

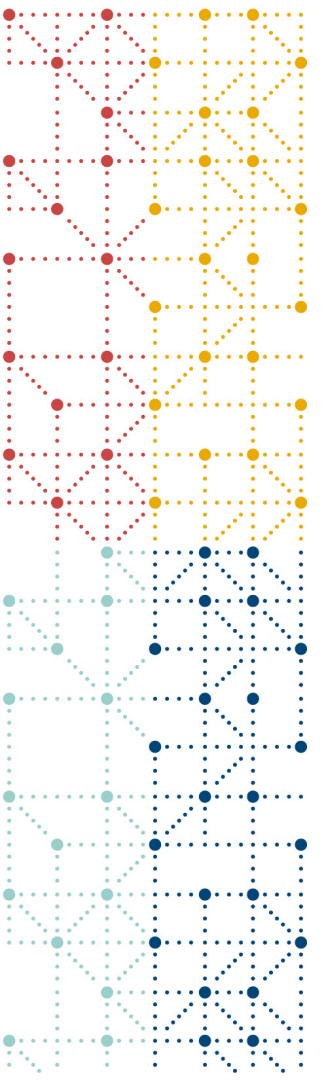


Tools for Data-driven Decision-making

Sally Cassells

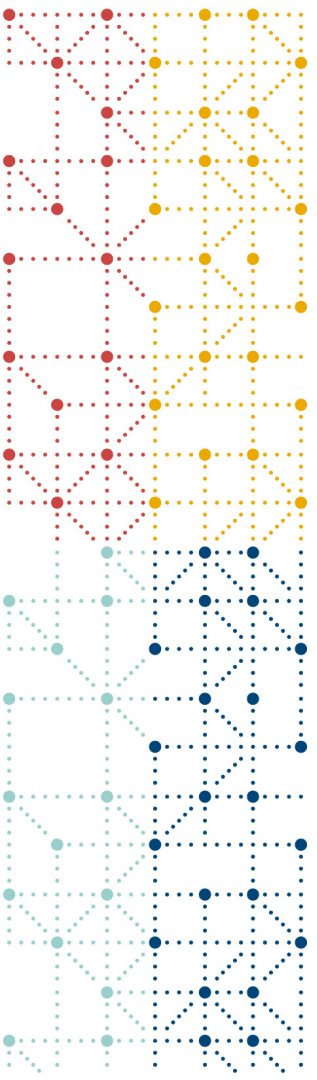
PhUSE Single Day Event August 15, 2019





Disclaimer

Materials in this presentation are for illustration purposes. Some content has been drawn from products or standards that are 'works in progress' and may differ from the final production versions.



Agenda

1. Why CDISC Standards are important for data driven decision making
2. CDISC Standards
3. CDISC Library – building for the future
4. Ongoing work to support data driven decision making

Why Are Standards Important for Data Driven Decision Making?

HealthData
Management

All Sections ▾

Resources Events 🔍

NOW READING: **The Latest**

HIT Think Why 'dirty data' can derail health plans' analytics efforts

Health plans use PatientPing services to advance pop health

New Intermountain company to aid providers transitioning to VBC

Digital health VC funding reaches \$5.1B in first half of year

CMS approves GuideWell Connect for ACA direct ...

HIT Think Why 'dirty data' can derail health plans' analytics efforts

By
Diana Manos

Published
July 10 2019, 12:46pm EDT

More in
Payer Edition
Payers
Healthcare analytics
Data governance
Value-based care



Print



Reprint

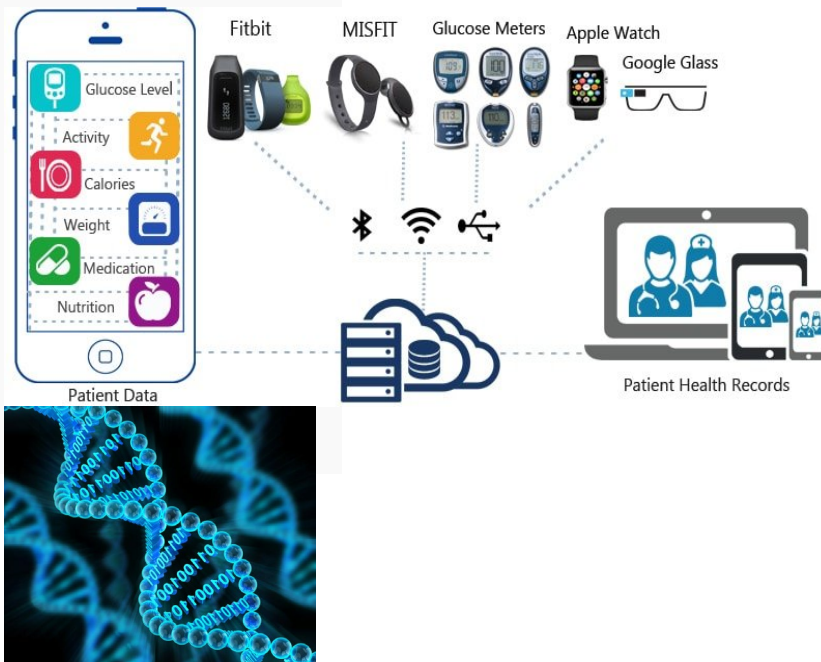


One of the biggest problems health plans face is dirty data, says Jordan Bazinsky, executive vice president and administrative officer at Atlanta-based Cotiviti.

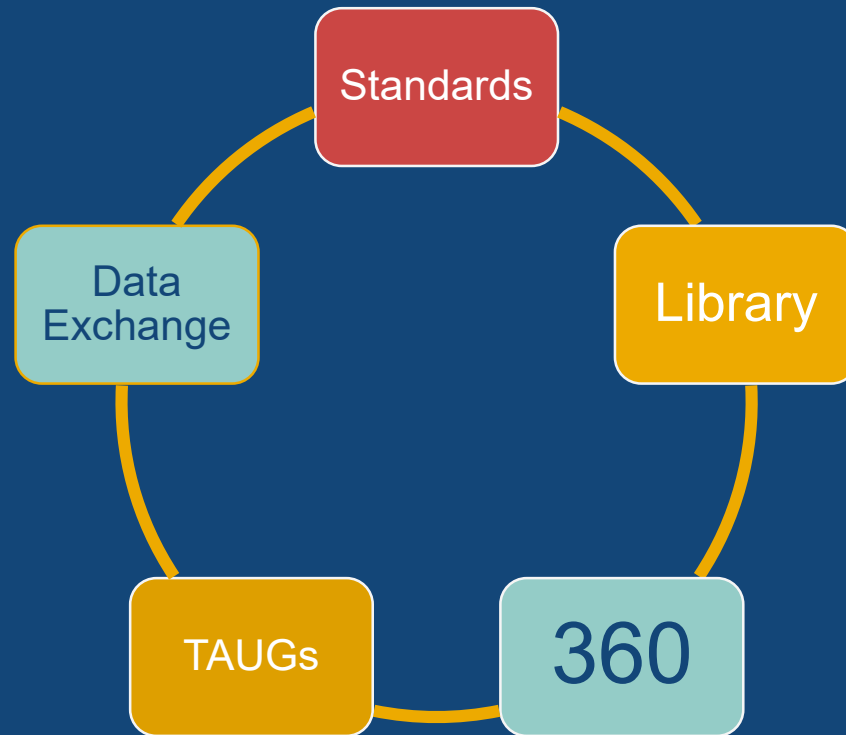
The healthcare solutions and analytics company reports having "several hundred" health insurance companies among its clientele, including 24 of the top 25 plans, he says.



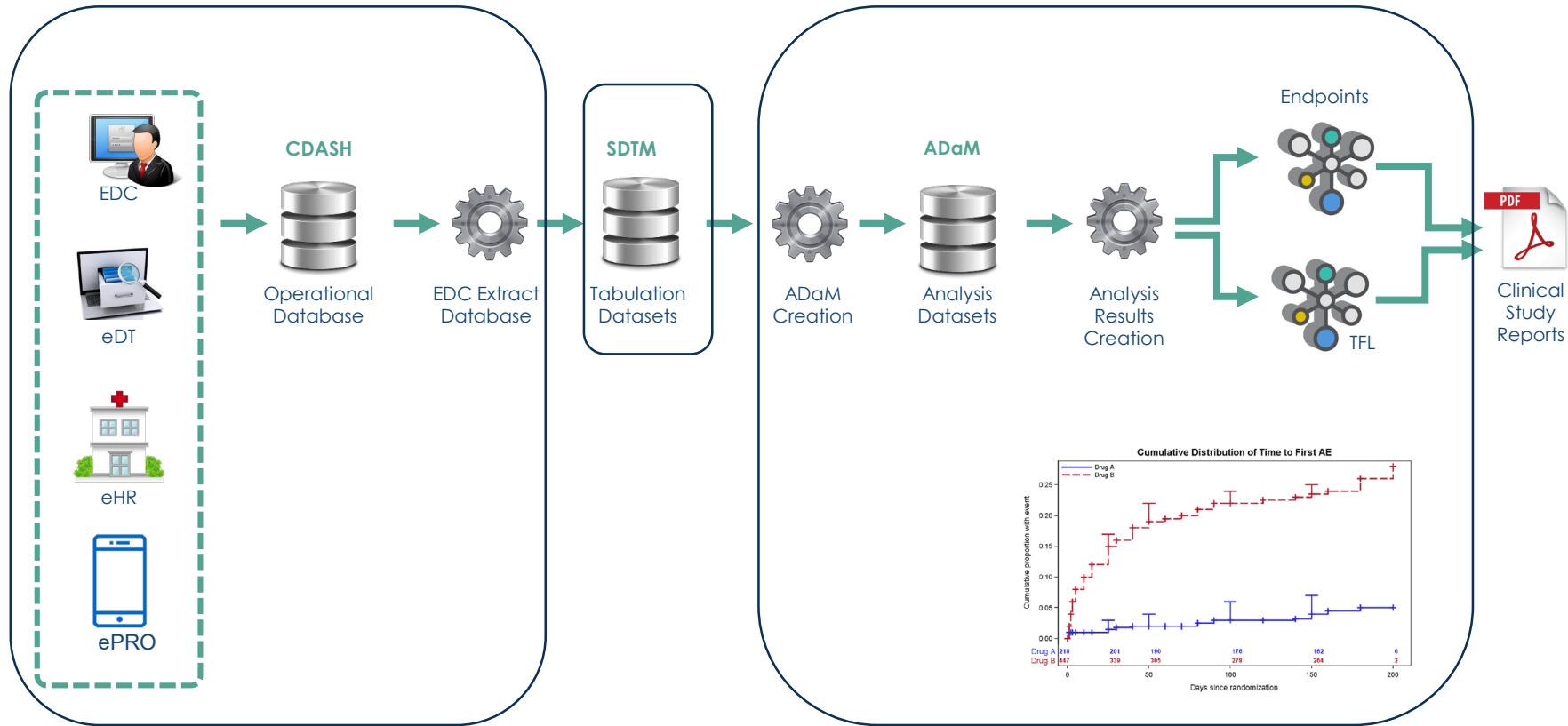
cdisc



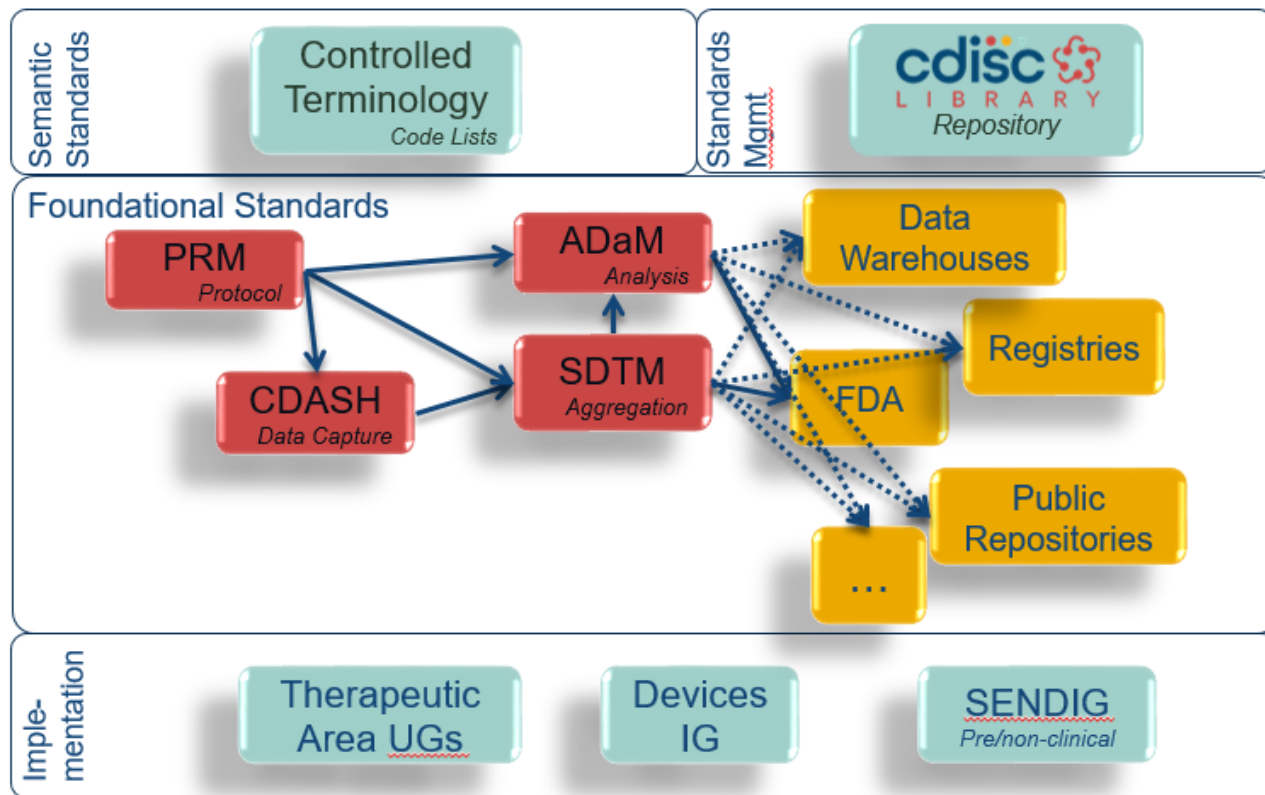
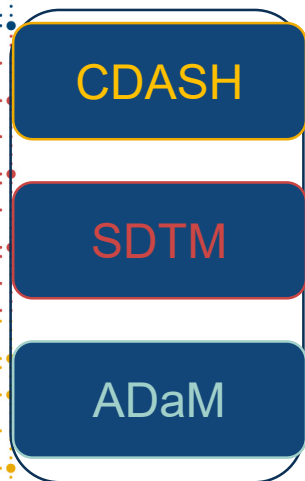
CDISC Tools



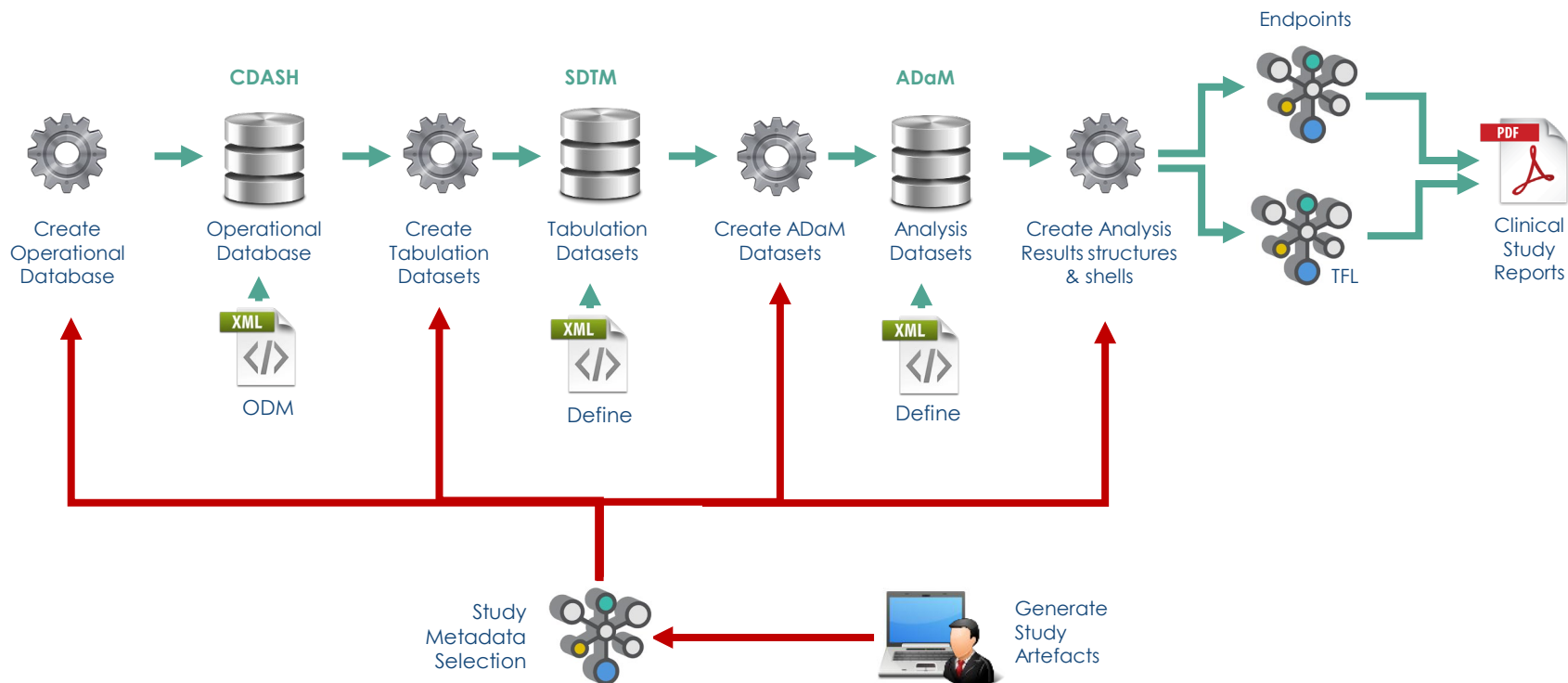
CDISC Standards



CDISC Standards



CDISC Data Exchange Standards



CDISC-Sample

- Supplemental Documents Standards
- Analysis Results Metadata
- Datasets
- Controlled Terminology
- Methods

Expand all VLM

Collapse all VLM

Date/Time of Define-XML document generation: 2018-11-15T11:01:00

Define-XML version: 2.1.0

Define-XML Context: Submission

Stylesheet version: 2019-02-11

Study Name	CDISC-Sample
Study Description	CDISC-Sample Data Definition
Protocol Name	CDISC-Sample
Metadata Name	Study CDISC-Sample, Data Definitions
Metadata Description	Study CDISC-Sample, Data Definitions

Standards for Study CDISC-Sample

Standard	Type	Status	Documentation
ADaMIG 1.1	IG	Final	
CDISC/NCI ADaM 2017-09-29	CT	Final	ADaM specific CT is applicable for a few variables only.
CDISC/NCI SDTM 2018-06-29	CT	Final	SDTM CT is applicable for variables copied from SDTM to ADaM.

Analysis Results Metadata - Summary

[Table 14-3.01](#) Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)

[Dose response analysis for ADAS-Cog changes from baseline](#)

[Pairwise comparisons to placebo for ADAS-Cog changes from baseline](#)

[Table 14-5.02](#) Incidence of Treatment Emergent Serious Adverse Events by Treatment Group

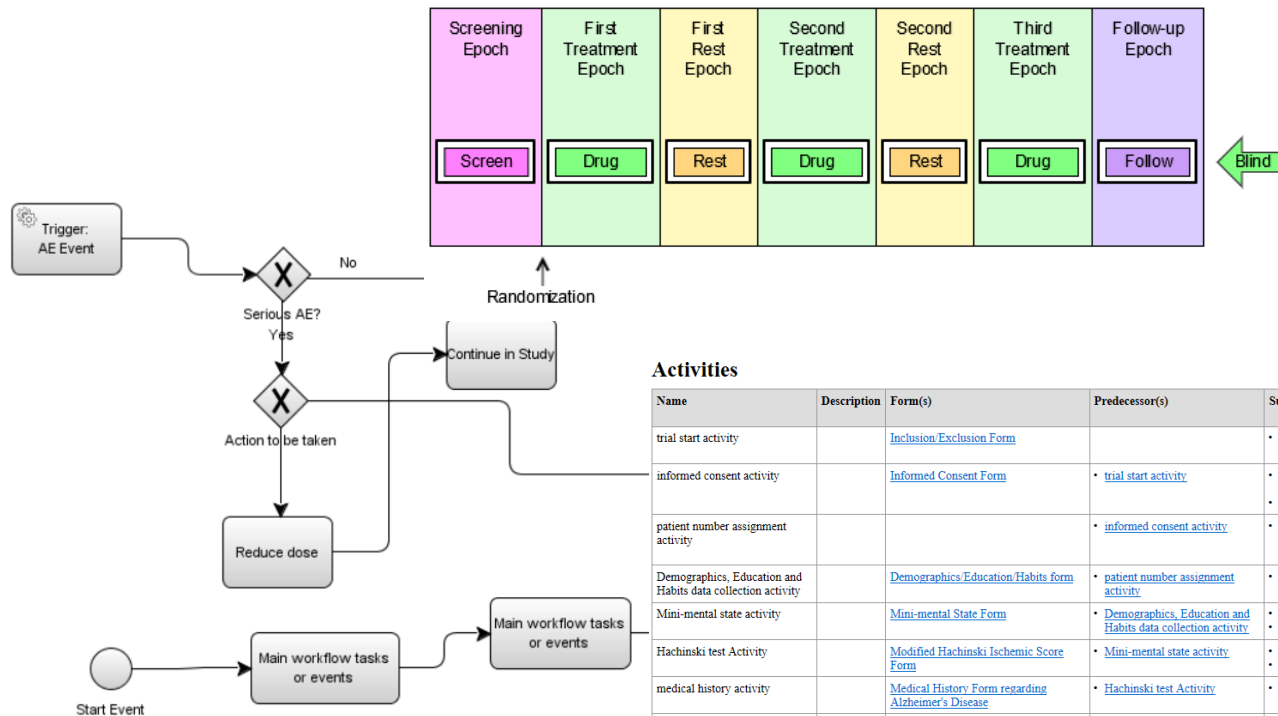
[Incidence of Treatment Emergent Serious Adverse Events by Treatment Group](#)

Analysis Results Metadata - Detail

Table 14-3.01

Display	Table 14-3.01 [2 &] Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)
Analysis Result	Dose response analysis for ADAS-Cog changes from baseline
Analysis Parameter(s)	PARAMCD = "ACTOT" (Adas-Cog(11) Subscore)
Analysis Variable(s)	ADRLPS:CHG (Change from Baseline)
Analysis Reason	SPECIFIED IN SAP

SDM-XML



Activities

Name	Description	Form(s)	Predecessor(s)	Successor(s)	Absolute Timing Constraint(s)	Relative Timing Constraint(s)
trial start activity		Inclusion/Exclusion Form		informed consent activity		
informed consent activity		Informed Consent Form	trial start activity	patient number assignment activity trial finish activity	Absolute timing constraint on informed consent activity	relative timing constraint between activity informed consent and activity patient number assignment
patient number assignment activity			informed consent activity	Demographics, Education and Habits data collection activity		relative timing constraint between activity informed consent and activity patient number assignment
Demographics, Education and Habits data collection activity		Demographics/Education/Habits form	patient number assignment activity	Mini-mental state activity		
Mini-mental state activity		Mini-mental State Form	Demographics, Education and Habits data collection activity	Hachinski test Activity trial finish activity		
Hachinski test Activity		Modified Hachinski Ischemic Score Form	Mini-mental state activity	medical history activity trial finish activity		
medical history activity		Medical History Form regarding Alzheimer's Disease	Hachinski test Activity	vital signs activity		
vital signs activity		Vital Signs Form	medical history activity			
ambulatory ECG placement activity						Timing constraint between ambulatory ECG placement and removal
ambulatory ECG removal activity						Timing constraint between ambulatory ECG placement and removal
patient randomization activity						Timing constraint for treatment visit 1 (0-4) Timing constraint for treatment visit 2 (0-5) Timing constraint for treatment visit 3 (0-6)

Examples of Use Cases Targeted by ODM v2.0

Study Setup

- Enable automated data capture using SDM integrated with ODM
- Support more flexible metadata representations

Integration

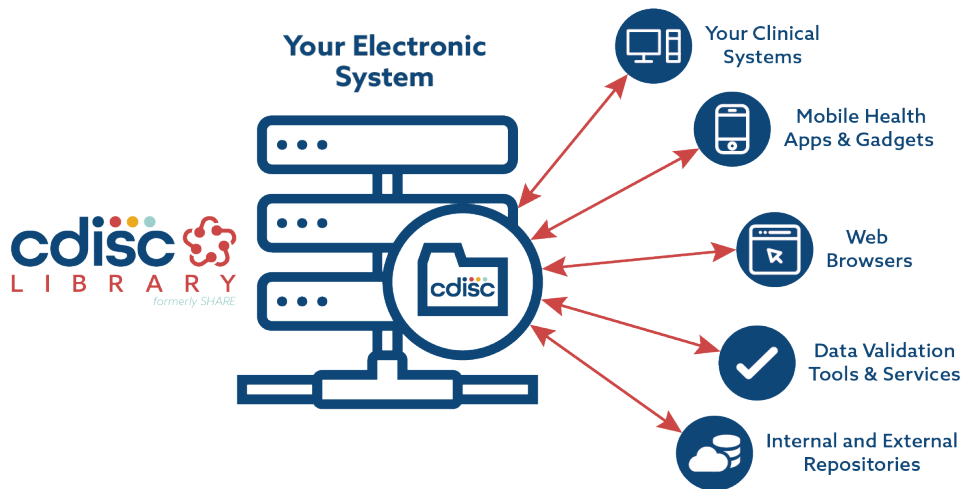
- Enhanced semantic representation
- More flexible metadata model increases compatibility with EDC systems

Data Exchange

- Use REST APIs to improve data exchange
- Operational dataset-xml to address gaps in transport coverage

End-to-end Standards

- CDISC 360
- Biomedical Concept representation
- Traceability enhancements with Trace-XML

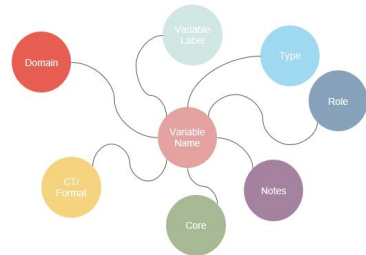


DM - Specification

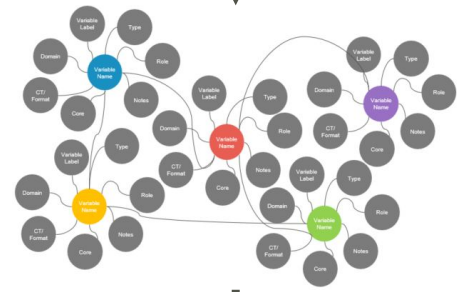
dm.xml_Demographics - Special Purpose, Version 1.3, One record per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, CodeList or Format ¹	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DM	Identifier	Two-character abbreviation for the domain.	Req
PSUBID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBID.	Req
SUBID	Subject Identifier for the Study	Char		Topic	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.	Req

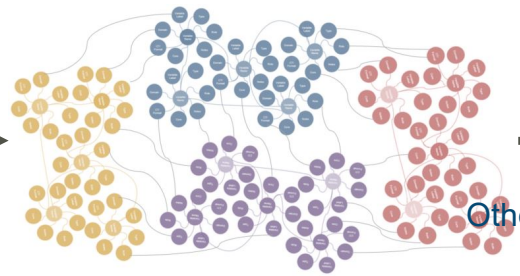
DM Variable as Linked Data



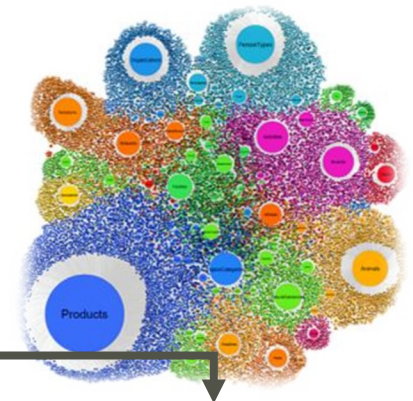
SDTMIG as Linked Data



CDISC as Linked Data



Other Standards as Linked Data



CDISC Library Data Standards Browser



Coming Soon

Data Collection

CDASH MODEL ...

CDASHIG V1.1

CDASHIG V2.0

Data Tabulation

SDTM V1.2

SDTM V1.3

SDTM V1.4

SDTM V1.5

SDTM V1.6

SDTM V1.7

SDTMIG V3.1.2

SDTMIG V3.1.3

SDTMIG V3.2

SDTMIG V3.3

SDTMIG-AP V1.0

SDTMIG-MD V1.0

SDTMIG-MD V1.1

SDTMIG-PGX V...

SENDIG 3.0

SENDIG V3.1

SENDIG-DART ...

Data Analysis

ADAM ADAE V1...

ADAM BDS FOR...

ADAM OCCDS ...

ADAM V2.1

ADAMIG V1.0

ADAMIG V1.1

Controlled Terminology

CT 2014 Q3

CT 2014 Q4

CT 2015 Q1

CT 2015 Q2

CT 2015 Q3

CT 2015 Q4

CT 2016 Q1

CT 2016 Q2

CT 2016 Q3

CT 2016 Q4

CT 2017 Q1

CT 2017 Q2

CT 2017 Q3

CT 2017 Q4

CT 2018 Q1

CT 2018 Q2

CT 2018 Q3

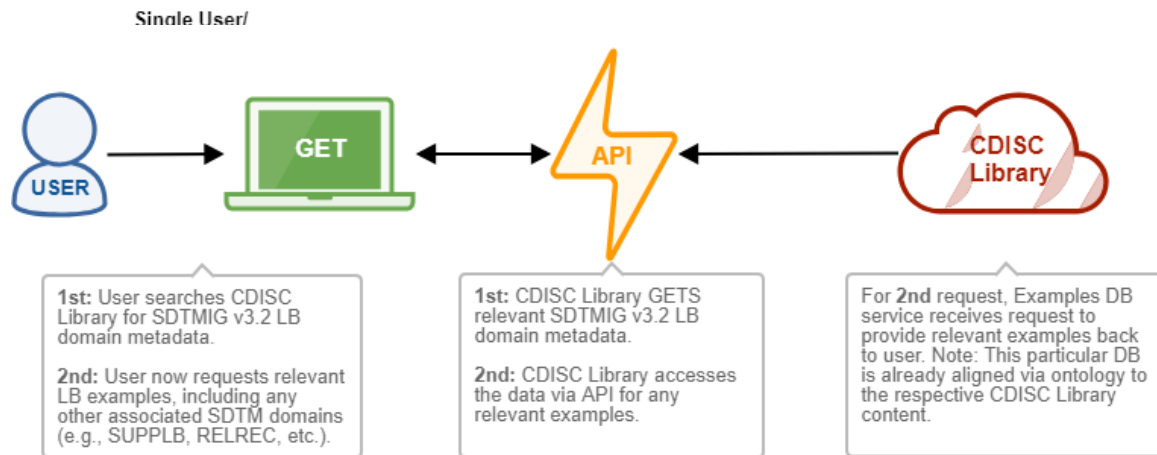
CT 2018 Q4

CT 2019 Q1

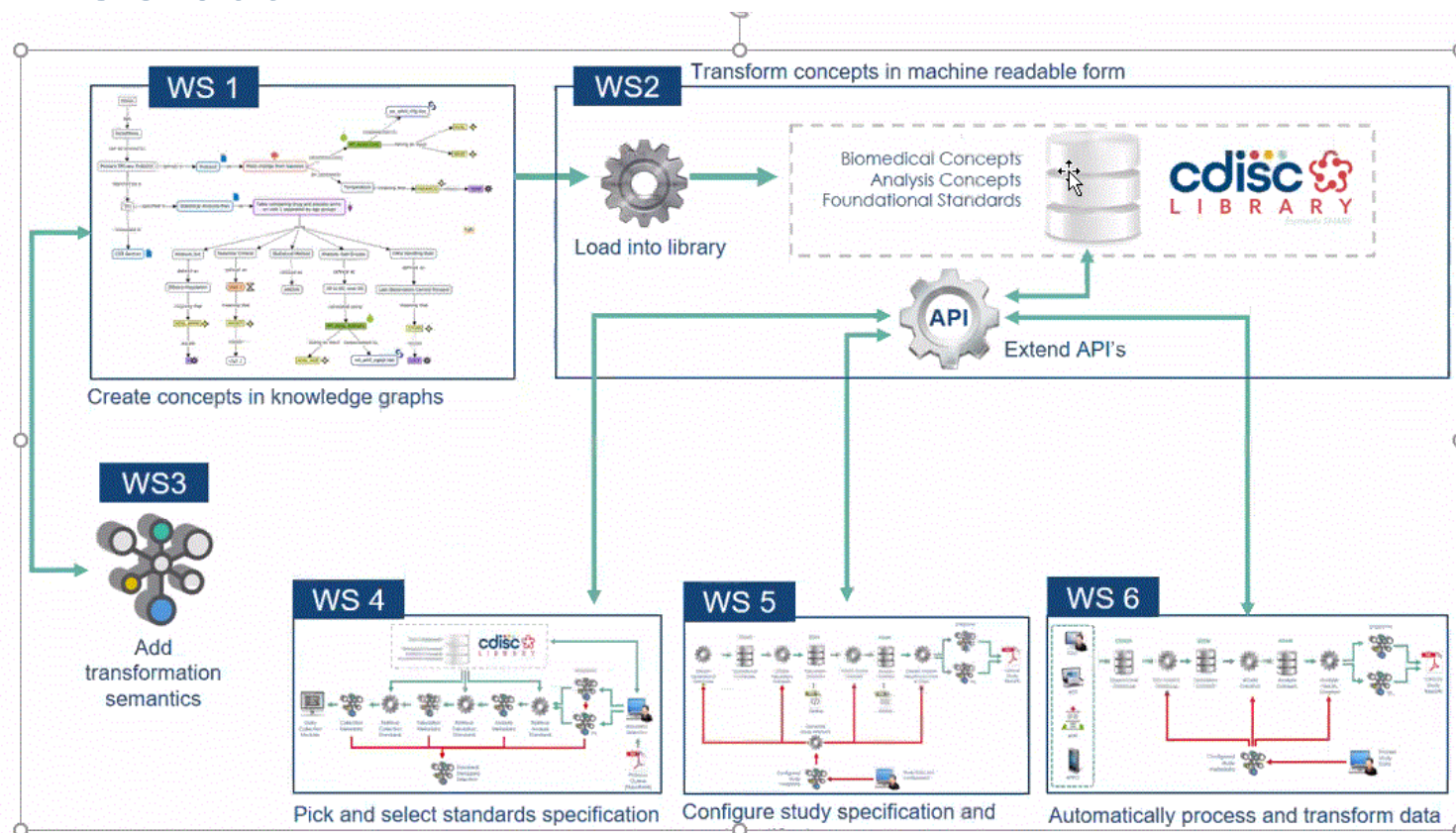
CT 2019 Q2

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Library Access through APIs



CDISC 360



Therapeutic Area User Guides

Autoimmune

Psoriasis
Rheumatoid Arthritis

Cardiovascular

Cardiovascular
Heart Failure
QT Studies
Traditional Chinese Medicine - Coronary Artery Disease/Angina

Endocrine

Acute Kidney Injury
Diabetes
Diabetes - Type 1
Diabetic Kidney Disease
Dyslipidemia
Kidney Transplant
Polycystic Kidney Disease

Gastrointestinal

CDAD
Crohn's Disease

Infectious

Ebola
Hepatitis C
HIV
Influenza
Malaria
Tuberculosis
Virology

Mental Health

Major Depressive Disorder
Post Traumatic Stress Disorder
Schizophrenia

Neurology

Alzheimer's
Multiple Sclerosis
Parkinson's Disease
Traumatic Brain Injury

Oncology

Breast Cancer
Colorectal Cancer
Lung Cancer
Prostate Cancer

Rare Diseases

Duchenne Muscular Dystrophy
Huntington's Disease

Respiratory

Asthma
COPD

Treatments

Pain
Vaccines

Other

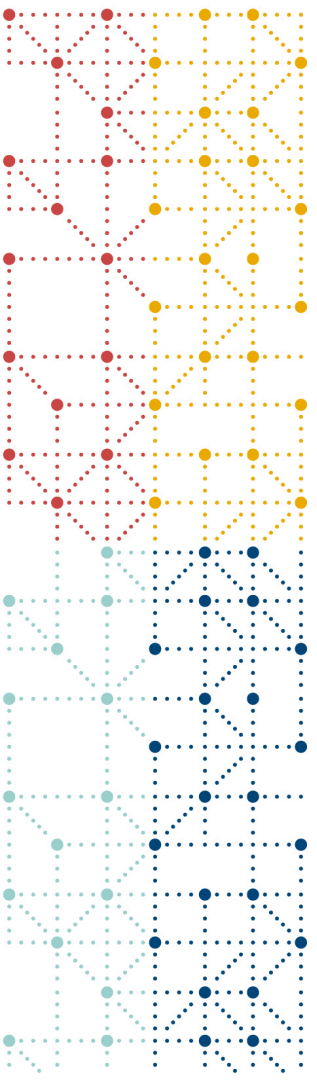
Nutrition
Traditional Chinese Medicine - Acupuncture

CDASH

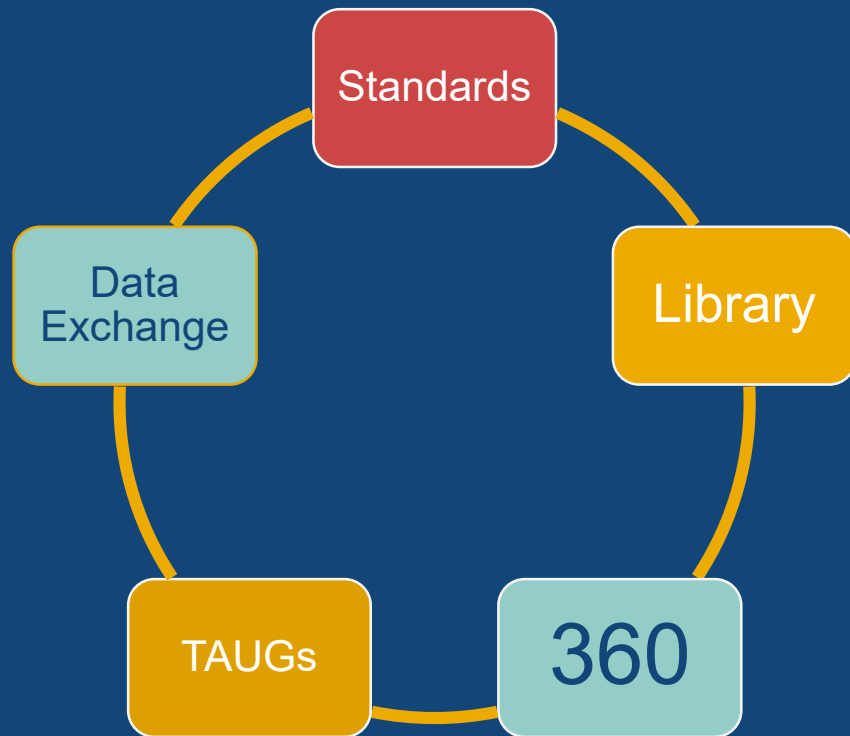
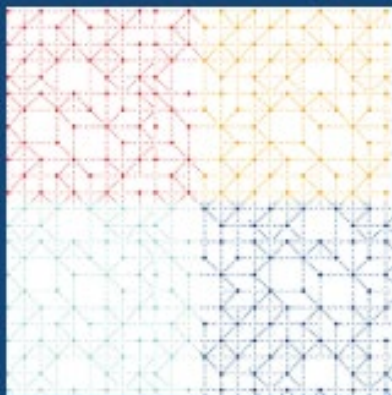
SDTM

ADaM





cdisc
Clear Data. Clear Impact.





Thank You!

