



CDISC 360:

Evolving our standards towards end to end automation

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Sam Hume
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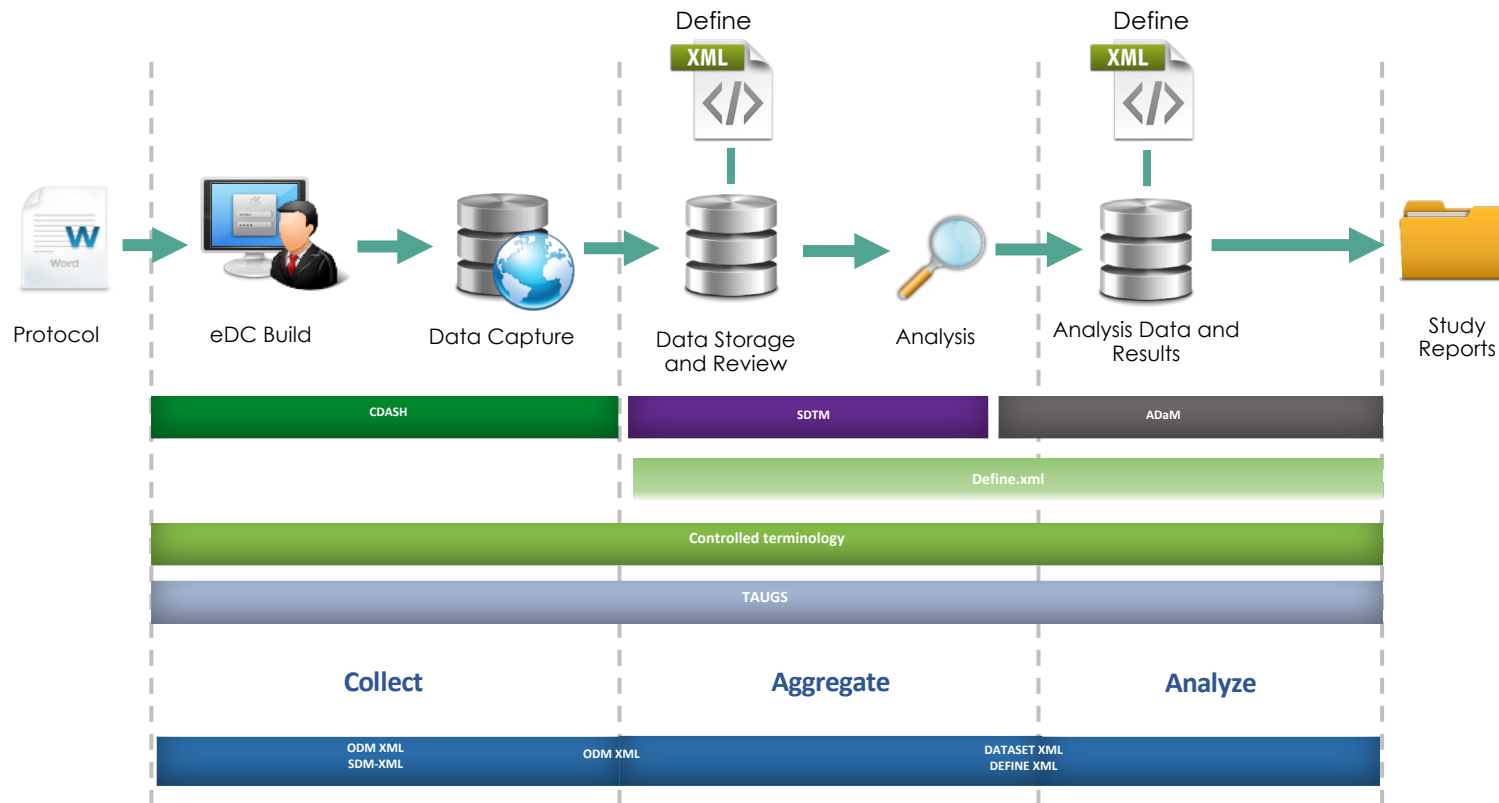
Agenda

1. Where are we today
2. Approach
3. Logistics
4. Relationship to Other Initiatives
5. Expected outcomes



1. Where are we today

Today we are here



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

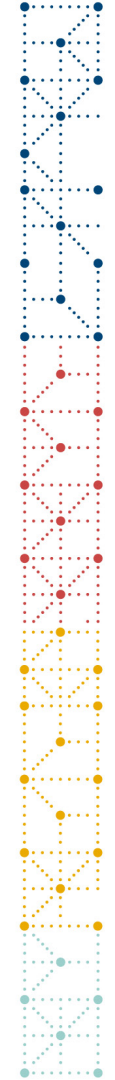
- We do not need new structures
- We need to define
 - Entities
 - Semantics (meaning)
 - Relationships between information
 - Rules in the data lifecycle

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	Performed/Observation 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.	0
2 On what date were the measurements performed?	Date	VSDAT	Performed/Activity 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 SDTMIG variable VSSTAT is derived from a "No" value in VSPERF. This field does not map directly to an SDTM variable.	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
VSRPID	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 VTEST. 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.



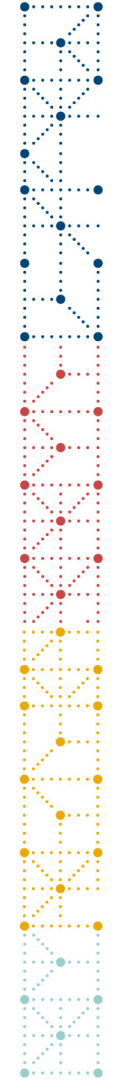
Why Change?

Industry needs are maturing

- Machine-readable standards
- Move beyond normative structural description of data
- Provide semantic relations between data – add meaning
- Add process metadata to enable end-to-end automation
- We want non-standard experts to use our standards



2. Approach



What is the CDISC 360 Project?

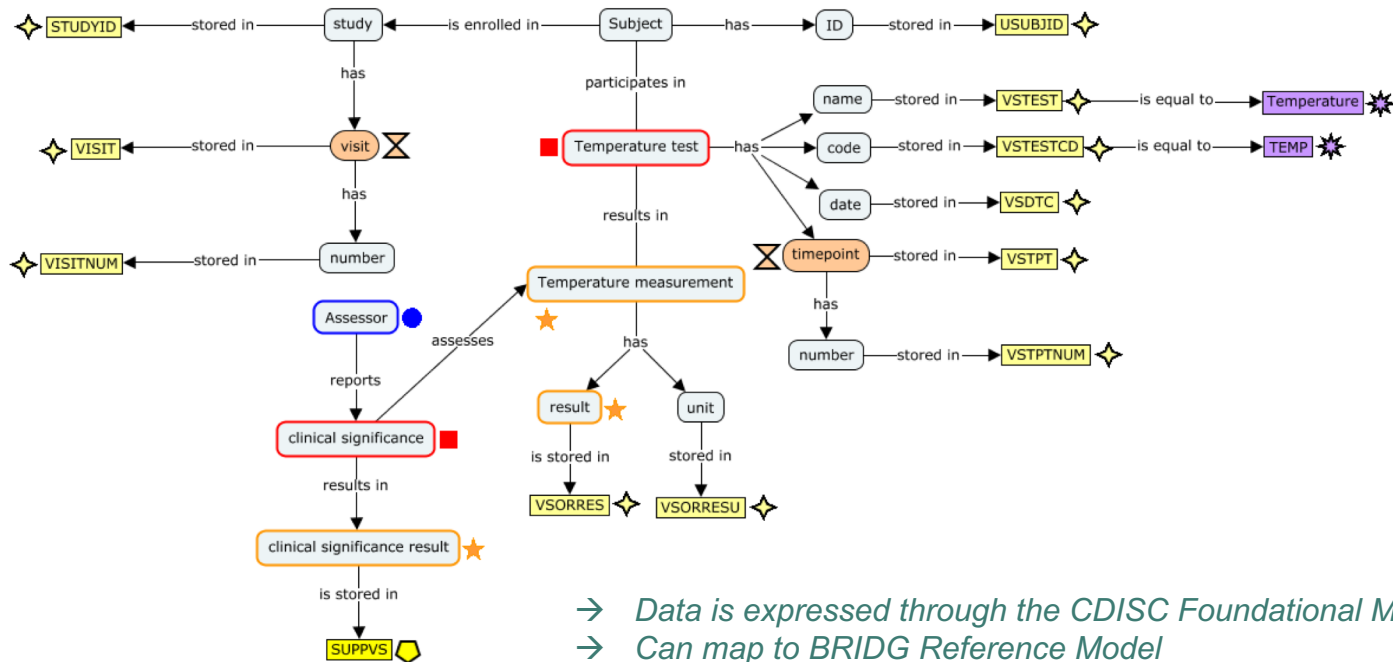
Adding a conceptual layer to standards

- Create and store standards as concepts which create meaning between data
- A serious attempt to store and use data standards as linked metadata
- Add computer readable process metadata which enables end to end automation
- Evolve from normative to informative standards
- CDISC 360 will develop concept-based standard definitions, and test and demonstrate end-to-end automation of study specification and data processing

➔ *Test and demonstrate, but **not building software***

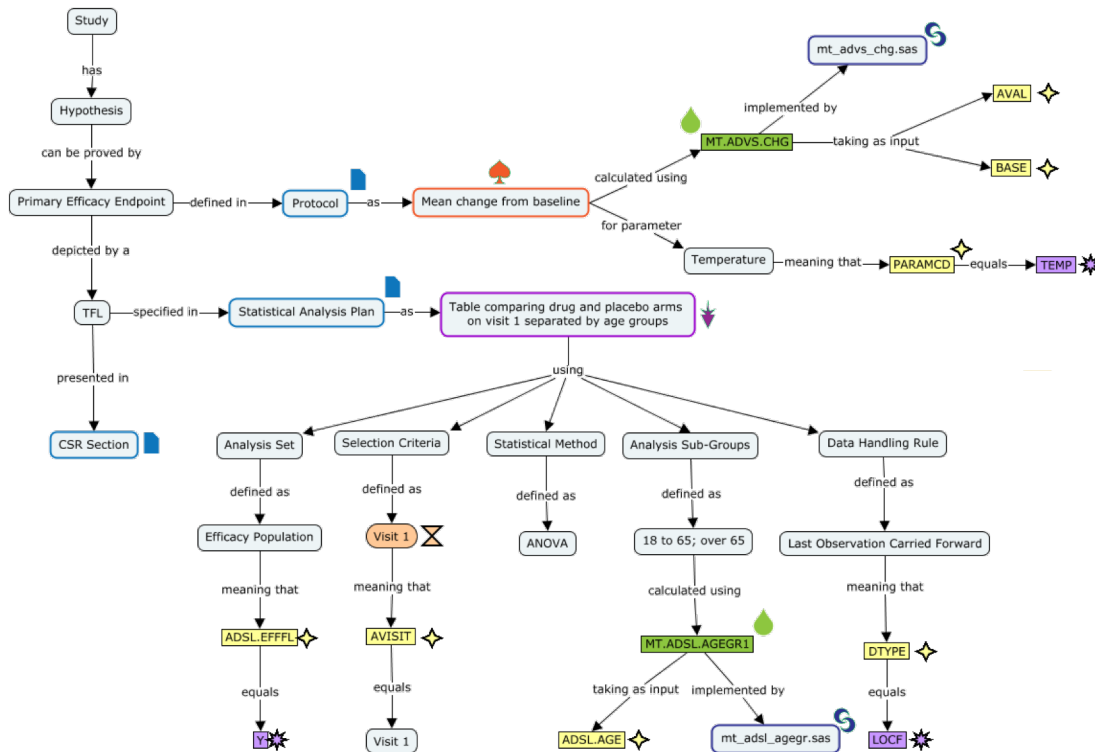
Store Standards in Concept Maps 1/2

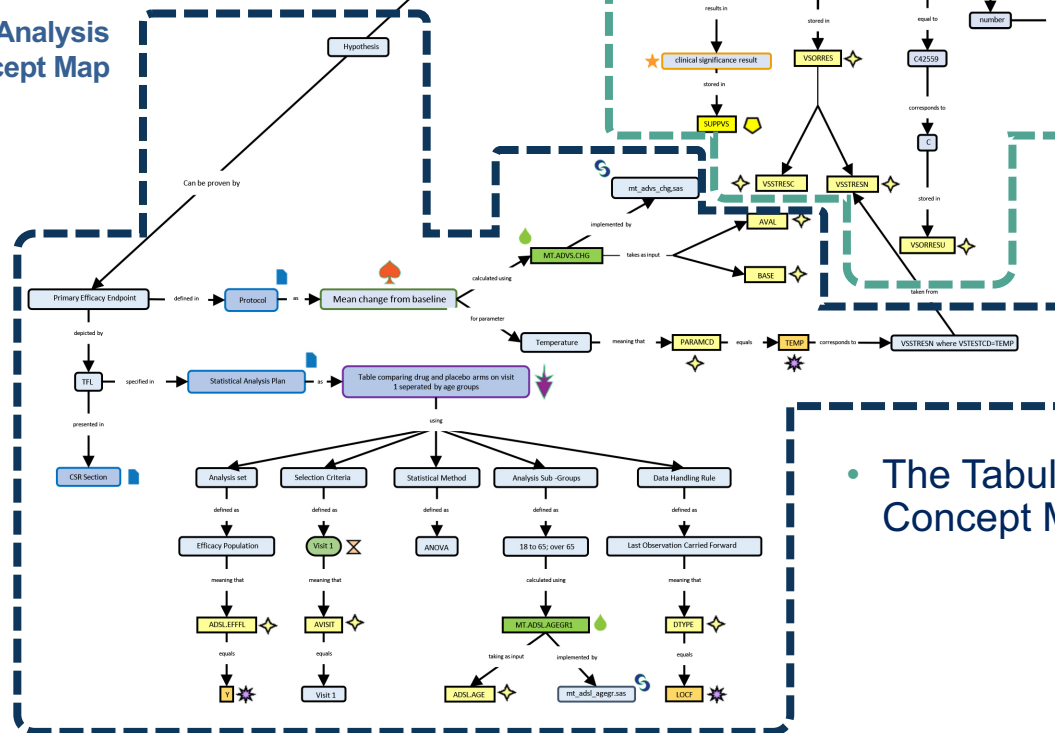
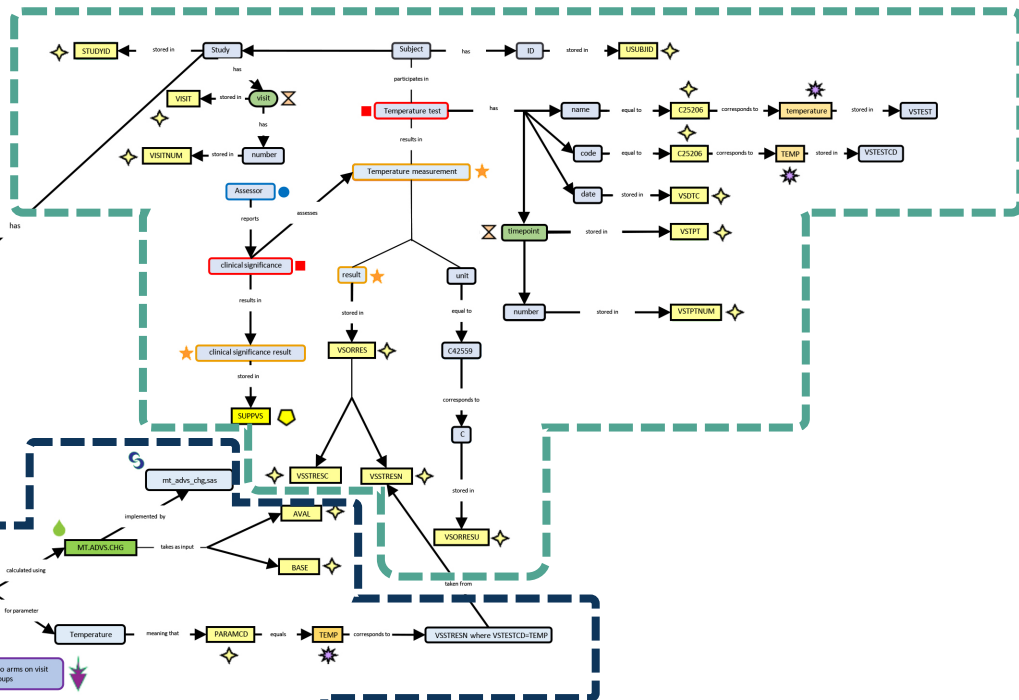
- Example of biomedical concept



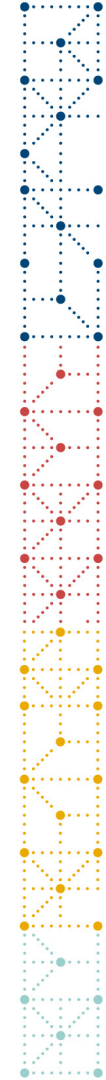
Store Standards in Concept Maps 2/2

- Example of statistical concept





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



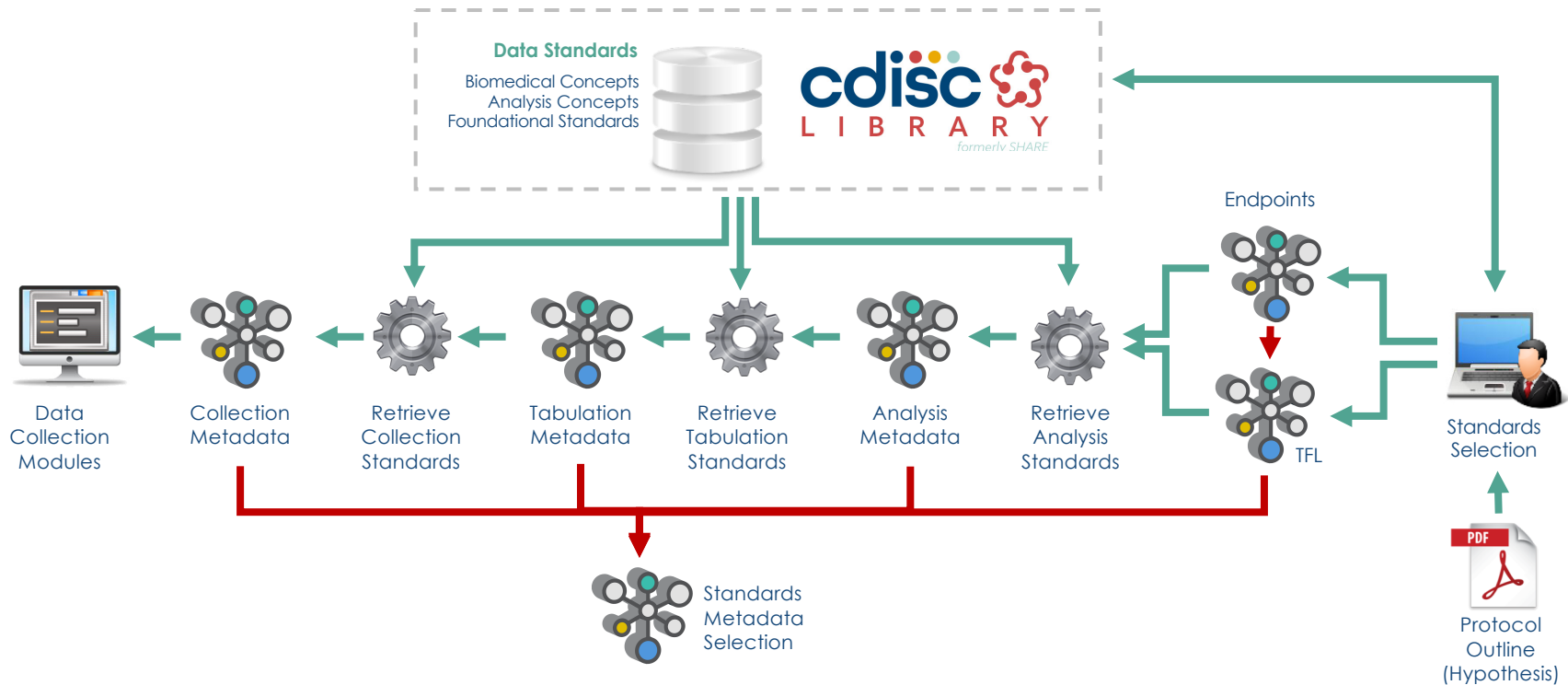
The Power of a Conceptual Model for Data Standards

- Linking controlled terminology to the variable – standardize value level metadata
- Machine readable definition of validation rules
- Linking derivations and algorithms to variable(s)
 - Include process metadata (ETL instructions)
- Possibility to standardize Analysis outputs and Collection instruments
 - Combining layout, variables, process information together
- Link Analysis Concepts to Biomedical Concepts
 - Choose an analysis and automatically obtain all related end-to-end metadata

→ **All of the above:** enables automation, increase confidence in results, true analysis traceability

Use Case 1 : End to Start Specification

Selecting standards concepts and linked metadata needed for a study





DISCLAIMER NOTE

The following is not a software demonstration

*Sole purpose is to illustrate how data
standards can enable tools*

Welcome

Login: CDarwin

Password: *****

SIGN IN >>





CDASH

DOMAIN
CDASH Variable
Value Level Metadata
Controlled Terminology

SDTM

DOMAIN
SDTM Variable
Value Level Metadata
Controlled Terminology
Computational algorithm

ADaM

DOMAIN
ADaM Variable
ADaM Parameters
Controlled Terminology
Computational algorithm

AE
Adverse
Events

EX
Exposure

CM
Concomitant
Medication

MH
Medical
History

VS
Vital Signs

LB
Laboratory
Test Results



Tables



Figures



Listings



End Points



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SELECTION

DATA
COLLECTION

ANALYSIS



Figures

Graphical Approaches to the Analysis of Safety Data from Clinical Trials". Amit, et. al.

From "Graphical Approaches to the Analysis of Safety Data from Clinical Trials". Amit, et. al.

Mean Change from Baseline in QTc by time and treatment.

Distribution of ASAT by time and treatment

Distribution of maximum LFT values by treatment.

Panel of LFT shift from baseline to maximum by treatment

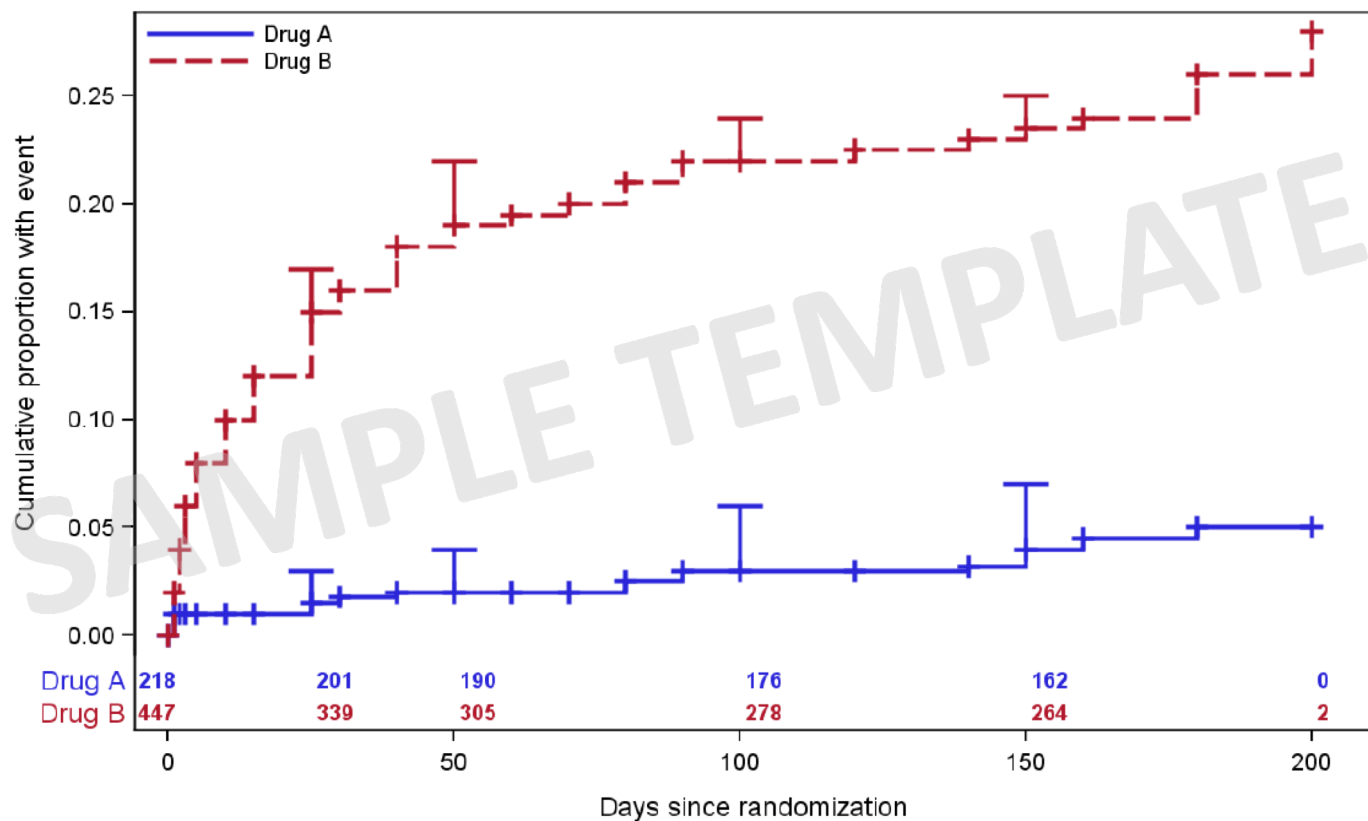
LFT Patient profiles

Most Frequent On Therapy Adverse Events

Cumulative distribution (with SEs) of time to first AE of special interest



Cumulative Distribution of Time to First AE





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Listings

Listing 2.4 Current Cancer History – All Treated Patients Experiencing Critical Events

Listing 2.5 Prior and Concomitant Medication – All Treated Patients Experiencing Critical Events

Listing 2.6 Physical Examination at Screening – All Treated Patients Experiencing Critical Events

Listing 3.1 Reference Chemotherapy and Concomitant Chemotherapies – All Treated Patients Experiencing ..

Listing 4.1 Adverse Event Listing. All Pre-Treatment Adverse Events – All Treated Patients Experiencing ...

Listing 4.2 Adverse Event Listing. Treatment Emergent Adverse Events – All Treated Patients Experiencing ...

Listing 4.3 Adverse Event Listing. Serious Treatment Emergent Adverse Events – All Treated Patients ..

Listing 4.4 Adverse Event Listing. Serious Treatment Emergent Adverse Events Related To Study Drug ...

Listing 4.5 Adverse Event Listing. Serious Treatment Emergent Adverse Events Related To Treatment



Listing 4.5 Adverse Event Listing. Serious Treatment Emergent Adverse Events Related To "Treatment" - All Treated Patients Experiencing Critical Events

Country	Site/ Patient ID	AE Verbatim Term MedDRA SOC Name MedDRA Preferred Term	Start Date/Time Stop Date/Time Duration (Days/Hours)	Day of onset	Occurrence	Intensity CTC grade	Relationship to Dexamethasone	Action Taken	Outcome
XXXXXXXX	XX/XXX	XXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXX	DDMMYYYY/HH:MM DDMMYYYY/HH:MM XXXXXX/XXXXXX	XX	Intermittent	Grade X	Possibly	None	Resolved

Analysis dataset: ADAE.SAS7BDAT ddmmmyyyy hh:mm

Note: Critical events are defined as: Serious Adverse Events (extracted from the clinical database reconciled with the safety database), Suspected Unexpected Serious Adverse Reactions (extracted from the safety database), wrong study medication used (patients who received a wrong medication kit by mistake in one cycle, resulting in the administration of drug from both treatment groups during the study).

Note: "Treatment" related adverse events are adverse events with a missing relationship to "Treatment" or assessed by the Investigator as definite, probable, possible or unassessable.

Program: <DIRECTORY PATH>\XXXXXX.sas; Date & Time program was run: ddmmmyyyy hh:mm; Date & Time analysis dataset was run: ddmmmyyyy hh:mm



SELECT



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Filter active: ADAE Domain



CDASH

DOMAIN
CDASH Variable
Value Level Metadata
Controlled Terminology

SDTM

DOMAIN
SDTM Variable
Value Level Metadata
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Computational algorithm

ADaM

DOMAIN
ADaM Variable
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Computational algorithm

ADaM

[Domain](#)[Variables](#)[Computational Algorithm](#)[SELECTION](#)[DATA
COLLECTION](#)[ANALYSIS](#)[Dataset](#)[Description](#)

ADAE

One record per subject per adverse event, per date



Related metadata: [SDTM](#)

[Domain](#)[Variables](#)[Computational Algorithm](#)[CDASH](#)[Domain](#)[Variables](#)[DCM](#)[Tables](#)[Figures](#)[Listings](#)



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CDASH Variable
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Controlled Terminology

SDTM

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SDTM Variable
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ADaM Variable
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Computational algorithm

ADaM

Domain

Variables

Computational Algorithm

DomainNameLabelComputational Algorithm

ADAE	USUBJID	Unique Subject Identifier	
ADAE	SUBJID	subject identifier for the study	
ADAE	SITEID	Study Site identifier	
ADAE	DOSEAEONU	Study Drug Dose at AE Onset Units	ADAE.DOSEAEONU
ADAE	DOSEAEON	Study Drug Dose at AE Onset	ADAE.DOSEAEON
ADAE	COUNTRY	Country	
ADAE	ASTTM	Analysis Start Time	ADAE.ASTTM
ADAE	ASTDT	Analysis Start Time	ADAE.ASTDT
ADAE	AETERM	Reported Term for the Adverse Events	

X



SELECTION

DATA
COLLECTION

ANALYSIS

Related metadata: SDTM

Domain

Variables

Computational Algorithm

CDASH

Domain

Variables

DCM

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Figures

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Computational algorithm

ADaM

Domain

Variables

Computational Algorithm



SELECTION

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ANALYSIS

Reference

Description

ADAE.AENDT	Equals to % SDTM_DATE_VARIABLE % transformed into % DATE_NUMERIC_FORMAT% when length (%SDTM_DATE_VARIABLE%) > 9
ADAE.ADURN	Equals to ADAE.AENDT – ADAE.ASTDT + 1.
ADAE.DOSEAEON	Equals to EX.EXDOSE where the numeric version of EX.EXSTDTC <= ASTDT <= the Numeric version of EX.EXENDTC.
ADAE.DOSEAEONU	Equals to EX.EXDOSU where the numeric version of EX.EXSTDTC <= ASTDT <= the Numeric version of EX.EXENDTC.
ADAE.DOSEAEON	Equals to "DAYS"

x

Related metadata: SDTM

Domain

Variables

Computational Algorithm

CDASH

Domain

Variables

DCM

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ADaM Variable
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Computational algorithm

ADaM

Domain

Variables

Computational Algorithm



SELECTION

DATA
COLLECTION

ANALYSIS

Reference

Description

ADAE.DOSEAEON	Equals to EX.EXDOSE where the numeric version of EX.EXSTDTC <= ASTDT <= the Numeric version of EX.EXENDTC.
---------------	--



Name Label Origin Role Core

AESTDTC	Start date/Time of Adverse Event	CRF	Timing	Exp
EXDOSE	Dose per administration	Derived	Record Qualifier	Exp
EXTDTC	Start date/Time of treatment	CRF	Timing	Exp
EXENDTC	End date/Time of treatment	CRF	Timing	Perm



Domain Name Question

AE	AESTDAT	Start Date
AE	AESTIM	Start Time
EX	EXAMONT	Dose
EX	EXAMONTU	Units
EX	EXENDAT	End Date
EX	EXENTIM	End Time
EX	EXSTDAT	Start Date

Related metadata: SDTM

Domain

Variables

Computational Algorithm

CDASH

Domain

Variables

DCM

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SDTM

DOMAIN
 SDTM Variable
 Value Level Metadata
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 Computational algorithm

ADaM

DOMAIN
 ADaM Variable
 ADaM Parameters
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ADaM Domain Variables Computational Algorithm

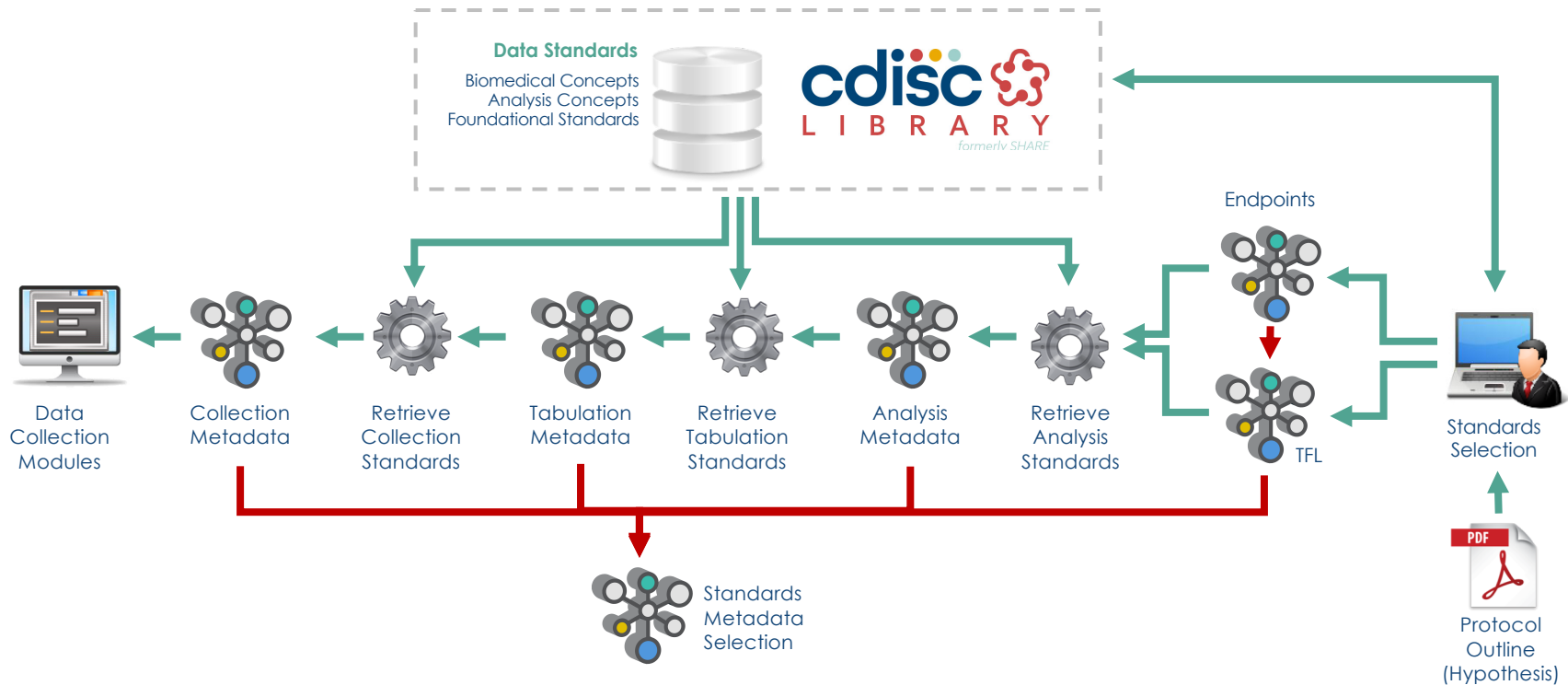


ADaM	ADaM	ADaM	ADaM	ADaM
ADaM ADaM Variable ADaM Parameters Controlled Terminology Computational algorithm	ADaM ADaM Variable ADaM Parameters Controlled Terminology Computational algorithm	ADaM ADaM Variable ADaM Parameters Controlled Terminology Computational algorithm	ADaM ADaM Variable ADaM Parameters Controlled Terminology Computational algorithm	ADaM ADaM Variable ADaM Parameters Controlled Terminology Computational algorithm



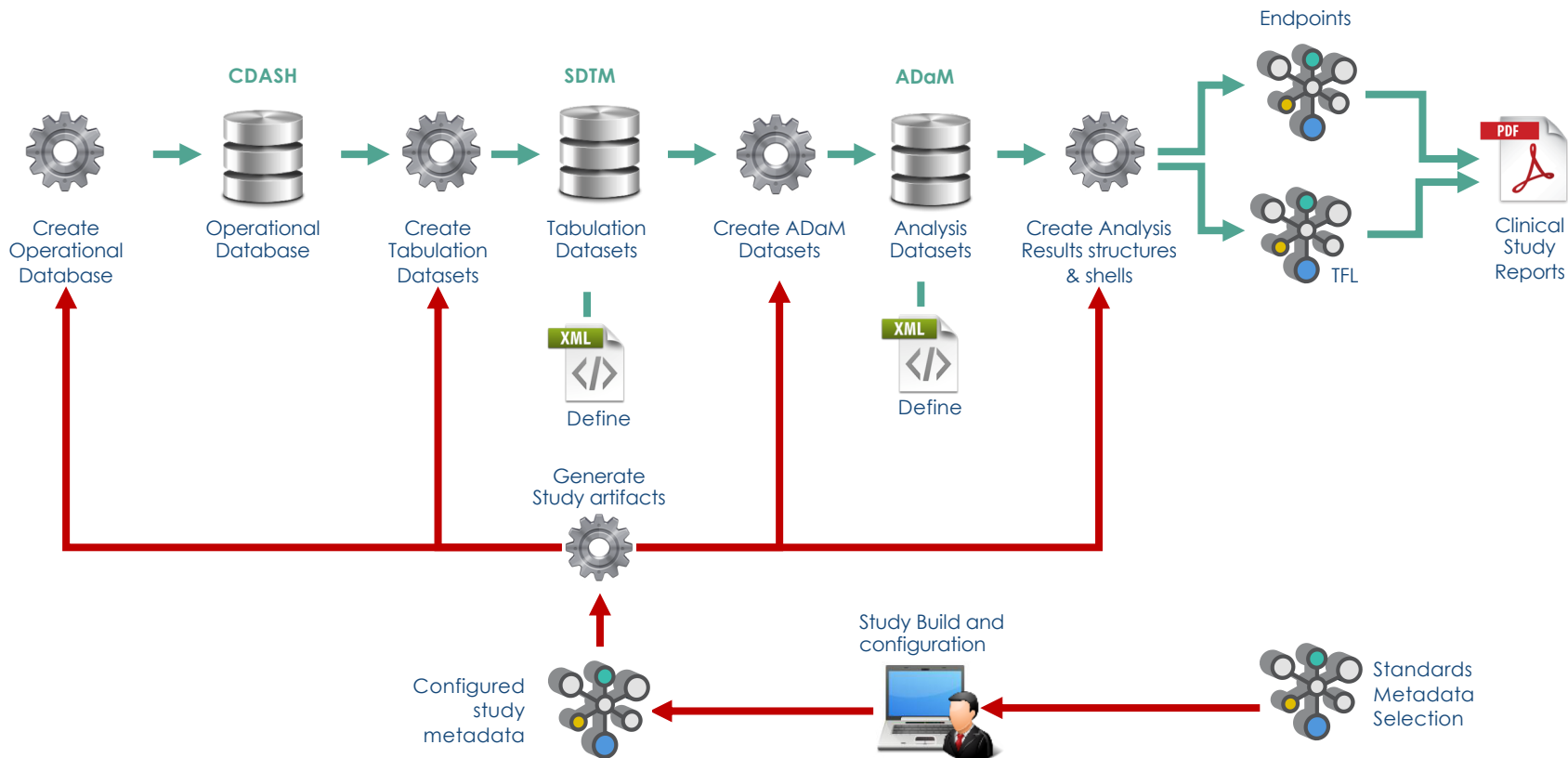
Use Case 1 : End to Start specification

Selecting standards concepts and linked metadata needed for a study



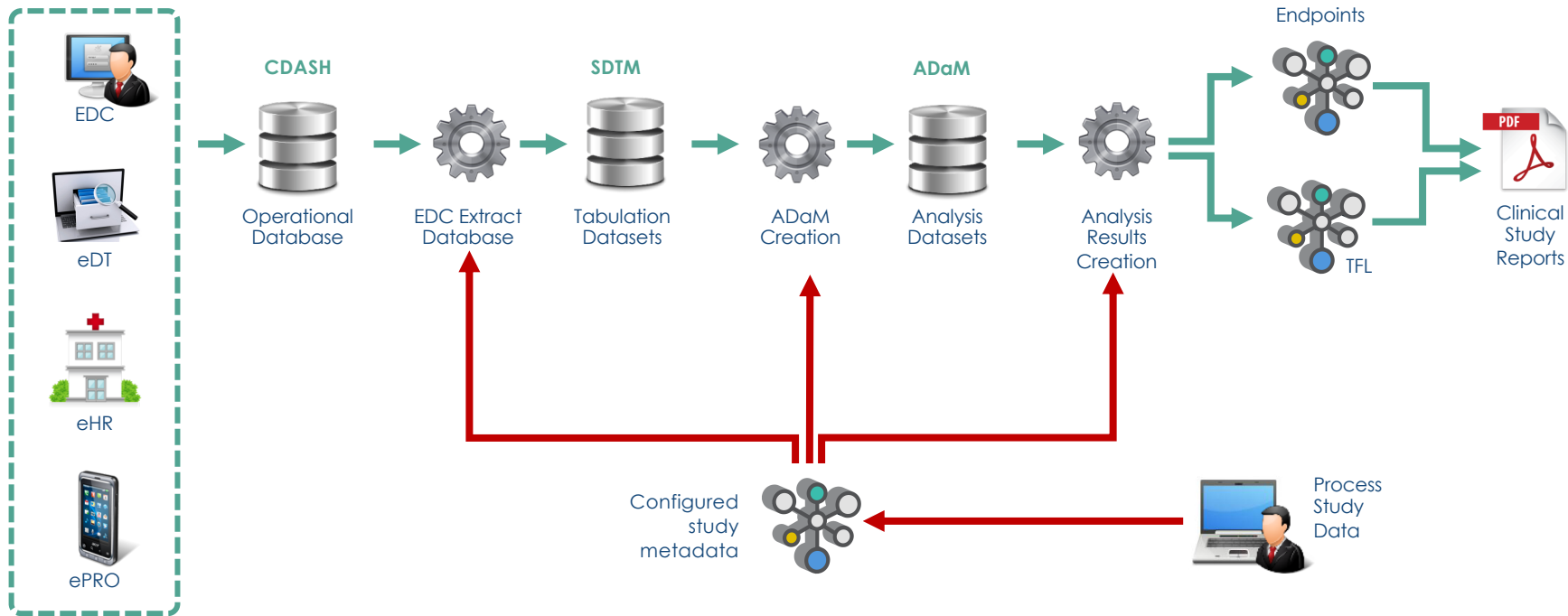
Use Case 2 : Start to End Study Metadata

Adding study design, concept configuration & generate artifacts



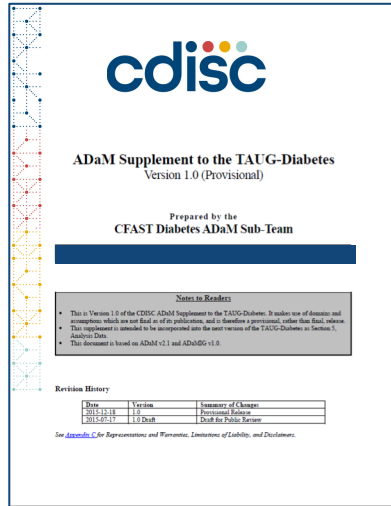
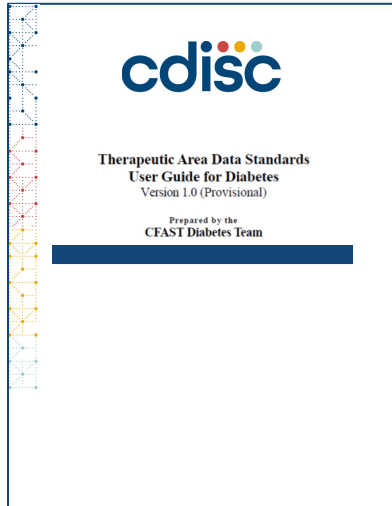
Use Case 3 : Start to End Data Processing

Automatic population of data into artifacts



Project Standards Scope

Diabetes TAUG



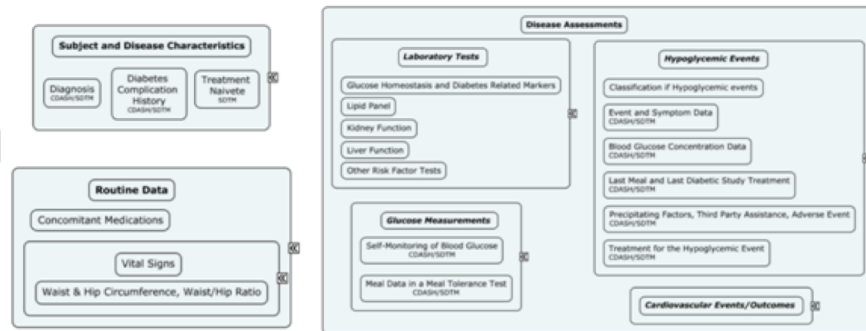
- 1 or 2 statistical endpoints
- 3 to 4 ADaM datasets
- 7 to 8 SDTM datasets
- 15 Data Collection Modules

→ Reason for this scope: the Diabetes TAUG provides standardized artifacts from analysis outputs to data collection. This allows the project team to focus on innovation and not on establishing a new data standard.

Diabetes TAUG

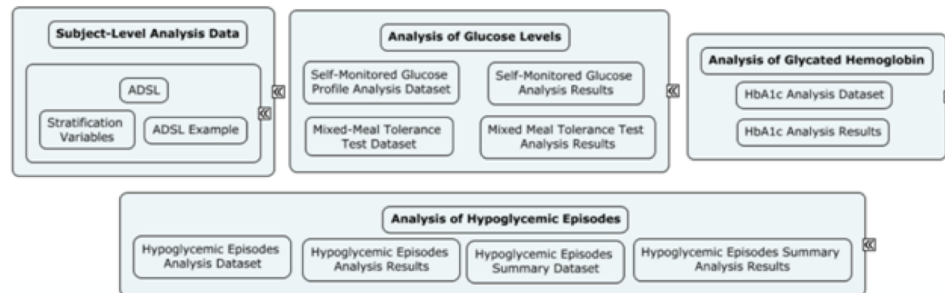
Diabetes V1

Diabetes Version 1.0
Released Aug 2014

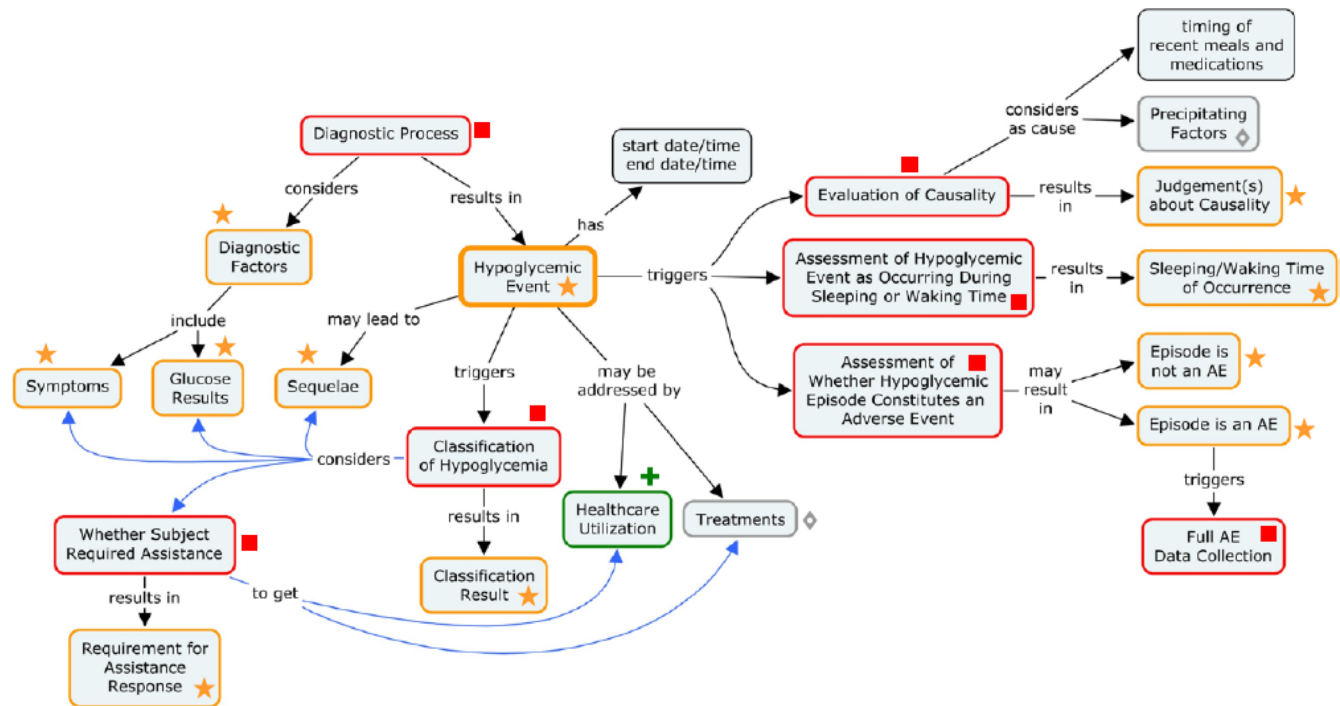


Diabetes ADaM V1

Diabetes ADaM Supplement
Released Dec 2015



Biomedical Concept Map



Analysis Results Shells

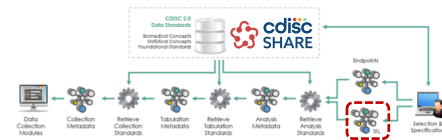


Table 3.2.1: Summary of Post-Meal Hypoglycemic Episodes by Severity – Table Shell
Hypoglycemic episodes within 2 hours since last meal by severity
Summary – Safety Analysis Set

	Drug A			Drug B		
	N	(%)	E	N	(%)	E
Number of subjects	xxx			xx		
Diurnal	xxx	(xx.x)	xxx	xx	(xx.x)	xxx
Documented Symptomatic	xx	(xx.x)	xx	xx	(xx.x)	xx
Pseudo Symptomatic	xx	(xx.x)	xx	xx	(xx.x)	xx
Probable Symptomatic	x	(xx.x)	xx	x	(x.x)	x
Nocturnal	x	(x.x)	x	x	(x.x)	x
Documented Symptomatic	x	(x.x)	x	x		
Probable Symptomatic	x			xx	(x.x)	x

N: Number of subjects; %: Percentage of subjects; E: Number of events

Analysis Dataset Metadata

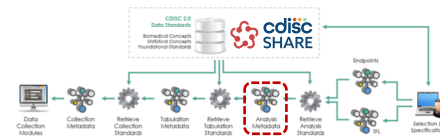


Table 3.3.1: ADHYSUM Analysis Dataset

Row	STUDYID	USUBJID	PARAMCD	PARAM	AVISIT	AVAL	TRTDURD	SEX	AGE	COUNTRY	TRTA
1	XYZ	000008	ASSYMP	Asymptomatic Hypoglycemia (frequency count)	Week 1	3	72	F	35	DZA	Drug B
2	XYZ	000008	ASSYMP	Asymptomatic Hypoglycemia (cumulative frequency count)	Week 1	3	72	F	35	DZA	Drug B
3	XYZ	000008	ASSYMP	Asymptomatic Hypoglycemia (frequency count)	Week 2	1	72	F	35	DZA	Drug B
4	XYZ	000008	ASSYMP	Asymptomatic Hypoglycemia (cumulative frequency count)	Week 2	4	72	F	35	DZA	Drug B
5	XYZ	000008	ASSYMP	Asymptomatic Hypoglycemia (frequency count)	Week 3	0	72	F	35	DZA	Drug B
6	XYZ	000008	ASSYMP	Asymptomatic Hypoglycemia (cumulative frequency count)	Week 3	4	72	F	35	DZA	Drug B
7	XYZ	000008	ASSYMP	Asymptomatic Hypoglycemia (frequency count)	Week 4	1	72	F	35	DZA	Drug B
8	XYZ	000008	ASSYMP	Asymptomatic Hypoglycemia (cumulative frequency count)	Week 4	5	72	F	35	DZA	Drug B
10	XYZ	000008	ASSYMP	Asymptomatic Hypoglycemia (cumulative frequency count)	End of Treatment	7	72	F	35	DZA	Drug B
...	...	...	...	...	...	...	...	...	...	...	...
20	XYZ	000008	DOCSEVC	Documented Symptomatic or Severe Hypoglycemia (cumulative frequency count)	End of Treatment	17	72	F	35	DZA	Drug B

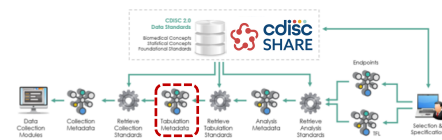
Table 3.3.2: ADHYSUM Dataset Metadata

Dataset Name	Dataset Description	Dataset Location	Dataset Structure	Keys	Class	Documentation
ADHYSUM	Hypoglycemic Episodes Summary Data	ADHYSUM.xpt	One record per subject per analysis visit per parameter	STUDYID, USUBJID, AVISIT, PARAMCD	BDS	ADHYSUM.SAS/SAP

Table 3.3.3: ADHYSUM Variable Metadata

Variable Name	Variable Label	Type	Length/Display Format	Codelist/Controlled Terms	Source/Derivation/Comment
STUDYID	Study Identifier	text	\$12		ADSL STUDYID
USUBJID	Unique Subject Identifier	text	\$20		ADSL USUBJID
PARAMCD	Parameter Code	text	\$8		See parameter value metadata. Note that the tables below do not present all possible values for PARAMCD but only those that correspond to the data display.
PARAM	Parameter	text	\$80		See parameter value metadata. Note that the tables below do not present all possible values for PARAM but only those that correspond to the data display.
AVISIT	Analysis Visit	text	\$13	Week -1; Week 0; Week 1; Week N; End of Treatment	Refer to Section X.X of the SAP for windowing and imputation algorithms based on ADHYPO.ADY. End-of-treatment is defined as the last week during which the subject is on treatment.
AVAL	Analysis Value	integer	8		See parameter value metadata.
TRTDURD	Total Treatment Duration (Days)	integer	8		ADSL TRTDURD
SEX	Sex	text	\$1		ADSL SEX
AGE	Age	integer	8		ADSL AGE
COUNTRY	Country	text	\$3		ADSL COUNTRY
TRTA	Actual Treatment	text	\$32		ADSL TRT01A

Tabulation Metadata



Row	STUDYID	DOMAIN	USUBJID	CESEQ	CECAT	CETERM	CEDECOD	CEPRES	CEOCCUR	CESTDTC	CESTDY
2	XYZ	CE	XYZ-001-001	2	HYPO SYMPTOMS	SWEATING	Hyperhidrosis	Y	N		
3	XYZ	CE	XYZ-001-001	3	HYPO SYMPTOMS	TREMORS/TREMBLING	Tremor	Y	N		
4	XYZ	CE	XYZ-001-001	4	HYPO SYMPTOMS	DIZZINESS	Dizziness	Y	N		
5	XYZ	CE	XYZ-001-001	5	HYPO SYMPTOMS	COGNITIVE IMPAIRMENT	Cognitive Disorder	Y	Y		
6	XYZ	CE	XYZ-001-001	6	HYPO SYMPTOMS	LOSS OF CONSCIOUSNESS	Loss of Consciousness	Y	Y		
7	XYZ	CE	XYZ-001-001	7	HYPO SYMPTOMS	CONVULSIONS/SEIZURES	Convulsion	Y	N		
8	XYZ	CE	XYZ-001-001	8	HYPO SYMPTOMS	COMA	Coma	Y	N		
9	XYZ	CE	XYZ-001-001	9	HYPO EVENTS	HYPOGLYCEMIC EVENT	Hypoglycaemia			2013-09-24T08:48	50

Row	RELMIDS	MIDS	MIDS DTC
1 (cont)		HYPO 1	
2 (cont)	DURING	HYPO 1	2013-09-01T11:00
3 (cont)	DURING	HYPO 1	2013-09-01T11:00
4 (cont)	DURING	HYPO 1	2013-09-01T11:00
5 (cont)	DURING	HYPO 1	2013-09-01T11:00
6 (cont)	DURING	HYPO 1	2013-09-01T11:00
7 (cont)	DURING	HYPO 1	2013-09-01T11:00
8 (cont)	DURING	HYPO 1	2013-09-01T11:00
9 (cont)		HYPO 2	

suppce.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
1	XYZ	CE	XYZ-001-001	CESEQ	1	WHEOCC	When did the hypoglycemic event occur?	BETWEEN BEDTIME AND WAKING
2	XYZ	CE	XYZ-001-001	CESEQ	8	WHENOCC	When did the hypoglycemic event occur?	BETWEEN BEDTIME AND WAKING

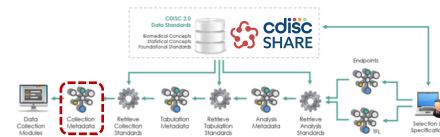
lb.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	LBSEQ	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU
1	XYZ	LB	XYZ-001-001	GLUCOSE METER	1	GLUC	GLUCOSE	60	mg/dL	3.3	3.3	mmol/l
2	XYZ	LB	XYZ-001-001	GLUCOSE METER	2	GLUC	GLUCOSE	65	mg/dL	3.6	3.6	mmol/l

ml.xpt

Row	STUDYID	DOMAIN	USUBJID	MLSEQ	MLTRT	MLSTDTC	RELMIDS	MIDS	MIDS DTC
1	XYZ	ML	XYZ-001-001	1	MEAL	2013-08-31T20:00	LAST MEAL PRIOR TO	HYPO 1	2013-09-01T11:00
2	XYZ	ML	XYZ-001-001	2	MEAL	2013-09-23T22:30	LAST MEAL PRIOR TO	HYPO 2	2013-09-24T08:48

Collection Metadata



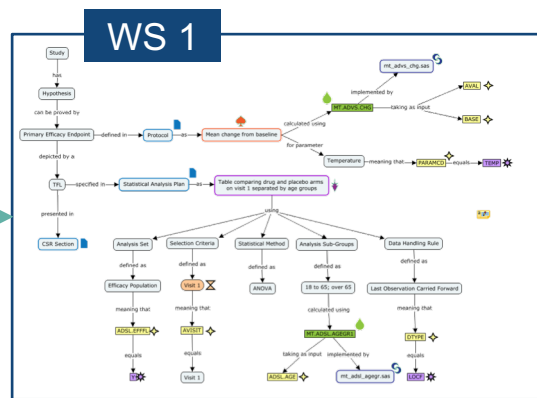
Example CRF 5: Hypoglycemia

CETBM= Hypoglycemic Event CECAT= HYPO EVENTS	
Any Hypoglycemic Events Experienced?	No Yes (If yes complete for each event) CEYN
Sponsor Defined ID	CESPID 001
Date/Time of Event	---- (DD-MMM-YYYY) - - - - (24 hour clock) CESTDAT CESTIM
When Did the Hypoglycemic Event Occur?	Between Bedtime and Waking Between Waking and Bedtime QVAL when QNAM= WHENOCOC and QLABEL= "When Did the Hypoglycemic Event Occur?"
In the Opinion of the Investigator Was This an Adverse Event?	No WASAEYN FAORRES where FATESTCD= "WASAEYN", FATEST= "Was this an adverse event?" and FAOB= "HYPOGLYCEMIC EVENT" Yes
Was a Glucose Measurement Obtained at the Time of the Event?	Yes (If yes enter result and unit below) LBPERF ---- Glucose Result mg/dL LBORRES mmol/L LBORRESU
Last Study Medication Taken	-----Name/Reference EXTRY
EXCAT= HIGHLIGHTED DOSE	EXSTDTC ---- (DD-MMM-YYYY) - - - - (24 hour clock) EXSTDAT EXSTTIM
	--- dose EXDOSE EXDSTXT
	--- units
Last Concomitant Diabetic Medication Taken	-----Name/Reference CMTRY
CMCAT= ANTI-HYPERGLYCEMIC MED	CMSTDTC ---- (DD-MMM-YYYY) - - - - (24 hour clock) CMSTDAT CMSTTIM
CMSCAT= HIGHLIGHTED DOSE	--- dose CMDOSE CMDSXTXT
	--- units CMDOSEU
Date/Time of Last Meal	---- (DD-MMM-YYYY) - - - - (24 hour clock) MLSTDAT MLSTTIM
Were Signs/Symptoms Present?	No Yes (If yes complete following) CEYN
CECAT= HYPO SYMPTOMS	
CETERM= SWEATING	Sweating No Yes CEOCOCUR WITH CEPRESPLY
CETERM= TREMORS/TREMBLING	Tremors/Trembling No Yes
CETERM= DIZZINESS	Dizziness No Yes
CETERM= COGNITIVE IMPAIRMENT	Cognitive Impairment No Yes
CETERM= LOSS OF CONSCIOUSNESS	Loss of Consciousness No Yes
CETERM= CONVULSIONS/SEIZURE	Convulsions/Seizure No Yes
CETERM= COMA	Coma No Yes
	Other (Specify) No Yes (if yes enter below)
FACAT= PRECIPITATING FACTORS, FAOB= HYPOGLYCEMIC EVENT and	CETERM
Were Any Precipitating Factors Reported?	No Yes (If yes complete following) HPFYN
FATEST= Alcohol Consumption as a Precip Factor	Alcohol Consumption No Yes
FATEST= Concurrent Illness as a Precip Factor	Concurrent Illness No Yes FAORRES
FATEST= Dosing Deviation as a Precip Factor	Deviation from Dosing Instructions No Yes
FATEST= Meal Variance as a Precip Factor	Missed, Delayed or Smaller Meal No Yes
FATEST= Physical Activity as a Precip Factor	Physical Activity No Yes
	Other (Specify) No Yes (if yes enter below)
CMCAT= HYPO TREATMENT	FATEST
Was Any Treatment Given for the Hypoglycemic Event?	No Yes (If yes complete following) HTGYN
CMTRY= DRINK	Drink No Yes CMOCOCUR WITH CIMPRESPLY
CMTRY= FOOD	Food No Yes
CMTRY= GLUCOSE TABLETS	Glucose Tablets No Yes
CMTRY= GLUCAGON INJECTION	Glucagon Injection No Yes
CMTRY= INTRAVENOUS GLUCOSE	Intravenous Glucose No Yes
If Treatment Given Indicate Assistance Needed?	None - Subject Treated Self Subject was Capable of Treating Self, but Received Assistance Subject was Not Capable of Treating Self and Required Assistance
	FAORRES where FAOB= HYPOGLYCEMIC EVENT, FACAT= TREATMENT ADMINISTRATION, FATESTCD= TXASSIST, FATEST= Treatment Assistance

CRF annotated to show mapping SDTM variables are in Red. If CDASH variable differs from SDTM the CDASH variable is in Blue.



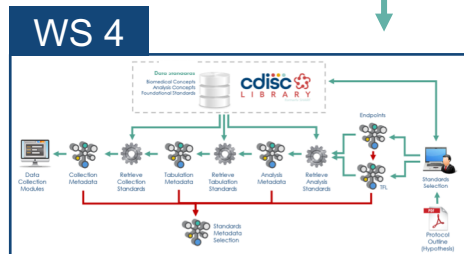
3. Logistics



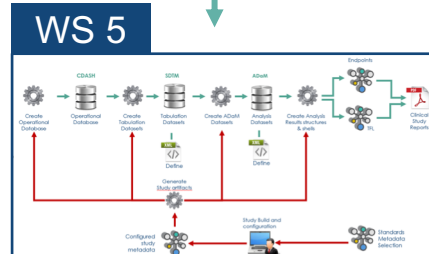
Create concepts in knowledge graphs



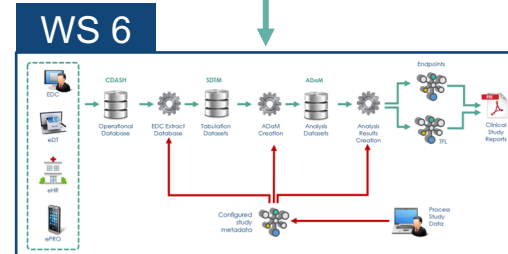
Add transformation semantics



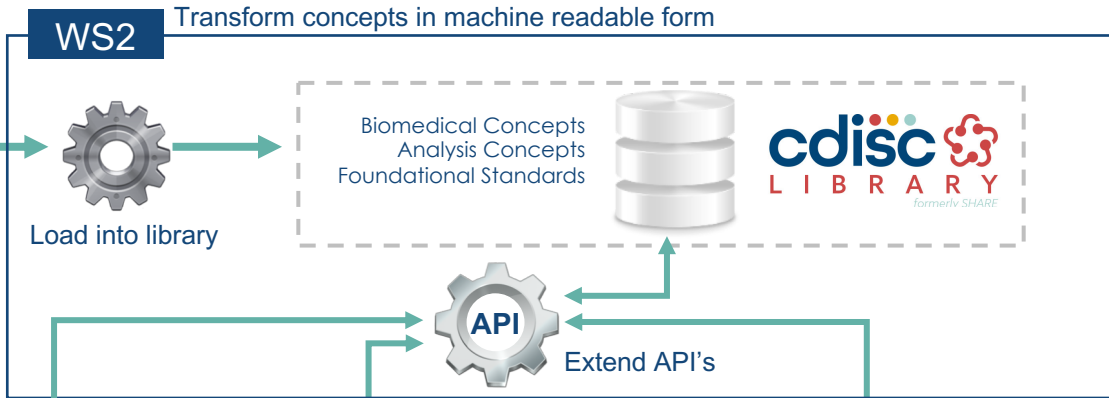
Identify and select standards specification (Use Case 1)



Configure study specification and create artifacts (Use Case 2)

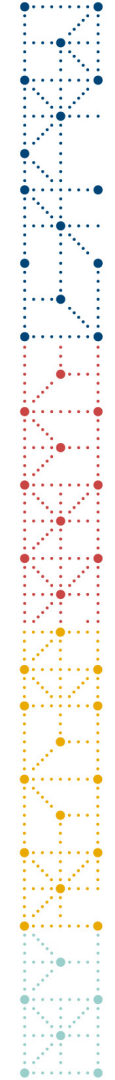


Automatically process and transform data (Use Case 3)





4. Relationship to other Initiatives



Relationship to other initiatives

- Helmsley Transformational Grant
- Blue Ribbon Commission
- TransCelerate Digital Data Flow
- CDISC Data Exchange Standards
 - ODM v2
 - SDM-XML

→ **CDISC 360**: a blueprint for the next generation data standards, aligned with key initiatives



5. Expected outcome

Expected Outcome

- Learn
 - What works and what doesn't
- Assessment
 - Technology Gap Analysis
 - Standards Gap Analysis
- Building a base for the future
 - Effort calculation
 - Cost / Benefit Analysis
 - Scale up to deliver the standards metadata needed
 - Partnerships with vendors to ensure tools are made available





Thank You!

Peter Van Reusel
Sam Hume
Barry Cohen

