



EDC Raw Data to SDTM Curation, Mapping and Automation with Xbiom Tool

*“Apply the 80/20 rule to ensure the Project **automates 80% of the end-to-end metadata and data processing** needed to generate study artifacts suitable for a regulatory submission.” Peter Van Reusel, Sam Hume, CDISC-360 Mission*

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What is Your SDTM Curation and Automation Role and Goals?

☐ **Statistical Programming Director – *Better Manage Timelines***

- Project Management, Time, Budget, Compliance, Metadata

☐ **Statistical Programmer – *Better Manage Submission Process***

- SDTMs / ADaMs / Define.xml, SDRG / ADRG, Mapping, Specifications

☐ **Translational Scientist – *Better Understand Safety Data Issues***

- EDC / Biomarker Raw Staging and Data Processing, Ingestion, Curation, Harmonization

☐ **Statistician – *Better Explore and Understand Study Conclusions***

- Analysis, Views, Ad-hoc, Tables, Listings and Figures, SAP, Data Meaning / Exploration, TLFs

Leverage a Unified Data Model (UDM) to Streamline Pathways to SDTM and ADaM Standards

○ Paradigm Shift

- Post CDISC Standards and Experience
- Non-Linear Accretive Processing
- Integrated CDISC Compliance

○ Xbiom with Unified Data Model (UDM)

- Low-Code User Interface
- Six Step Visualization Process

○ Unified Data Model (UDM) Design

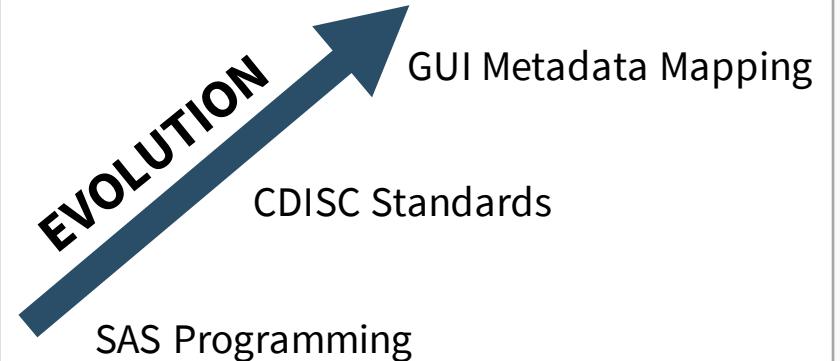
- Reusability and Repeatability
- Direct to Review and Analysis
- Monitoring and Accretive Resolution of Data Issues

○ SDTM Generation

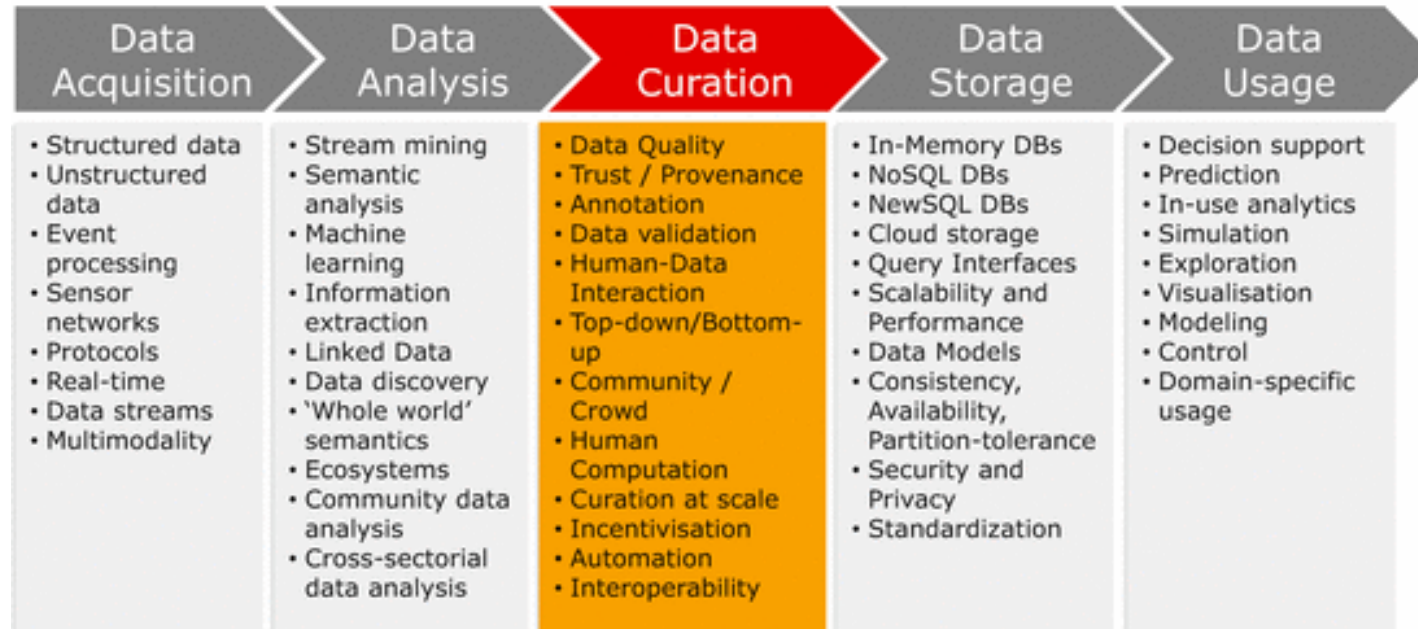
- SDTM IG Specifications, CDISC 360's Mission
- Metadata Repository, Auto-Mapping and User Confirmation
- Continuous Learning Process



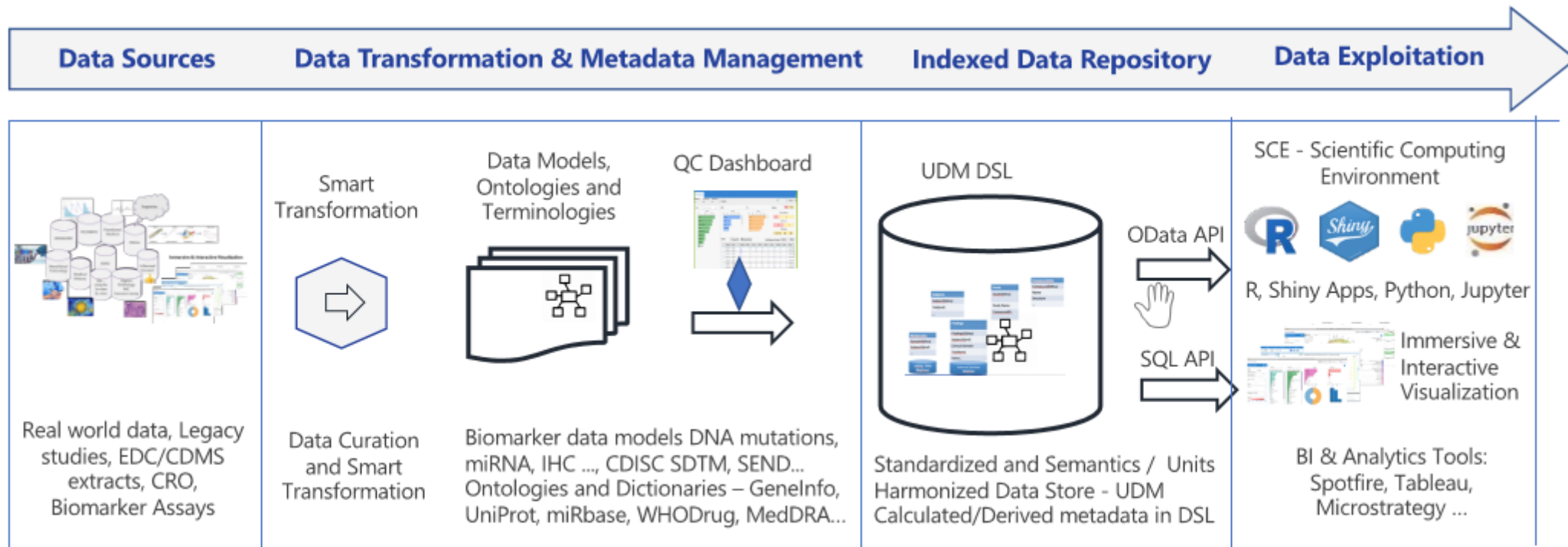
- > Search and Query Interactive Database
- > Ingest, Catalog, Index and Link All Data



Big Data Value Chain



Data Curation is the Repetitive Process to Optimize Data and Metadata to ensure Valuable use of Data.





CDISC 360 MISSION:

SDTM Design And Automation

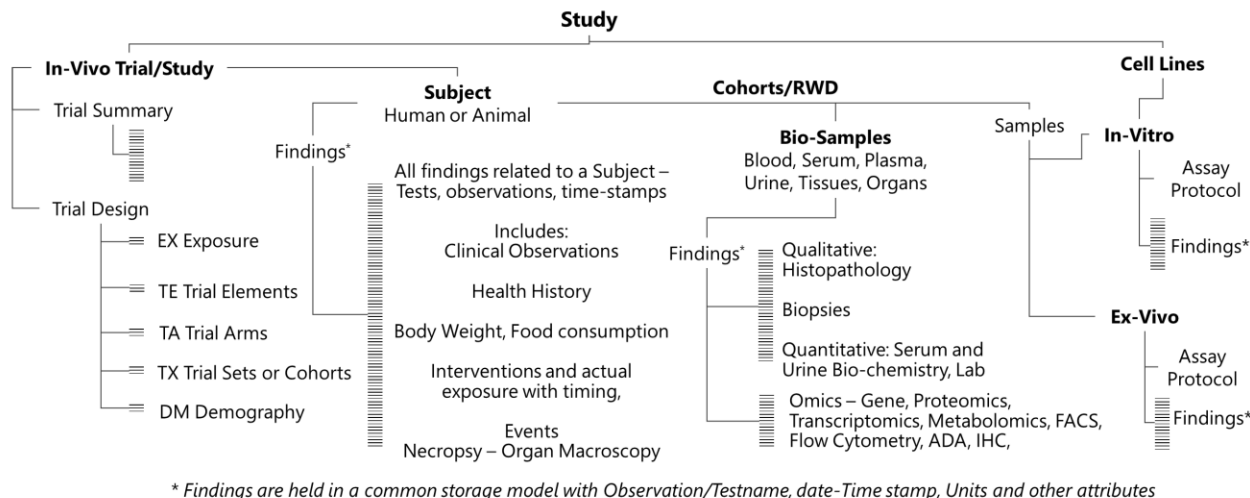
Input: Metadata & Raw Clinical Data

Create End-to-Start Specification

- Produce a standards-based, machine readable specification

Generate Start-to-End Metadata

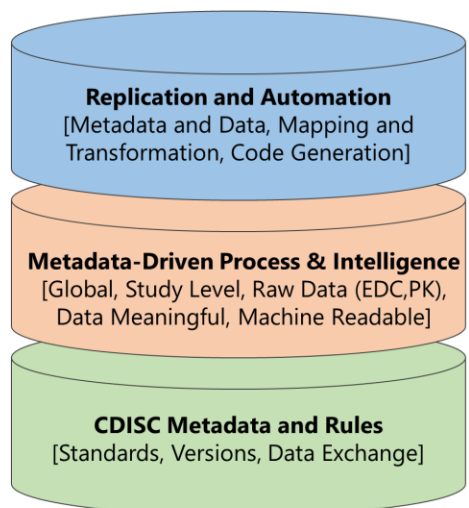
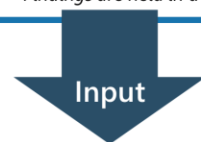
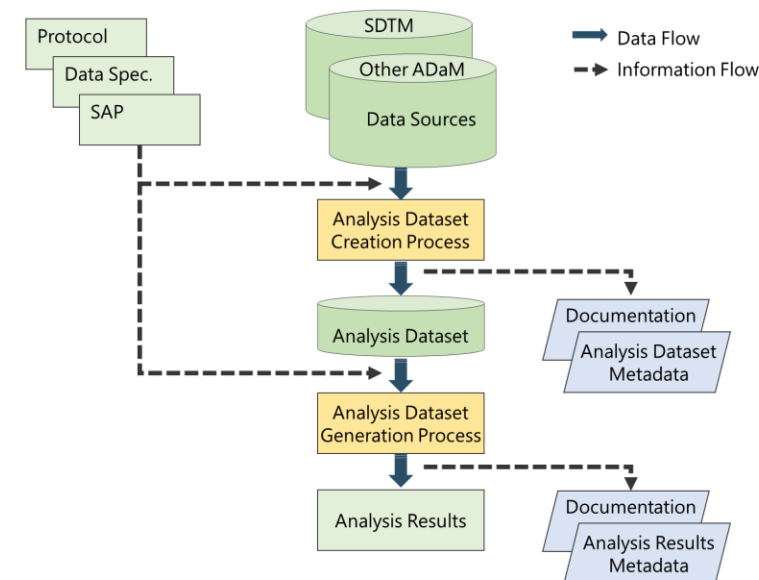
- Use standards specification to generate study metadata artifacts
- Demonstrate the ability to generate study metadata given a specification



Output: SDTMs, ADaMs, Define.xml & TFLs

Data Curation

- Repetitive Process to Optimize Data and Metadata to ensure Valuable use of Data



Transformation and Automation: Reusability & Repeatability

Transformation Data Start-to-End

- Use machine-readable metadata to generate study data artifacts
- Demonstrate the ability execute data transformations given the study

Replication and automation are the focuses

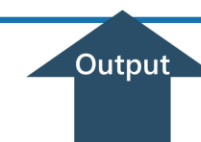
- Use or create utilities to replicate the process: Project Set Up, Mapping Specification, Mapping Creation
- Use analytics tool to identify the areas for replication and automation: Data Profiling & Data Rules for Source Data Review / Edit Checks

Metadata-driven process is the key for automation

- Metadata makes data meaningful
- Metadata is machine readable
- Metadata is the base for automation

Standard adoption is the key for code reusability

- Train people to understand the standards
- Define standard templates
- Build public libraries for code snippets and public transformation: Custom functions, procedures and packages; public data rules; and public Experts
- Group code snippets and functional transformation into modular mapping and transformation: pluggable maps
- Define workflow to govern the process: Workflow Manager and Process Flows



End-to-End Clinical Study MetaData-Driven Process and Intelligence CDISC and Submission Flow

Raw Data, Metadata, Xbiom Tool



CDISC / Analysis



Documentation



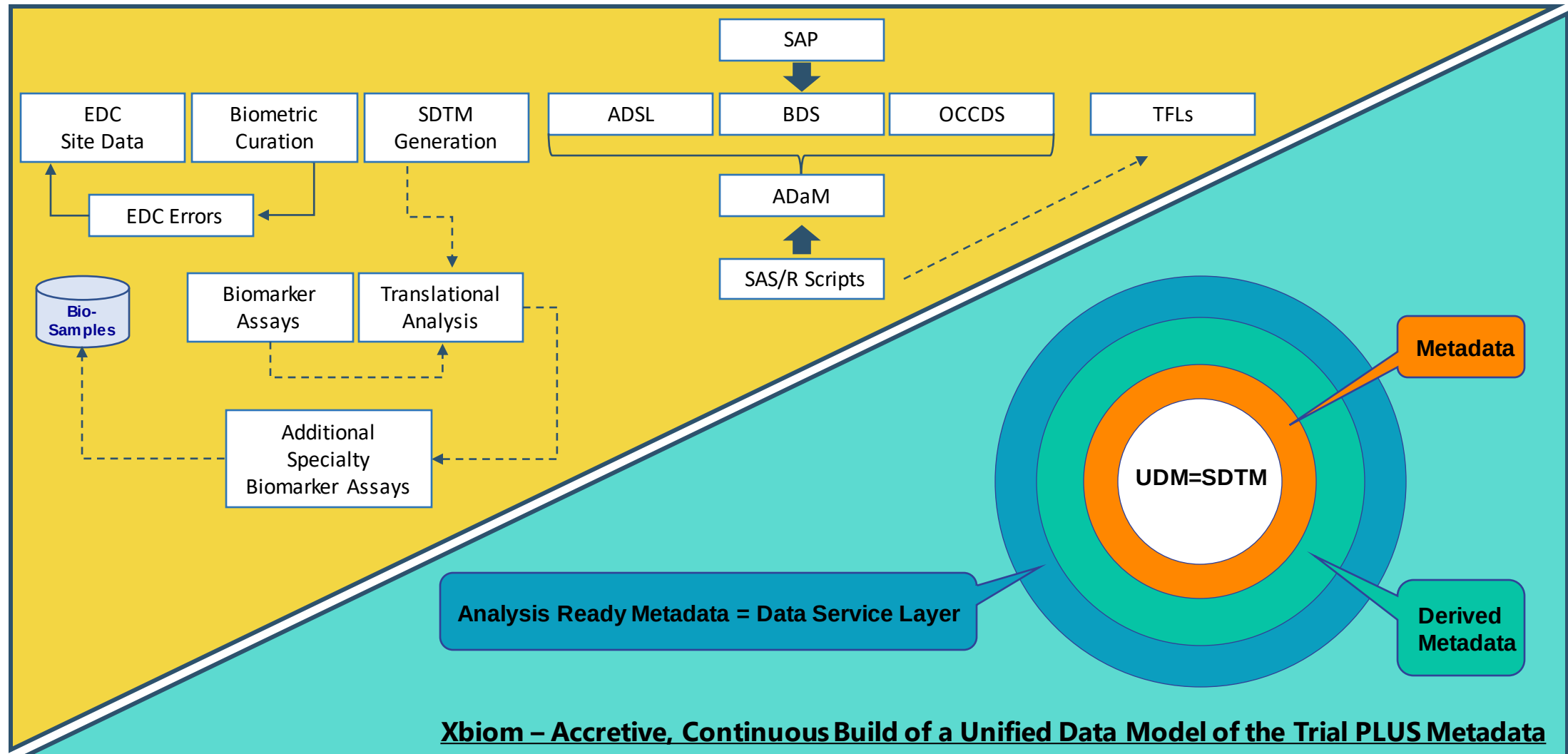
QA

EDC / Labs / CRF	Metadata / CDISC Deliverables			Study Documentation Define.xml	Regulatory Compliance eDV / SDRG / ADRG
	SDTMs	ADAMs	TFLs		
DATA: Raw Codelists	Standard Domains Standard Variables Standard Terminology Codelists	Safety / Efficacy Derived Variables Codelists	SAP	Documentation Control Terminology Value-Level Metadata Raw / Derived Variables	Documentation Data Issues Compliance Issues
METADATA / CDASH SPECIFICATIONS: Attributes, Structure, PRM	SDTM IG Rules Control Term IG Rules MedDRA Export Specifications	ADAM IG Rules Control Term IG Rules (Optional) Export Specifications	ARMs BDS Independent of ADaMs	Define.xml IG Rules SDTMs / ADaMs Snapshot Integrated Links to CRF pages User-Interface Edits	Snapshots / Links
USER INTERFACE MACHINE LEARNING PRODUCTIVITY:	Joins / Transpose Auto / User Mapping Templates Drop-down lists	SAP Mapping Auto / User Mapping SAP Cohorts Drop-down lists	SAP Cohorts Domain Templates Drop-Down Lists	IG Mapping Templates	Template Mapping PhUSE Templates
TRADITIONAL PROGRAMMING PRODUCTIVITY:	Source / QC				
	Attribute Macros Variable Macros	Attribute Macros Variable Macros	Reporting Macros	Separate Tool Out-of-Sync	Separate Tool Manual Updates

Paradigm Shift: Non-Linear Accretive Processing

From Sequential Processing of Files to Create SDTMs & ADaM for TLFs

To A Single Accretive, Curated Unified Data Model - Select Cohorts, Analyze Data to SAP,
and Automatically Generate SDTM, ADaM for Submission



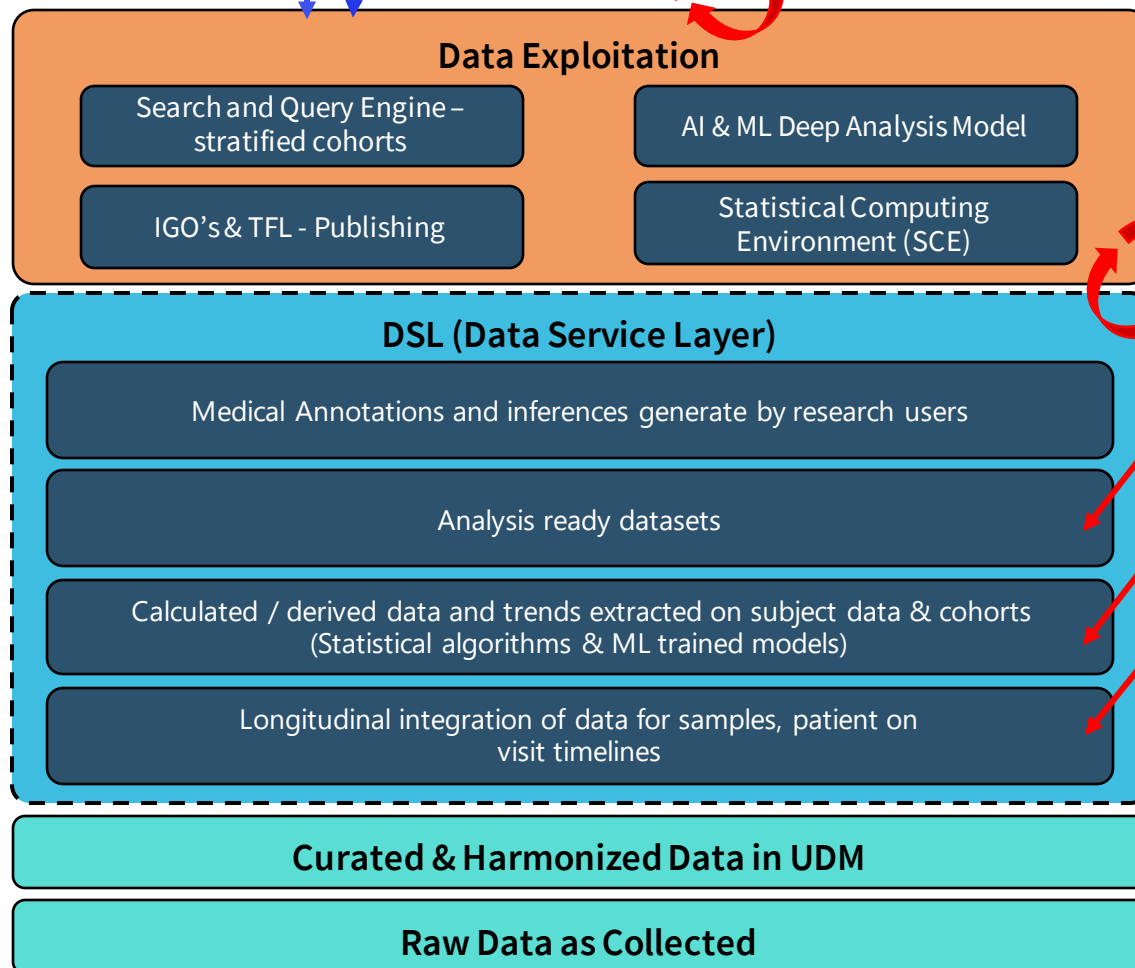
Unified Data Model (UDM) with Data Service Layer

INGISHTS
DECISIONS

KNOWLEDGE

INFORMATION &
DERIVED METADATA

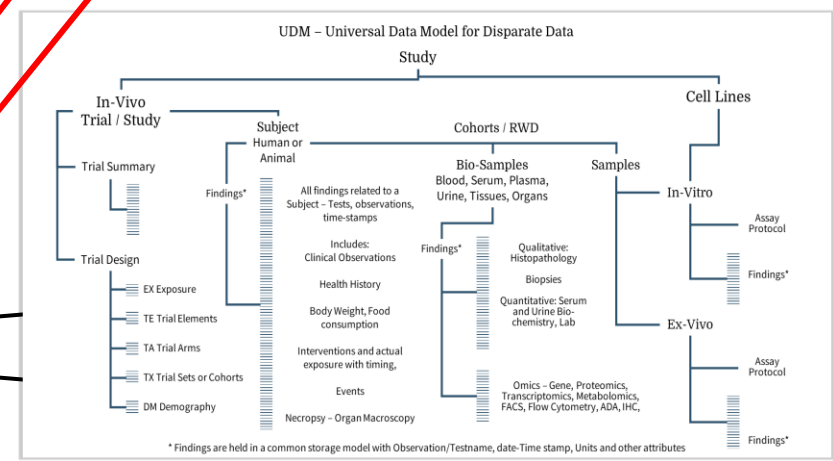
DATA



Cohort Search

Cohort Analysis

Curation, Xform



Xbiom: Low-Code User Interface and Visualization Tool

Xbiom is a one-stop SCE platform designed for integrating Study Data and Submission Packages



CAPABILITY

Insights for Translational
Research in Monitoring Ongoing
Studies / Trials

Data Curation, Transformation,
Harmonization, Quality, and
Ingestion

Regulatory Data
Standardization, Submission
Planning and Preparation

Insights:
Clinical &
Biomarker

Insights:
Nonclinical

Smart
Transformation

**Xbiom built on
Metadata and
Ontology
Platform**

eData Validator
(SDTM, ADaM,
Define.xml, SEND)

Regulatory:
Clinical

Regulatory:
Nonclinical



R&D BUSINESS VALUE

Speed to reliable, analyzable,
and submittable data

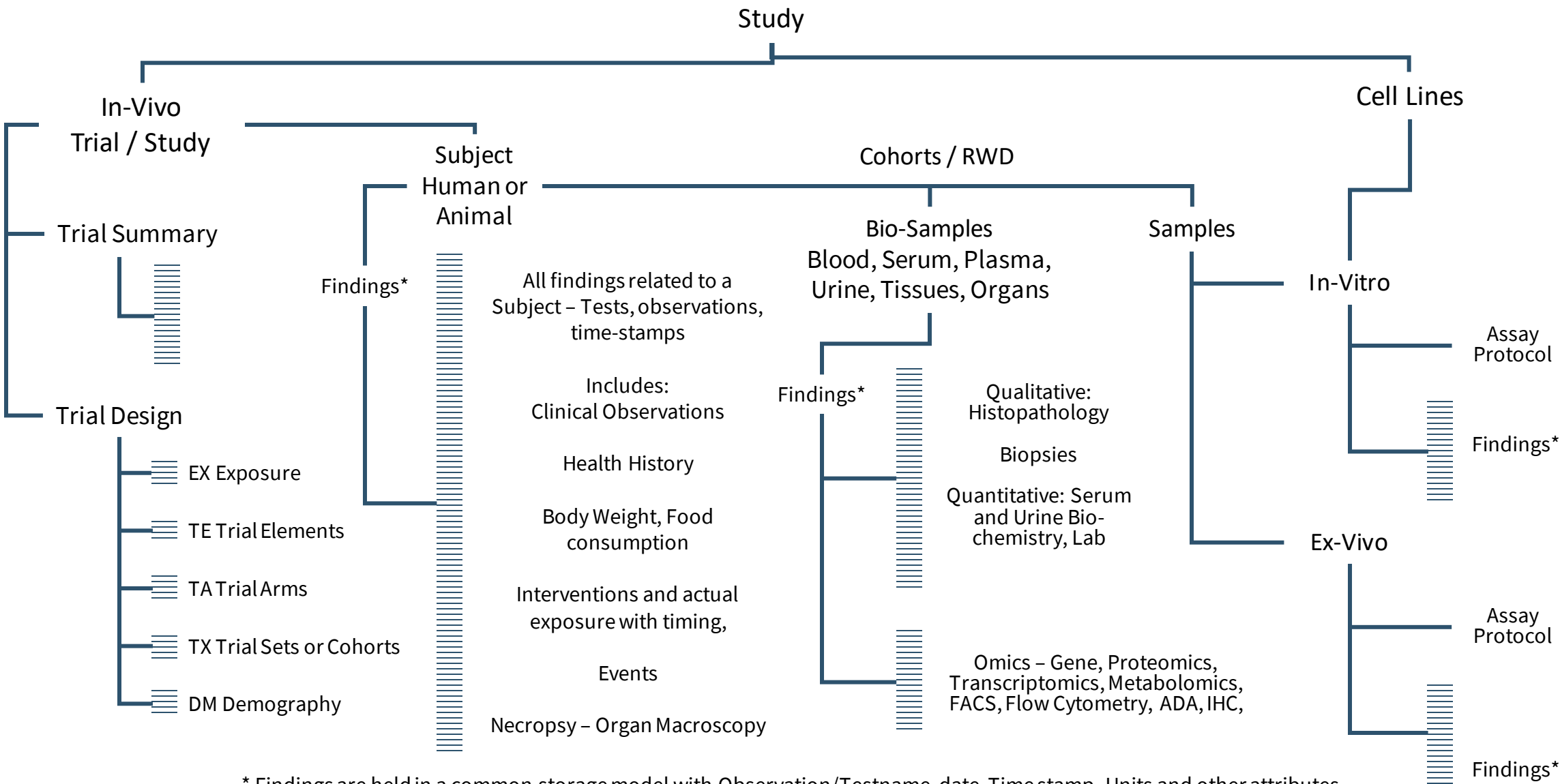
Search, define, and analyze
stratified cohorts

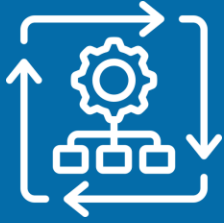
Longitudinally integrated
subject and patient data

Rapidly generate TFLs for
publication and collaboration

Unified Data Model: Reusability and Repeatability, Direct to Review & Analysis, Monitor and Accretive Resolution of Data Issues

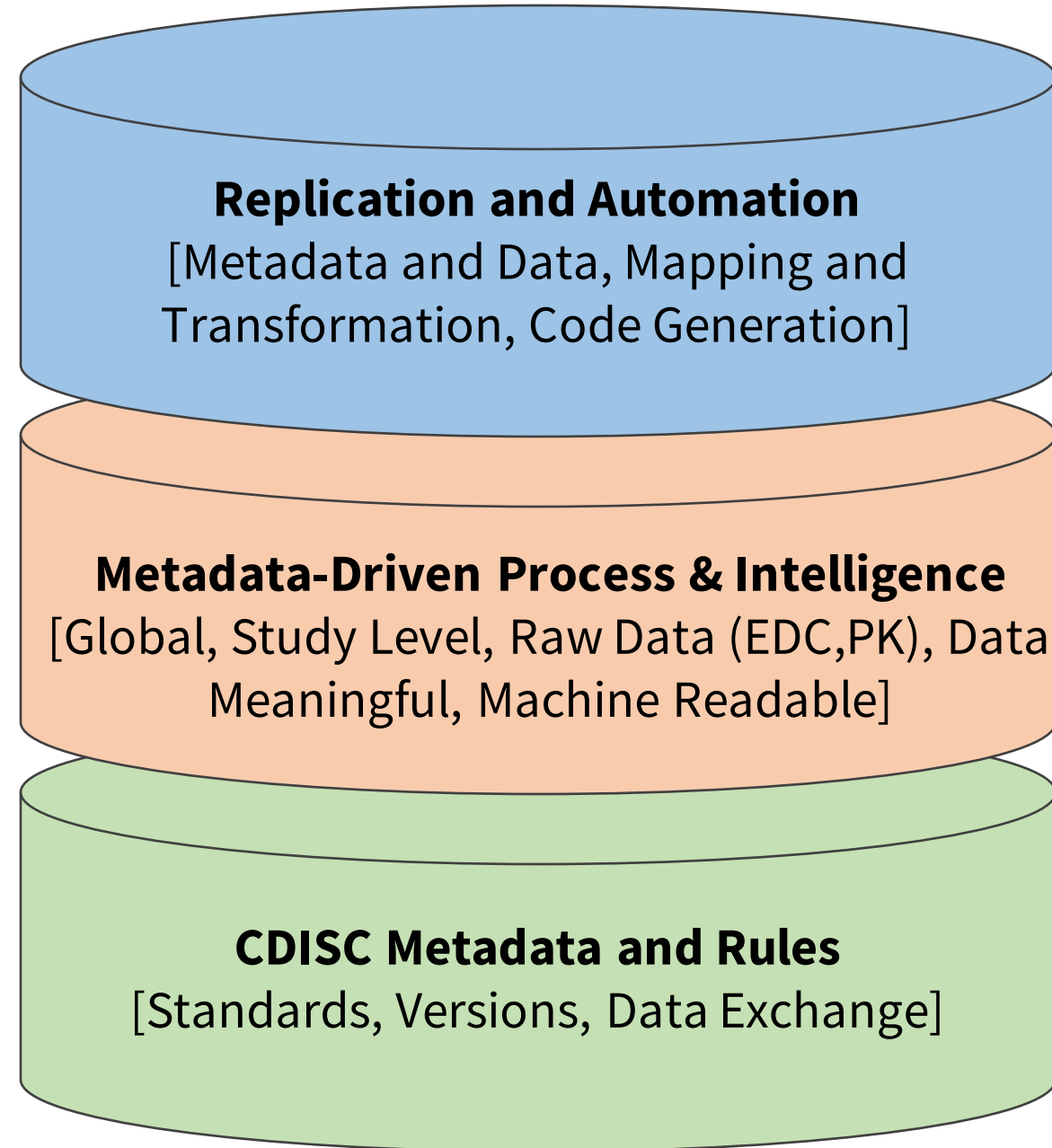
UDM – Unified Data Model for Disparate Data



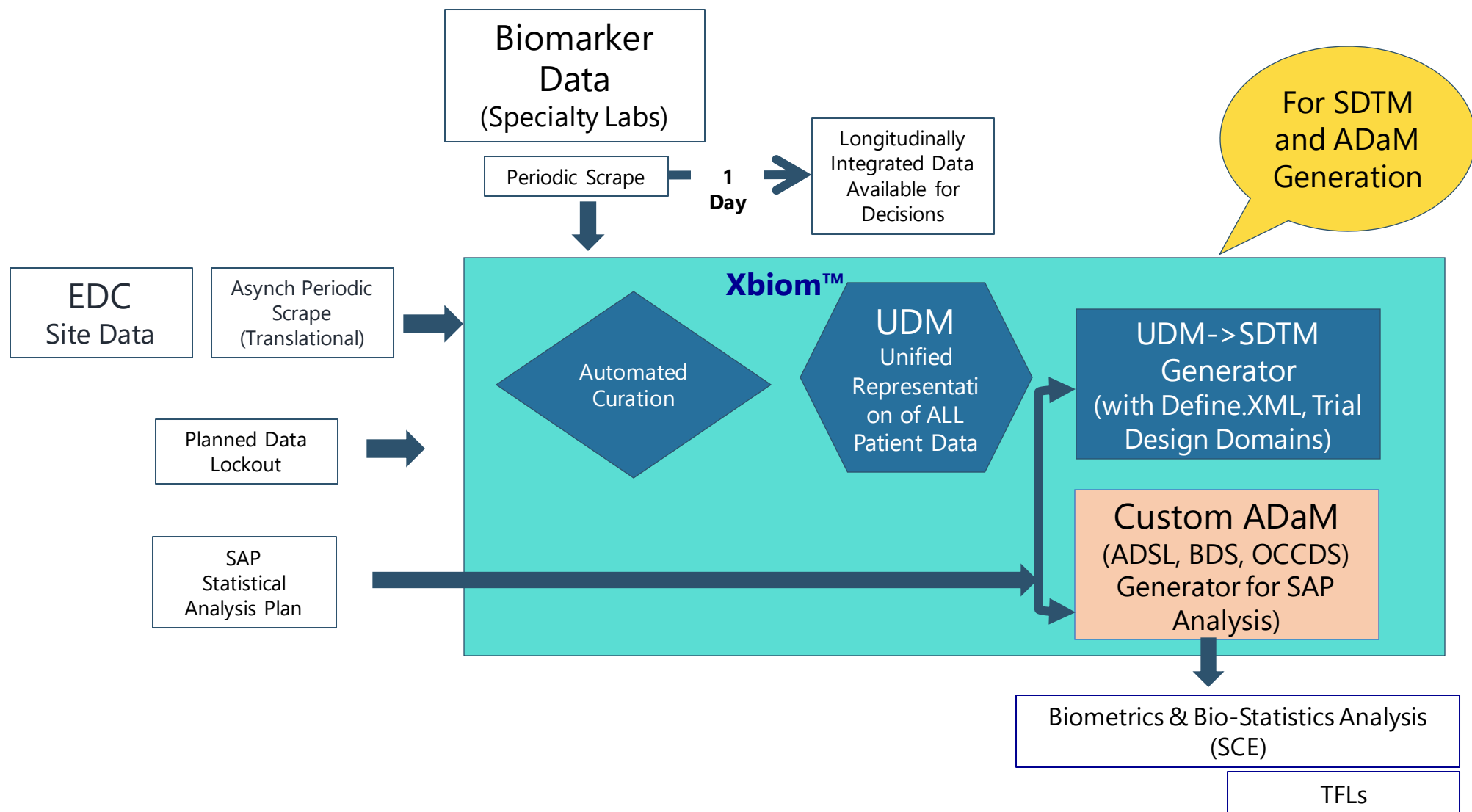


SDTM Automation By Reusability and Repeatability

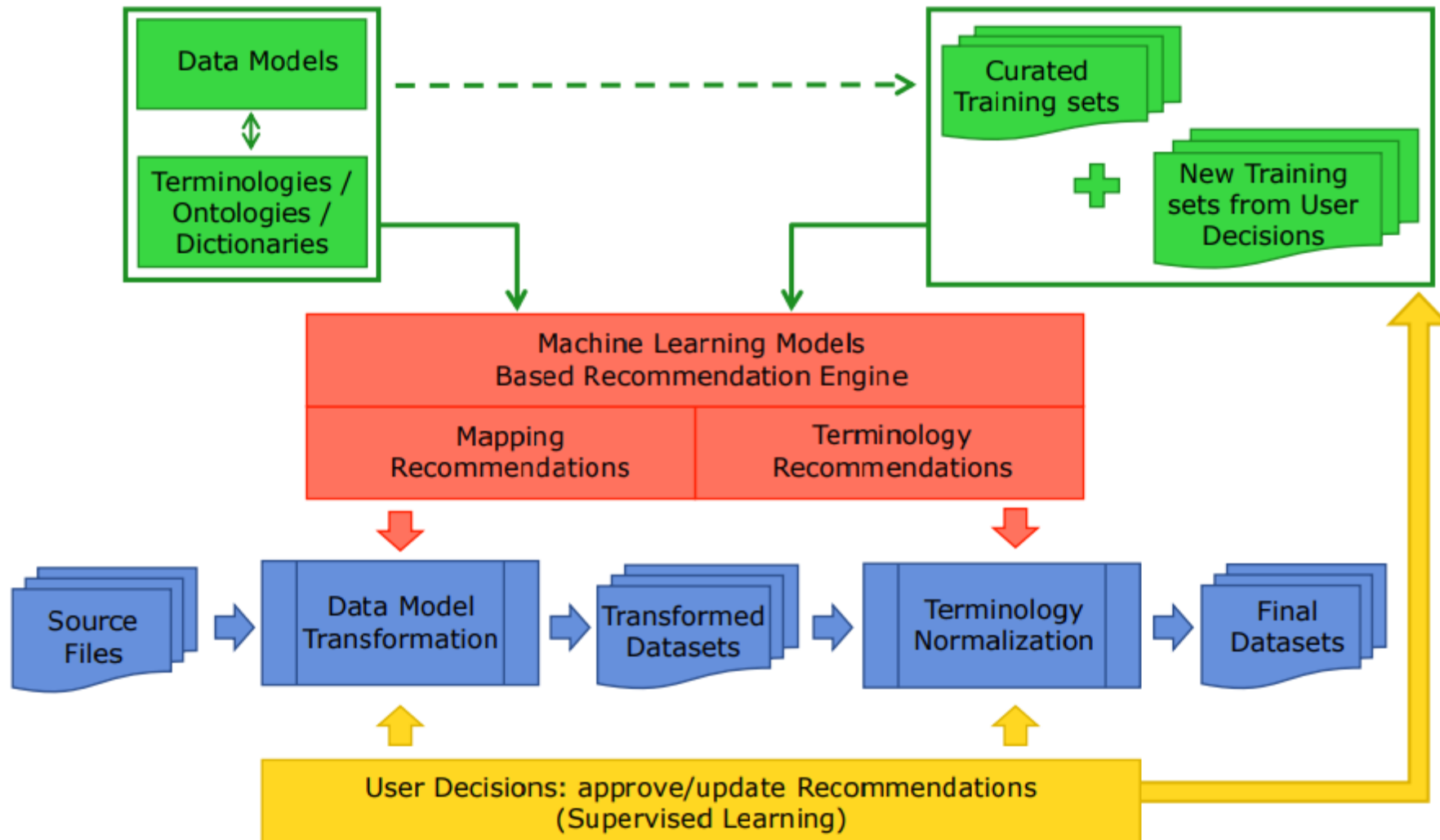
CDISC 360: Seeks to demonstrate
how standards enable metadata-
driven end-to-end automation.



SDTM: Automapping and User Confirmation, Metadata Repository and Continuous Learning Process



Machine Learning and Data Transformation Work Flow



SDTM Curation Enables Monitoring and Accretive Resolution of Data Issues



Clinical Data Issues

- Missing Data Values
- Invalid Dates and Data Values
- Character / Numeric Variable Type Conversion
- Zero Records



Study Protocol Data Issues

- Standardized Terms – no loss of data or context
- Lab Data – identify duplicate records, missing values, invalid units, etc.
- Primary Endpoints – correctly derived
- Survival Analysis – subgroup analysis
- Safety – maximum patients and events
- Deaths – maximum patients
- Related Adverse Events – minimum patients and events
- Protocol Compliance – visit in visit window range

The screenshot displays the Xbiom Platform interface for cohort and biosample selection. The top navigation bar includes links for 'Cohort and Biosample Selection', 'Support', 'I Wish...', and 'Production'. The user is logged in as 'Gupta, Sunil' on '29-SEP-2022 10:19:26 (UTC -07:00)'. The interface shows a search bar with 'Enter Search Criteria' and a table of results with columns for 'Study Drug', 'Events', 'Findings About Interventions/Events', 'Test Findings', 'Tumor Findings', and 'Interventions'. A red box highlights the 'Vital Signs' variable in the sidebar and the 'Clinical Parameters' tab in the main content area. A yellow box highlights the 'User Defined Temperature Range' in the main content area. A yellow box on the right highlights the 'Six Levels to Create Cohorts Variables' and 'Useful for grouping or subsetting TLFs'.

Six Levels to Create Cohorts Variables

Useful for grouping or subsetting TLFs

User Defined Temperature Range

Create Patient Cohort Query Across Any Domain Variables, Ex. CHOLFLG

- Subject Population: TRT01A='Drug A', SAFFL='Y'
- Safety Population: AEREL='Y', AESER='Y'
- Efficacy Population: PARAMCD='CHOL', VISIT='12 WEEK', PCHG=-30

Data and Visual Cohort Review and TLFs

- Cohort, Subject, Multiple-Endpoints, Summary, Statistics, Cross-Reference, Comparisons, Safety Vitals, Efficacy Vitals, Demographics

Scientists and Statisticians can select from a variety of pre-defined Table Templates across all Domains to automatically create TLFs

Sponsor can Export ADaM Specifications and TLF R programs for Traceability

Drill Down from Summary to Details

Auto-Mapping and Continuous Learning Process

CDISC 360: Apply the 80/20 rule to ensure the **Project automates 80%** of the end-to-end metadata and data processing needed to generate study artifacts suitable for a regulatory submission.

Overall Process

- Pre-processing Batch
 - **Variable** Mapping Methods
 - Control Terms Mapping Methods
 - User Approval Methods
 - New Variable Derivations
- Data Update Batch

A. Variable Mapping Methods

1. Direct
2. Transformation, SQL, ex. trim, concatenating
3. Transpose to Vertical Structure
4. One Raw Data to Multiple SDTMs
5. Multiple Raw Data to One SDTM

B. Control Terms Mapping Methods

1. Exact Value Match
2. Approximate Value Match

D. 100% User Approval Methods

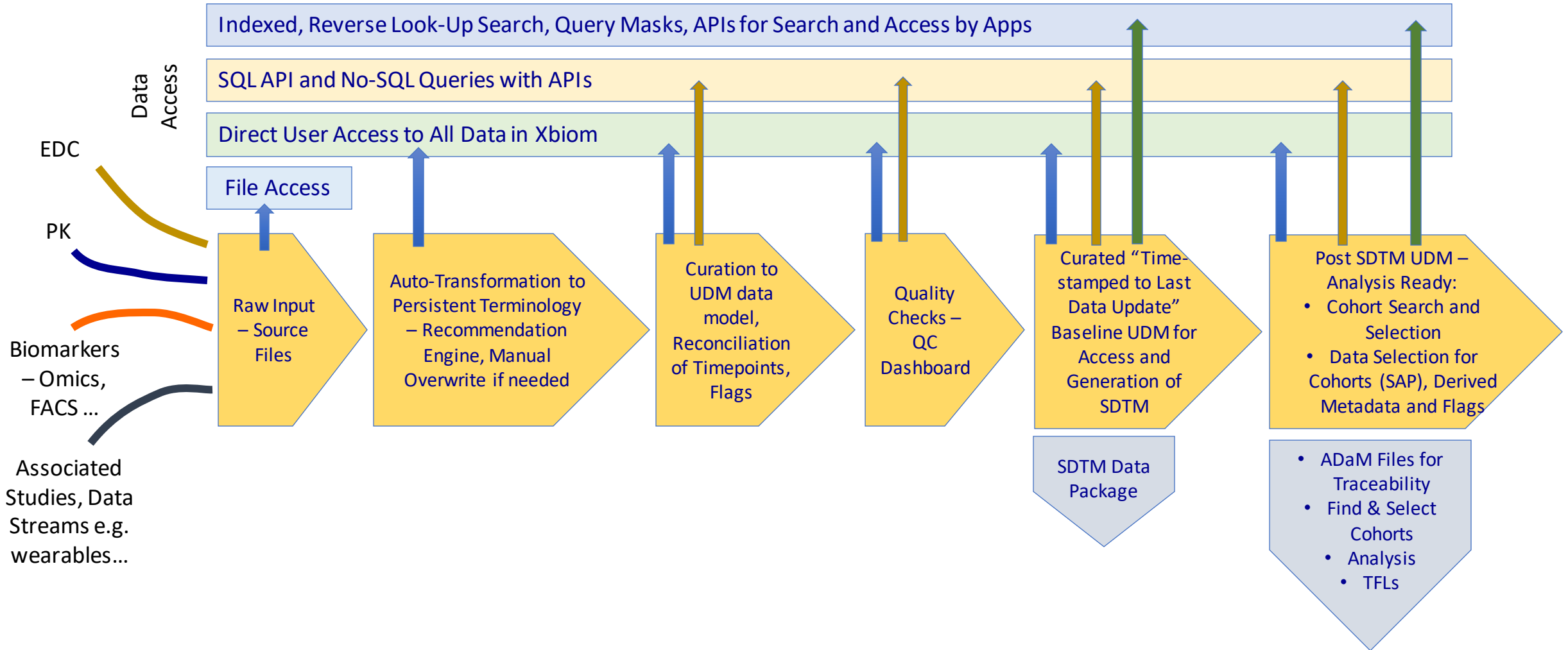
1. Machine Recommended* 
2. Previous Decision** 
3. Preview Raw data and SDTM standard values
4. SUPPXX, RELREC, FA

E. New Variable Derivations

DY, STDY, ENDY, DTC, SDTC, ENDTC, BLFL, VISIT

* Learn from sample studies, ** Learn from clinical studies

Data Curation and Standardization Stages to SDTM and Beyond



Clinical Study Workflow

Home

Study ID: PC202301

Initiate

Data Imp

Study Details

Role Allocation

Study Specification

Study Data Package Listing

Files and Folders

Model :: Tabulation

Define Version * :

2.1

IG Version * +

	IG Name	Default	IG Status	Comments
	SDTMIG 3.4	☒	Final	
	SDTMIG-PGX 1.0	☒	Final	
	SDTMIG-MD 1.0	☒	Final	

CT Version * +

	CT Name	Default	CT Status	Comments
	SDTM Terminology 2022-09-30	☒	Final	

Validation Rules

PointCross Data Validator Rules * :

FDA Validator Rules 1.5 x PMDA Rules for SDTM 3.0 x

PointCross Define Validator Rules:

CDISC Define Conformance Rules x

Study Data Package		Study Data \ Raw Data \ EDC			
☐ SDTM	  	☐	File Name	File Size	Version
☐ UDM data	 	☐	AE.csv	231.62 KB	1.00
☐ Analyzed Biomarkers		☐	AE_YN.csv	231.62 KB	1.00
☐ Metadata		☐	BMBLL1.csv	231.62 KB	1.00
☐ Assays		☐	BT.csv	231.62 KB	1.00
☐ Documents		☐	BT_YN.csv	231.62 KB	1.00
☐ Raw Data	 	☐	CM.csv	231.62 KB	1.00
☐ EDC	 	☐	CM2.csv	231.62 KB	1.00
☐ ADA	 	☐	CM2_YN.csv	231.62 KB	1.00
☐ PK	 	☐	CM3.csv	231.62 KB	1.00
☐ FACS	 	☐	CM3_YN.csv	231.62 KB	1.00
☐ Cytokines	 	☐	CM_YN.csv	231.62 KB	1.00
☐ Informed Consent		☐	CRS_IRR.csv	231.62 KB	1.00
☐ Transformation Logs		☐	DM.csv	231.62 KB	1.00

- ☐ Import EDC, PK and other Data Files into Metadata Repository System
- ☐ Automatic Conversions
- ☐ XPTs, CSV files
- ☐ One excel file with multiple sheets into unique raw data files

Batch Details

Batch Details: Provide input (source) and output (target model and CT)

Auto Generate

Auto Generate: Used if STUDYID, DOMAIN, SEQ (Sequence) values to be automatically generated by system.

Dataset Transformations

Scripts for any Transformations: Three sections (Dataset Transformations, Additional Transformations, Additional Scripts) are provided to write any custom scripts in SQL, Python or PySpark languages for file processing or for any data derivations or corrections.

Metadata Mappings

Metadata Mappings: Used to map source data structure to target model domains and columns. System recommends mappings based on training sets and users' previous decisions. User can approve or modify the recommended mappings.

Terminology Normalization

Terminology Normalization: Used to map the source terms to target terms. External dictionaries like MedDRA, NCBI Gene Info, UniProt, mirBase, HMDB also supported. System recommends mappings to target terms based on Xbiom global CT and loaded external dictionaries. User can approve or modify the recommended mappings.

Controlled Terminology

MedDRA

NCBI Gene Info

UniProt

mirBase

HMDB

Additional Transformations

Derivations

Derivations: to derives the data, if missed to collect in source systems.

Additional Scripts

Data Updates

Data Updates: To perform custom data updates.

Output

Batch Details

Auto Generate

Dataset Transformations

Metadata Mappings

▼ Terminology Normalization

Controlled Terminology

MedDRA

NCBI Gene Info

Auto Generate

☐ Auto Generate

☒ STUDYID

☒ DOMAIN

☒ --SEQ

Batch Details

Auto Generate

Dataset Transformations

Metadata Mappings

Terminology Normalization

Controlled Terminology

MedDRA

NCBI Gene Info

UniProt

mirBase

HMDB

Additional Transformations

Derivations

Additional Scripts

Data Updates

Output

New Transformation +



SQL Query



Python Script



PySpark

SV_Derivation

tl2

nml2

DS_EOT

Select Files:

ds x

eot x

1 select

```
eot.*,d.DSSTDAT,d.DSSTDAT_RAW,d.DSSTDAT_INT,d.DSSTDAT_YYYY,d.DSSTDAT_MM,d.DSSTDAT_DD,d.DSDHDAT,d.DSDHDAT_YYYY,d.DSDHDAT_MM,d.DSDHDAT_DD,d.DSTERM,d.DSTERM_STD,d.DSDHCAUS,d.DSDHCAUS_STD,d.DSOTHSP from EOT left join (select SUBJECT,DSSTDAT,DSSTDAT_RAW,DSSTDAT_INT,DSSTDAT_YYYY,DSSTDAT_MM,DSSTDAT_DD,DSTERM,DSTERM_STD,DSDHDAT,DSDHDAT_YYYY,DSDHDAT_MM,DSDHDAT_DD,DSDHCAUS,DSDHCAUS_STD,DSOTHSP from ds) d on eot.SUBJECT=d.SUBJECT
```

Script

Output File Name:

DS_EOT

> Preview

Choose Study:

SDTM01

Number of Records 10, Displaying 10 Records

SITENUMBER	SITEGROUP	INSTANCEID	INSTANCENAME	INSTANCEREPEATNUMBER	FOLDERID	FOLDER	FOLDERNAME
3	World	5099	End of Treatment Visit (1)	0	13161	EOT	End of Treatment V
42	World	6985	End of Treatment Visit (1)	0	13161	EOT	End of Treatment V
32	World	6875	End of Treatment Visit (1)	0	13161	EOT	End of Treatment V
3	World	7480	End of Treatment Visit (1)	0	13161	EOT	End of Treatment V
42	World	8477	End of Treatment Visit (1)	0	13161	EOT	End of Treatment V

Preview of script output

Batch Details

Auto Generate

Dataset Transformations

Metadata Mappings

Terminology Normalization

Controlled Terminology

MedDRA

NCBI Gene Info

UniProt

mirBase

HMDB

Additional Transformations

Derivations

Additional Scripts

Data Updates

Output

ae

302 103 1

Target Domain: AE

#	Source	Mapping	Target ↓	Recommend...	N...
44	AESEV	→	AESEV	✓	
48	AESER	→	AESER	✓	
62	AEREL	→	AEREL	✓	
82	AETERM_PT_CODE	→	AEPTCD	✓	
42	AEOUT	→	AEOUT	✓	
80	AETERM_LLT_CODE	→	AELLTCD	✓	
79	AETERM_LLT	→	AELLT	✓	
78	AETERM_HLT_CODE	→	AEHLTCD	✓	
77	AETERM_HLT	→	AEHLT	✓	
76	AETERM_HLGT_CODE	→	AEHLGTC	✓	

Preview

Choose Study: SDTM01

Source
AESEV
Grade 1 Mild
Grade 2 Moder...
Grade 1 Mild
Grade 2 Moder

Target
AESEV
Grade 1 Mild
Grade 2 Moder...
Grade 1 Mild
Grade 2 Moder

Previous Decision

Approved

Machine Recommended

- User Interface to Confirm Automapping Structures (Variables, Units, Values)
- User to define non-auto mapped Raw Data

ae

3021031

Target Domain: AE

#	Source	Mapping	Target ↓	Recommend...	N...
44	AESEV	→	AESEV	📄	✖
48	AESER	→	AESER	📄	✖
62	AEREL	→	AEREL	📄	✖
82	AETERM_PT_CODE	→	AEACNOTH <i>Other Action Taken</i>	📄	✖
42	AEOUT	→	AEBDSYCD <i>Body System or Orga...</i>	📄	✖
80	AETERM_LLT_CODE	→	AEBODSYS <i>Body System or Orga...</i>	📄	✖
79	AETERM_LLT	→	AECAT <i>Category for Adverse...</i>	📄	✖
78	AETERM_HLT_CODE	→	AECONTRT <i>Concomitant or Additi...</i>	📄	✖
77	AETERM_HLT	→	AEDECOD <i>Dictionary-Derived Te...</i>	📄	✖
76	AETERM_HLGT_CODE	→	AEDIR <i>Directionality</i>	📄	✖

Preview▶

Choose Study: SDTM01

Source

AESEV	AESER	AEREL	AETERM_PT_CODE	AEOUT
Grade 1 Mild	No	Related	10013911	Not recovered
Grade 2 Moder...	No	Related	10001551	Recovered/re
Grade 1 Mild	No	Related	10001551	Recovered/re
Grade 2 Moder...	No	Not Relat...	10028372	Not recovere

Target

AESEV	AEREL	AEPTCD	AEOUT	
Grade 1	Related	10013911	Not recovered/not resolv	
Grade 2	Related	100015...	Recovered/resolved	
Grade 1 Mild	No	Related	100015...	Recovered/resolved
Grade 2 Moder...	No	Not Relat...	100283...	Not recovered/not resolv

vs: Variable level mapping

Variables

*

DATAPAGEID

DIABP_VSORRES

DIABP_VSORRES_RAW

DIABP_VSORRESU

DIABP_VSORRESU_STD

ENVIRONMENTNAME

FILENAME

FOLDER

FOLDERID

FOLDERNAME

FOLDERPATH

FOLDERSEQ

HEIGHT_VSORRES

HEIGHT_VSORRES_RAW

HEIGHT_VSORRESU

HEIGHT_VSORRESU_STD

Select Variables to Transpose as Rows

	Variable	Label	Condition		Map Var Name to	Map Label to	Map Value to	Additional Variables
✖	HEIGHT_VSORRES	Height		🔄	VSTESTCD	VSTEST	VSORRES	HEIGHT_VSORRESU as VSORRESU
✖	WEIGHT_VSORRES	Weight		🔄	VSTESTCD	VSTEST	VSORRES	WEIGHT_VSORRESU as VSORRESU
✖	SYSBP_VSORRES	Systolic Blood Pressure		🔄	VSTESTCD	VSTEST	VSORRES	"mmHg" as VSORRESU
✖	DIABP_VSORRES	Diastolic Blood Pressure		🔄	VSTESTCD	VSTEST	VSORRES	"mmHg" as VSORRESU
✖	HR_VSORRES	Heart Rate		🔄	VSTESTCD	VSTEST	VSORRES	"Beats/min" as VSORRESU
✖	RESP_VSORRES	Respiratory Rate		🔄	VSTESTCD	VSTEST	VSORRES	"Breaths/min" as VSORRESU

Select Key Variables

Add Expression

	Variable	Label		Target Variable
✖	RECORDID	Internal id for th	→	RECORDID
✖	MINCREATED	Earliest data cre	→	CREATEDON
✖	MAXUPDATED	Latest data upd	→	UPDATEDON
✖	DATAPAGENAME	eCRF page nam	→	VSCAT
✖	INSTANCENAME	Folder instance	→	VISIT

Target Domain:

VS

Apply

Cancel

Target					
X	ETHNIC	RACE	RACE1	RACE2	RACEOTH
ile	NOT HISPANIC OR LATINO	Asian			
ile	NOT HISPANIC OR LATINO	MULTIPLE	Asian	White	
ile	HISPANIC OR LATINO	White			
male	NOT HISPANIC OR LATINO	White			
ile	NOT HISPANIC OR LATINO	White			

- Batch Details
- Auto Generate
- Dataset Transformations
- Metadata Mappings
 - Terminology Normalization**
 - Controlled Terminology
 - MedDRA
 - NCBI Gene Info
 - UniProt
 - mirBase
 - HMDB
- Additional Transformations
- Derivations
- Additional Scripts
- Data Updates
- Output

Controlled Terminology

	Source	Target	Expression	Recommendation
+ AE				
+ CM				
- DM				
+ AGEU		(AGEU)		
+ ETHNIC		(ETHNIC)		
- RACE		(RACE)		
+ Asian	Asian	ASIAN		Approved ✓
+ Black	Black	BLACK OR AFRICAN AMERIC...		Approximate Match 🗨
+ MULTIPLE	MULTIPLE	MULTIPLE		Same term as is ➡
+ White	White	WHITE		Exact Match 🗨
+ SEX		(SEX)		
+ DS				
+ EG				

Batch Details

Auto Generate

Dataset Transformations

Metadata Mappings

Terminology Normalization

Controlled Terminology

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mirBase

HMDB

Additional Transformations

Derivations

Additional Scripts

Derivations

Select the variables required for derivation

Reference Day *: 1

☒ --DY ☒ --STDY ☒ --ENDY ☐ --DTC ☐ --STDTC ☐ --ENDTC ☐ --BLFL ☐ VISIT

☒ --TPTREF ☒ --RFTDTC Domains LB,EG,VS,PE

☒ Populate --STRESN --STRESC --STRESU

☒ Derive using Standard Units

☐ Copy ORRES ORRESU

Raw SDTM Datasets

Variable Derivations

SDTM Variables

	A	B	C	D	E	F	G	H
1	Source File Name	Target Domain	Source Column Name	Source Column Label	Mapping	Target Variable	Status	Parent Column
307	cm	CM	INSTANCENAME		Direct	VISIT	Approved	
324	cm	CM	CMINDC		Direct	CMINDC	Recommended (Previous Decision)	
333	cm	CM	CMONGO_STD		Direct	CMMODIFY	Recommended	
341	cm	CM	CMDOSU		Direct	CMDOSU	Recommended (Previous Decision)	
351	cm	CM	CMTRT		Direct	CMTRT	Recommended (Previous Decision)	
356	cm	CM	CMTRT_ATC2		Direct	CMSCAT	Approved	
360	cm	CM	CMTRT_ATC4		Direct	CMCLAS	Approved	
361	cm	CM	CMTRT_ATC4_CODE		Direct	CMCLASCD	Approved	
372	cm	CM	substring(CMINDC,3,3)		Expression	RVALUE	Approved	CMINDC
373	cm	CM	'SPID'		Expression	RVAR	Approved	CMINDC
374	cm	CM	"		Expression	POOLID	Recommended (Previous Decision)	SITEGROUP
375	cm	CM	case when CMDOSFRQ='Other' then CONCAT_WS(':', 'Other', CMFRSPEC) else CMDOSFRQ end		Expression	CMDOSFRQ	Approved	CMDOSFRQ
376	cm	CM	case when CMROUTE='Other' then CONCAT_WS(':', 'Other', CMRTSPEC) else CMROUTE end		Expression	CMROUTE	Approved	CMROUTE
377	cm	CM	case when CMTRT_PRODUCT<>" then CMTRT_PRODUCT else CMTRT end		Expression	CMDECOD	Approved	CMTRT_PRODUCT

PointCross's Xbiom Solution for SDTM Automation & Compliance

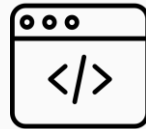
Sunil Gupta
CDISC SME, Trainer & Author
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Manage Projects with Automation and Standards



- ✓ One SCE integrate tool for all Submission Deliverables
- ✓ Reduce Time and Budget per Clinical Study

Manage Submission Process with Low-Code Programming



- ✓ Reduce writing SAS programs and macros
- ✓ Faster SDTMs, Define.xml and SDRG
- ✓ Auto Generate SDTM Mapping Specifications

Monitor Safety Data Issues with Early Alerts



- ✓ Faster Ingestion, Curation and Harmonization
- ✓ User Interface to create SAP Cohorts

Explore with Pre-defined Templates



- ✓ Reduce Time to Tables, Lists and Figures
- ✓ Drill down from summary to patient level detail

- ❖ CDISC-360 Mission: SDTM Design and Automation ([Download PDF](#))
- ❖ End-to-End Clinical Study MetaData-Driven Process ([Download PDF](#))