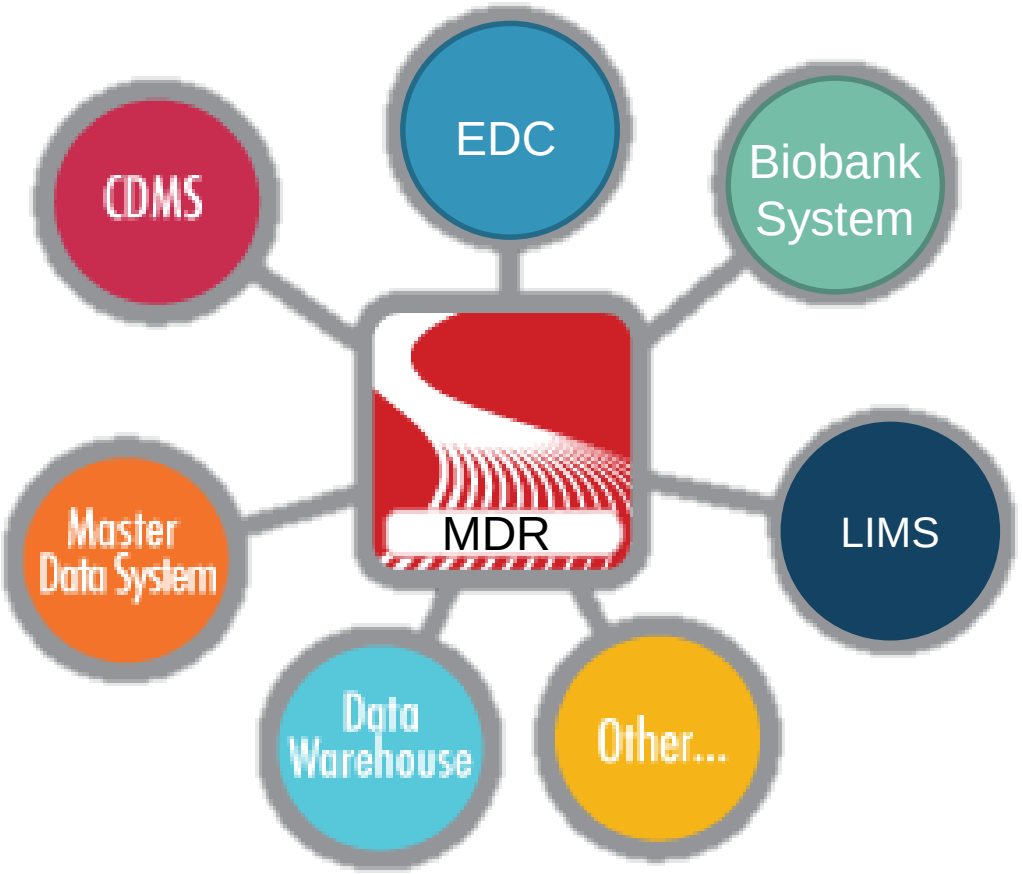
- Curated, computable CDISC standards
- Supports reuse and management of standards, meaningful research data exchange

- Over time, reduces costs
- Helps maintain compliance of data submission to FDA, PMDA
- Used by academic, biopharma, CRO, IT, non-profit research groups & nutrition companies

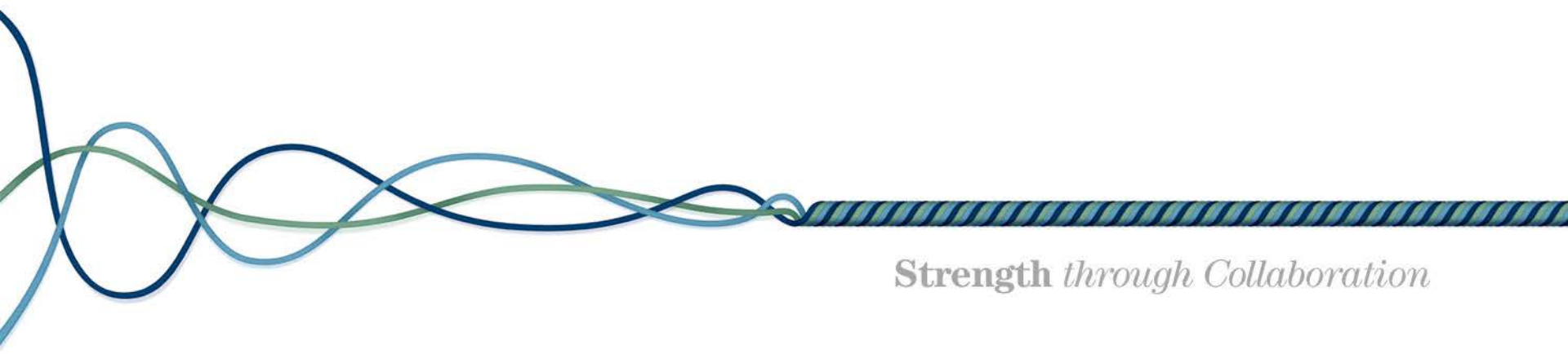
Typical Research Organization's MDR

Benefits

- Deploy the same metadata through multiple electronic systems
- Define common data via shared metadata in multiple systems, traceability
- Synchronize metadata automatically across multiple systems
- Version control
- Multiple language/dialect support
- Consistency & quality of data across systems
- Facilitated interoperability & data aggregation/reporting
- Up-front investment, downstream savings



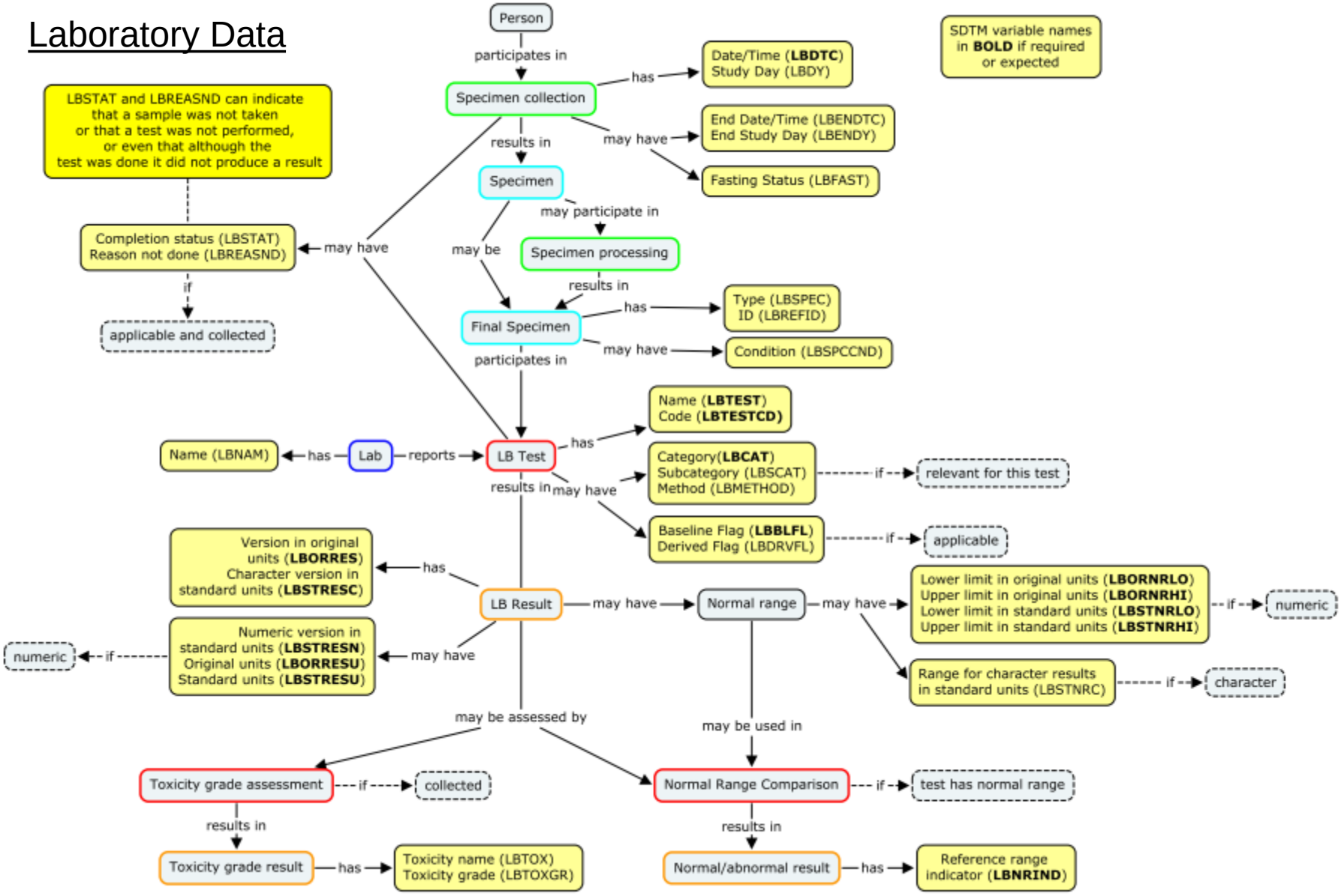
Concept Mapping



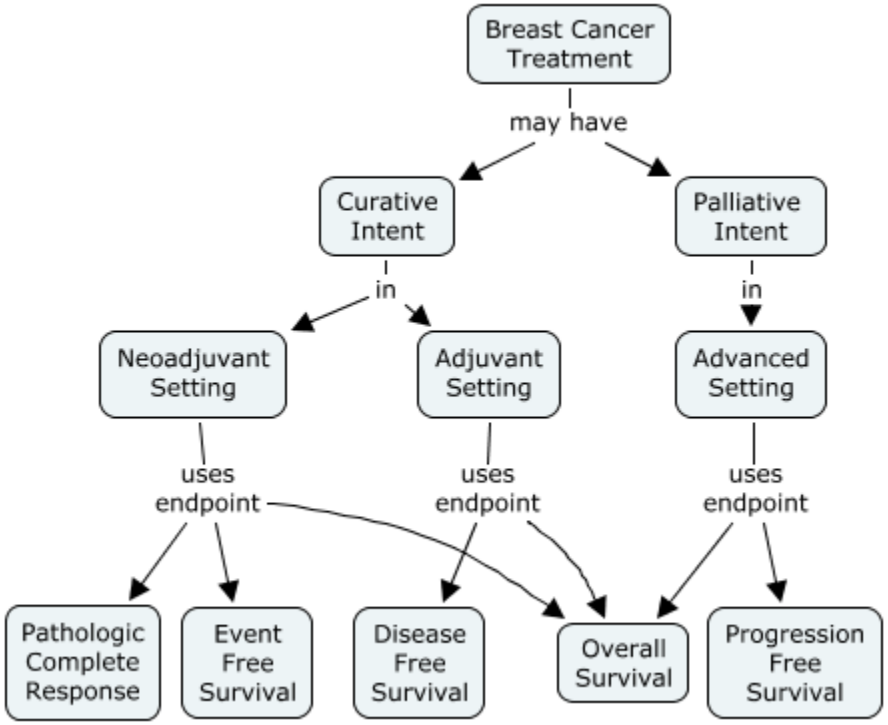
Concepts maps

- A way to organize thoughts and share ideas between different disciplines
- Enable clinicians and subject matter experts to communicate with technical standards developers
- Facilitate the translation, or mapping, of clinical concepts into CDISC standards

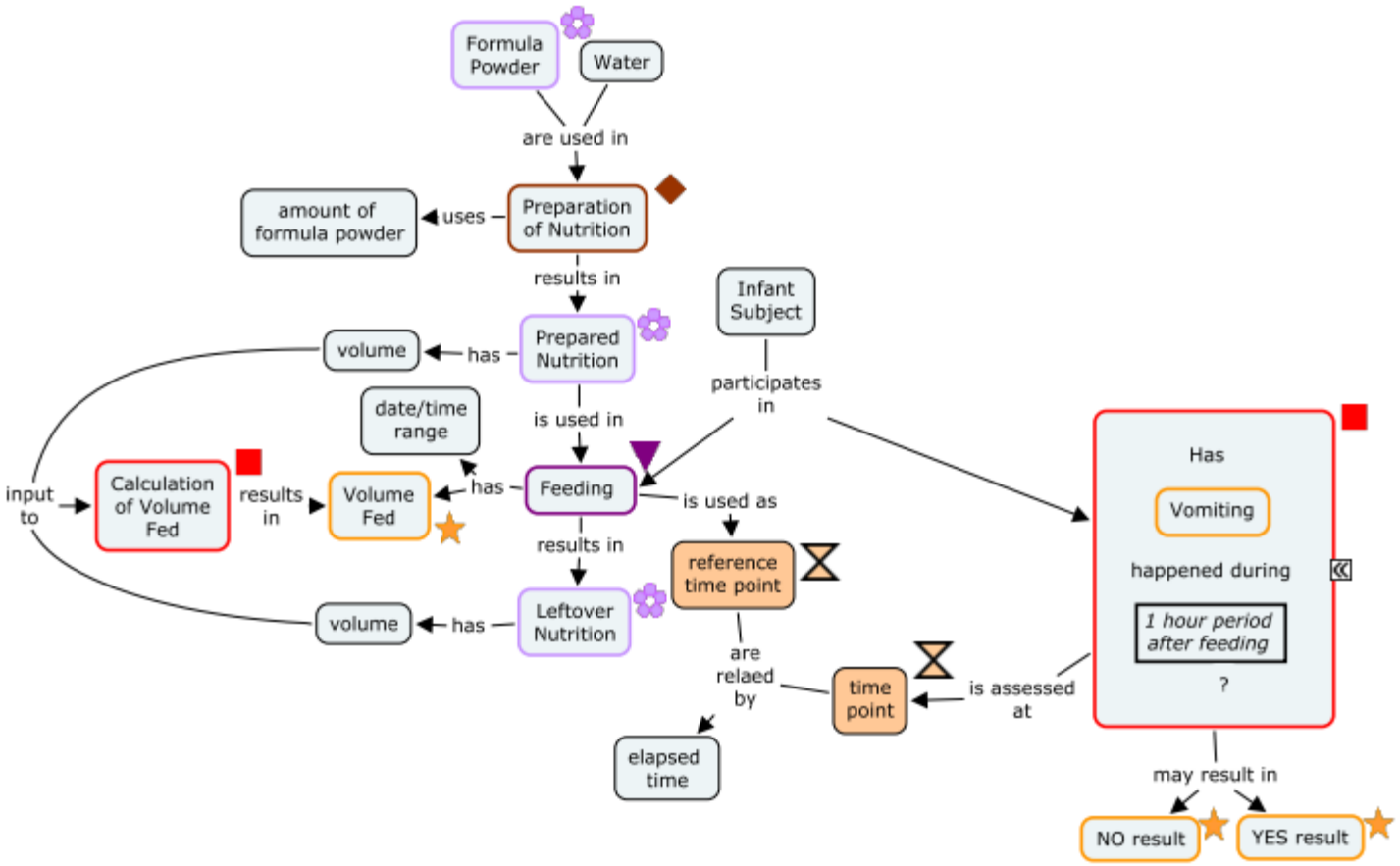
Laboratory Data



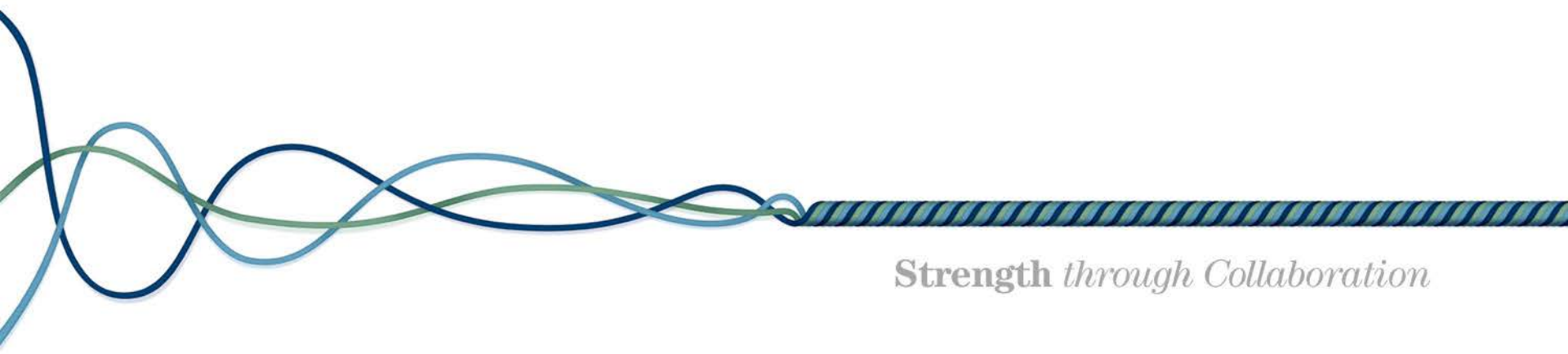
Treatment Setting



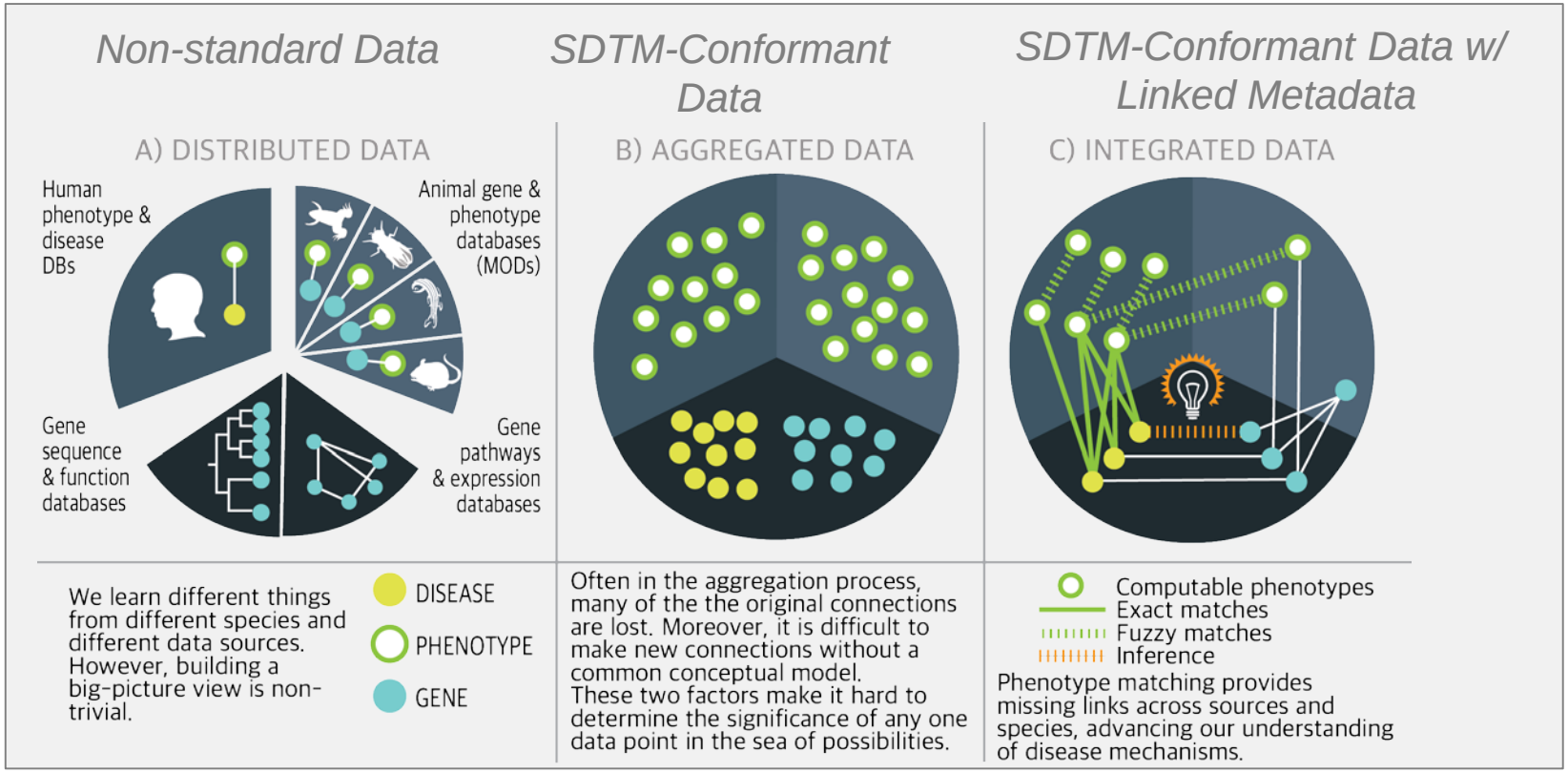
Infant Feeding



Biomedical concepts



Biomedical Concepts & Ontologies Can Drive Big Data Analyses



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