What's New

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CDISC E3C member

2018 Goals

1

Build a customer-centric Culture.

2

Generate greater member value.

3

Ensure sustainability of CDISC Standards.

4

Optimize standards development and release process.

5

Lay the foundation for a CDISC 2.0 Vision.

Agenda

1. **Rebranding**
2. Blue Ribbon Commission
3. Overview of TA work
4. Proof of Concept

Brand Essence

Brand Personality

Passionate

Inspired but not over-zealous
Resolute but not inflexible
Purpose-driven but not impractical

Inclusive

Open but not without a perspective
Collaborative but not passive
Partners but not pushovers

Expert

Confident but not arrogant
Authoritative but not dictatorial
Astute but not pretentious

Enterprising

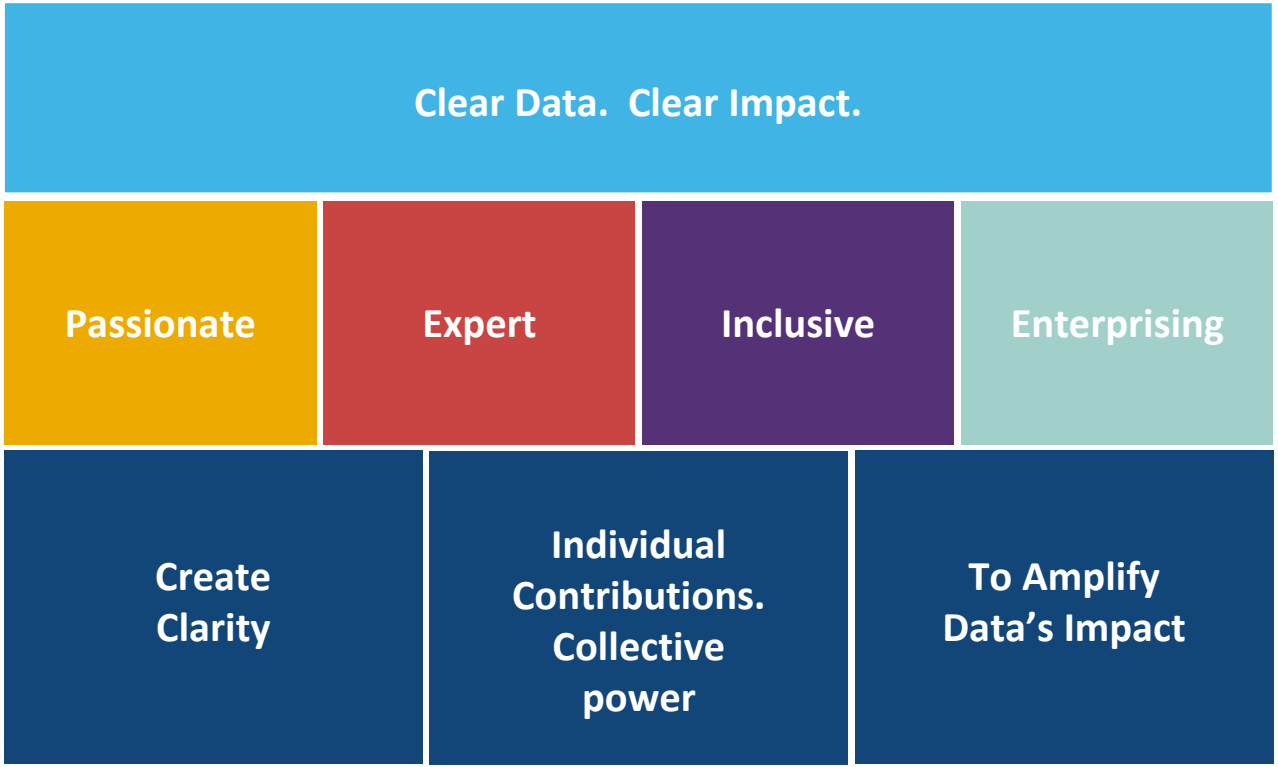
Visionary but not idealistic
Intrepid but not reckless
Influential but not domineering

CDISC brand platform

Brand essence
The compelling core idea of your brand

Brand personality
Traits evident in all you say and do

Brand pillars
Key strengths that form the foundation of your promise



Agenda

1. Rebranding
2. **Blue Ribbon Commission**
3. Overview of TA work
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Timeline for Blue Ribbon Commission

Jul 2017 — Board approves Strategic Plan.

Oct 2017 — Draft charge document. Outreach to regulators.

Nov 2017 — Board empanels Commission and selects Chairs.

Jan-Feb 2017 — Invitations to Commissioners.

Mar 2018 — Final Commissioner selection

Apr 2018 — Blue Ribbon Commission officially begins meeting regularly.

Oct 2018 — Commission reports to BoD. Public comment period.

Dec 2018 — New Three-Year Strategic Plan

Commissioners

Co-Chairs
- Joyce Sensmeier, RN (HIMSS)
- Dr. Rob Califf (Verily, Duke University, former FDA)

Academia
- Dr. Barbara Bierer (Harvard, MRCT, Vivly)
- Dr. Laura Merson (Oxford University, IDDO)
- Dr. Frank Rockhold (Duke University)
- John Speakman (NYU Langone)
- Dr. Sam Volchenboum (University of Chicago, Litmus Health)
- Dr. Anita Walden (University Arkansas for Medical Sciences)

Regulators
- Dr. Yuki Ando (PMDA)
- Dr. Allison Cave (EMA)
- Dr. Lilliam Rosario (US FDA)
- Helena Sviglin (US FDA)

Biotech, Devices
- Paul Franson (Medtronic, Inc.)
- Joanna Koft (Biogen)

Nonprofit Partners
- Scott Bahlavooni (PhUSE)
- Dr. Lynn Hudson (C-Path)
- Maria Picone (TREND Community)

Pharmaceuticals
- Jonathan Chainey (Roche, CAC)
- Dr. Hidetoshi Misawa (Pfizer, CDISC J3C)
- Dr. Ulo Palm (Allergan) and Manny Anid (Allergan)
- Dr. Zibao Zhang (dMed, CDISC C3C)

Commissioners

Government Agencies
- Dr. Ken Gersing (NIH/NCATS)
- Dr. Tatsuya Maruyama (AMED)
- Dr. Lyuba Remenik (NIH/NCI)

Technology/Services
- Dr. Wenjun Bao (SAS JMP)
- Dr. Jeff Brown (Sentinel, Harvard Pilgrim)
- Dave Evans (Accenture)
- Hugh Glover (Blue Wave Informatics)
- Dr. C. David Hardison (Deloitte)
- Dave Iberson-Hurst (Assero Limited)

CROs/Labs
- Sherry Chou (Parexel)
- Phil Pochon (Covance)

Research Funders
- Scott Kahn (Helmsley Charitable Trust)
- Dr. Steven Kern (Gates Foundation)
- Dr. Jennifer O'Callaghan (Wellcome Trust)

Staff
- David R. Bobbitt, MSc, MBA
- Anthony Chow
- Dr. Sam Hume
- Rhonda Facile, MS
- Marine Laurent
- Bess LeRoy, MPH
- Peter Van Reusel

Key Insights: #1 Refine the model

- **Focus on the CDISC core business, building excellent standards from inception**
  - Alignment across the standards for ETE automation
  - A machine-readable protocol standard
  - Move to a 3D model back-end built on biomedical concepts
  - A refined model is the best way to respond to new technologies, new sources of data

- **Support consistent implementation**
  - Continue and expand educational offerings
  - Metadata to transform data across the foundational standards
  - Completeness of new versions of the standards
  - A majority of Commissioners wants CDISC to consider offering implementation advice

Key Insights: #2 Volunteers and #3 Focus & Clarity

- **Optimize the volunteer laborforce**
  - Ask member companies for volunteers on specific projects but not as a condition of membership
  - Train volunteers to utilize CDISC SHARE for standards development
  - Centralize strategy for teams
  - Utilize technology tools to help volunteers focus on the core strengths
  - Utilize staff to reduce bottlenecks in development

- **Focus and clarity**
  - Be excessively transparent
  - Reduce high threshold to entry

Key Insight: #4 Build a strong standards ecosystem

- More access to CDISC SHARE API
- Be very specific, strategic in mappings to other terminologies and standards in SHARE, but resist the urges for total interoperability Support developers, open source to build tools on SHARE API
- Launch CDISC certification program
- Observe and be engaged with: HL7 FHIR, AI/machine learning, IOT, medical devices and wearables, BYOD data

Key Insight: #5 Rely on key partnerships

- **CDISC should be a good partner, fair and transparent**
- **Some areas where other partners should lead**
  - Curation of donated data
  - Data sharing platforms
  - Development of a machine-readable protocol standard
  - Voice of the patient/ways to share data back with patients

Key Insight: #6 Growth

- **Growth by use case: support expanded use of CDISC standards by academics**
  - Specific trainings, tools
  - Partner with funders, open science advocates, data sharing platforms

- **Geographic Growth**
  - China, India, EU, UK post-Brexit
  - Other global markets: South Korea, Australia, New Zealand, Singapore
  - Be opportunistic!

Key Insight: #7 Membership and revenue

- Consider a “freemium” model for CDISC SHARE
- Approach funders of academic research and data sharing to support the academic use case development
- Earn revenue from a certification program
- Consider tweaking the membership model for academics
- Listen to members: what do they need and expect?

Areas where consensus has eluded us…

- RWD
- Branding of the foundational standards
- CDISC offers implementation advice/services
- Simplified versioning system
- Deprecation system

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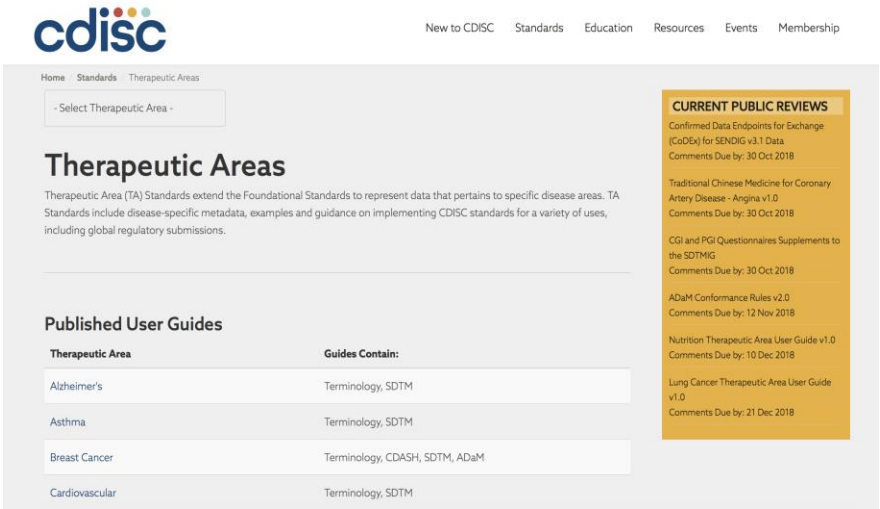
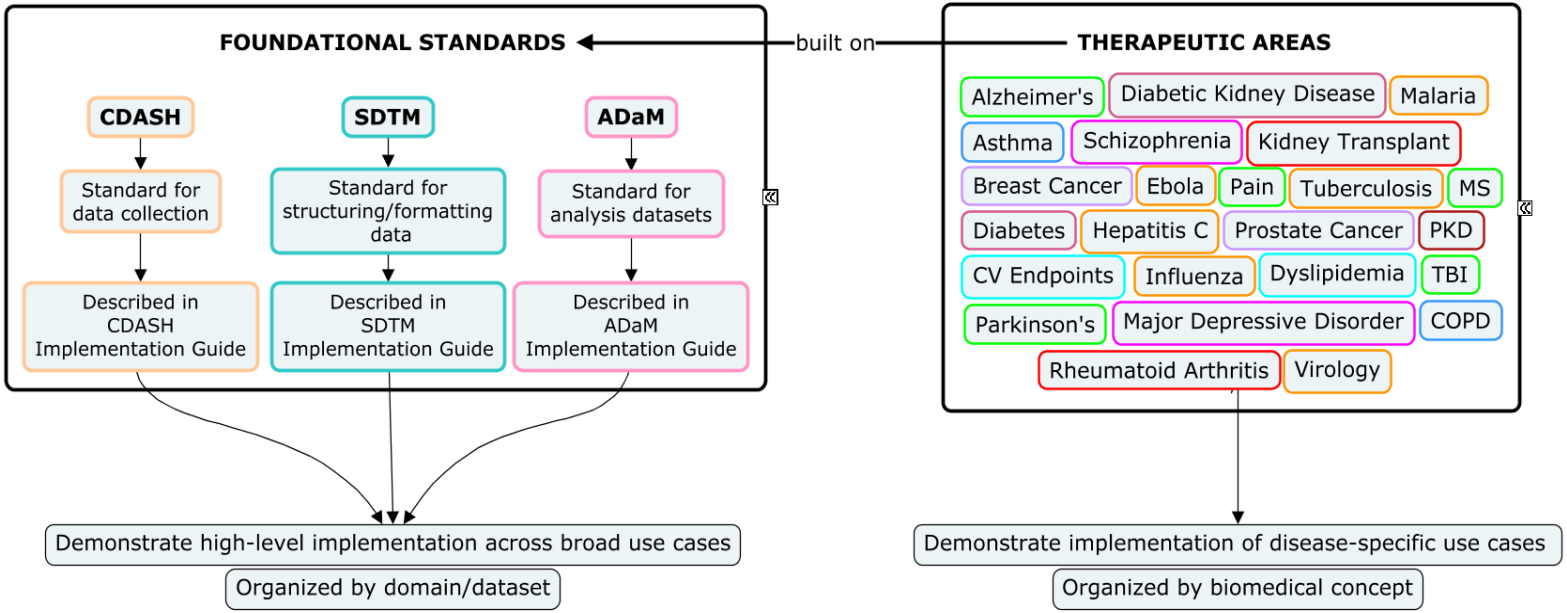


https://www.cdisc.org/standards/therapeutic-areas

CDISC Standards



*The full list of foundational standards is available at https://www.cdisc.org/standards/foundational

Therapeutic Area User Guides (TAUGs)

- Guides for the implementation of CDISC foundational standards in specific disease areas
- Include examples from *across CDISC foundational standards*
- TAUGs extend the foundational standards and thus they must be used in conjunction with the foundational standards
- Based on biomedical concepts identified by subject matter experts

Overview of Therapeutic Area Work

Upcoming Publications

- Colorectal Cancer v1.0
- HIV Prevention and Treatment v1.0
- Post Traumatic Stress Disorder v1.0
- Traditional Chinese Medicine for CAD v1.0
- CV Imaging v1.0

Current Public Reviews

- Nutrition v1.0 –
  Comments Due 10 Dec 2018
- Lung Cancer v1.0 –
  Comments Due 21 Dec 2018

Overview of Therapeutic Area Work

- **Upcoming Public Reviews**
  - CDAD – 2nd Public Review (30 days) for additional FMT example
  - Animal Rule (Nonclinical)

- **Ongoing Work**
  - Type 1 Diabetes (Pediatrics and Devices)
  - Traditional Chinese Medicine – Acupuncture

- **Newly Forming Therapeutic Areas – Seeking Volunteers**
  - Type 1 Diabetes (Prevention and Exercise)
  - Crohn's Disease
  - Acute Kidney Injury
  - Congestive Heart Failure
  - Psoriasis

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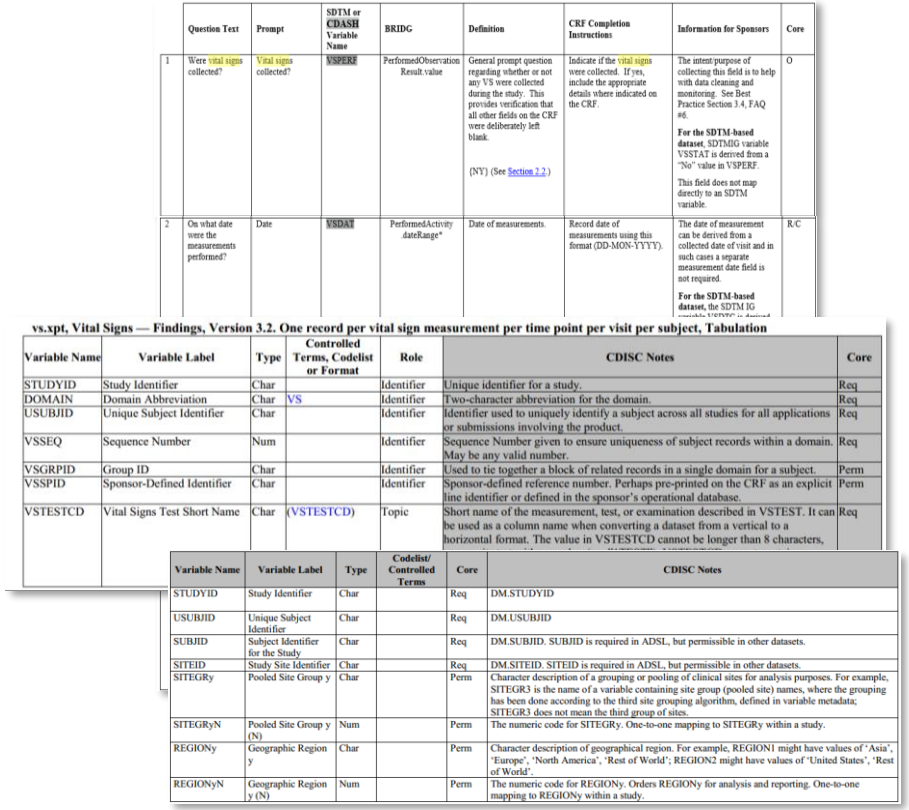
Defined Structures

- **CDISC Foundational models provide much needed structure**
  - Normative Content
  - 2 dimensional (tables, columns)
  - Standard to represent data

- **The information itself is not defined**
  - We do not need new structures
  - We need to define
    - Entities
    - Semantics (meaning)
    - Relationships between information
    - Rules in the data lifecycle



	Question Text	Prompt	SDTM or CDASH Variable Name	BRIDG	Definition	CRF Completion Instructions	Information for Sponsors	Core
1	Were vital signs collected?	Vital signs collected?	VSPERF	PerformedObservation Result.value	General prompt question regarding whether or not any VS were collected during the study. This provides verification that all other fields on the CRF were deliberately left blank. (NY) (See Section 2.2.)	Indicate if the vital signs were collected. If yes, include the appropriate details where indicated on the CRF.	The intent/purpose of collecting this field is to help with data cleaning and monitoring. See Best Practice Section 3.4, FAQ #6. **For the SDTM-based dataset**, SDTMIG variable VSSTAT is derived from a "No" value in VSPERF. This field does not map directly to an SDTM variable.	O
2	On what date were the measurements performed?	Date	VSDAT	PerformedActivity .dateRange*	Date of measurements.	Record date of measurements using this format (DD-MON-YYYY).	The date of measurement can be derived from a collected date of visit and in such cases a separate measurement date field is not required. **For the SDTM-based dataset**, the SDTM IG	R/C

vs.xpt, Vital Signs — Findings, Version 3.2. One record per vital sign measurement per time point per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	VS	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
VSSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
VSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
VSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Perm
VSTESTCD	Vital Signs Test Short Name	Char	(VSTESTCD)	Topic	Short name of the measurement, test, or examination described in VSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than 8 characters,	Req

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
STUDYID	Study Identifier	Char		Req	DM.STUDYID
USUBJID	Unique Subject Identifier	Char		Req	DM.USUBJID
SUBJID	Subject Identifier for the Study	Char		Req	DM.SUBJID. SUBJID is required in ADSL, but permissible in other datasets.
SITEID	Study Site Identifier	Char		Req	DM.SITEID. SITEID is required in ADSL, but permissible in other datasets.
SITEGRy	Pooled Site Group y	Char		Perm	Character description of a grouping or pooling of clinical sites for analysis purposes. For example, SITEGR3 is the name of a variable containing site group (pooled site) names, where the grouping has been done according to the third site grouping algorithm, defined in variable metadata; SITEGR3 does not mean the third group of sites.
SITEGRyN	Pooled Site Group y (N)	Num		Perm	The numeric code for SITEGRy. One-to-one mapping to SITEGRy within a study.
REGIONy	Geographic Region y	Char		Perm	Character description of geographical region. For example, REGION1 might have values of 'Asia', 'Europe', 'North America', 'Rest of World'; REGION2 might have values of 'United States', 'Rest of World'.
REGIONyN	Geographic Region y (N)	Num		Perm	The numeric code for REGIONy. Orders REGIONy for analysis and reporting. One-to-one mapping to REGIONy within a study.

Why Change ?

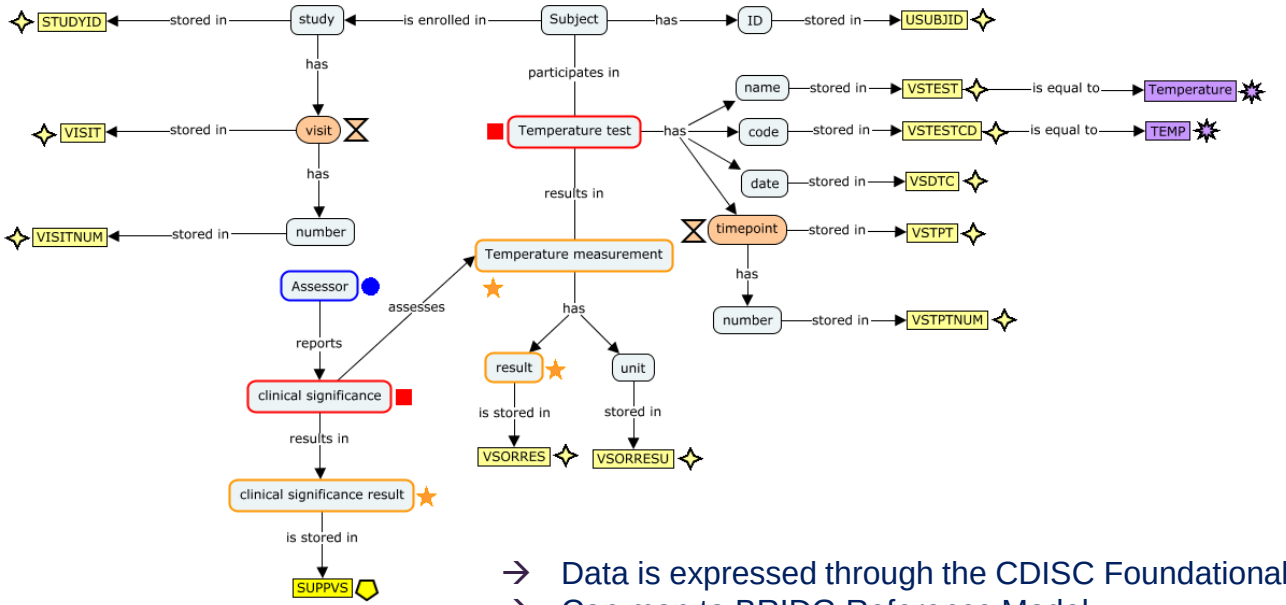
- Industry needs are evolving
- Our standards need to enable end-to-end automation
- Our standards need to be machine-readable
- Continuous need to be more efficient and save costs
- We want non-standard experts to use our standards

What is the CDISC proof of concept?

- A serious attempt to store and use data standards as linked metadata
- Create and store standards as concepts and create meaning between concepts
- Add computer readable metadata which enables end to end functionality
- The Proof of Concept will test and demonstrate this functionality
- Evolve from normative to informative standards
- Make implicit relationships explicit

Store Standards in Concept Maps 1/2

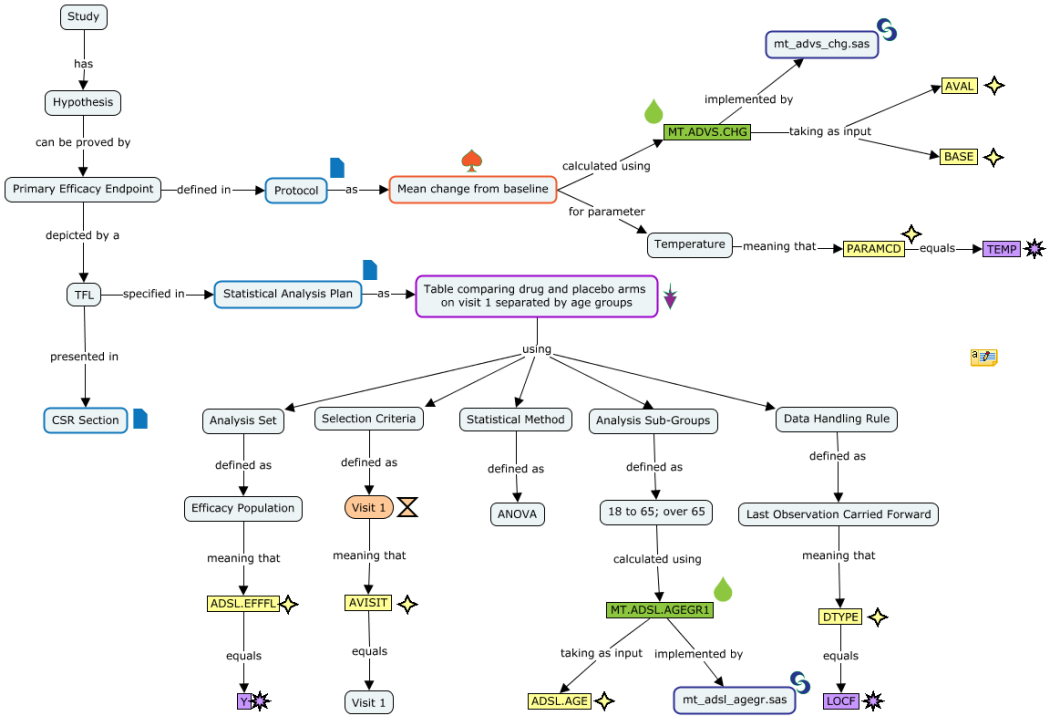
- Example of **biomedical concept**

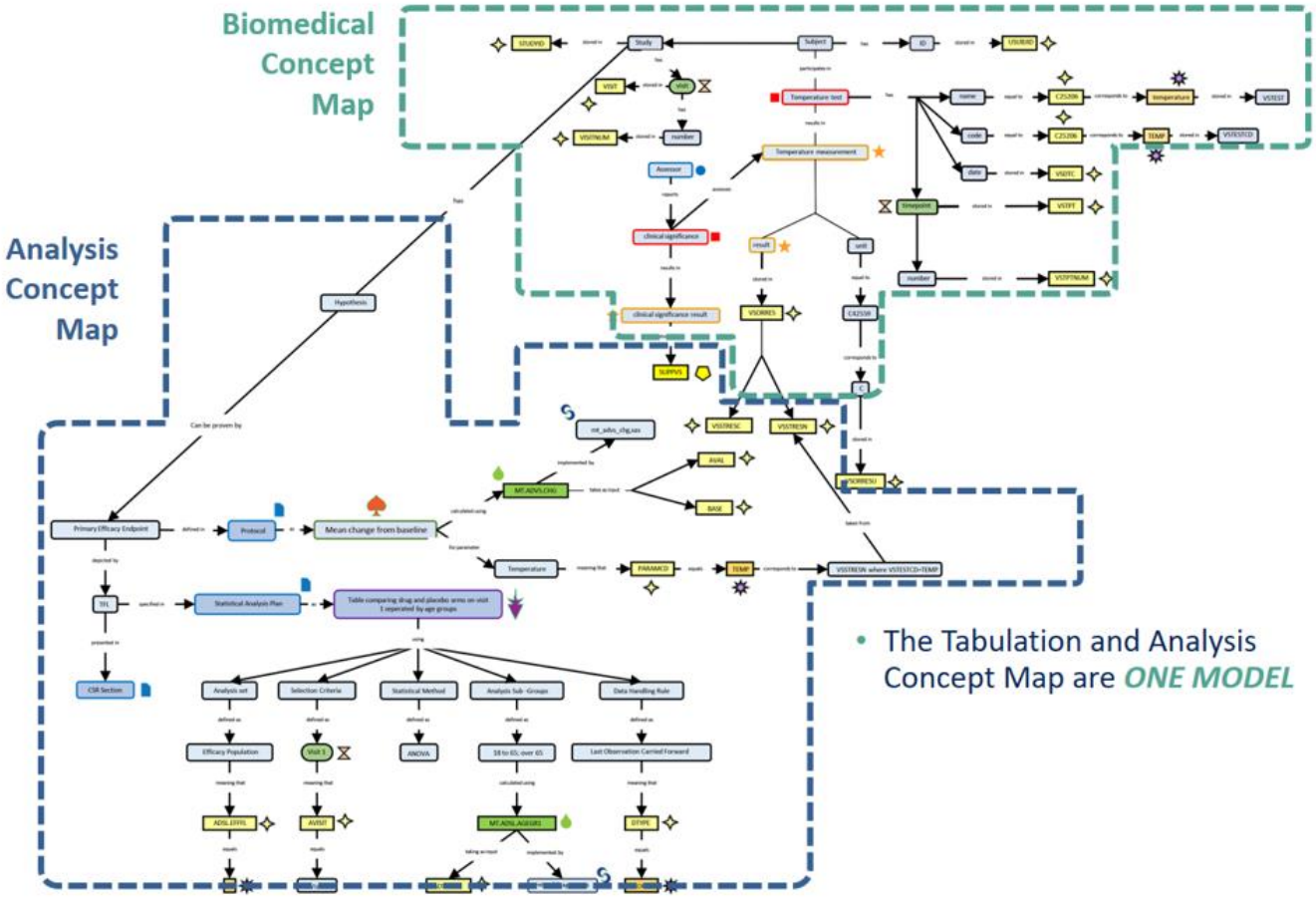


→ Data is expressed through the CDISC Foundational Models
→ Can map to BRIDG Reference Model

Store Standards in Concept Maps 2/2

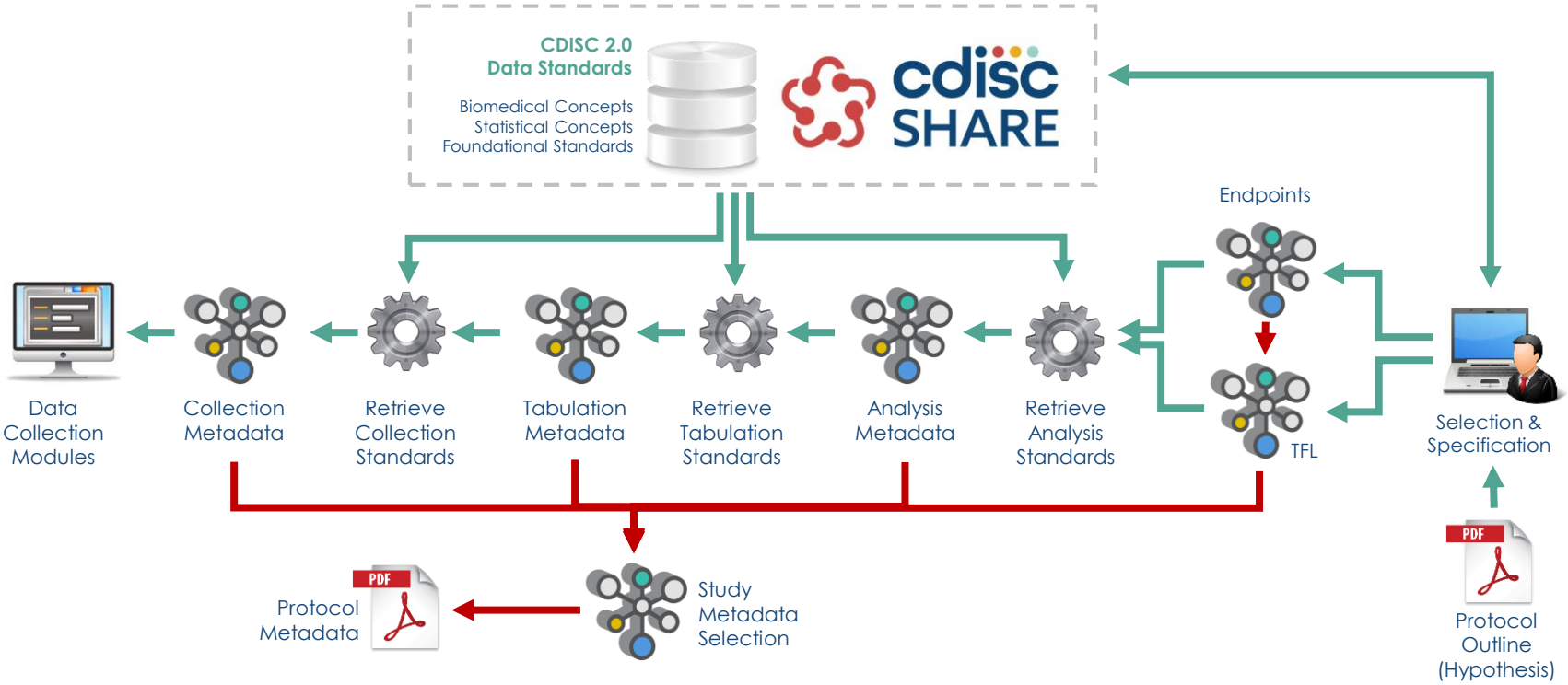
- Example of **statistical concept**



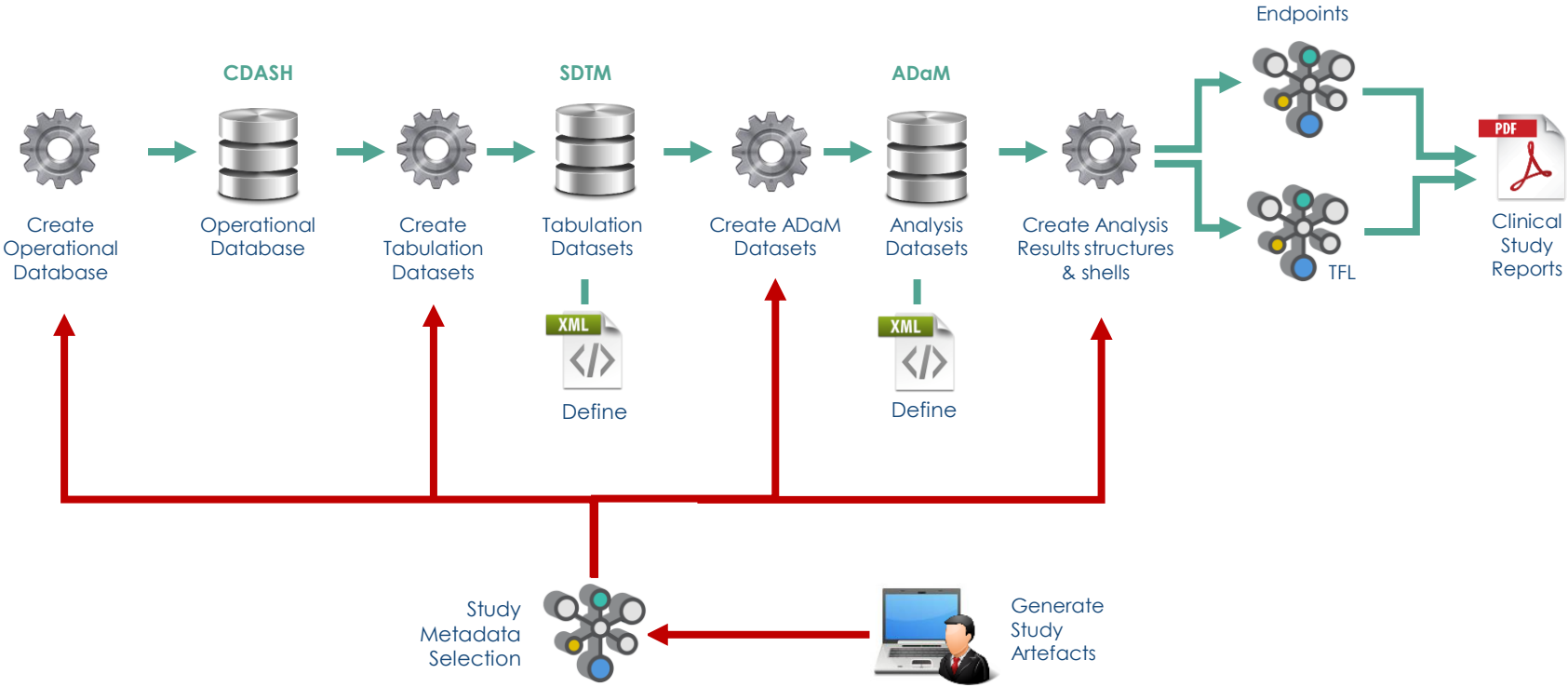


- The Tabulation and Analysis Concept Map are *ONE MODEL*

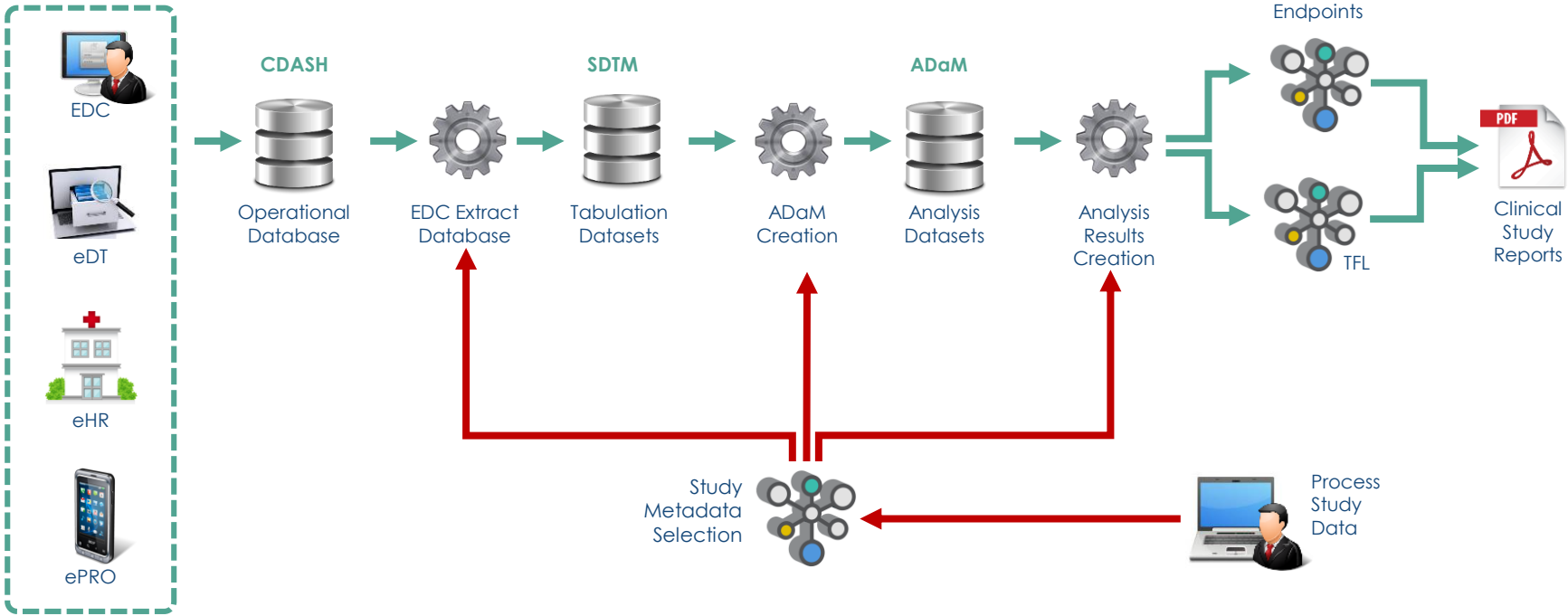
Use Case 1: **End to Start specification**



Use Case 2: **Start to End Metadata**



Use Case 3: **Start to End Data Processing**



Proof Of Concept Outline

- The Proof of Concept will need an estimated 18 months

- We need help from our community
  - Define Use Cases
  - Provide Examples of success, experience
  - Provide demo data

- Agile Development, regular presentations in user groups

Expected POC Outcome

- **POC Outcome**
  - What works and what doesn't
- **Can we create true end to end**
  - Technology Gap Analysis
  - Standards Gap Analysis
- **Building a base for the future**
  - Scale up to deliver the standards metadata needed
  - Effort calculation
  - Cost / Benefit Analysis
  - Partnerships with vendors to ensure tools are made available

Questions

THANK YOU !

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