CDISC GUF Webinar

26 mai 2020

Merci pour votre participation virtuelle mais active !

Conditions de ce Webinar

Votre son sera **éteint** tout au long du webinar

Ce webinar est enregistré

Questions?
Ecrivez les dans la section Q&A. Après chaque présentation, il y a aura un temps pour y répondre

Problèmes de sons? Quittez et redémarrez l'application Zoom

Les slides de la presentation et l'enregistrement de ce webinar seront disponibles dans quelques jours

Ce webinar n'est pas une formation homologuée par le CDISC et n'a pas été developpée sous les CDISC Operating Procedures.

GUF CDISC

Groupe des Utilisateurs Francophones du CDISC

- Groupe LinkedIn
  https://www.linkedin.com/groups/2160071/
- Lien sur le site wiki du CDISC
  https://wiki.cdisc.org/display/FRUN
- Une section dans chaque CDISC Newsletter trimestrielle
  Exemple pour Q1 2020
  https://www.cdisc.org/newsletter/issue/first-quarter-2020/french-user-group-welcomes-new-members

GUF CDISC

Catherine	BOULARD	Ipsen	
Nicolas	de SAINT-JORRE	Quanticsoft	
Nicolas	DUFOUR	Bioprojet Pharma	
Karen	FANOUILLERE	SANOFI	Présidente
Umit	GULER	Théa Pharma	
Wafaa	JEBERT	Ichnos Sciences	Secrétaire
Pierre-Yves	LASTIC		Vice-président
Isabelle	LAUGEL	Life Sciences Expertise	
Julie	Le BOULICAUT	eXYSTAT	
Simon	LEBEAU	Danone Research	Vice-président
Jérémy	MAMBRINI	Airbus	
Yoani	MATSAKIS	Telemedicine Technologies S.A.S.	
Fabien	MAUGARD	AP-HP	
Khaled	MOSTAGUIR	Hôpitaux Universitaires de Genève	
Marc-Antoine	PRODHOMME	Janssen Pharmaceutical	
Jonathan	RICHES	SAS	
Nathalie	SABIN	OXMO CDM	
Michelle	VANDENBERGH	SGS - Life Sciences	Secrétaire

CDISC GUF Webinar

26 mai 2020

• Informations sur CDISC et le dernier InterChange Europe	Pierre-Yves Lastic
• CDISC 360	Nicolas De Saint Jorre
• COVID-19 Guideline	Assia Bouhadouza / Karen Fanouillere

Summary of the

CDISC 2020 Europe Interchange

Virtual Conference held on 1-2 April

Pierre-Yves Lastic, Privacy & Information Management in Life Sciences,
Vice-president, French CDISC User Group, Former Chairman of the CDISC Board

State of CDISC Standards

Presented by Bess LeRoy, MPH
Head of Standards Development

European Interchange 2020

Agenda

- Accomplishments in 2019
- What are we working on now?
  - COVID-19 Response
  - Knowledge Base
  - Examples Collection
  - CDASH eCRF Project
  - CDISC Implementation Primer

What has happened over the last year?

Standards Published Since Amsterdam Interchange

Foundational Standards

- CDASH v2.1
- ADaMIG v1.2
- SDTM v1.8
- SENDIG-Animal Rule v1
- CoDEx v1.0 for SENDIG v3.1
- Define.XML v2.1

Therapeutic Area Standards

- TAUG-Nutrition v1
- TAUG-CAD-Angina v1
- TAUG-Lung Cancer v1
- TAUG-CDAD v1

QRS (Questionnaires, Ratings & Scales) **Supplements**

FOLLOWS STANDARD DEVELOPMENT PROCESS OUTLINED IN COP-001

POSTED FOR 30-DAY PUBLIC REVIEW

PUBLISHED IN BATCHES SEVERAL TIMES A YEAR

Conformance Rules

CDISC Foundational Standards Teams are actively developing conformance rules for their respective standards

- ADaM v2.0 Conformance Rules – Completed
- SEND v3.0 Conformance Rules – Completed
- Define XML v2.1 Conformance Rules – Development ongoing

Guiding Principles

- CDISC organization principles – Completed
- Overarching technical principles – Completed
- SDTM technical principles – Completed September 2019
- SDTMIG, SEND, CT, Define XML, CDASH, and ADaM technical principles – Complete by end of Q1 2020
- Harmonization across all principles – Complete May 2020

What Are We Working on Now?

CDISC Response to COVID-19

CDISC Response to COVID-19

- **Interim User Guide - COVID-19**
  - 1.0, Release Date: 21 Apr 2020
  - The Interim User Guide for COVID-19 describes the most common biomedical concepts relevant to COVID-19, and the necessary metadata to represent such data consistently with Terminology, CDASH, and SDTM. CDISC Standards specify how to structure the data; they do not specify what data should be collected or how to conduct clinical trials, assessments or endpoints.

- **Guidance for Ongoing Studies Disrupted by the COVID-19 Pandemic**
  - The Guidance addresses how to represent changes in current studies if the conduct is impacted by COVID-19.

- **Resources for Public Health Researchers**
  - The zip file comprises an annotated case report form and a mapping spreadsheet to support public health researchers utilizing the Novel Coronavirus (nCoV) Acute Respiratory Infection Clinical Characterisation Data Tool. Developed by the World Health Organization (WHO) and the International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC), the Data tool is being used as the foundation for many COVID-19 research studies globally across numerous countries.

CDISC would like to express our profound gratitude to the task force participants for their involvement in the development of these resources.

Work icludes:

- Virology (TAUG-Virology/TAUG-Influenza)
  - Rate of virus inhibition
  - Virus identification
  - Viral genetics
  - Assay kits (SDTMIG-MD and relevant TAUGs)
- Vaccines (TAUG-Vaccines)
- Labs (SDTMIG)
  - Additional Controlled Terminology
  - Biospecimen domains
- Vital Signs (SDTMIG)
  - Respiratory rate
  - Body temperature
  - Oxygen saturation
- Respiratory Findings (TAUG-Tuberculosis/TAUG-COPD/TAUG-Asthma)
  - Imaging
  - Pulmonary function tests
- Clinical Events (SDTMIG and relevant TAUGs)
  - Cough
  - Shortness of breath
- Healthcare Encounters (multiple TAUGs)
- Procedures (TAUG-Influenza)
  - Mechanical ventilation

Foundational Standards and TAUGs

Foundational Standards in Development

Conformance Rules

SDTM v2.0

SENDIG v3.1.1

SDTMIG v3.4

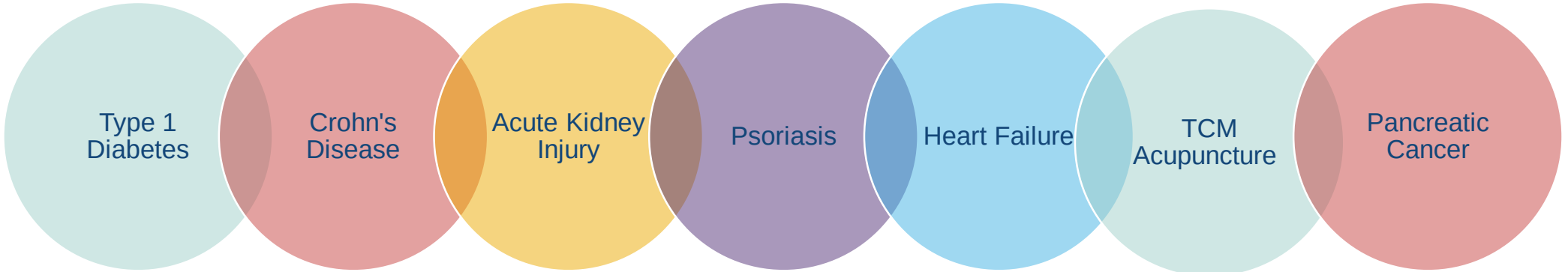
SDTM Variable Definitions

Multiple QRS and ADQRS Supplements

CDASH-SAE Supplement

https://www.cdisc.org/standards/in-development

Therapeutic Area User Guides Currently In Development



https://www.cdisc.org/standards/in-development

Knowledge Base

CDISC Knowledge Base

An open, assessible, searchable and user-friendly interface on the CDISC Website to host new and existing website content for CDISC implementers

Knowledge Base – Components

Coordinated with standards website pages

CDISC-generated content

Community-generated content, curated by CDISC

Community Questions

Links to external useful content

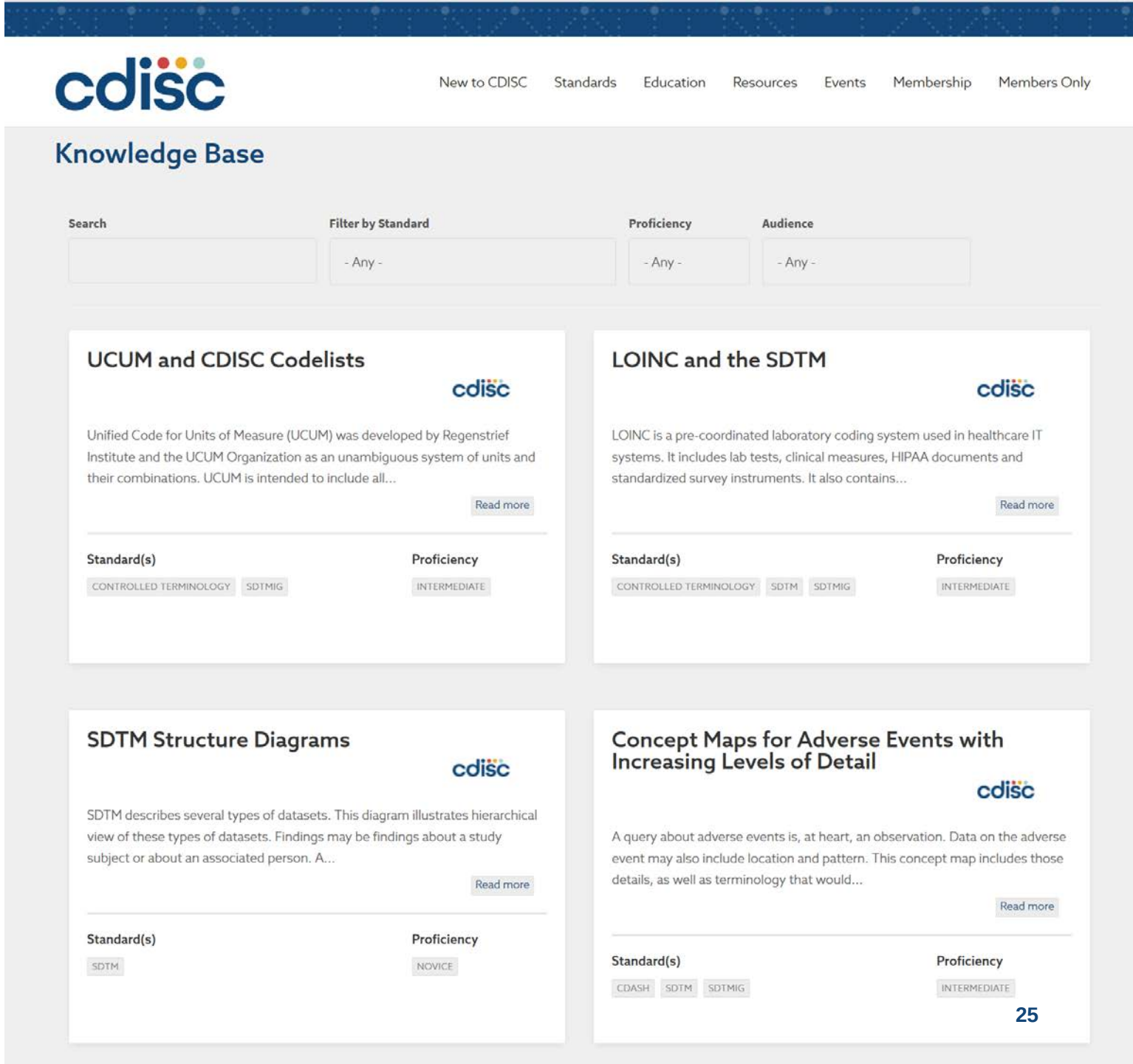
Knowledge Base Contents

PHASE 1

PHASE 2

Phase 1 - Articles

- Technical articles written by CDISC staff and teams



Phase 2 - Known Issues

Small errors such as typos that do not affect conformance

Items that affect conformance

Inconsistencies within a CDISC standard

- Inconsistencies between standards
- Inconsistencies between a CDISC standard and regulatory agency advice
- Gaps in standards

Examples of Known Issues in Review

Known Issues

Created by Bess LeRoy, last modified by Diane Wold on Sep 20, 2019

- Multiple Study Participations
- Subject Characteristics and Subject Status
- Occurrence of one of a group of Events or Interventions
- Examinations with pre-specified targets
- Extending the EPOCH Codelist for Multiple Epochs of the Same Type

Phase 2 - Community Generated Content

Useful content generated by CDISC team members and organizations

Content to be identified and added as available

Phase 2 - Community Questions

- Questions received from the community may be answered and posted
- Requirements:
  - system agnostic
  - reflect areas of strong community interest
  - a consensus answer is available
- Curation by CDISC team members
- Answers will be posted on the Knowledge Base Community Questions page

Examples Collection

Curated Examples

- Examples exist across many Implementation and User Guides in PDFs
- Goal is to make examples easily accessible for implementors through the CDISC Knowledge Base
- Users will be able to select examples by biomedical concept, therapeutic area, observation class, domain etc.
- Curation to ensure examples remain consistent with one another
- Initial scope: Diabetes v1.0, Diabetic Kidney Disease v1.0, Type 1 Diabetes v1.0
- First content will be available later this year

Dashboard
Expand All

Examples Collection
Knowledge Base
eCRF Library
CDISC Primer
CDISC Library

Metadata

End Stage Renal Disease (ESRD) 1

Export | New Issue

Renal Replacement Therapy

Kidney Transplant PRTRT

Has the subject received a kidney transplant? PROCCUR	☐ Yes ☐ No
If yes, provide kidney transplant date (DD-MMM-YYYY) PRSTDTC PRSTDAT	__/___/____ (DD/MMM/YYYY)

Dialysis PRTRT

Has the subject received dialysis? PROCCUR	☐ Yes ☐ No
If yes, provide the following information:	
Start Date (DD-MMM-YYYY) PRSTDTC PRSTDAT	__/___/____ (DD/MMM/YYYY)

Below are sample records for subjects who have undergone dialysis or a kidney transplant. Because, dialysis and kidney transplant are considered procedures, they are represented in the Procedures (PR) domain.

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRTRT	PRSTDTC	PRENDTC	PRENRTPT	PRENTPT	RSDISC
1	XYZ	PR	XYZ-001	1	DIALYSIS	2012-05-01	2012-05-26			No longer medically necessary
2	XYZ	PR	XYZ-001	2	DIALYSIS	2013-06-01	2013-06-21			No longer medically necessary
3	XYZ	PR	XYZ-001	3	DIALYSIS	2014-06-23		ONGOING	2014-08-02	
4	XYZ	PR	XYZ-002	1	KIDNEY TRANSPLANT	2014-06-17				
5	XYZ	PR	XYZ-003	1	DIALYSIS	2014-08-05		ONGOING	2014-08-25	
6	XYZ	PR	XYZ-004	1	DIALYSIS	2014-08-05	2014-09-10			Subject refused dialysis

CDASH eCRF Project

CDASH eCRF Project

- Developing machine-readable, visual representations of case report form (CRF) layout
- Project scope
  - CDASHIG v2.1
  - Therapeutic Area User Guides
  - Questionnaires, Ratings and Scales (QRS Instruments)
- Formedix offered the CDISC community MDR use at no cost to help deliver this project

Purpose

Utilize	Utilize the benefits of CDASH with annotated CRFs in various formats
Provide	Provide value for new investigators and other researchers
Enable	Enable data sharing
Expand	Expand adoption of CDASH
Align	Align with CDISC 360’s vision for end-to-end automation

Create Initial CRF Package for Posting

- Excel metadata table
- PDF visualizations
- ODM-XML File
- HTML and XSL rendering

Review CRF Visualization

Form DM - Demographics		
1 DM - Demographics		
1.1	Birth Date (DD-MMM-YYYY)	__ __ _____ **BRTHDAT**
1.2	Age	__ __ **AGE**
1.3	Age Unit	☐ [YEARS] **AGEU**
1.4	Sex	○ [F] Female **SEX** ○ [M] Male ○ [U] Unknown ○ [UNDIFFERENTIATED] Intersex
1.5	Ethnicity	○ [HISPANIC OR LATINO] Hispanic or Lati **ETHNIC** ○ [NOT HISPANIC OR LATINO] Not Hispanic or Latino ○ [NOT REPORTED] Not Reported ○ [UNKNOWN] Unknown

CDISC Implementation Primer

Background

As the CDISC implementation community increases, new implementers, especially those not directly connected to the pharmaceutical industry and regulators, need a starting point for their implementation journey

Need a way to assemble, organize and surface useful information to make using CDISC standards easier

Feedback From Our Community

- Implementation is complex
- Large volume of information
- Compliance confusion
- Can be overwhelming for newcomers

Call to Action

PHUSE heard concerns, CDISC collaborated

Launched at 2018 PHUSE CSS

- Part of “Optimizing the use of data standards” working

Leadership: Beate Hientzsch, Yvonne Moores, Wendy Dobson, Bess LeRoy

- Over 20 volunteers from many different stakeholders

Everything to be freely available to all

Four Initial Topics

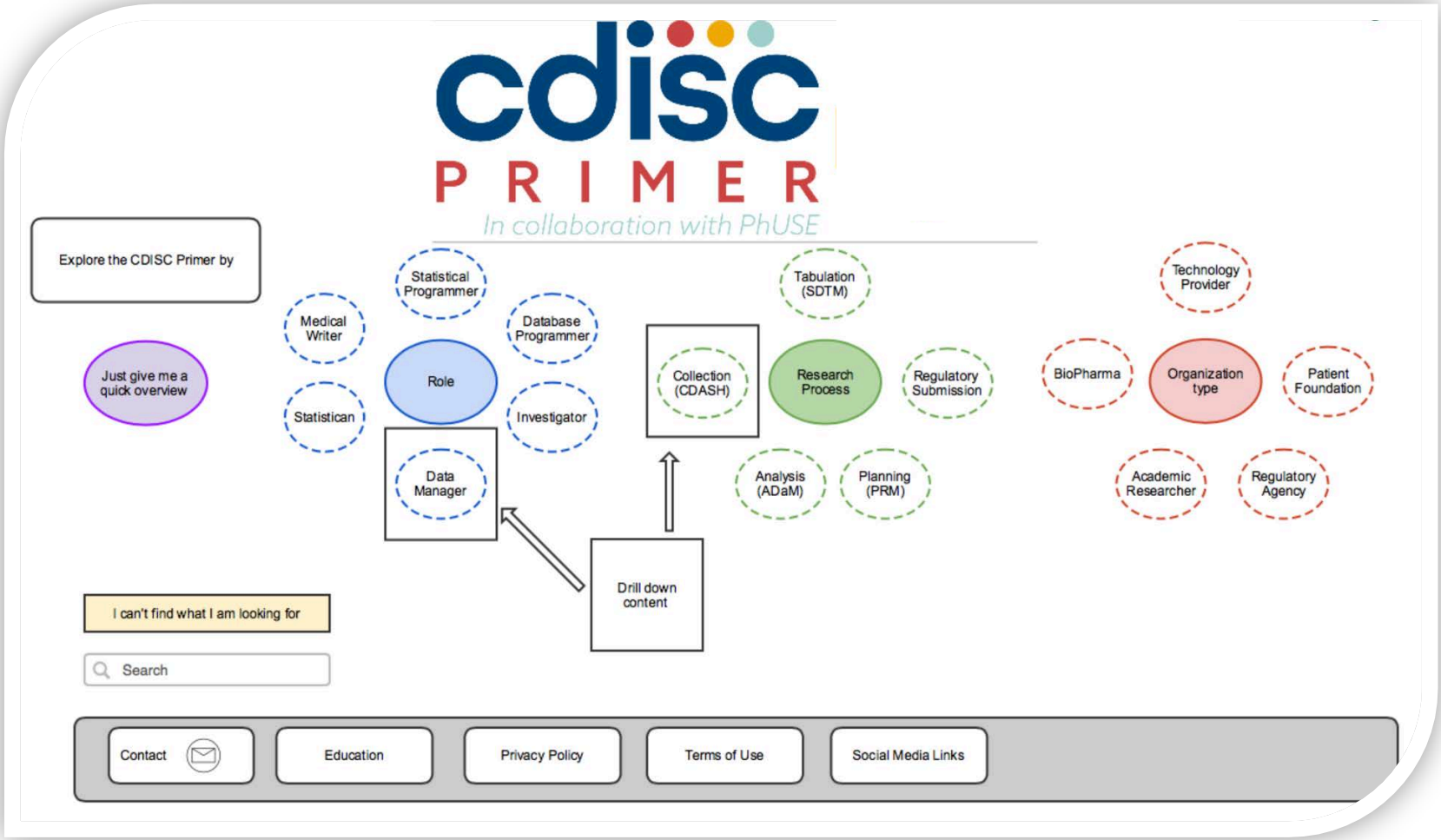
Topic 1: How to Get Started with CDISC

Topic 2: Links Among CDISC Standards

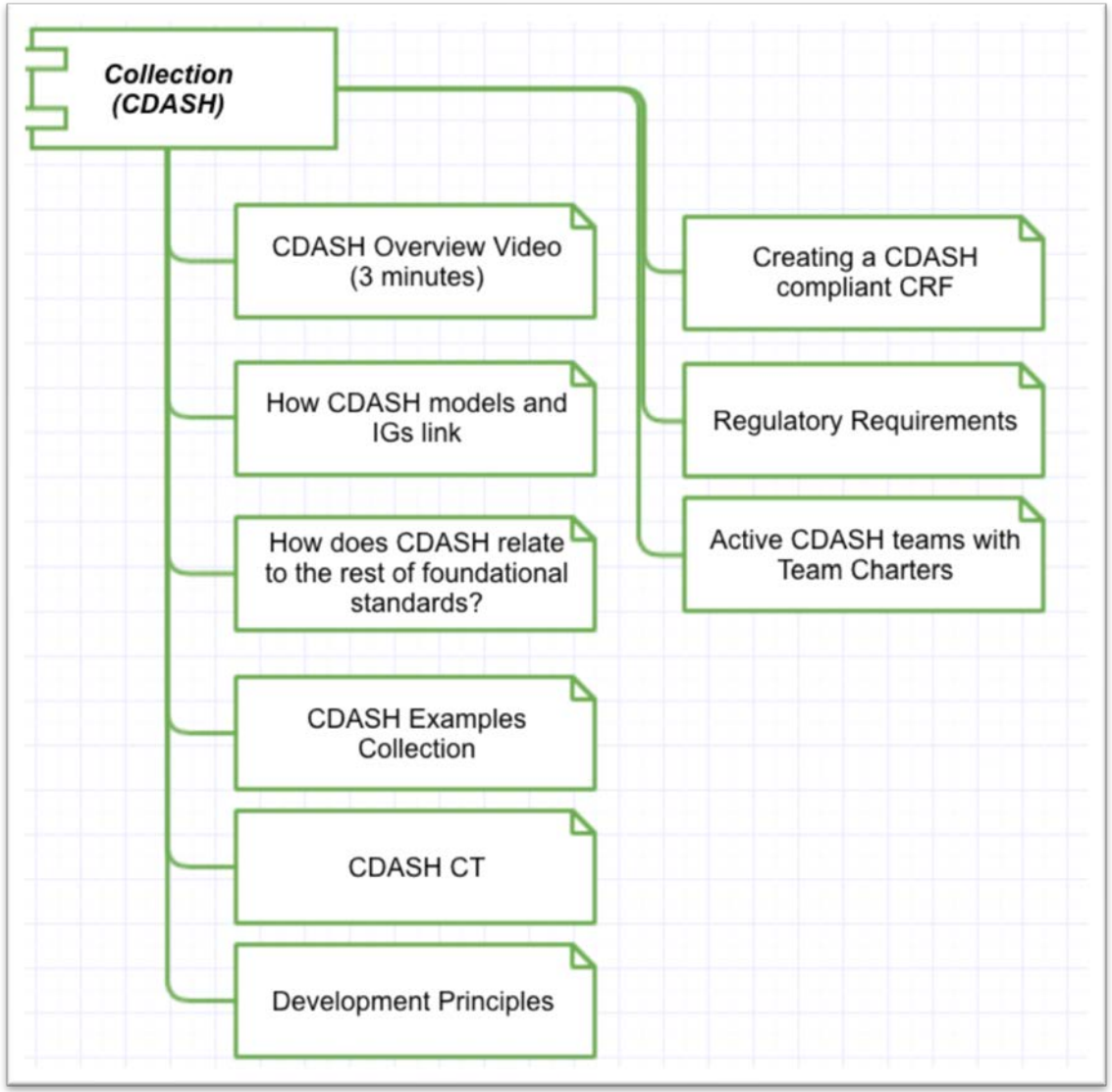
Topic 3: Traceability

Topic 4: Compliance

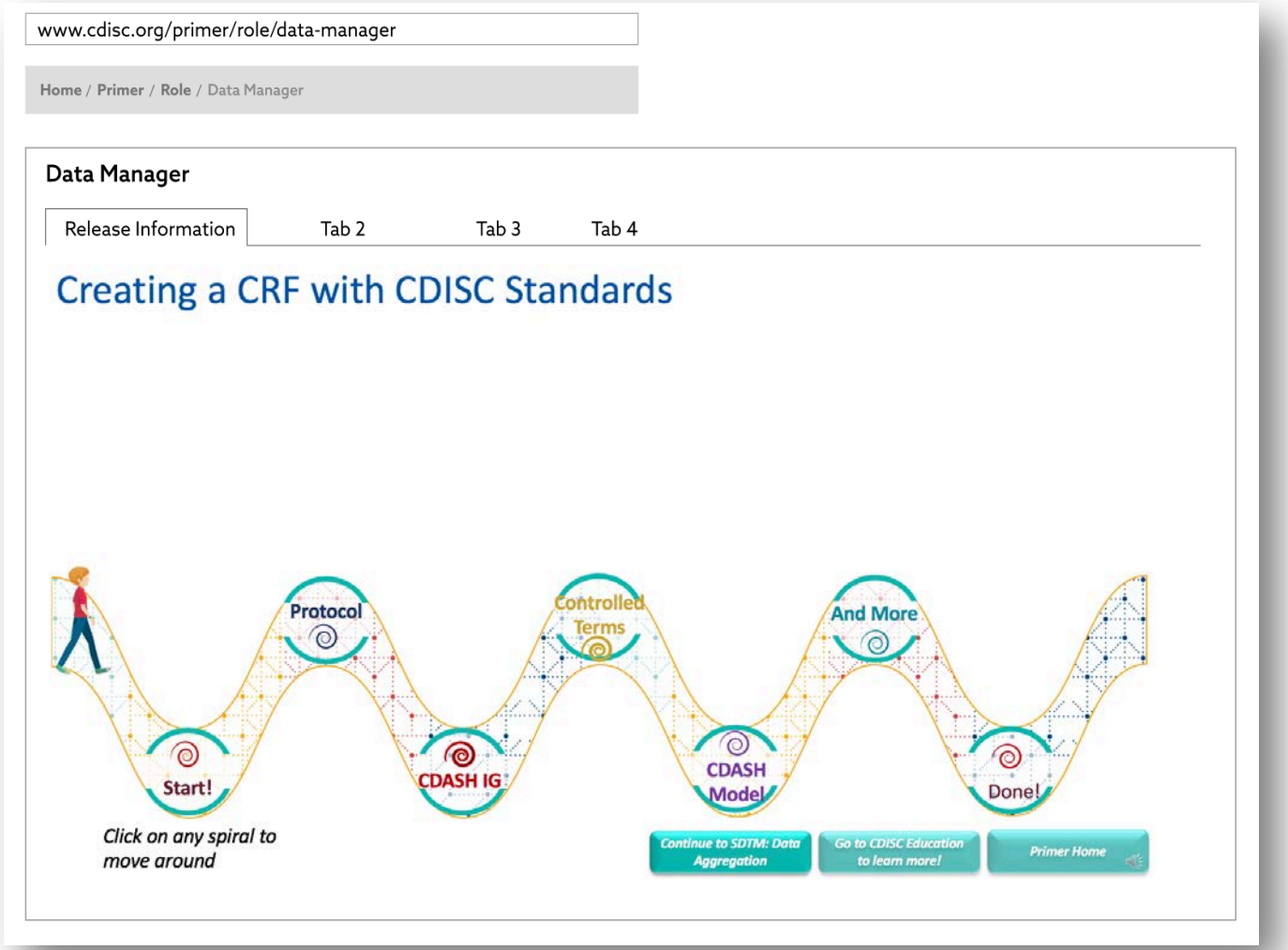
Topic 1: Getting Started with CDISC



Getting Started with CDISC: CDASH

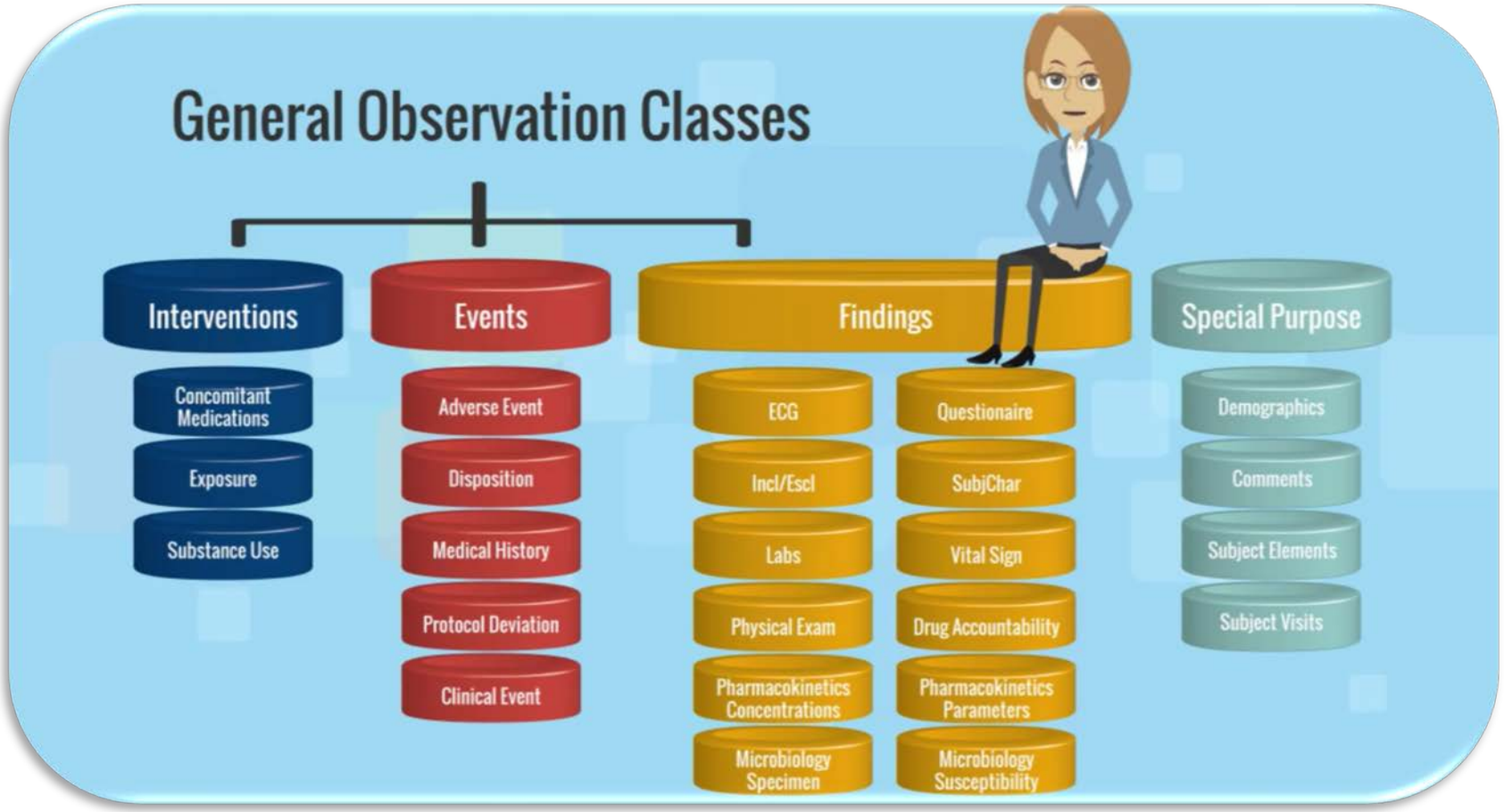


Getting Started with CDISC: Layout



3 Minute Whiteboard Videos for Standards

3 Minute Whiteboard Videos for Standards



Thank you!

Questions pendant le Webinar

- Quand se termine la public review du SDTM 3.4?
  La page suivante: https://www.cdisc.org/standards/in-development indique que le Guide est en phase Comments avec une deadline le 1er Juin 2020...!
  Il faut faire vite...
- Est-ce que tu peux nous en dire plus sur le CDASH eCRF project? quels sont les livrables de ce groupe?
  Jozef AERTS: En ce moment, on essaie d'utiliser le CDISC Library pour créer CDASH-ODM-XML de manière automatique et ça marche.

CDISC 360
The Journey so Far and the Road Ahead

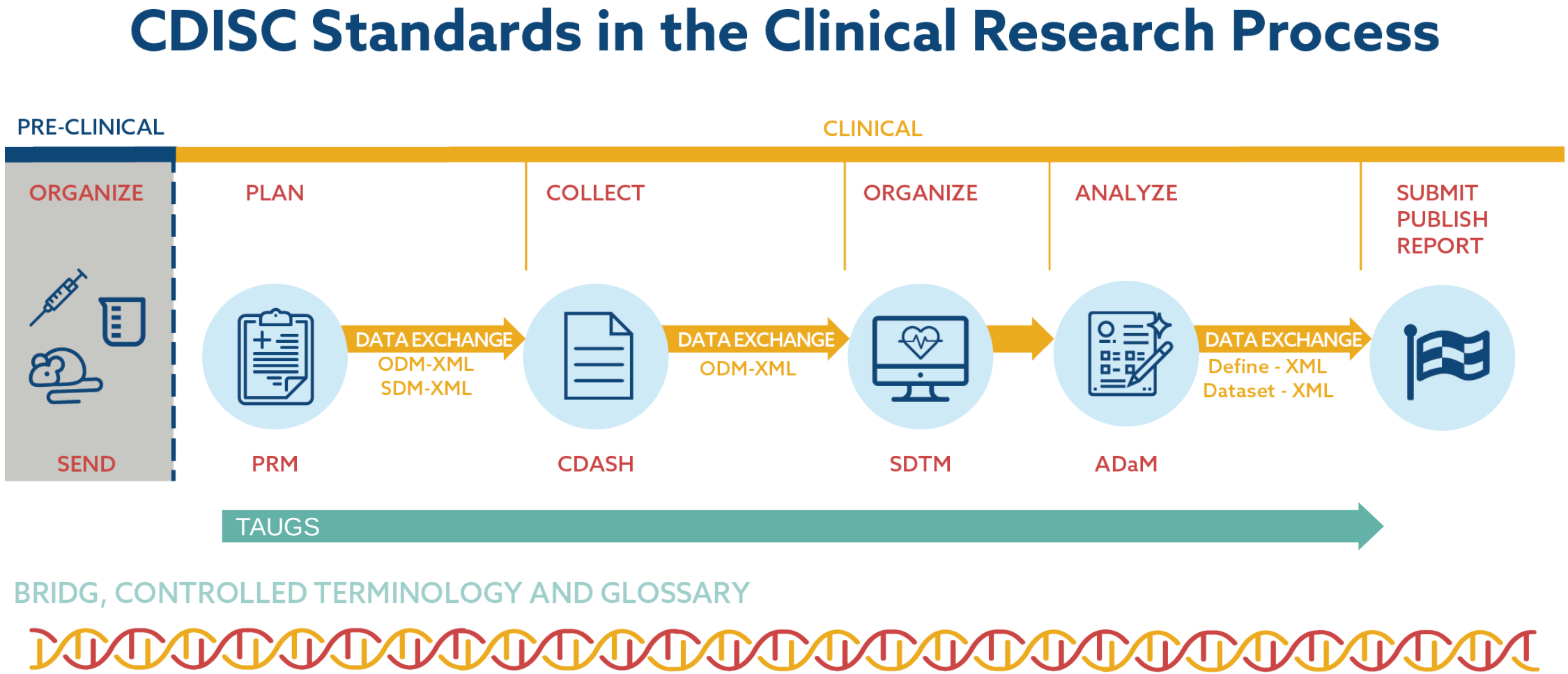
Derived from Peter Van Reusel

28 April 2020

Agenda

1. What is CDISC 360?
2. The Art of the Possible
3. Project Approach
4. The Journey So Far
5. What Follows 360?

Today we are here



Benefits Today

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

- Standards must now evolve to address further challenges to take standards benefits to next level

	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.

How do we evolve?

The CDISC 360 Project: Adding a conceptual layer to standards

- Create and store standards as concepts which create meaning between data
- Electronically publish data standards as linked metadata
- Add computer executable process metadata which enables end to end automation
- CDISC 360 will develop concept-based standard definitions, and test and demonstrate end-to-end automation of study specification, data processing, and analysis

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

360 Participation Summary

Project Kickoff:

36 Resources specified

20 Organizations

Today:

107 Resources specified

38 Organizations

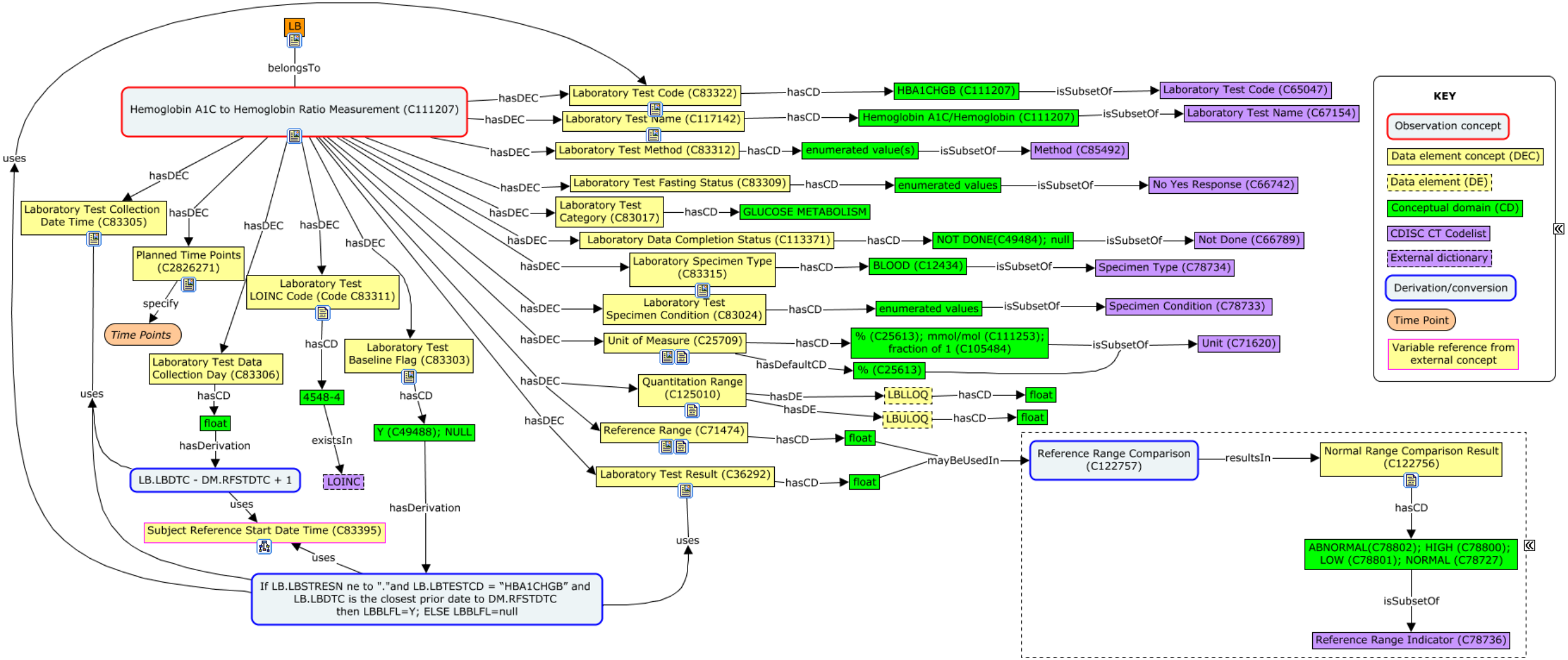
- Pharma-Biotech Sponsor: 20
- CRO: 6
- Technology Provider: 11
- Regulatory: 1

➔ *Still onboarding new participants*

➔ *Contributions vary due to project complexity and time available*

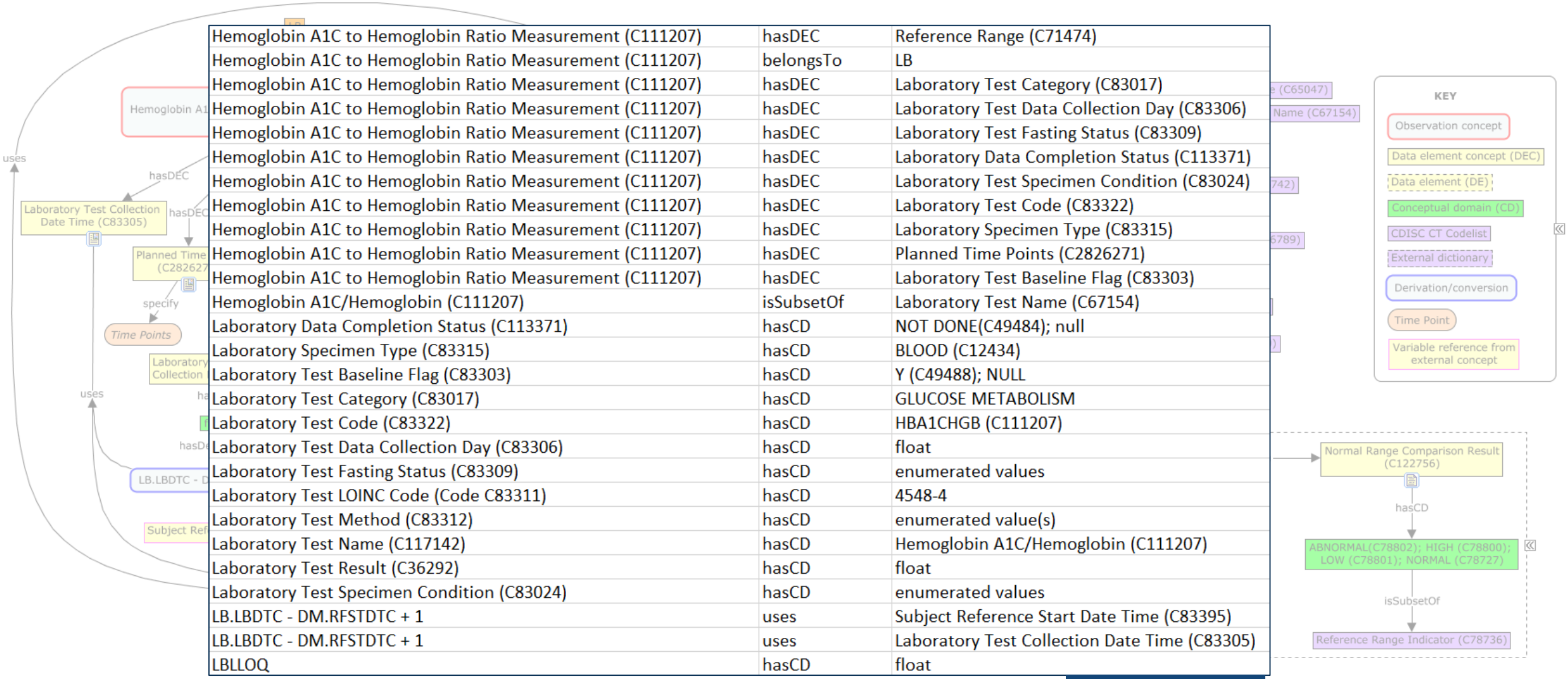

abbvie
Allergan
AMGEN
AstraZeneca
Bayer HealthCare
BeiGene
Biogen
BIOMARIN
RESEARCH C&R RESEARCH
Celgene
Cytel
STATISTICAL SOFTWARE & SERVICES
Deloitte.
dMed 缔脉
FDA
formedix
frontier science foundation
GILEAD
Inductive Quotient
.Research .Bigdata .Analytics
Johnson & Johnson
Lilly
Mel Consulting
MERCK
Microsoft
novo nordisk
ORACLE
Otsuka
Pfizer
PharmaStat
PINNACLE 21
POINT CROSS
S-CUBED
SANOFI
sas
Syneos Health
TALENTMINE
VITA DATA SCIENCES
a division of SOFTWORLD
xclinical
Clinical Solutions Group

Biomedical Concept



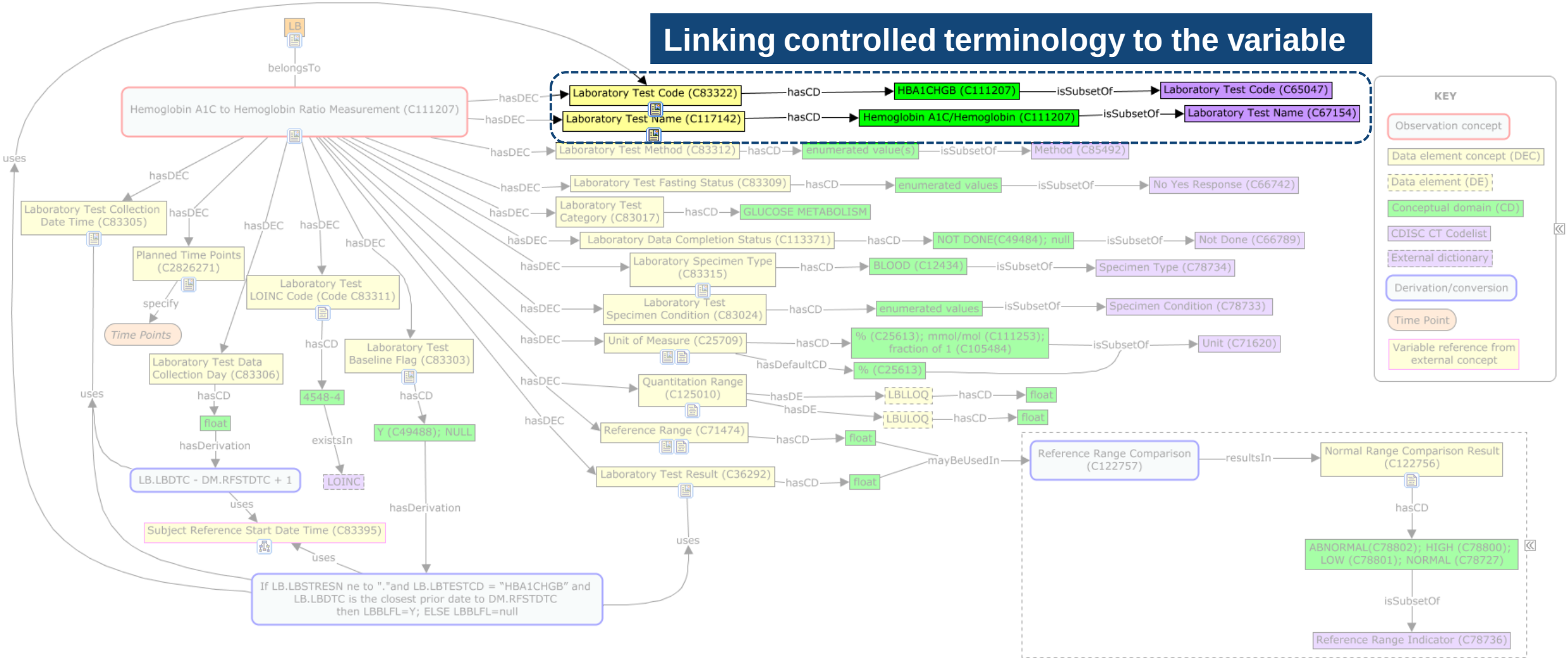
Biomedical Concept

Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207)	hasDEC	Reference Range (C71474)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207)	belongsTo	LB
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207)	hasDEC	Laboratory Test Category (C83017)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207)	hasDEC	Laboratory Test Data Collection Day (C83306)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207)	hasDEC	Laboratory Test Fasting Status (C83309)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207)	hasDEC	Laboratory Data Completion Status (C113371)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207)	hasDEC	Laboratory Test Specimen Condition (C83024)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207)	hasDEC	Laboratory Test Code (C83322)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207)	hasDEC	Laboratory Specimen Type (C83315)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207)	hasDEC	Planned Time Points (C2826271)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207)	hasDEC	Laboratory Test Baseline Flag (C83303)
Hemoglobin A1C/Hemoglobin (C111207)	isSubsetOf	Laboratory Test Name (C67154)
Laboratory Data Completion Status (C113371)	hasCD	NOT DONE(C49484); null
Laboratory Specimen Type (C83315)	hasCD	BLOOD (C12434)
Laboratory Test Baseline Flag (C83303)	hasCD	Y (C49488); NULL
Laboratory Test Category (C83017)	hasCD	GLUCOSE METABOLISM
Laboratory Test Code (C83322)	hasCD	HBA1CHGB (C111207)
Laboratory Test Data Collection Day (C83306)	hasCD	float
Laboratory Test Fasting Status (C83309)	hasCD	enumerated values
Laboratory Test LOINC Code (Code C83311)	hasCD	4548-4
Laboratory Test Method (C83312)	hasCD	enumerated value(s)
Laboratory Test Name (C117142)	hasCD	Hemoglobin A1C/Hemoglobin (C111207)
Laboratory Test Result (C36292)	hasCD	float
Laboratory Test Specimen Condition (C83024)	hasCD	enumerated values
LB.LBDTC - DM.RFSTDTC + 1	uses	Subject Reference Start Date Time (C83395)
LB.LBDTC - DM.RFSTDTC + 1	uses	Laboratory Test Collection Date Time (C83305)
LBLLOQ	hasCD	float

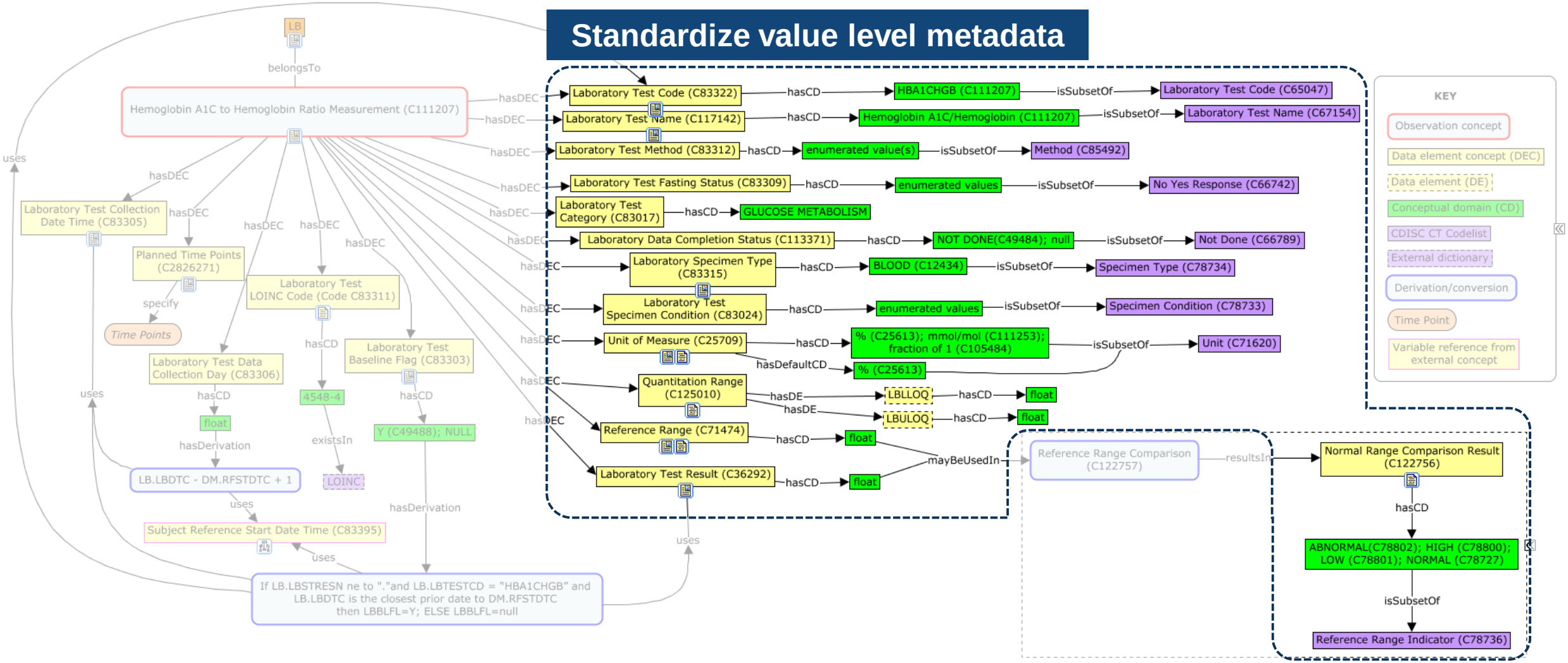


Triple Store

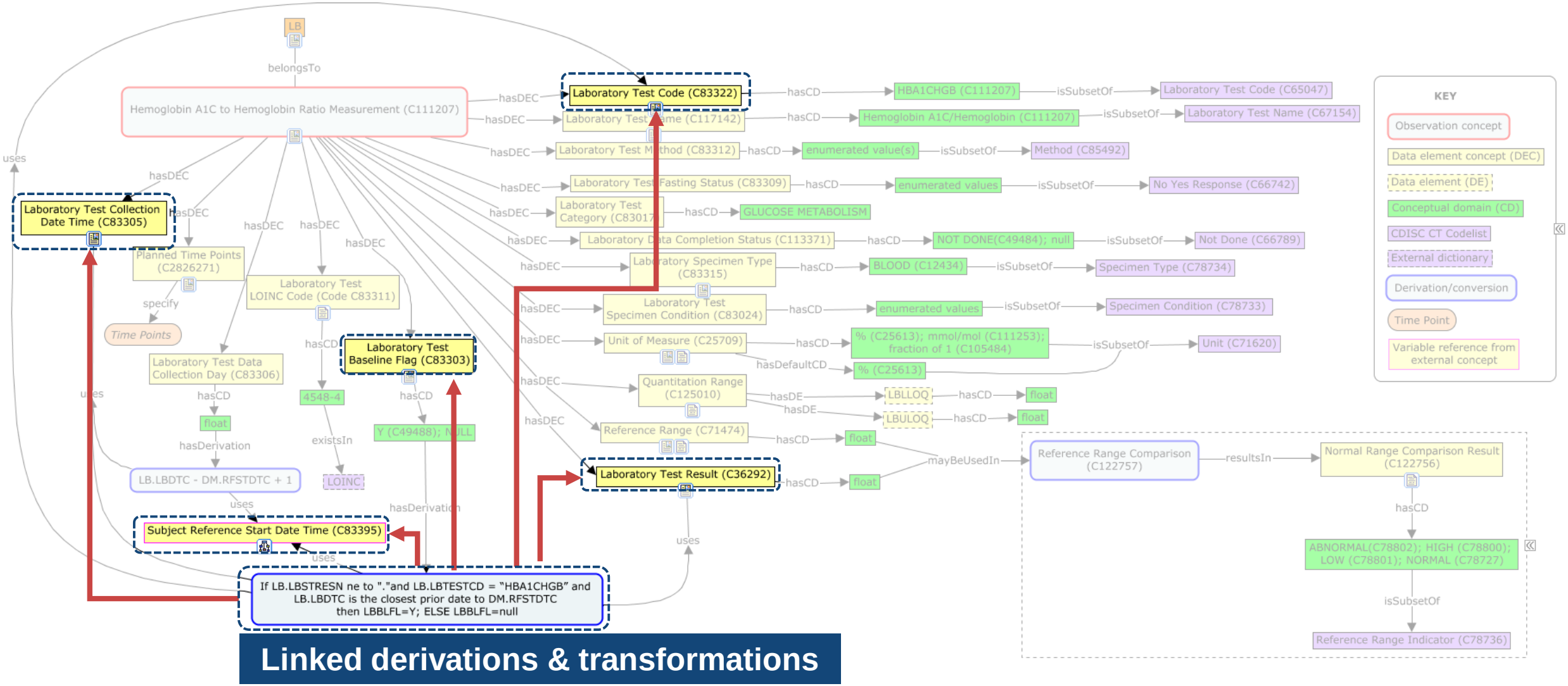
Biomedical Concept



Biomedical Concept

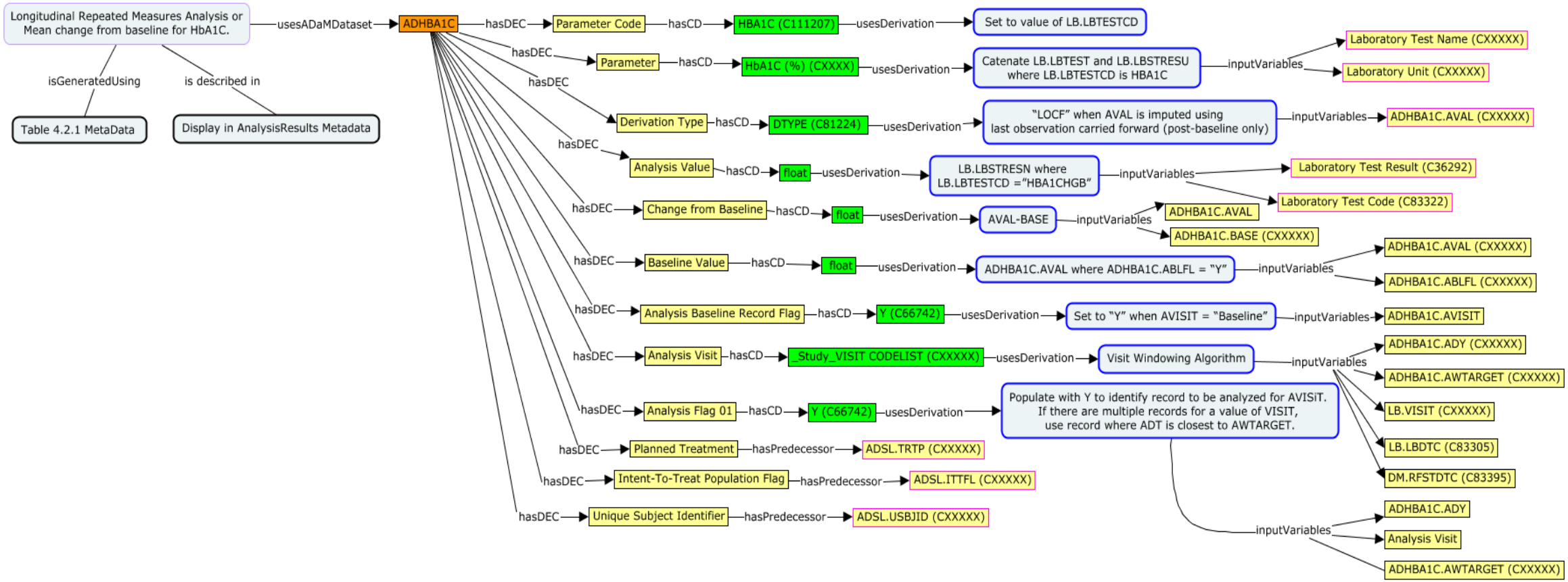


Biomedical Concept



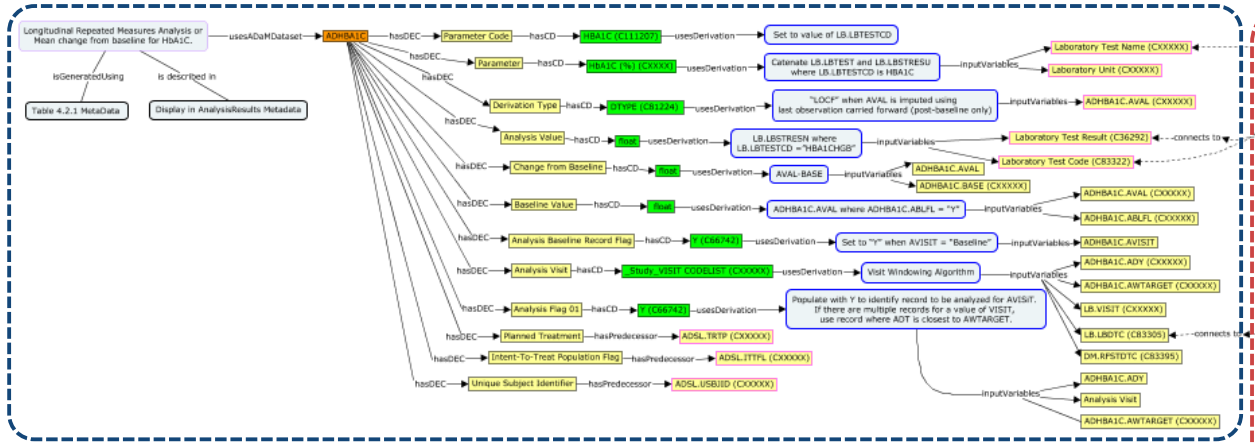
Linked derivations & transformations

Analysis Concept

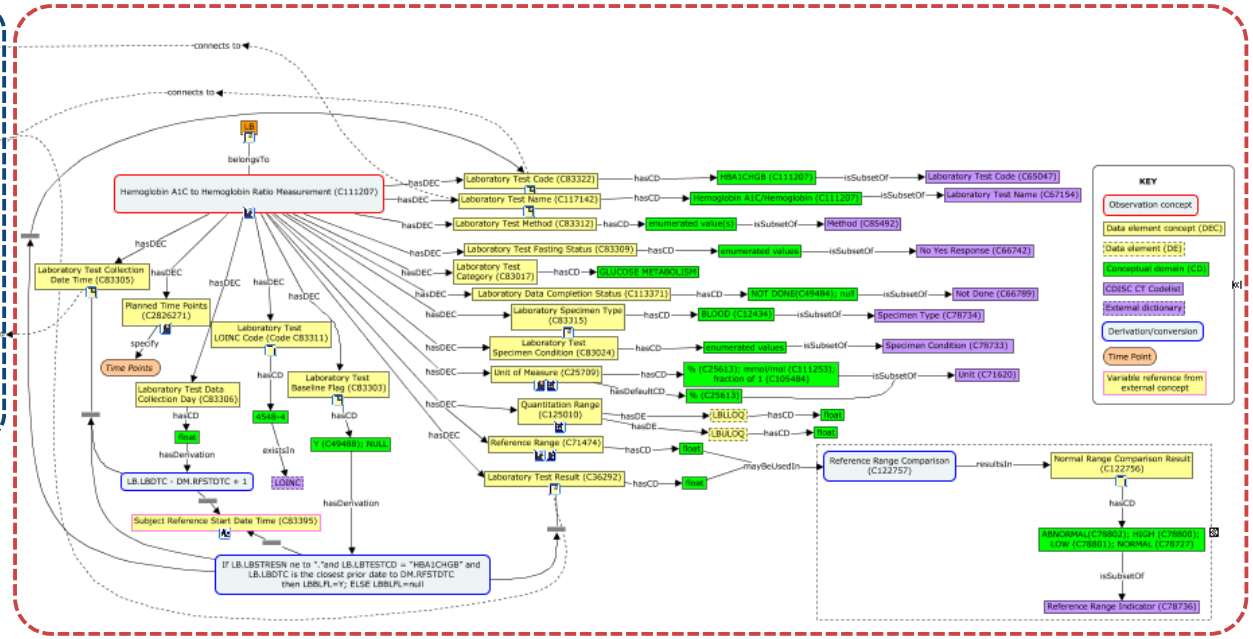


One Model

Biomedical Concept Map



Analysis Concept Map



→ The Biomedical Concept and Analysis Concept are ***ONE MODEL***

Agenda

1. What is CDISC 360?
2. The Art of the Possible
3. Project Approach
4. The Journey So Far
5. What Follows 360?

CDISC 360 – Art of the Possible

- What will follow is a User Experience presentation
- Purpose:
  - Illustrate how the CDISC 360 concept model will enable automation
  - For illustration only: CDISC 360 will not deliver software to the industry
- UX presentation link:
  - https://xd.adobe.com/view/93e3e8f6-5b33-405f-4e76-e17af5f29990-e5d2/

Agenda

1. What is CDISC 360?
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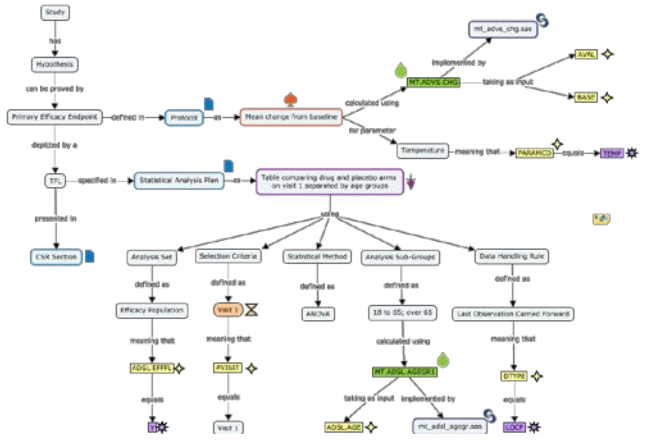
CDISC 360 Workstreams

Workstream 1 - *ENHANCE STANDARDS*



Create concepts in knowledge graphs

Workstream 2 - *PUBLISH STANDARDS*

Load into library

Biomedical Concepts
Analysis Concepts
Foundational Standards

cdisc LIBRARY formerly SHARE

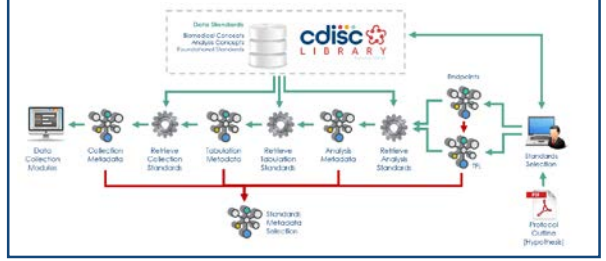
API

Extend API's

Transform concepts in machine readable form

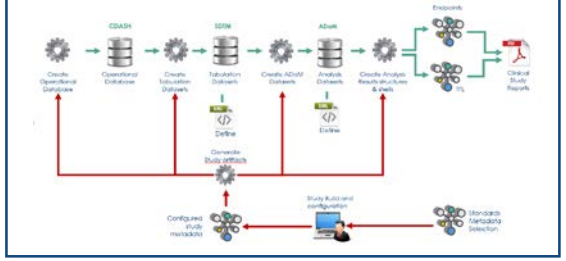
Study Metadata Library

Workstream 4 - *DEFINE*



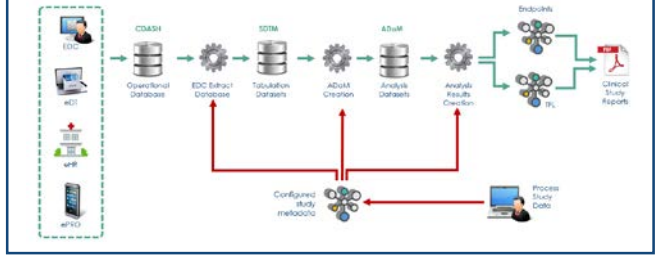
Identify and select standards specification (Use Case 1)

Workstream 5 - *BUILD*



Configure study specification and create artifacts (Use Case 2)

Workstream 6 - *EXECUTE*



Automatically process and transform data (Use Case 3)

Study Build

TransCelerate BIOPHARMA INC.
ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

Digital Data Flow Project

SDM / XML

XML

cdisc LIBRARY

Create artifacts (use case 2)

Configured study metadata

Study Designer tool

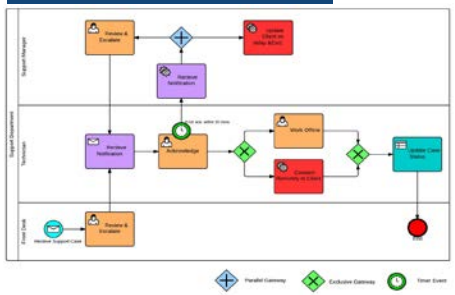
Standards Selection

Study Configuration

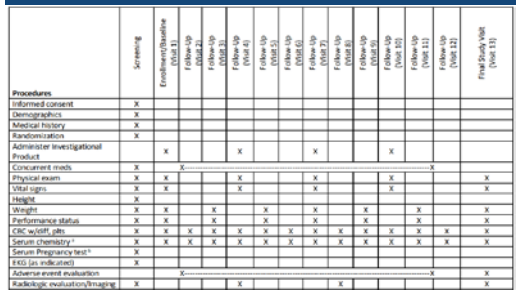
Study design
- Visits
- Arm's
- Epochs .....

- Study parameters (TS)
- Eligibility criteria
- Schedule of activities (SOA)
- Study workflow

Study workflow

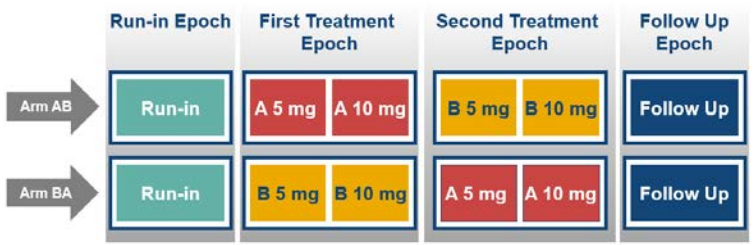


Schedule of Activities (SoA)



Procedures	Screening	Enrollment/Baseline (Visit 1)	Follow-up (Visit 2)	Follow-up (Visit 3)	Follow-up (Visit 4)	Follow-up (Visit 5)	Follow-up (Visit 6)	Follow-up (Visit 7)	Follow-up (Visit 8)	Follow-up (Visit 9)	Follow-up (Visit 10)	Follow-up (Visit 11)	Follow-up (Visit 12)	Final Study Visit (Visit 13)
Informed consent	X													
Demographics	X													
Medical history	X													
Randomization	X													
Administer investigational Product		X				X			X			X		
Concurrent meds	X	X												X
Physical exam	X	X				X			X			X		X
Vital signs	X	X				X			X			X		X
Height	X													
Weight	X	X			X		X		X		X		X	X
Performance status	X	X			X		X		X		X		X	X
CBC w/diff, plts	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Serum chemistry[1]	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Serum Pregnancy test[2]	X													
EKG (as indicated)	X													
Adverse event evaluation		X												X
Radiologic evaluation/Imaging	X				X				X					X

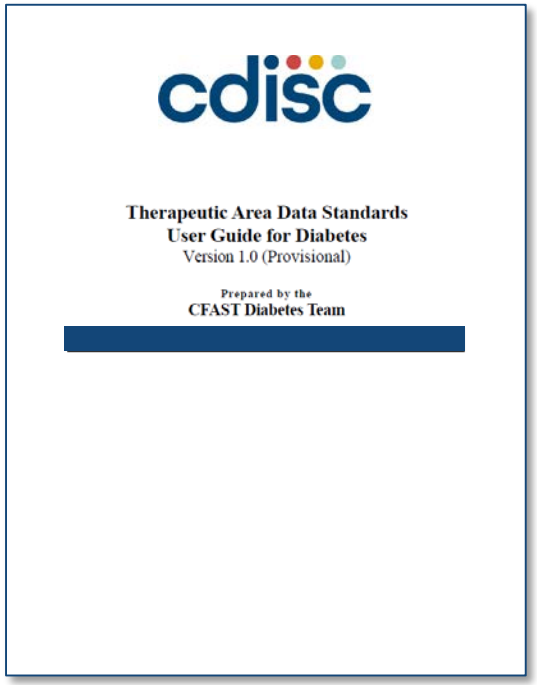
Study Design



Study Parameters (TS)

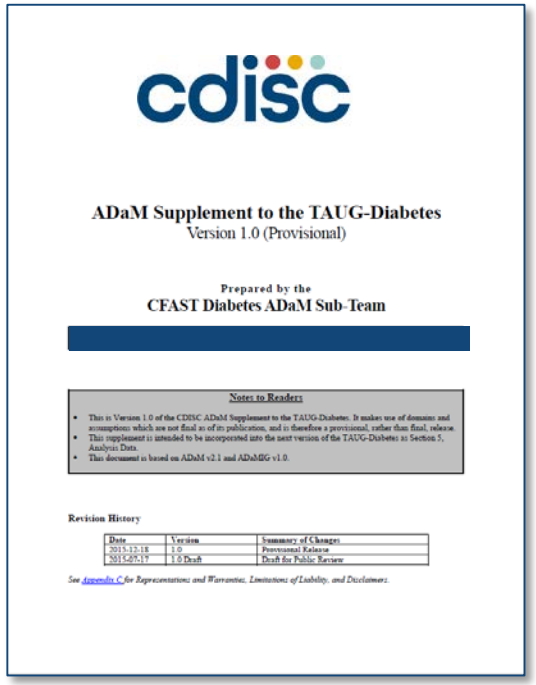
STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
XYZ	TS	1		ADDON	Added on to Existing Treatments	Y		C49488	CDISC	2011-06-10
XYZ	TS	1		AGEMAX	Planned Maximum Age of Subjects	P70Y			ISO 8601	
XYZ	TS	1		AGEMIN	Planned Minimum Age of Subjects	P18Y			ISO 8601	
XYZ	TS	1		LENGTH	Planned Trial Length	P3M			ISO 8601	
XYZ	TS	1		PLANSUB	Planned Number of Subjects	300				
XYZ	TS	1		RANDOM	Trial is Randomized	Y		C49488	CDISC	2011-06-10
XYZ	TS	1		SEXPOP	Sex of Participants	BOTH		C49636	CDISC	2011-06-10
XYZ	TS	1		STOPRULE	Study Stop Rules	INTERIM ANALYSIS FOR FUTILITY				
XYZ	TS	1		TBLIND	Trial Blinding Schema	DOUBLE BLIND		C15228	CDISC	2011-06-10
XYZ	TS	1		TCNTRL	Control Type	PLACEBO		C49648	CDISC	2011-06-10
XYZ	TS	1		TDIGRP	Diagnosis Group	Neurofibromatosis Syndrome (Disorder)		19133005	SNOMED	
XYZ	TS	1		TINDTP	Trial Indication Type	TREATMENT		C49656	CDISC	2011-06-10

Project Standards Scope
Diabetes TAUG


cdisc

Therapeutic Area Data Standards
User Guide for Diabetes
Version 1.0 (Provisional)

Prepared by the
CFAST Diabetes Team


cdisc

ADaM Supplement to the TAUG-Diabetes
Version 1.0 (Provisional)

Prepared by the
CFAST Diabetes ADaM Sub-Team

Notes to Readers

- This is Version 1.0 of the CDISC ADaM Supplement to the TAUG-Diabetes. It makes use of domains and assumptions which are not final as of its publication, and is therefore a provisional, rather than final, release.
- This supplement is intended to be incorporated into the next version of the TAUG-Diabetes as Section 5, Analysis Data.
- This document is based on ADaM v2.1 and ADaMIG v1.0.

Revision History

Date	Version	Summary of Changes
2015-12-18	1.0	Provisional Release
2015-07-17	1.0 Draft	Draft for Public Review

See Appendix C for Representations and Warranties, Limitations of Liability, and Disclaimers.

- 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.*

Agenda

1. What is CDISC 360?
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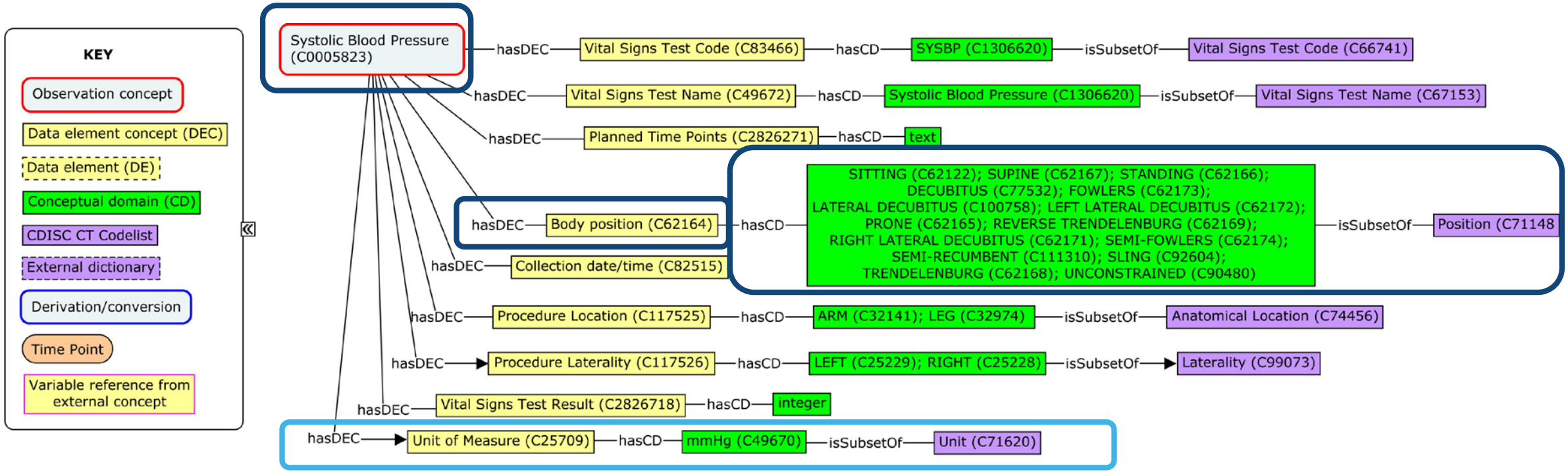
Project Timeline

#	Stage	Start	End
1	Initiation, scoping, and internal staffing	Oct 2018	Nov 2019
2	Planning, recruiting CDISC member participants	Dec 2019	Feb 2019
3	Align with Transcelerate Digital Data Flow Initiative	Oct 2018	Jan 2019
3	Onboarding CDISC member participants	Mar 2019	Apr 2019
5	Kickoff, workstreams briefing	Apr 2019	Apr 2019
6	Execution of agile sprints	Apr 2019	Oct 2019
7	Project evaluation – Stage 1 (CDISC US Interchange)	Oct 2019	Oct 2019
8	Execution of agile sprints	Nov 2019	Mar 2020
9	Project evaluation – Stage 2 (CDISC EU Interchange)	Mar 2020	Mar 2020
10	Execution of agile sprints	Apr 2020	Nov 2020
11	Project evaluation – Stage 3 (CDISC US Interchange)	Oct 2020	Oct 2020

Concept Development based on ISO 11179: Systolic Blood Pressure

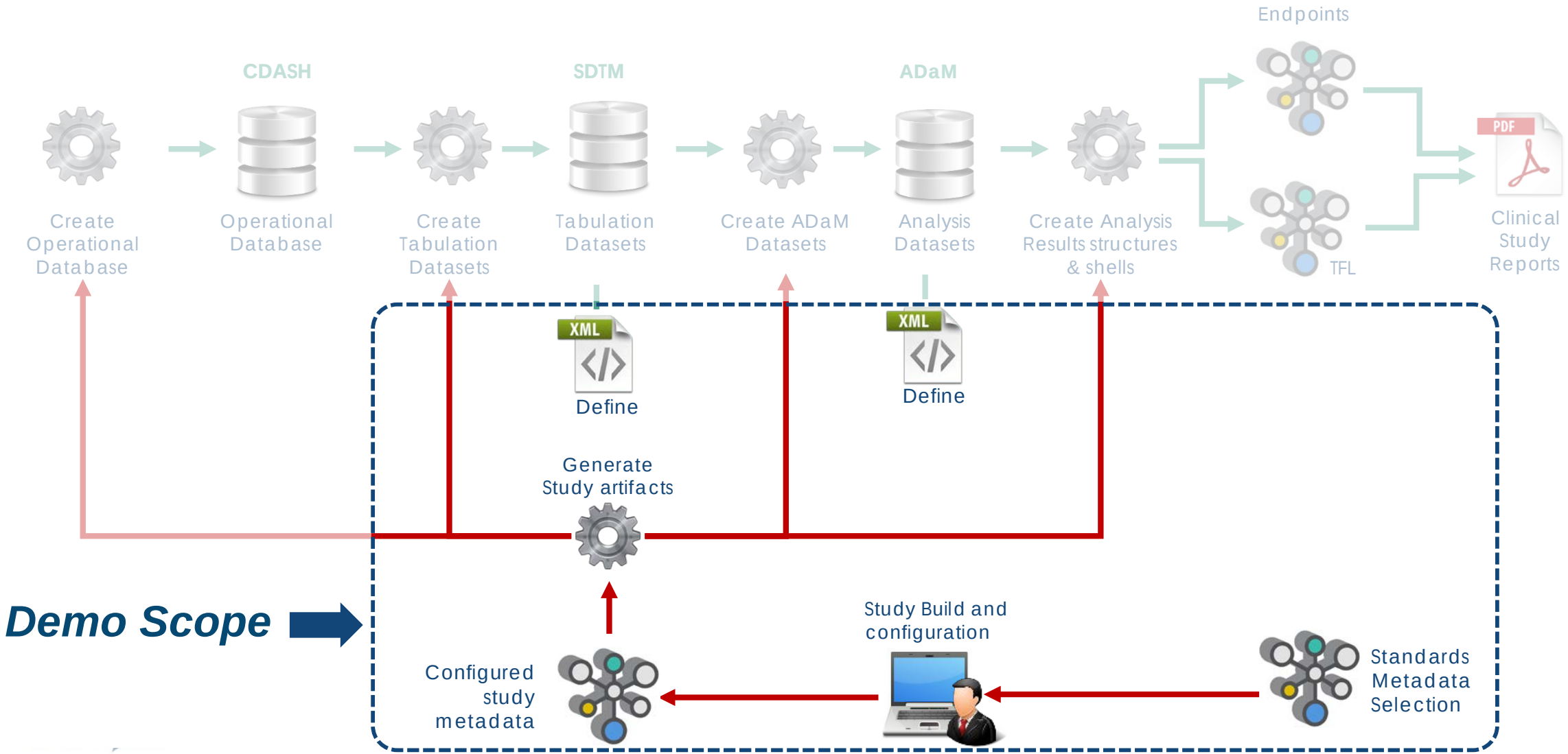


Concept Development: Next Steps

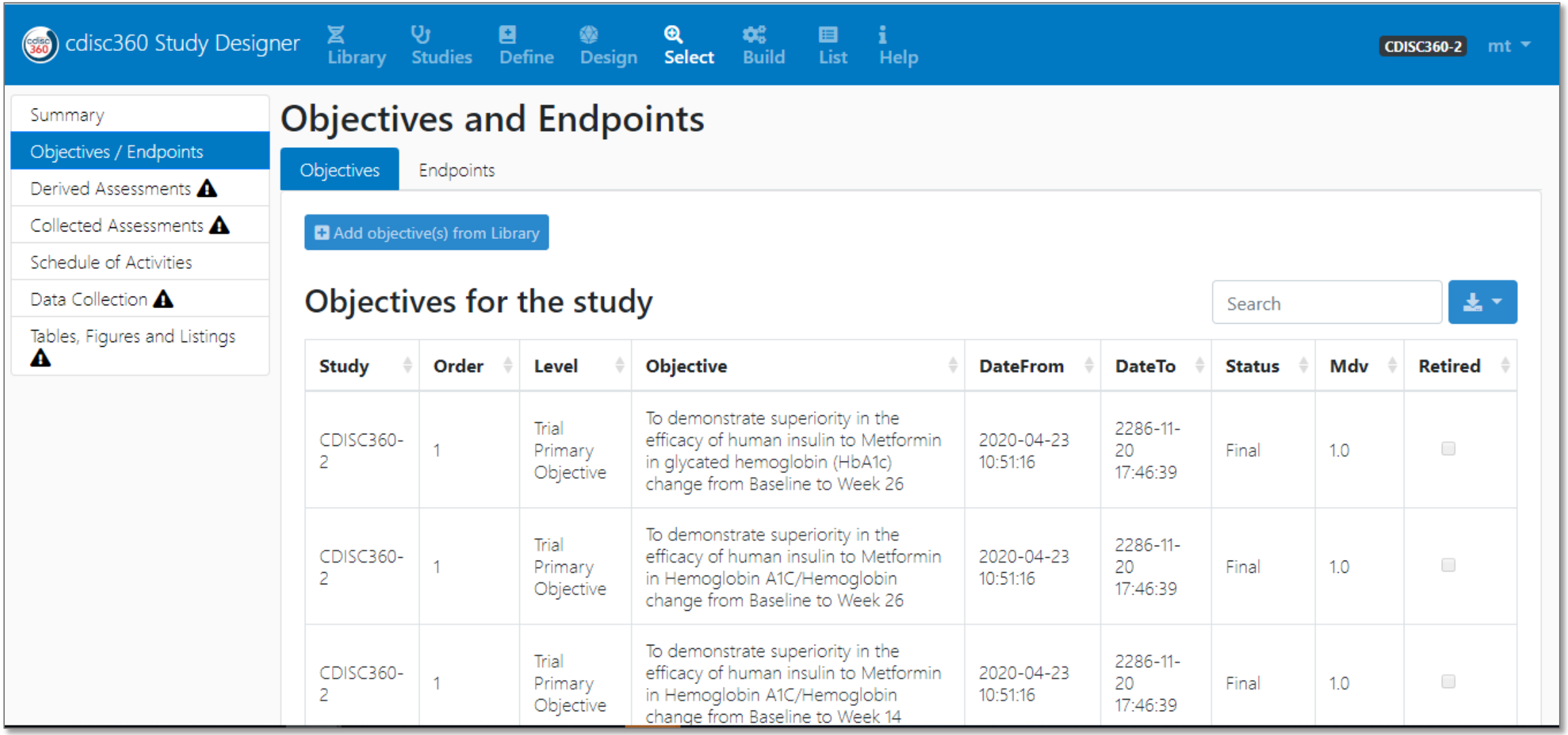
- Biomedical and Analysis concepts model and templates:
  - Test BCs (Lab, Exposure, Demographics, Trial Design, Vital Signs)
  - Test ACs (ADSL)
  - CRFs
- Data flow metadata:
  - System-agnostic transformations and derivations
  - Link data flow metadata to concepts
  - Test use of data flow metadata
- End-to-End from CDASH to ADSL:
  - For metadata (data state and data flow) and data

Use Case 2 : Build

Adding study design, concept configuration & generate artifacts

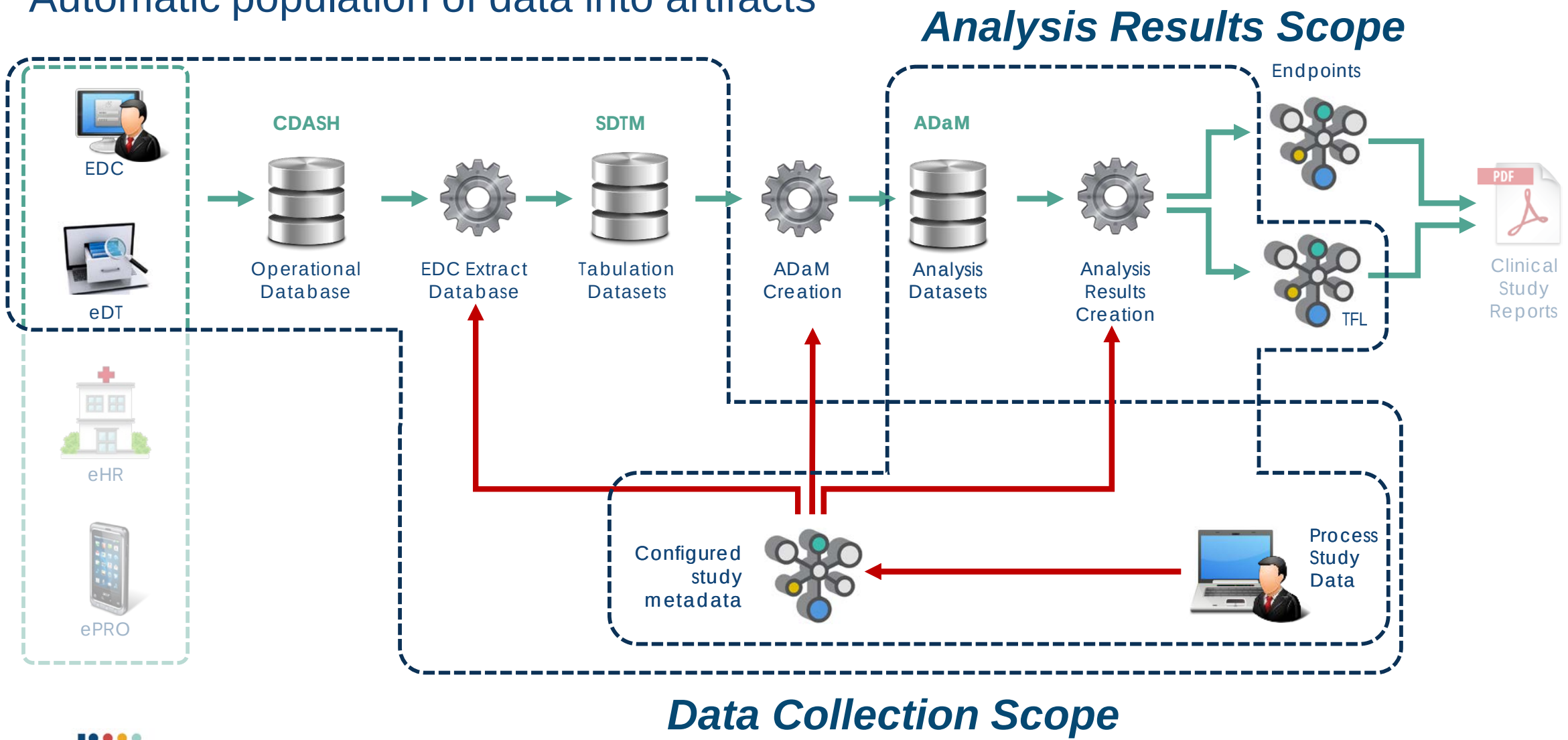


360 Use Case 1-2 Demo – Study Designer



Use Case 3 : Execute

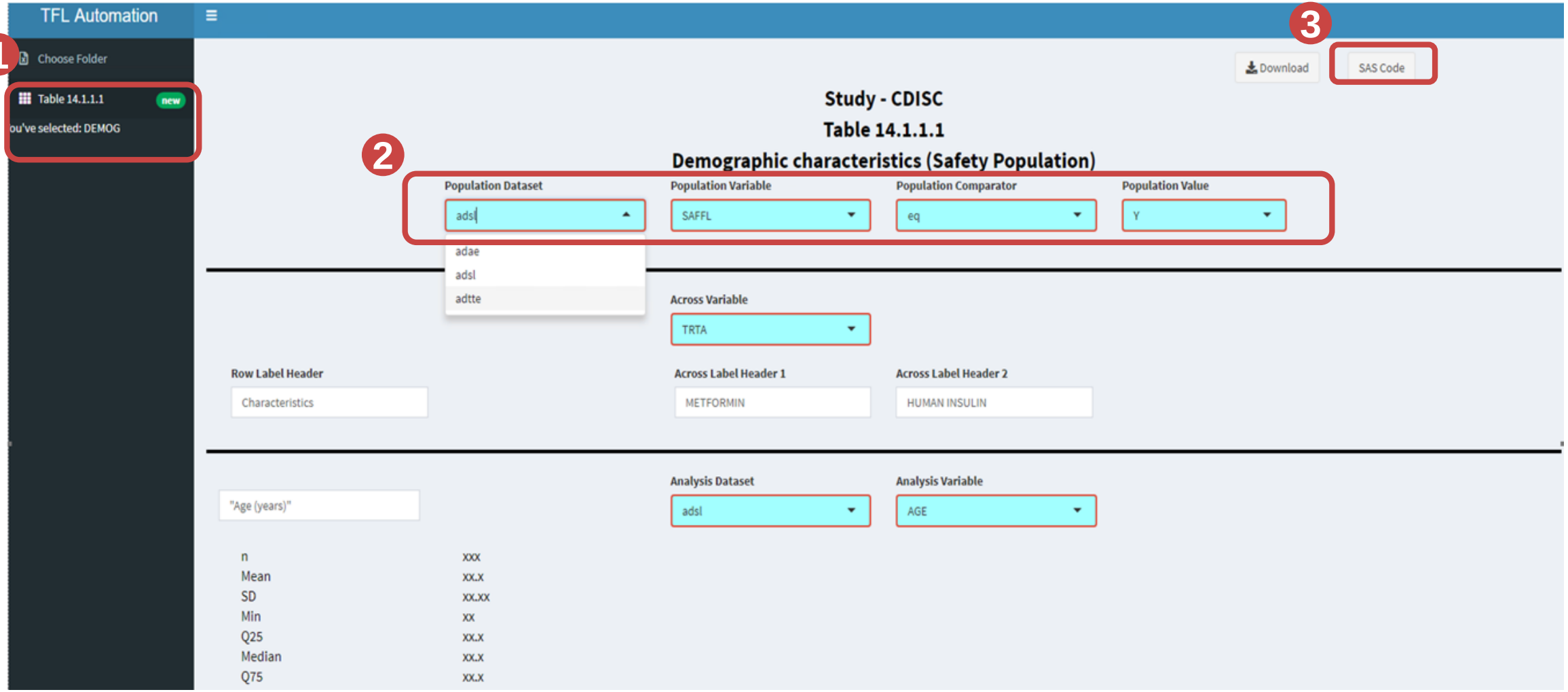
Automatic population of data into artifacts



CDISC360 – WS6 TFL Automation

Customize Template

Generate SAS Program and XML



Agenda

1. What is CDISC 360?
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What Follows 360 - Inventory of Work (1)

- **Missing** standards
  - Data Collection instruments
  - Analysis Results
  - Endpoint definitions
  - Safety User Guide
    - Collection ➔ Tabulation ➔ Analysis
- **Enrich** existing standards
  - What
    - Clinical assessments
    - Interventions
    - Events
    - Therapeutic Areas
  - How
    - Stabilize Biomedical and Analysis concept templates
    - Add transformations and derivations content

What Follows 360 - Inventory of Work (2)

- Evolve **library** technology and schema
  - Refine and test the CDISC 360 models
  - Refine and deploy CDISC 360 software tools
  - Integrate the CDISC 360 models into the CDISC Library model
  - Update the API to add new CDISC 360 model endpoints
  - Update the CDISC Library Data Standards Browser to include CDISC 360 content
  - Update the CDISC Library standards load software

- Evolve toward collaborative **curation**
  - Develop and rollout governance process
  - Create CDISC Library standards development and curation tools
  - Develop standards curation training
  - Enhance CDISC Library to load community standards implementations

Thank you

Questions pendant le Webinar

- C’est typiquement une approche sémantique RDF-like.. n'est-ce pas? OUI
  y a-t-il une chance que ça devienne le core structurel de CDISC à long terme? C’est possible

- Comment envisagez-vous de travailler en collaboration avec TransCelerate?
  Il y a déjà des connexions avec Transcelerate Digital Data Flow

- Le nb de biomédical concepts nécessaire a-t-il été quantifié/estimé?
  Non, il est difficile de trouver un consensus

- L’application qui génère les TLF, utilise bien ADaM ? OUI
  Est-ce que CDISC envisage de proposer des Metadata pour les TLF
  A long terme, oui

- Quelle est la différence entre la composante CDASH dans CDISC 360 et le projet CDASH eCRF, il y a des similitudes entre les deux ?
  CDASH eCRF créé les fonctionnalités pour etre machine-readable, qui est pré-requis de CDISC 360

CDISC COVID – 19 Guideline

https://www.cdisc.org/standards/therapeutic-areas/covid-19

Controlled Terminology COVID-19 Package 41a du 8 mai 2020
→ https://www.cancer.gov/research/resources/terminology/cdisc

Assia Bouhadouza
Sanofi, Global SDTM and Controlled Terminology Manager

Karen Fanouillere
Sanofi, Head of Clinical Information Governance and Clinical Data Foundation Program Leader
President, French CDISC User Group

Historique

- Besoin initial de développer un guideline pour les nouvelles études COVID-19

- CDISC a regroupé une Task Force en mars 2020:
  - Des membres de l'Industrie
  - Des académiques
  - Des réglementaires
  - Des membres du CDISC

- D'autres besoins ont été exprimés
  - Guidance pour les études en cours touches par la pandémie COVID-19
  - Resources pour les chercheurs Public Health – Formes annotées WHO et les Mappings
  - Supplément QRS en dévelopment pour le National Early Warning Scale 2 (NEWS2)
  - Controlled Terminology spécifique pour COVID-19

Interim User Guide Topics Covered

- Risk Factors
  - Pre-existing Medical Conditions
  - Personal Protective Equipment (PPE)
  - Travel
  - Contacts
  - Substance Use
  - Exposure to Animals
- Onset of Disease
- Signs and Symptoms
- Laboratory Test Results
- Diagnostics and Virology
  - Virus Identification
  - Antibody Testing
  - SARS-CoV-2 Viral Load
- Vital Signs and Urine Output
- Concomitant Medications
- Respiratory Findings
  - Imaging
  - Pulmonary Function Tests
- Cardiac Events/Findings
- Hospitalization
- Procedures
  - Assisted Ventilation and Oxygen Treatments
  - Renal Treatment
- Vaccines
- Questionnaires, Ratings, and Scales

Guidance for Ongoing Studies Disrupted by the COVID-19 Pandemic

- Listing of COVID-19 Related Impacts as Part of CSR
- Relationships to COVID-19
- Protocol Deviations
- Disposition
- Missed Visits
- Missed Assessments
- Changes to Drug Accountability
- Changes to Adverse Event Data Collection
- Changes in Exposure
- Transfer to Another Site
- Trial Summary to Provide Pandemic Relationship

Multiple Approaches

- It may not be possible to update case report forms (CRFs) for ongoing trials
- Collection of relevant information can be performed multiple ways
  - Key words such as "COVID-19" in existing text fields
  - Comments on the CRF
  - Documentation outside the regular CRF
- Instead of showing one way to model the data in SDTM, multiple options were shown
- Data about impacts of the epidemic, whether from CRFs or other sources, may be represented different ways
  - Standard SDTM variables,
  - Non-standard variables (NSVs),
  - Custom domains
  - Flag SDTM dataset records that document epidemic impacts using indicator NSVs

Ressources pour la Recherche

Outcomes

Twelve annotated CRF pages

Mapping file with 950 variables, associated metadata, implementation recommendations and CDASH equivalent variables

Most concepts mapped with minimal adjustment

A few concepts required non-standard variables or new modeling

CRFs and mapping file facilitate production of SDTM tables for combination with data from other sources

Perhaps future efforts can be designed to align a little more closely

Merci!

Jennifer Alf
Rebecca Baker
Cathy Bezek
Dana Booth
Assia Bouhadouza
Stephanie Chen
Karen Fanouillere
Nikki Flores
Nate Freimark
Praveen Garg
Tom Guinter
Ajay Gupta
Brian Harris
Keith Hibbetts
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Smitha Karra
Kalynn Kennon
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Laura Merson
Erin Muhlbradt
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David Parkinson
Nik Pemble
Chris Price
Heather Ribaudo
Justin Ritz
Lauren Shinaberry
Trisha Simpson
Lorraine P. Spencer
Will Stevens
Alana St. Clair
Sarah Strobino
Helena Sviglin
Peter Van Reusel
Robin White
Diane Wold
Jennifer Xio

PERSONNAL FEEDBACK

SANOFI IMPLEMENTATION

- Great experience and opportunity to contribute in this task force
- Very collaborative, CDISC team is very comitted to support its community
- Use of wiki were efficient and prompt feedback were appreciated
- Being able to share its own CRF has been advantagous : Experts perspective ++

- CHALLENGES:
- Conciliate follow-up on both CDISC Guidelines and Sanofi studies
  - COVID-19 impact were major and became Sanofi top priority
  - Couldn’t implemente exactly CDISC guideline due to timelines: compromise when possible ++
- Short and intensive review sessions, on top of current activities

Impact of FDA Guideline on SDTM

FOCUS

FDA Guidance	CDISC COVID-19 Interim User Guide	Associated Domains
The Introduction of the guidance discusses how restrictions related to COVID-19 may lead to changes in study conduct, and states the need to document the changes, their durations, and which trial participants were affected.	The Introduction to the guidance does not provide specifics on how or where the documentation should happen (e.g., documentation could reside in the site's files and not necessarily appear in collected data).	n/a
The Discussion section provides an overview of process, data, and analysis changes that may be needed for ongoing studies. Per Section III.B, when data are missing due to COVID-19-related reasons, both the data that was missed and the pandemic-associated reason must be clearly noted on the CRF. Section III.B provides context for the specifics listed in Section III.C.	For missing protocol-specified information, the preference is to capture subject-level data on a CRF. If this is not possible, data can be captured systematically across sites in a way that allows the regulatory body to analyze its impact. See the Protocol Deviations, Missed Visits, and Missed Assessments sections for direction. The domain-specific information on missing data will primarily appear in the domains, using standard variables such as --STAT and --REASND, and non-standard variables such as --REASOC and others proposed in this guide (see Appendix A. Non-standard Variables (NSVs)). When visits are missed, a different solution is needed. Advantages and disadvantages of these approaches are discussed in Missed Visits. How data are acquired to populate each of these depends upon how the sponsor's data capture is set up. Extending the Subject Visits (SV) domain was considered, but this approach was rejected because the model does not allow additional standard or NSVs in that domain. If data on site-level reasons for missing information are captured in such a way that individual subjects affected could be identified, the effects of site-level disruptions on individual subjects can be represented in SDTM-based datasets.	VE (Visit Events; interim custom) DV (Protocol Deviations)
Section III.C describes specific information to be included in the CSR, including • the contingency measures implemented during study disruption, • a listing of all participants affected by COVID-19-related study disruptions and specifics about how participation was disrupted, • analyses and discussions addressing the impact of implemented contingency measures on safety and efficacy, and • protocol deviations and specific reasons for them.	For the information required in Section III.C: • Contingency measures would be derived from protocol amendments, addenda to monitoring guidelines, data management plans, and documentation in the trial master file. Because some of this may come from the sponsor's administrative database content, it is probably not related to CDISC standards. • The listing of participants affected by COVID-19-related disruptions will probably be a highly derived compilation of data from many different domains, the specific content of which will depend on the data in the study. The domains that are most likely to be impacted by the COVID-19 pandemic are addressed in this interim guide. • A significant concern when processes or data are changed during a study is the potential impact on the primary outcome. Impacts will vary greatly from study to study, and	DV (Protocol Deviations) DS (Disposition) DA (Product Accountability) PR (Procedures) AE (Adverse Events) EC/EX (Exposure as Collected/ Exposure) ST (Site Transfer; custom domain) Any/all domains holding data which may be missed due to the pandemic

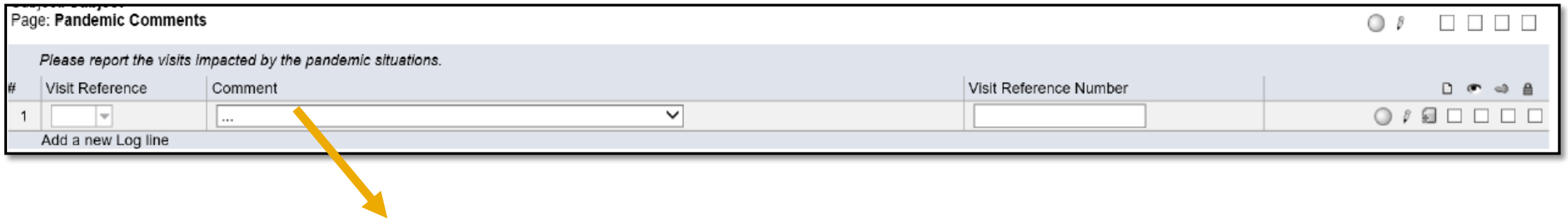
COVID-19: SDTM MAPPING APPROACHES

- Background

Due to FDA Guideline, ongoing studies had to be updated to collect information regarding missing data

- Sanofi: in order to not disrupt studies, decision has been made to use Comment Form (CO) already available in Standard Library

"Changes in study visit schedules, missed visits, or patient discontinuations may lead to missing information (e.g., for protocol-specified procedures). It will be important to capture specific information in the case report form that explains the basis of the missing data, including the relationship to COVID-19 for missing protocol-specified information (e.g., from missed study visits or study discontinuations due to COVID-19)."



COVID-19-COMPLETE VISIT DONE BUT DELAYED
COVID-19-MISSING DATA VISIT NOT DONE
COVID-19-MISSING DATA VISIT PARTIALLY DONE BY PHONE
COVID-19-MISSING DATA VISIT PARTIALLY DONE ON SITE

COVID-19: SDTM MAPPING APPROACHES

SANOFI IMPLEMENTATION

- SDTM Mapping_PHARMA

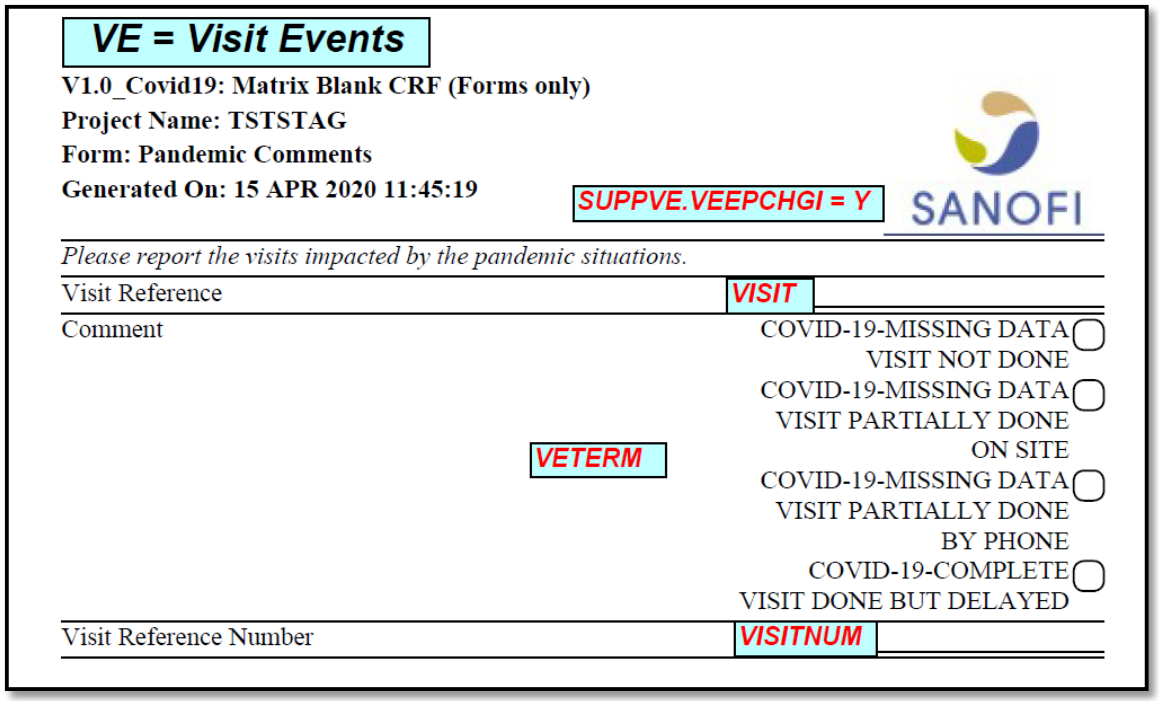
New custom domain **VE** (Visit Events) proposed by CDISC COVID-19 TAUG has been used for mapping.

FDA position during Task Force meeting:

- Whatever Sponsor decision, traceability is the key.
- Chosen approach should be discussed with Division Review
- VE is a good fit due to current SDTM limitations (i.e. SUPPSV is not allowed in current model)

→ Permits to collect any finding related to a planned visit with flag Epidemic Change Indicator.

→ This flag is used in deviation too



COVID-19: SDTM MAPPING APPROACHES

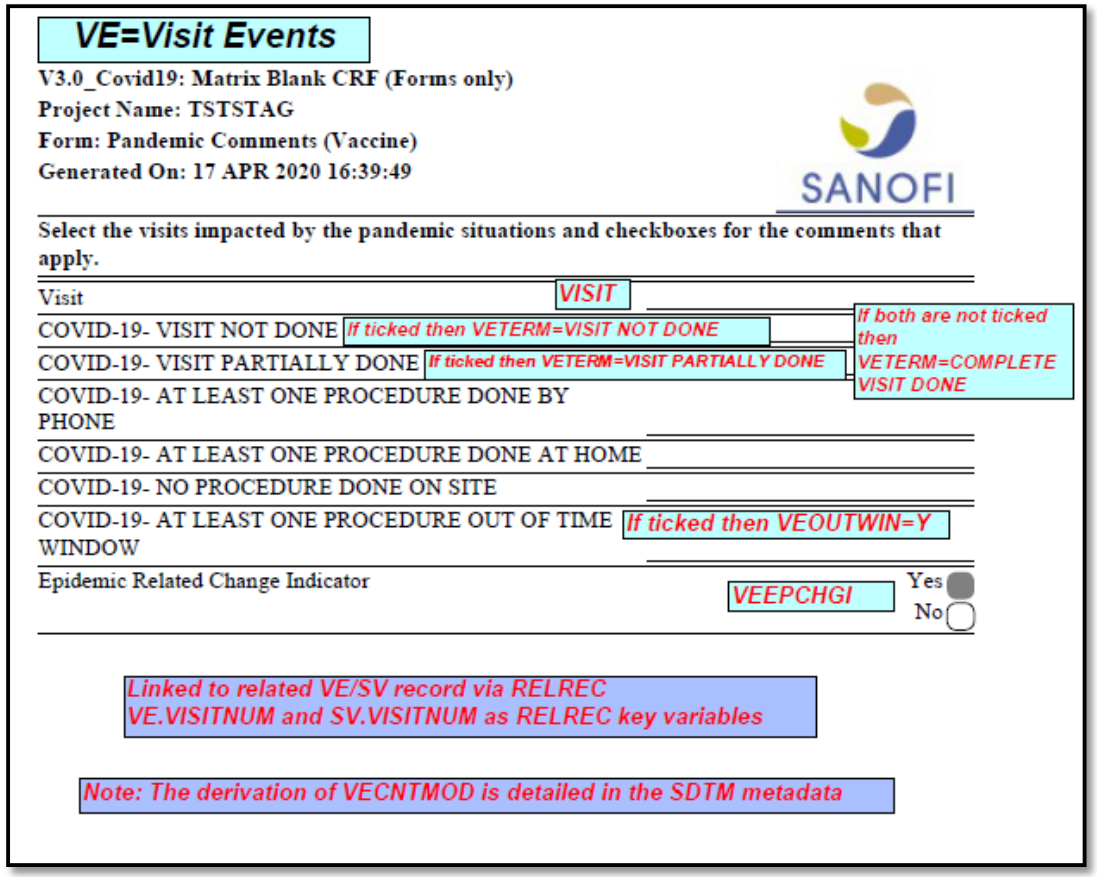
SANOFI IMPLEMENTATION

- SDTM Mapping_VACCINE

Timelines permit to design form in VE domain

  - Straighforward mapping.

  - « Epidemic Related indicator » flag will also be used for deviations (SUPPDV).



COVID-19: SDTM MAPPING APPROACHES

SANOFI IMPLEMENTATION

- DEVIATIONS
  - Creation of new categories for DVCAT
    - Deviation-Exceptional Situation Critical**
    - Deviation-Exceptional Situation Major**
    - Deviation-Exceptional Situation Minor **
    - Critical
    - Major
    - Minor
  - Use of Non Standard Variable Flag in SUPPDV: DVEPRELI (Epi/Pandemic Related Indicator)
    - Derived by programming using DVCAT value

**NEW

COVID-19: SDTM MAPPING APPROACHES

SANOFI IMPLEMENTATION

- STUDY SPECIFIC ASSESSMENTS/FORMS FOR :
  - Nasopharyngial Swab for SARS-CoV-2 detection
    - Mapped to MB domain
  - NEWS-2 (National Early Warning Score – 2)
    - Mapped to CC domain (Clinical Classifications)
  - Pnemonia Status at Screening (Medical History)
    - Mapped to MH / PR / CM
  - Oxygen Admin and Oxygenation
    - Mapped to VS / CM / PR / LB

NEXT STEPS

SANOFI IMPLEMENTATION

- CIG Lessons Learned
  - Internal process for Study Review couln't be followed: quick review/set up
  - Importance of Governance in Study Review
  - Automation of Study Review is helpful when timelines are reduced
  - Importance of regular CDISC watch (i.e. Controlled Terminology)
  - … ELSE?

- Escalate COVID-19 related forms to Standard Library?
  - Need Stakeholders feedback
    - Data Management, SDTM programmers, Stats…etc.
  - Update of SDTM Implementation Guide: documentation of SDTM selected approaches

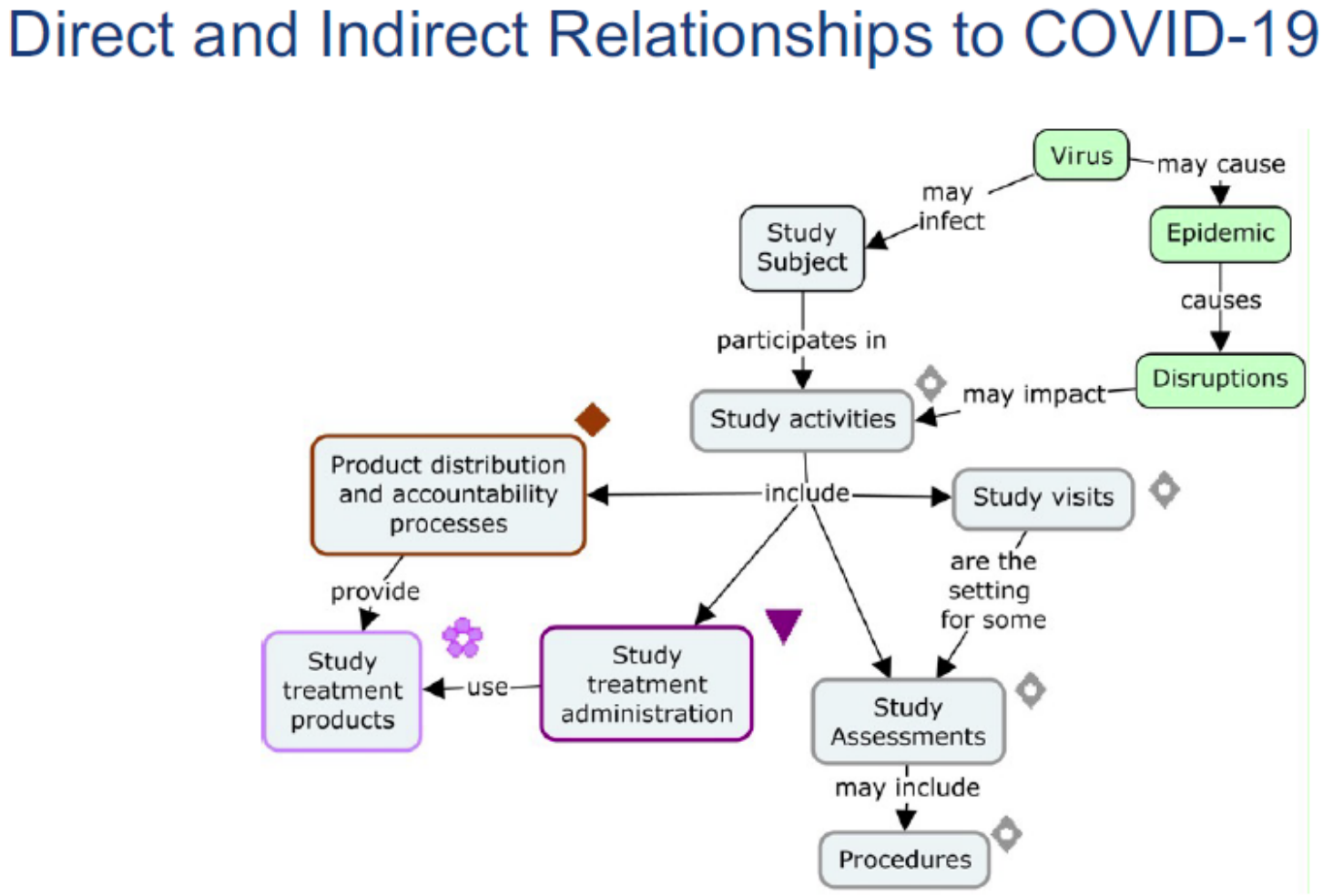
Questions pendant le Webinar

- Le FDA a demandé de rajouter du détail par rapport aux impacts de COVID19 sur la participation des sujets dans l'essai clinique, par exemple : COVID19 : Missed visits due to travel restriction, subject fears, site closure etc. … comment cette information est collectée dans le CRF?
  Au vu de l'urgence pour mettre en place ce CRF, ces informations sont collectés dans un champ commentaire

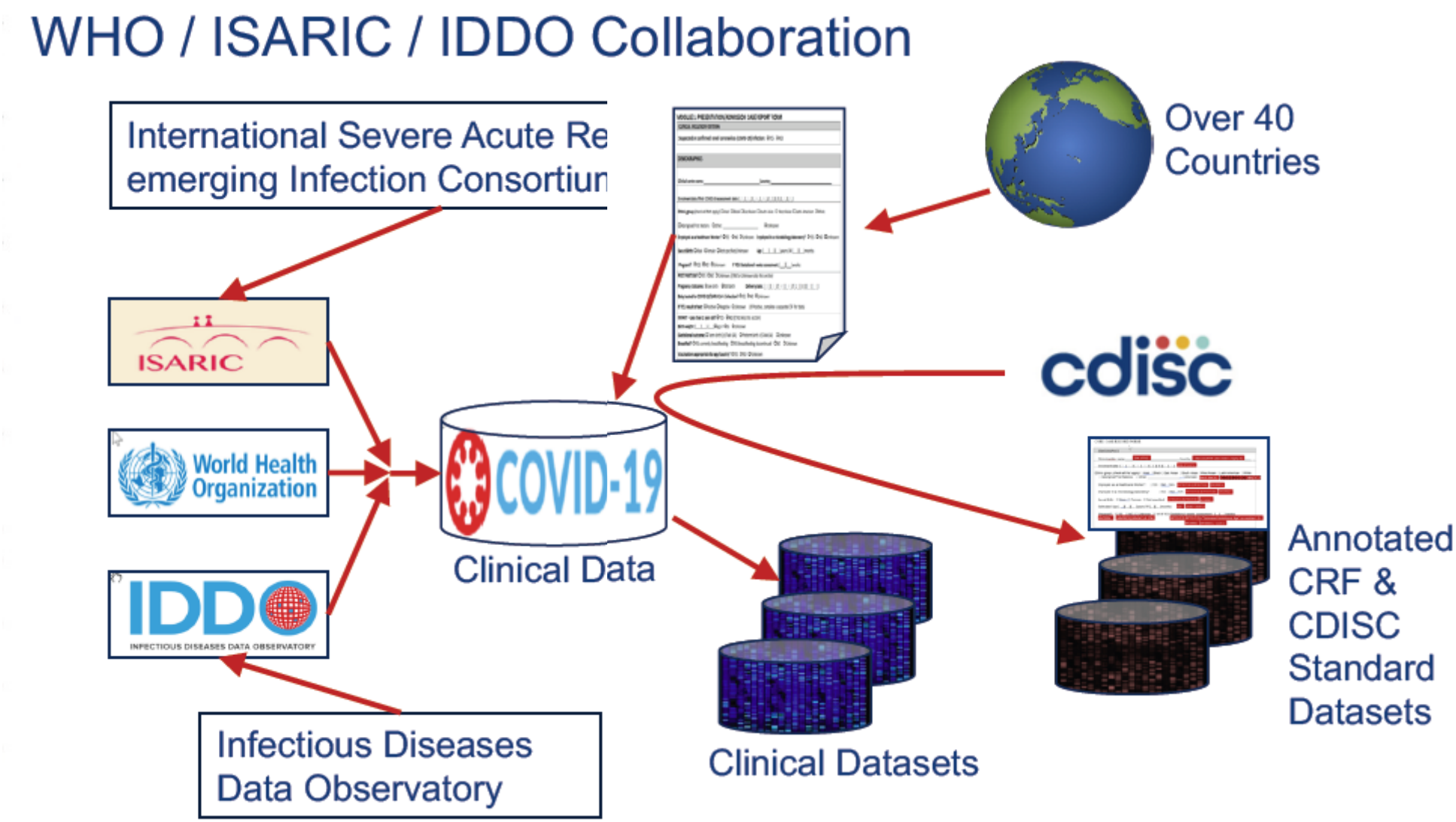
- Un flag pour les AE liés au COVID19 a été proposé par le guide, est-ce l'intérêt du flag de juste marquer les symptômes liés au COVID19 ou aussi liés à la pandémie e.g. Depression due to travel restrictions ? Juste les symptomes du COVID
-
- Est-ce que le groupe de travail envisage de proposer un template pour le listing que le FDA a demandé pour lister les sujets impactés par COVID19 dans l'étude et le détail de l'impact? Pas pour l'instant
-
- Note de Jozef : Je suis en train de développer un mapping entre les nouveaux LOINC codes pour Tests SARS-Cov-2 (Corona Virus) et le domaine MB. Un RESTful web Service est deja disponible pour tester: http://xml4pharmaserver.com/WebServices/LOINC2CDISC_webservices.html#loinccorona2mb

Back up

Impacts du COVID-19 sur les études



Ressources pour la Recherche



NEWS-2 (National Early Warning Score – 2)

CC = Clinical Classifications

V2.3_LIVE_07APR20: Matrix Blank CRF (Forms only)
Project Name: EFC16844
Form: National Early Warning Score 2 (NEWS2)
Generated On: 17 APR 2020 08:42:20

SANOFI

CCCAT = NEWS2

Was the assessment completed for this visit? **CCSTAT = NOT DONE if No** Yes ☐ No ☐

Date of Assessment **CCDTC**

Consciousness (ACVPU) **CCORRES when CCTESTCD = NEWS107**

Alert (A) ☐
Confusion (C) ☐
Voice (V) ☐
Pain (P) ☐
Unresponsive (U) ☐

Nasopharyngial Swab for SARS-CoV-2 detection

MB = Microbiology Specimen

V2.3_LIVE_07APR20: Matrix Blank CRF (Forms only)
Project Name: EFC16844
Form: Nasopharyngeal swab for SARS-CoV-2 detection
Generated On: 17 APR 2020 08:42:20

SANOFI

No ☐

If yes, complete the following questions.

Collection Date — **MBDTC**

Test Name — SARS Coronavirus 2

Result — **MBORRES when MBTESTCD = SAR2RNA** — Negative ☐ Positive ☐

MBTSTDTL = DETECTION

MBMETHOD = QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION

MBSPEC = SWABBED MATERIAL

Pnemonia Status at Screening

MH = Medical History | PR = Procedures | CM = Concomitant Medications

D1.0_REVIEW_24MAR20_KL: Matrix Blank CRF (Forms only)
Project Name: EFC16844
Form: Pneumonia Status at Screening
Generated On: 24 MAR 2020 22:08:10

SANOFI

Reported Term	MHTERM	PNEUMONIA
Occured?	MHOCCUR	Yes ■ / No ☐
Pre-Specified?	MHPRESP	Yes ■ / No ☐
Does the subject have a history of or current Chronic hypercapnic respiratory failure? MHTERM = Chronic Hypercapnic Respiratory Failure	MHOCCUR / MHPRESP = Y	Yes ☐ / No ☐
Was evidence of pneumonia present based on historical chest X-ray or CT scan or MRI or lung auscultation?	MHEVIIND in SUPPMH	Yes ☐ / No ☐
Type of Oxygen Delivery Device PROCCUR = Y if ticked; PRPRESP = Y; PREVINTX = DURING PNEUMONIA		Nasal cannula ☐ Simple face mask ☐ Non-rebreather face mask ☐ High-flow nasal cannula ☐ Non-invasive ventilation ☐ Invasive mechanical ventilation ☐ [NOT SUBMITTED] Other ☐
If Other, specify	PRTRT	
Procedure Name	PRTRT	
Use of extracorporeal life support (eg, extracorporeal membran oxygenation) PRTRT = ECMO; PREVINTX = DURING PNEUMONIA	PROCCUR / PRPRESP = Y	Yes ☐ / No ☐
Use of vasopressors CMTRT; CMEVINTX = DURING PNEUMONIA; CMINDC = PNEUMONIA	CMOCCUR / CMPRESP =Y	Yes ☐ / No ☐
Use of renal replacement therapy PRINDC = PNEUMONIA; PRTRT = Renal Replacement Therapy; PREVINTX = DURING PNEUMONIA	PROCCUR / PRPRESP = Y	Yes ☐ / No ☐
Signs and Symptoms MHCAT = PNEUMONIA SYMPTOMS; MHEVINTX = DURING PNEUMONIA	MHTERM	FEVER
Occured?	MHOCCUR	Yes ☐ / No ☐
Pre-Specified?	MHPRESP	Yes ■ / No ☐
Onset Date	MHSTDTC	

Oxygen Admin and Oxygenation

VS = Vital Signs | CM = Concomitant Medications | PR= Procedures

V2.3_LIVE_07APR20: Matrix Blank CRF (Forms only)
Project Name: EFC16844 | LB = Laboratory Test Results
Form: Oxygen Administration and Oxygenation
Generated On: 17 APR 2020 08:42:20

SANOFI

If the patient **does not receive oxygen supplementation: Do not record** *the oxygen flow rate and the FiO2.*

If the patient **is using: high flow nasal cannula, non-invasive ventilation, invasive mechanical ventilation: Please record FiO2**

If the patient **receives extracorporeal membrane oxygenation (ECMO),** *alone or in combination with any other oxygen supplementation:* **Record the FiO2 of ECMO.**

Was the assesment performed? [NOT SUBMITTED] Yes ☐ No ☐

Date of Assessment VSDTC | CMSTDTC | PRSTDTC | LBDTC

Time

SpO2 Fixed Unit: %

VSORRES / VSORRESU when VSTESTCD = OXYSTAT

Was any supplemental Oxygen or mechanical ventilation used? CMOCCUR Yes ☐ No ☐
CMTRT = OXYGEN THERAPY | CMINDC = PNEUMONIA | CMPRESP = Y

Type of Oxygen Delivery Device PRTRT | PROCCUR = Y if ticked | PRINDC = PNEUMONIA | PRPRESP = Y
- Nasal cannula ☐
- Simple face mask ☐
- Non-rebreather face mask ☐
- High-flow nasal cannula ☐
- Non-invasive ventilation ☐
- Invasive mechanical ventilation ☐
- [NOT SUBMITTED] Other ☐

If Other, specify PRTRT

Use of extracorporeal life support (eg, extracorporeal membrane oxygenation) PRINDC = PNEUMONIA | PROCCUR | PRTRT = ECMO | PREVINTX = DURING HOSPITALIZATION | PRPRESP = Y Yes ☐ No ☐

Oxygen flow rate CMDOSFRQ = CONTINUOUS | CMEVINTX = DURING HOSPITALIZATION Fixed Unit: L/min

CMDOSE / CMDOSU

FiO2 Fixed Unit: %

LBORRES / LBORRESU when LBTESTCD = FIO2