CDISC 360 status update: starting the journey

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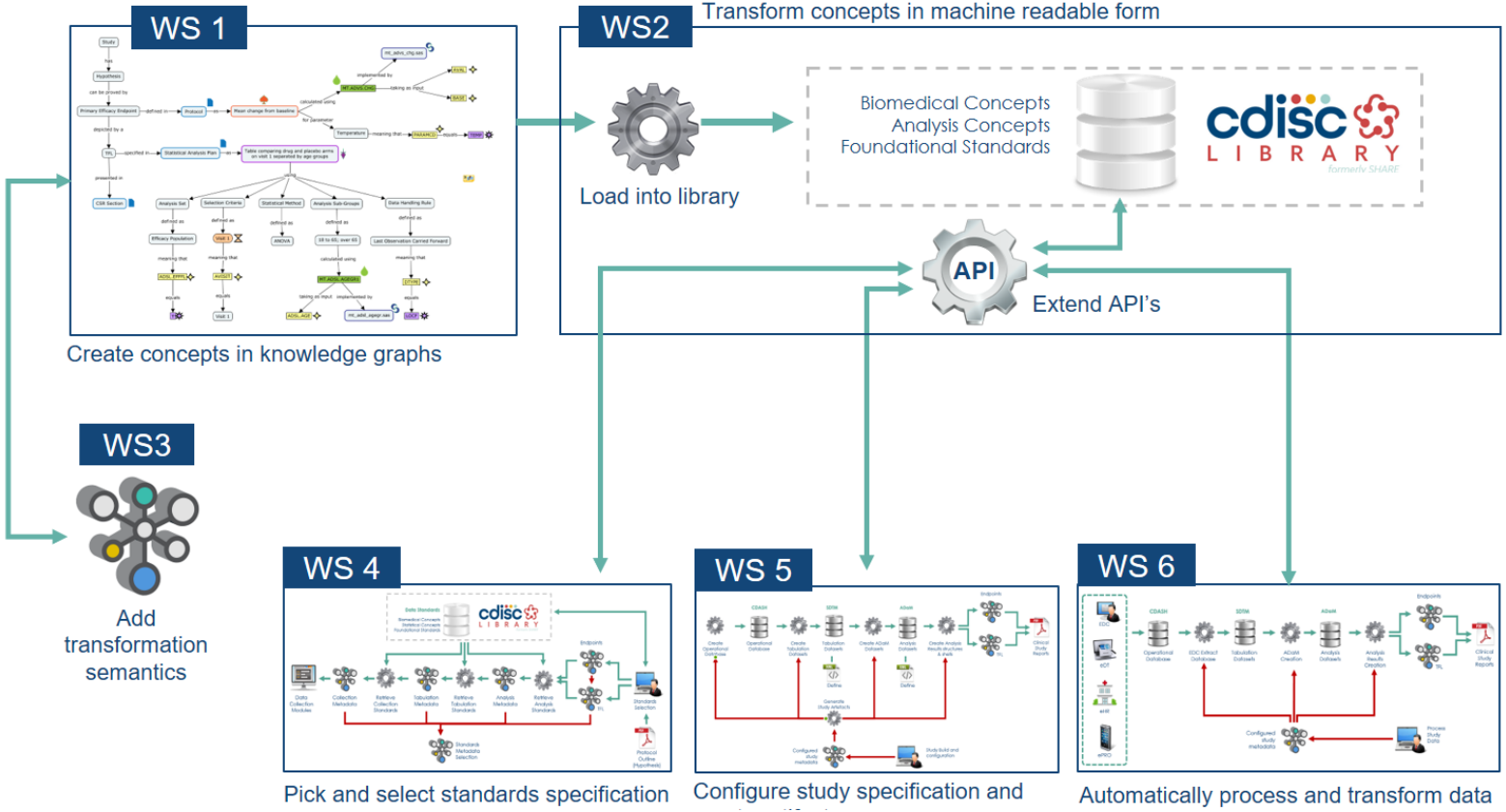
24 June-2019

CDISC 360

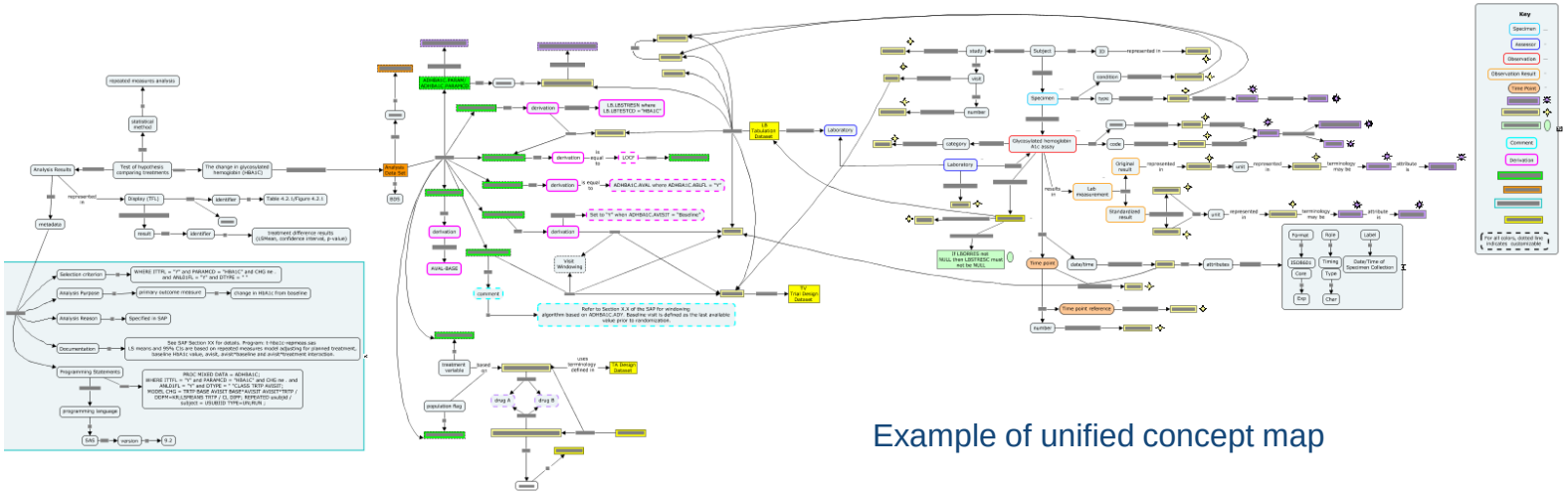
What is CDISC 360?

Workstreams Overview



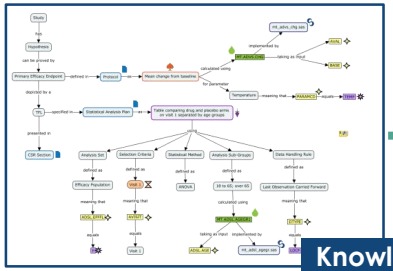
WS1 Inputs

- 360 Cmap cloud – has initial mapping of one Diabetes TAUG endpoint:
  - Unified concept map (analysis and biomedical concept combo)
  - Split concept map
    - Analysis results map
    - Analysis parameter map
    - Biomedical concept map to SDTM
    - Biomedical concept map to Data Collection



Example of unified concept map

CDISC Library API extension



Knowledge graph

LOAD

Biomedical Concepts
Analysis Concepts
Foundational Standards

cdisc LIBRARY
formerly SHARE

Call

API

Extend Current Set of APIs

Return

API metadata Return

PAA	BBB	X-3	Y+H	DEF	1+2	…

- Dataset metadata
- Concept metadata
- Concept relations
- Controlled terminology
- Process metadata
- Configuration Defaults and options

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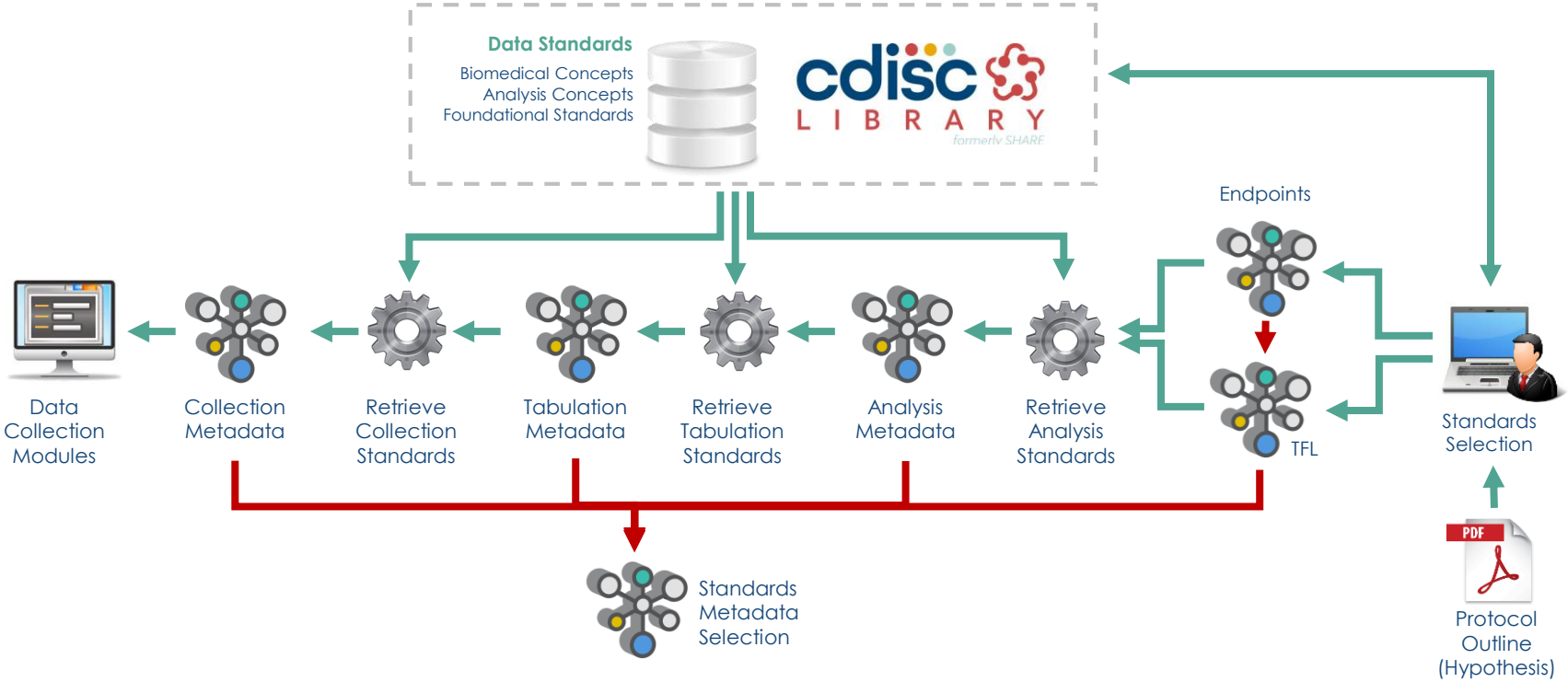
Use Case 1 : End to Start specification

Selecting standards concepts and linked metadata needed for a study



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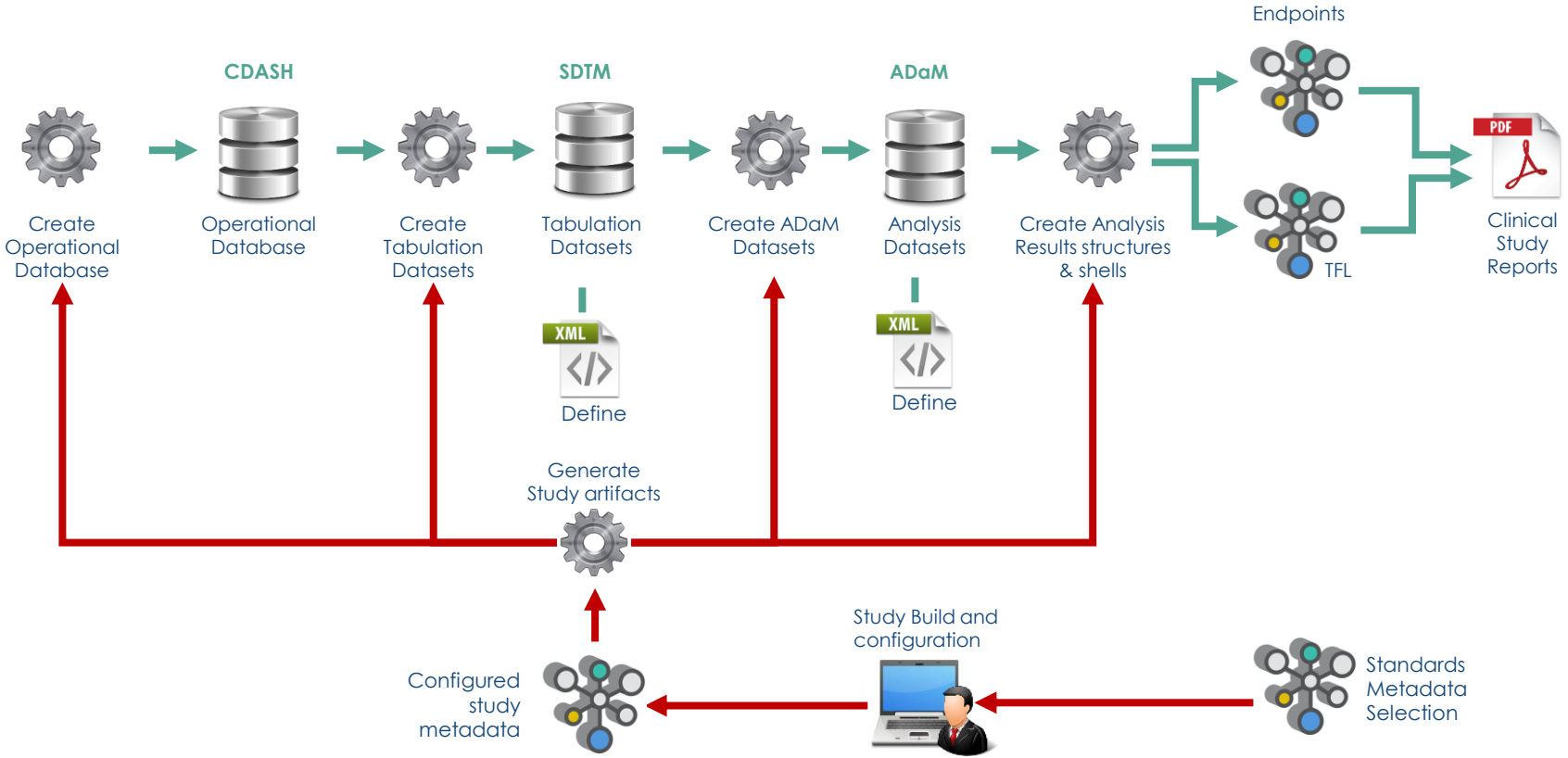
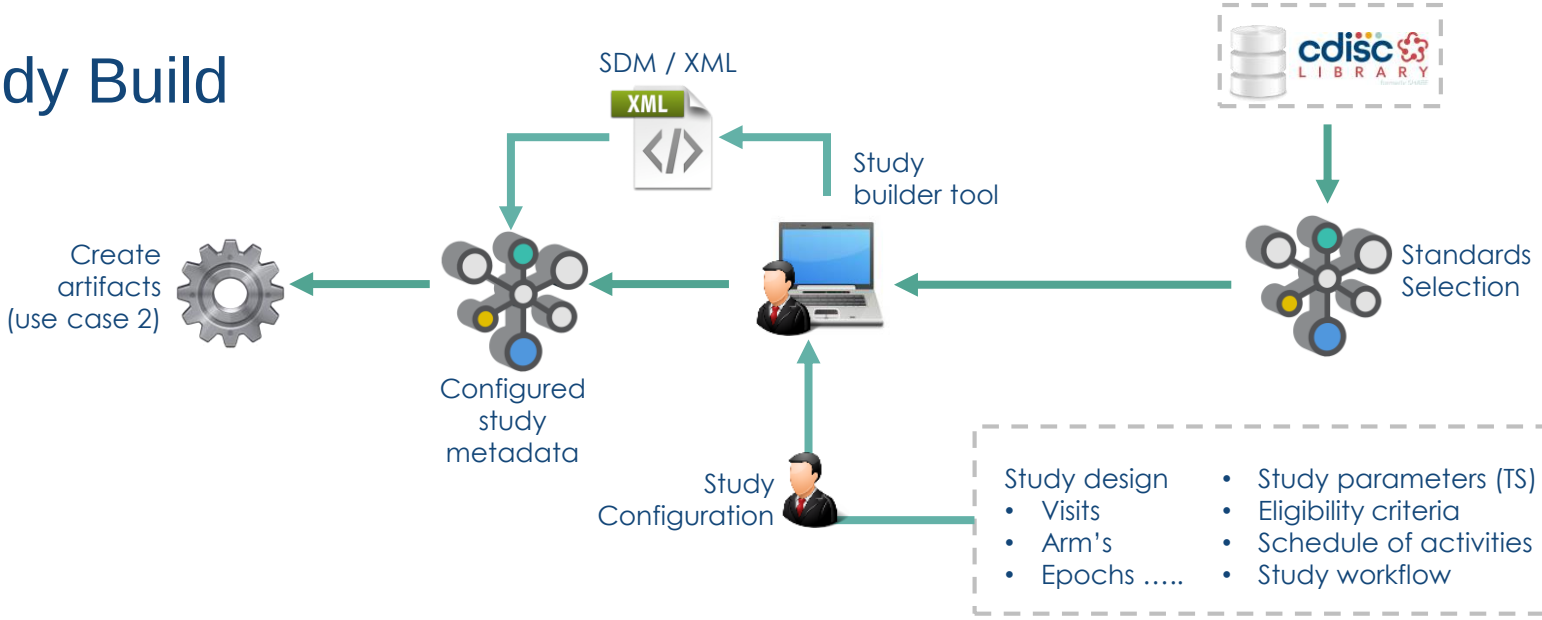
Use Case 2 : Start to End Study Metadata

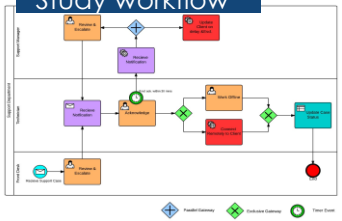
Adding study design, concept configuration & generate artifacts



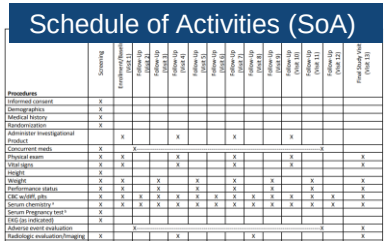
Study Build



Study workflow

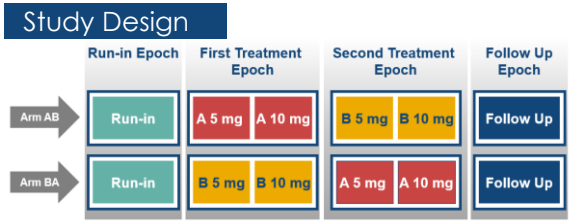


Schedule of Activities (SoA)



Procedures	Screening	Enrollment/Baseline (Visit 1)	Follow-Up (Week 4)	Follow-Up (Week 8)	Follow-Up (Week 12)	Follow-Up (Week 16)	Follow-Up (Week 20)	Follow-Up (Week 24)	Follow-Up (Week 28)	Follow-Up (Week 32)	Follow-Up (Week 36)	Follow-Up (Week 40)	Follow-Up (Week 44)	Follow-Up (Week 48)	Follow-Up (Week 52)	Final Study Visit (Week 53)
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
Performance status	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		X
Serum chemistry*	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X
Serum Pregnancy test*	X															
EKG (as indicated)	X															
Adverse event evaluation		X													X	X
Radiologic evaluation/imaging	X					X					X					X

Study Design

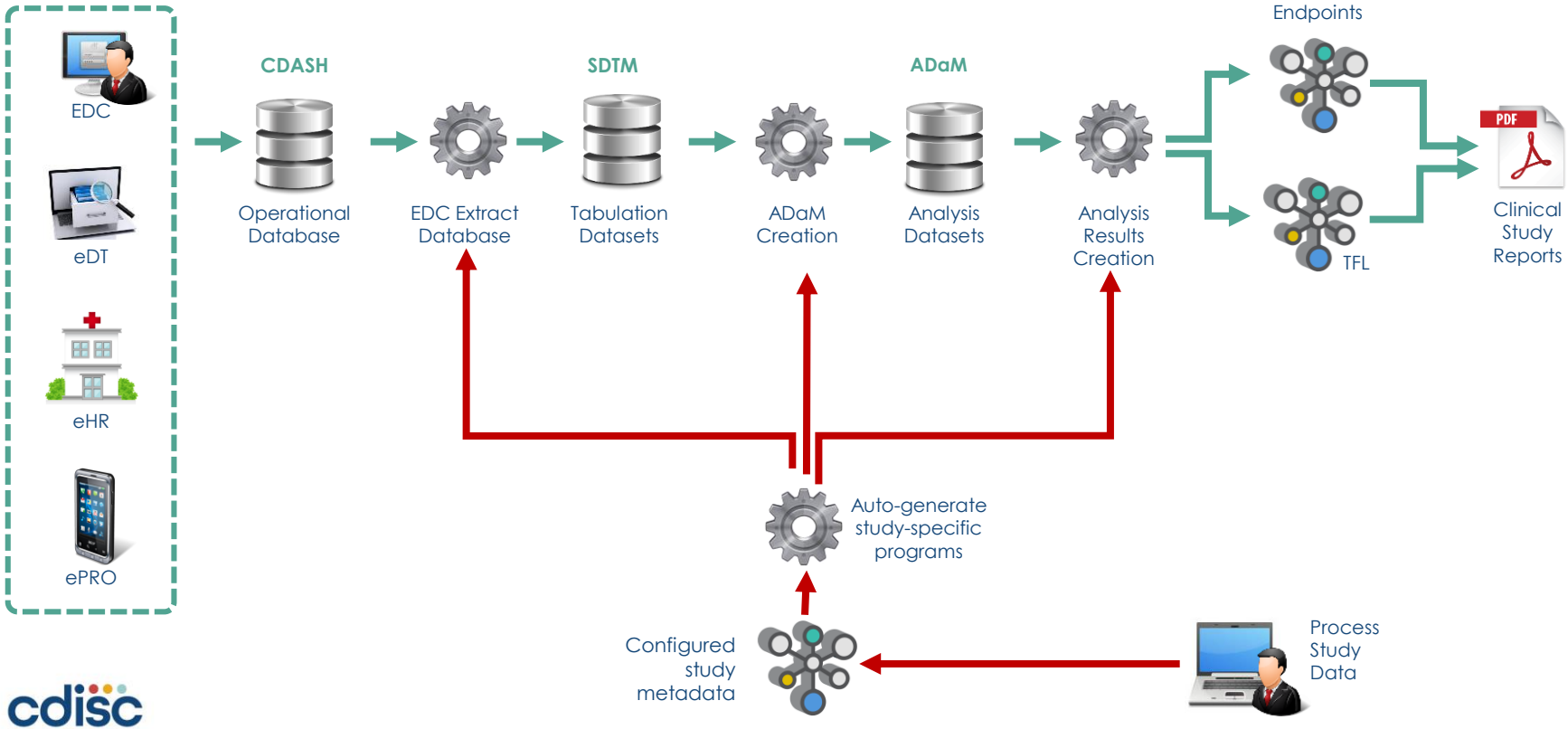


Study Parameters (TS)

STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
XYZ	TS	1		ADDON	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	P18M			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

Use Case 3 : Start to End Data Processing

Automatic population of data into artifacts



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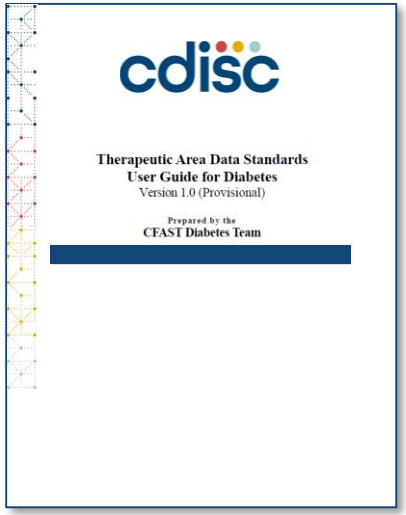
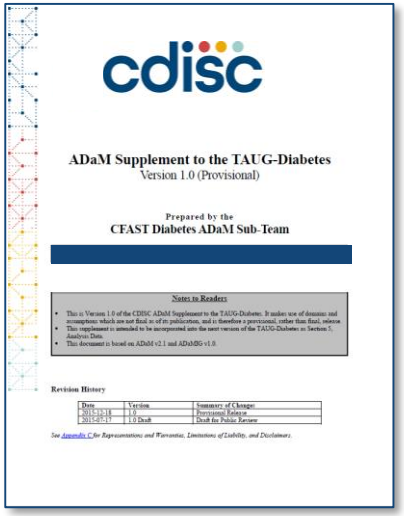
Project Standards Scope

Diabetes TAUG





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

→ Looking for your contribution: Anonymized Diabetes data

Standards Selection
(for the “360 Test Study”)

For the “360 Test Study” we will, for these standards:
- Develop standard concepts
- Store concepts in prototype CDISC Library
- Pick & select standards from Library (use case 1)
- Configure study spec & create artifacts (use case 2)
- Populate study artifacts with data (use case 3)

- 1 or 2 statistical end points
  - Analysis of Glycated Hemoglobin
  - Summary of Hypoglycemic episodes
- ~3-4 ADaM datasets
  - ADSL(**Subject-Level Analysis Data (ADSL)**)
  - Hemoglobin A1C Analysis Dataset (**HbA1c Analysis Dataset**)
  - Hypoglycemic Episodes Analysis Dataset (**Hypoglycemic Episodes Analysis Dataset**)
  - Hypoglycemic Episodes Summary Dataset (**Hypoglycemic Episodes Summary Dataset**)
- ~7-8 SDTM datasets
  - DM (Demographics, to support standard variables in ADSL)
  - VS (Vital Signs, for height and weight in ADSL)
  - CM (Concomitant Meds, to support stratification by background treatment, and for treatments of hypoglycemic events)
  - LB (for Hemoglobin A1C data)
  - CE and FACE (for data on hypoglycemic events)
  - EX, ML (for data about meals and study treatments relative to hypoglycemic events)
  - Trial Design datasets (for arms, visit schedule, definition of hypoglycemic events as disease milestones)
- ~15 CDASH CRFs
  - CDASH CRFs needed to support SDTM datasets above. One CRF will support collection of data about hypoglycemic events that will be mapped to multiple SDTM domains.

CDISC 360

The CDISC 360 journey has started…

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)	Nov 2020	Nov 2020

CDISC 360 Advisory Committee

CDISC 360 Leadership Team

- David Bobbitt
  CDISC Chief Executive Officer
- Peter Van Reusel
  CDISC Chief Standards Officer
- Sam Hume
  CDISC Vice President Data Sciences
- Barry Cohen
  CDISC 360 Project Manager

CDISC 360 Board Representation

- Chris Decker - dWise
- Dave Evans - Accenture
- Dave Hardison - Deloitte
- Pandu Kulkarni - Lilly
- Steve Rosenberg - Oracle
- Ulo Palm - * Transcelerate

CDISC 360 Committee Members

- Praveen Garg - Astra Zeneca
- Patrick Genyn - Johnson & Johnson
- Brooke Hinkson - Merck
- Ulo Palm - Allergan
- Mike Hamidi - CDISC

Participation Summary

23 Companies

63 Resources specified

Organization Types:

- Pharma-Biotech Sponsor: 13
- CRO: 4
- Technology Provider: 6


abbvie
Allergan
AMGEN
BIOMARIN
C+R RESEARCH
Celgene
dMed 缔脉
GILEAD
Johnson & Johnson
Lilly
MERCK
Microsoft
novo nordisk
ORACLE
Otsuka
Pfizer
PharmaStat
PINNACLE 21
S-CUBED
sas
TALENTMINE
VITA DATA SCIENCES a division of SOFTWORLD
xclinical
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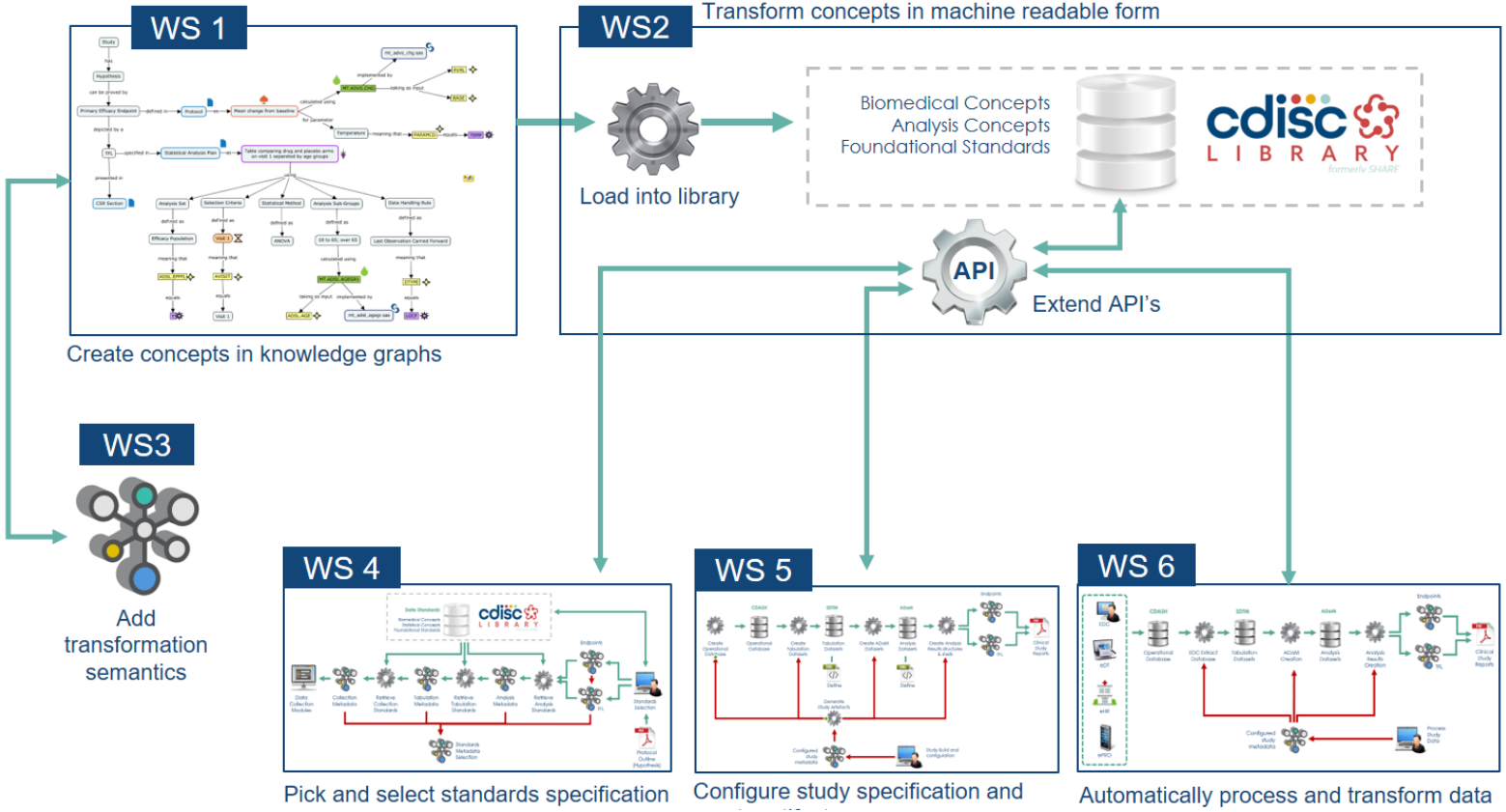
Workstreams Overview



Workstream Teams

WS 1

Lead: Bess LeRoy
Jon Neville

Ryan Tubbs
Manuel Anido
John Wang
Erika Liu
Manjula Reddy
Guang-liang Wang
Manjula Reddy
Kathleen Hectors
Joyce George
Nik Pemble
Swarupa Sudini

Sally Cassells
Mikkel Traun
Ryan Tubbs
Smitha Karra
Chithra Subramaniam
Gloria Jones
Pei-Ling Chu

WS3

Lex Jansen
Carol Baker
Greg Steffens

WS 2

Lead: Sam Hume

Francis Dsa
Stephen Pearce
Edward Altman
Haiping Yu
Jeanne Wagner
Erika Liu
Dave Iberson-Hurst
Nicolas de Saint Jorre

WS 4

Lead: Mikkel Traun

Trevor Mankus
Stephen Pearce
Rajesh Modi
Bharat Palakurthi
Lex Jansen
Sujit Khune

WS 5

Lead: Tianna Umann
Lauren Shinaberry

Asavari Mehta
Ram Govindaraju
Devi Gohimukkula
Nik Pemble
Rick Rozinskas
Francis Dsa

WS 6

Lead: Bhavin Busa

Rick Rozinskas
Julie Smiley
Guang-liang Wang
Gloria Jones
Gina Selby
Naveen Kommuru
Jimmy Zhao
John Brega
Kathleen Hectors
Anoop Ambika
Spandana Chelmilla

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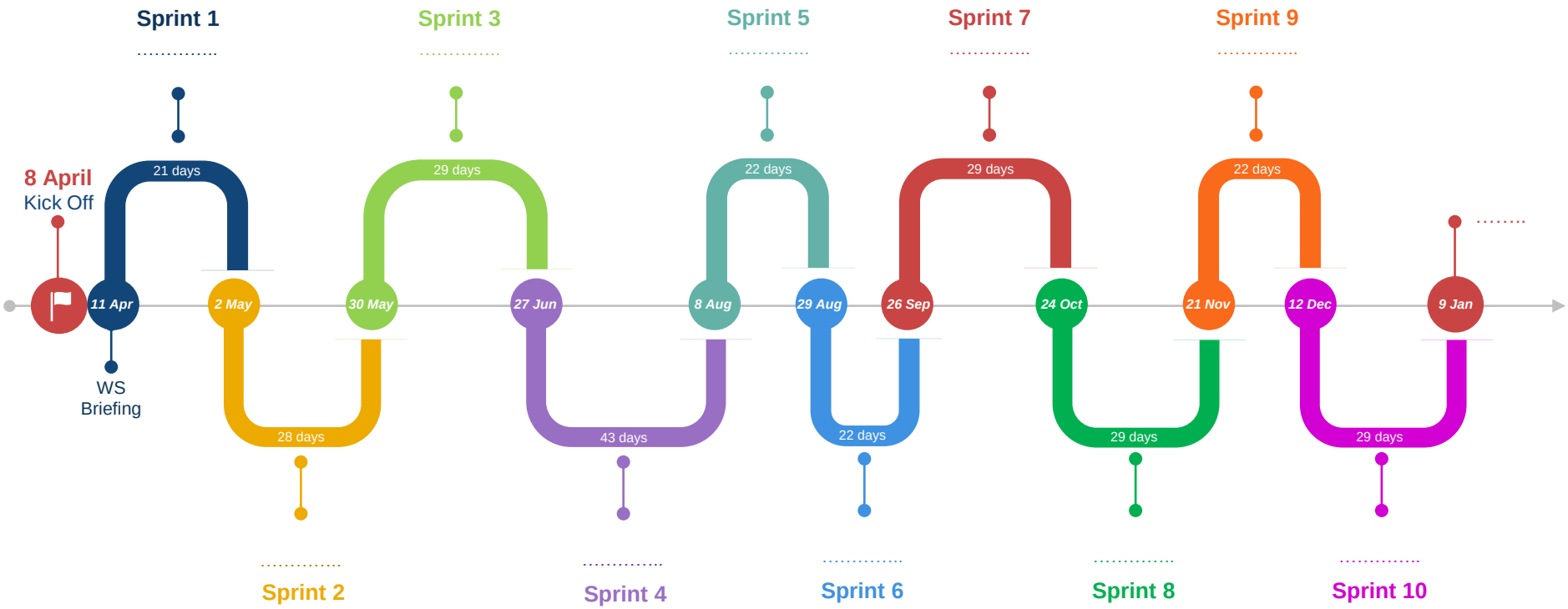
360 Sprint Cycles for 2019



Collaboration Tools

- CDISC 360 Wiki
  - Collaborative content
- Jira
  - Issues management
- CMAP Cloud
  - Concept map development
- Slack
  - Instant messaging
- Technology Platform
  - Use case demo environment

Microsoft & CDISC 360

Collaboration, Development & Proof of Capability Platform

Paul Slater and Ryan Tubbs – Co-founders, Clinical Research Innovation Hub
Kirk Carver , Solution Architect
Tianna Umann PA-C, MA, Solution Architect

Set-up Collaborative Computing platform

- Microsoft will work with CDISC to
  - Set up an Azure Cloud subscription
  - Provide admin rights to the technical team and workstream leads

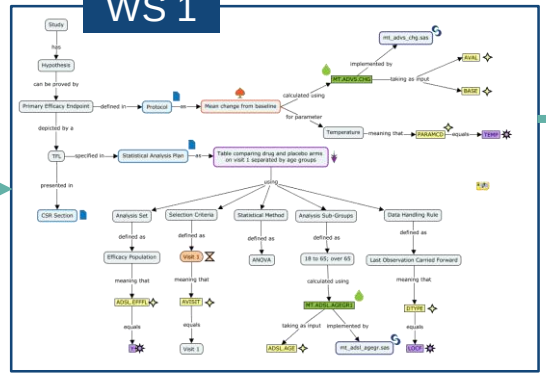
- Microsoft will deploy and support the following platform services:
  - Azure Active Directory structure - for admin and role based access control
  - Azure Data Lake Storage (ADLS v2) - for meta data storage and data sharing
  - Azure Data Science Virtual Machine - to enable statistical programs (R, Python, etc.)
  - Azure Virtual Machines - to enable applications such as Pinnacle 21 and SAS

➔ CDISC to discuss deployment licenses with Pinnacle 21 and SAS

FDA Use Case

- Use case to include one or more safety analyses for diabetes
  - FDA SMEs to provide exact requirements and definitions
    - May include a commonly used safety analysis and a rarely used safety analysis
- Develop concept maps for the safety analyses as defined by FDA SMEs
  - Use WS1 concept maps as a starting point
- Goal: ensure the standards meet the needs of the reviewer
  - Could be used as a data fitness test to confirm the needed data is present for the safety analyses
  - These templates could be very useful to implementers/sponsors
- FDA is very interested in following the progress of the FHIR, LOINC, and UCUM use cases

WS 1



Create concepts in knowledge graphs

WS2

Transform concepts in machine readable form

Load into library

Biomedical Concepts
Analysis Concepts
Foundational Standards

cdisc LIBRARY
formerly SHARE

WS 7

WS3

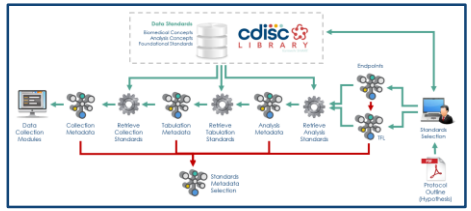
Add transformation semantics

Document FDA Analysis Requirements in knowledge graphs

FDA

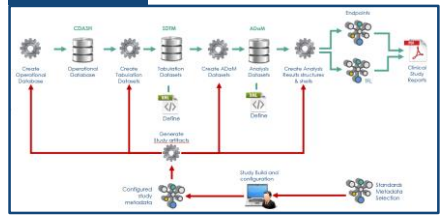
Verify analysis requirements
Verify data & metadata traceability

WS 4



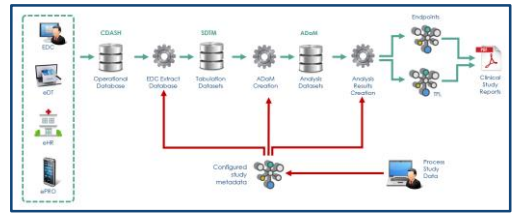
Identify and select standards specification (Use Case 1)

WS 5



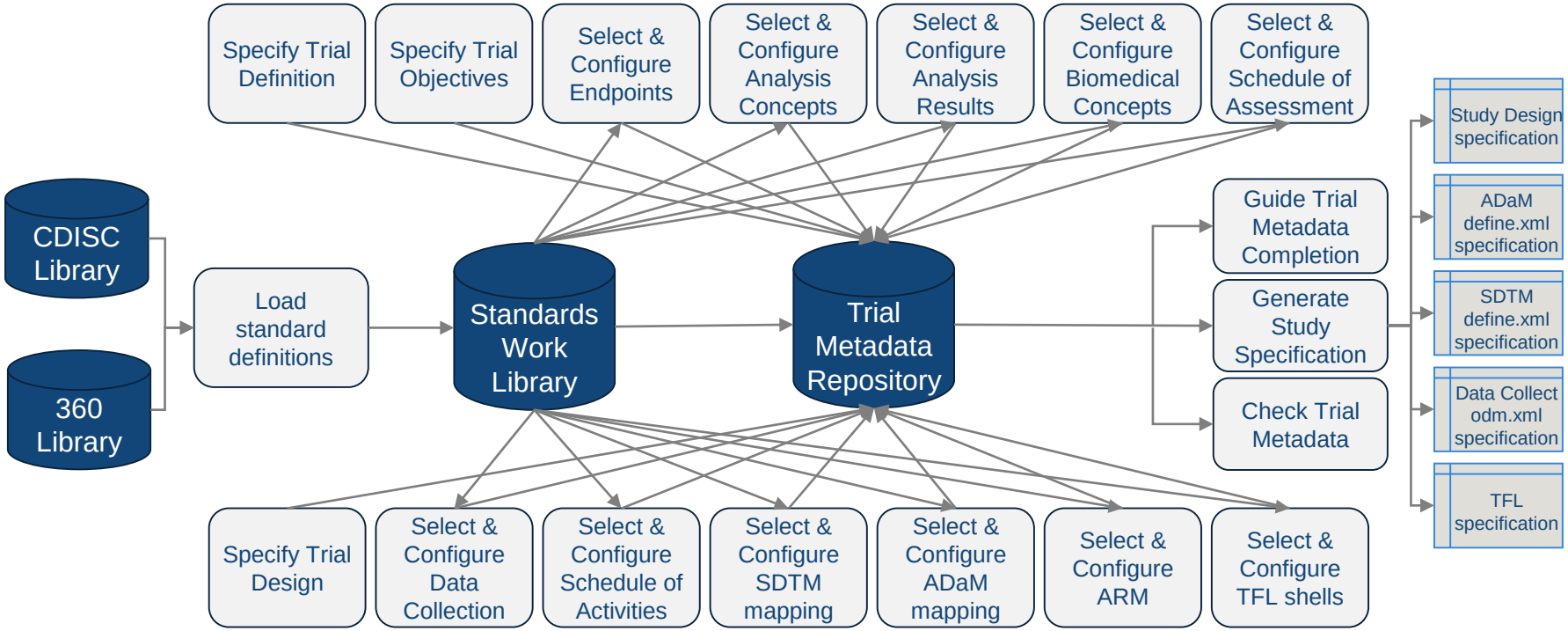
Configure study specification and create artifacts (Use Case 2)

WS 6



Automatically process and transform data (Use Case 3)

Current activity: Draft user stories



Courtesy of Mikkel Traun – Novo Nordisk – WS4 Leader

CDISC 360

Expected Outcome

Expected Outcome (1)

- 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

Expected Outcome (2)

Provide the groundwork/blueprint to:

CDISC

- Scale up development of concept-based standards definitions for clinical data
- Continued Development and Curation of CDISC 360 Standards

Pharma-Biotech

- Change environments to automate study build and data processing
- More focus on sciences, less on repeating tasks
- Collaborative Data Standards donation to CDISC 360

Technology Providers

- Support Pharma-Biotech organizations by providing tools and solutions that enable end to end automation

Regulatory

- Communicate to industry its requirements for standardized analyses through CDISC 360 standards

Thank You!