cdisc

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The Digital Blueprint: Automating End-to-End Workflows using Standards

Nathan Johnson | VP, Digital Innovation | eClinical Solutions

Meet the Speaker

Nathan Johnson

Title: VP, Digital Innovation

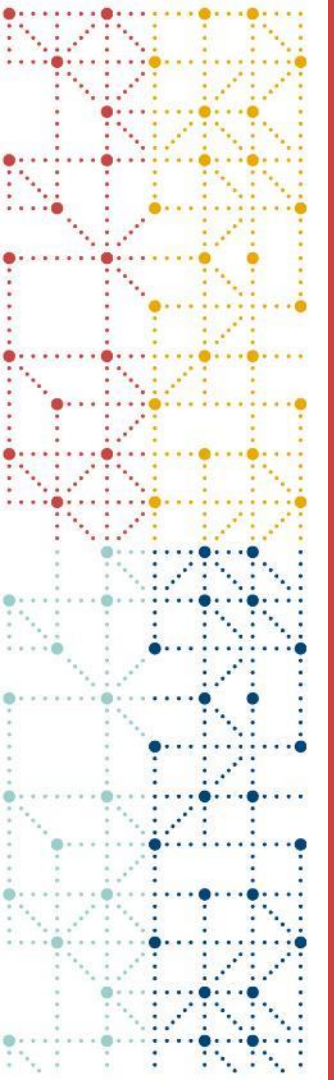
Organization: eClinical Solutions

Nathan has 20 years experience in clinical research as an innovator and programmer with expertise in statistical analysis and reporting, SAS programming, standards development, and data management. He is passionate about reshaping clinical trials through digital transformation, intelligent technology, and increased automation. Nathan has a Masters in biostatistics from Case Western Reserve University.

Disclaimer and Disclosures

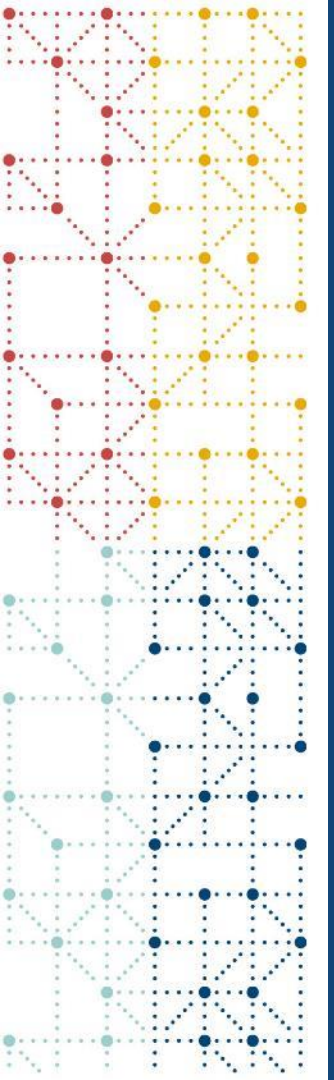
- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author has no real or apparent conflicts of interest to report.*



Agenda

1. The Clinical Data Problem
2. Changes in Perspectives in Clinical Trial Data
3. The Digital Blueprint
4. Architectural Plans
5. Structural Plans
6. Engineering Plans
7. Conclusions



Clinical Data Problem

Clinical Data Problem

The 5Vs of Clinical Data

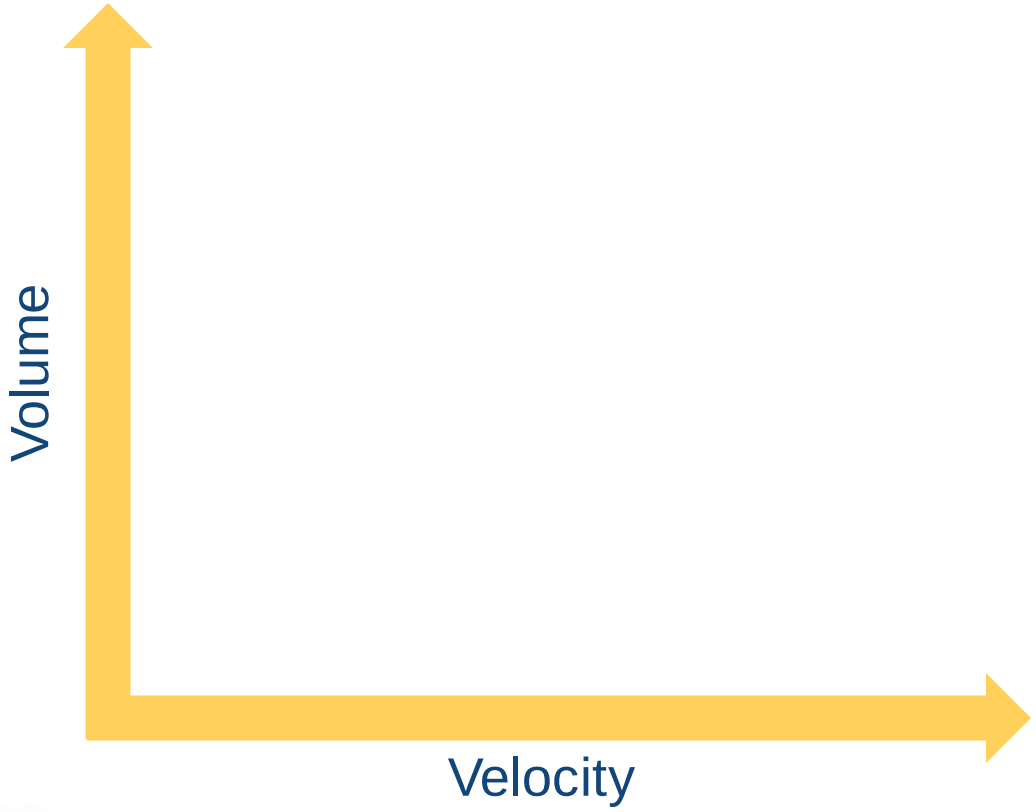
Society for Clinical Data Management
DATA DRIVEN

Reference: https://scdm.org/the-5vs-of-clinical-data/

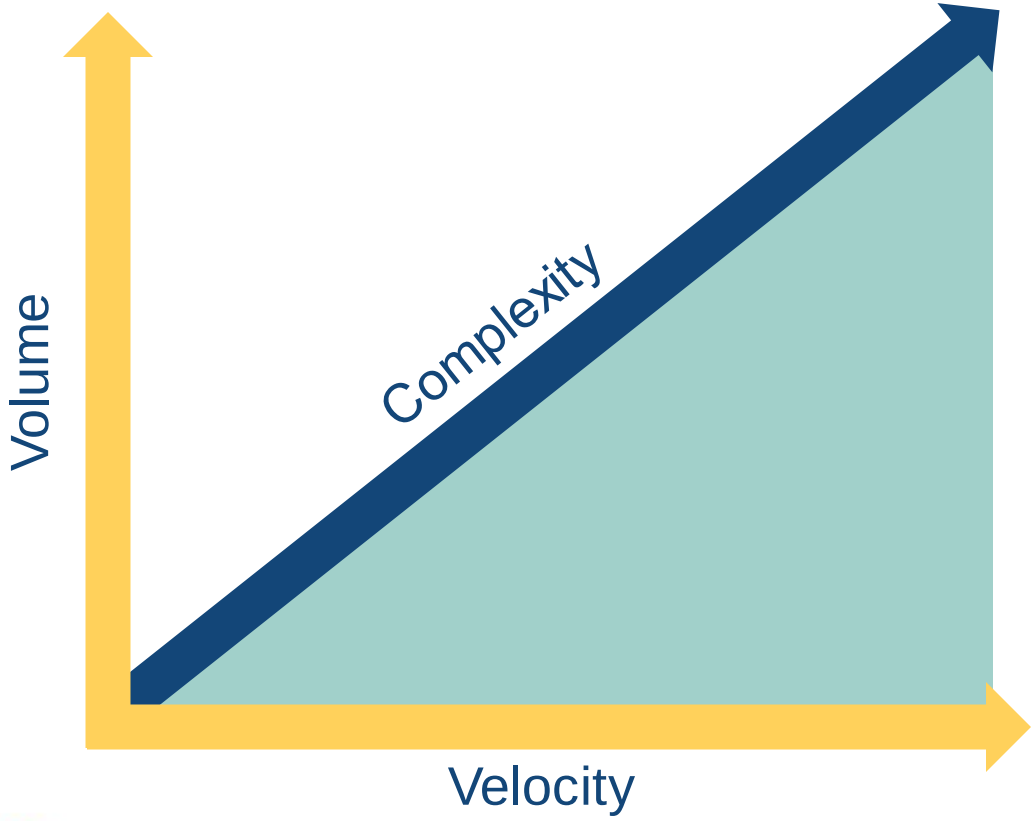
Clinical Data Problem

Volume

Clinical Data Problem



Clinical Data Problem



The Reality of Modern Trial Data: Changes in Perspective

EDC

Data Manager

Image Credit: https://monstertruck.fandom.com/

The Reality of Modern Trial Data: Changes in Perspective

Image Credit: Corridor Crew corridordigital.com

The Reality of Modern Trial Data: Changes in Perspective

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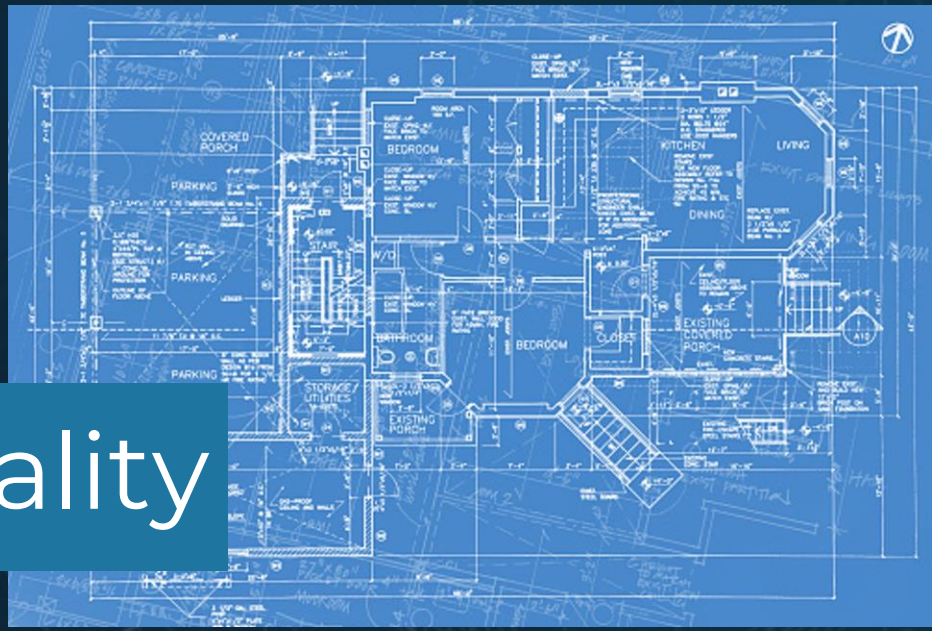
The Digital Blueprint

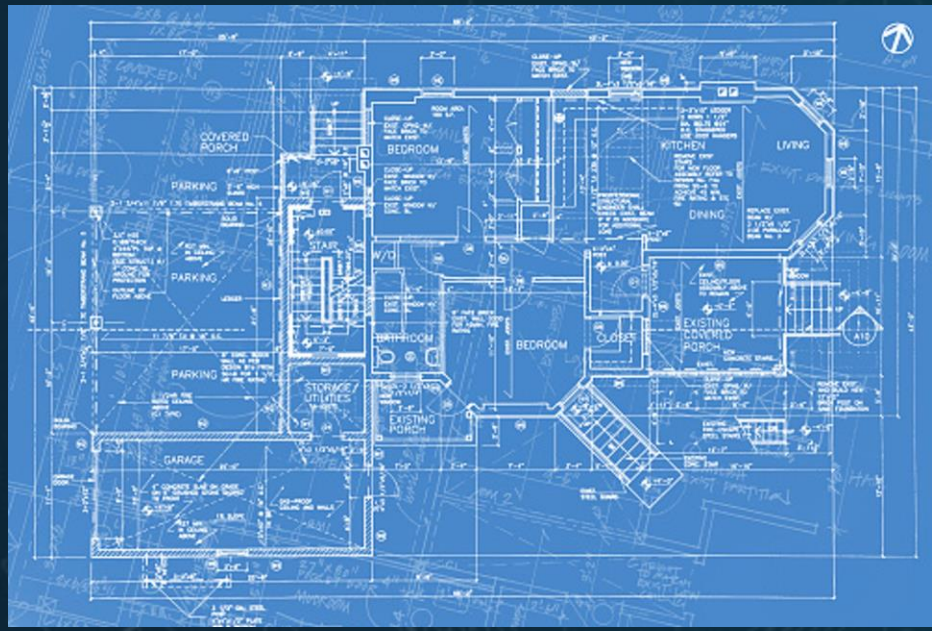
The Digital Blueprint

Vision

Reality

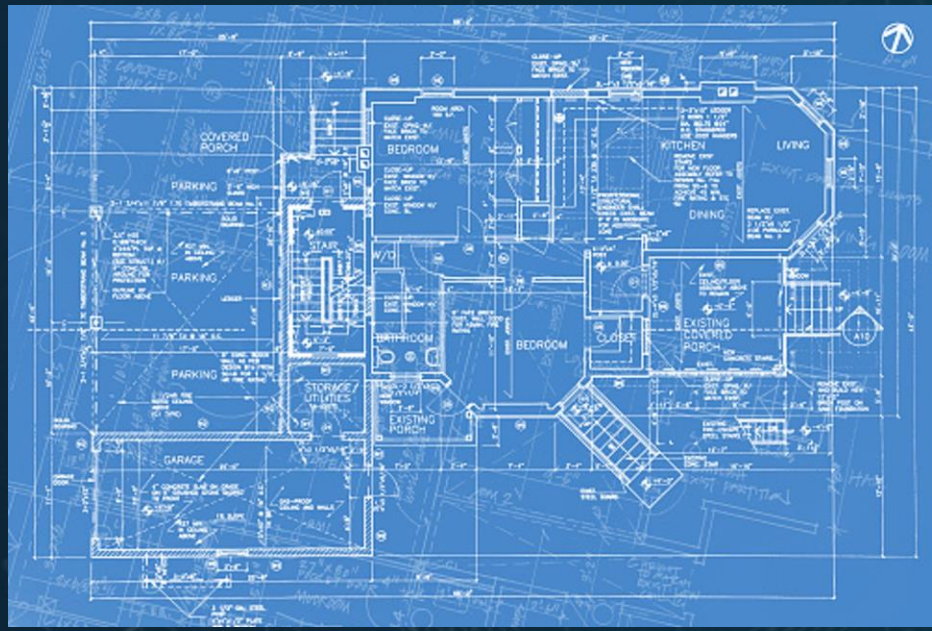


The Digital Blueprint



The Digital Blueprint

- A Sheets – Architectural Plans
  - Elevation drawings
  - Floor plans
  - Slice views
- S Sheets – Structural Plans
  - Foundation
  - Framing
  - Roof
- E Sheets – Engineering Plans
  - Electrical Plans
  - Mechanical Plans
  - Plumbing Plans

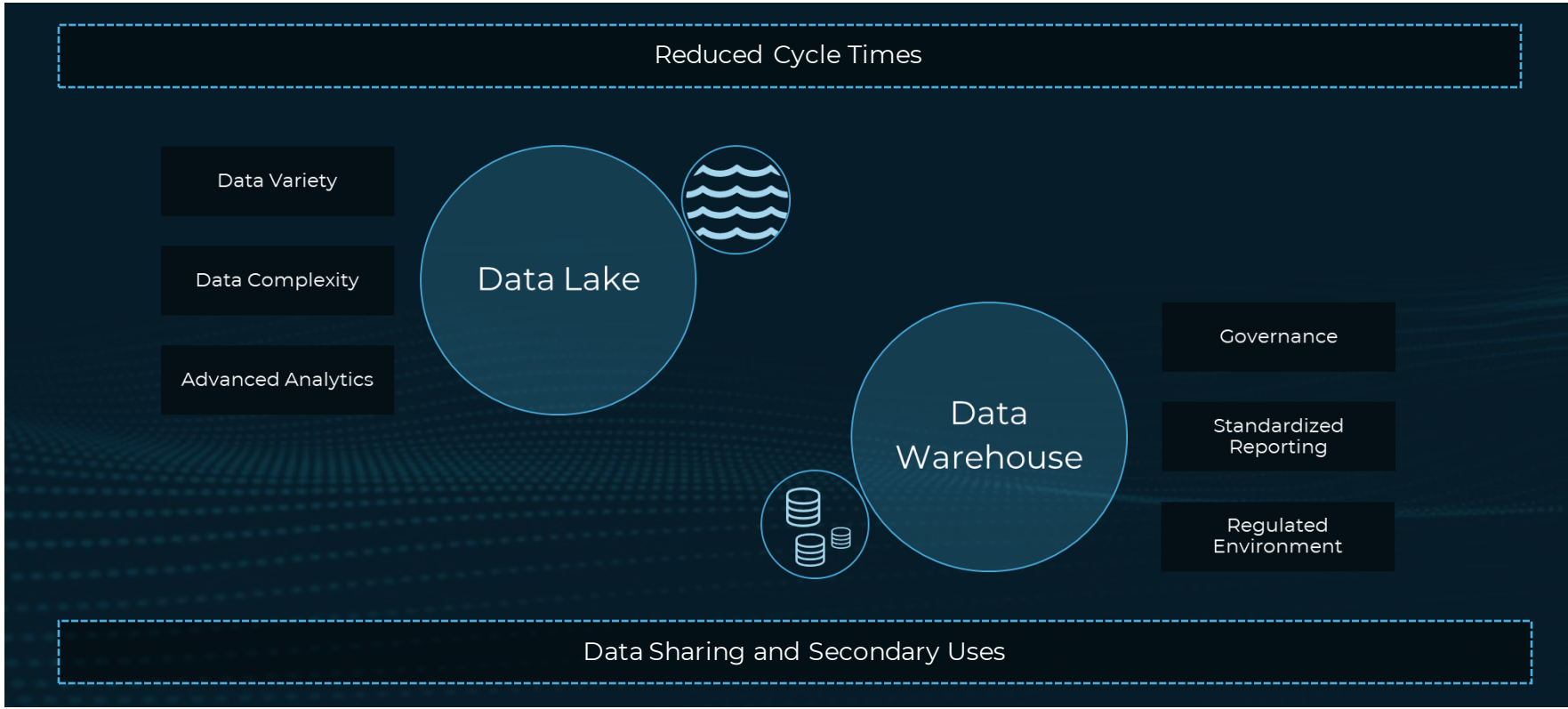


The Digital Blueprint

The Digital Blueprint: Architectural Plans

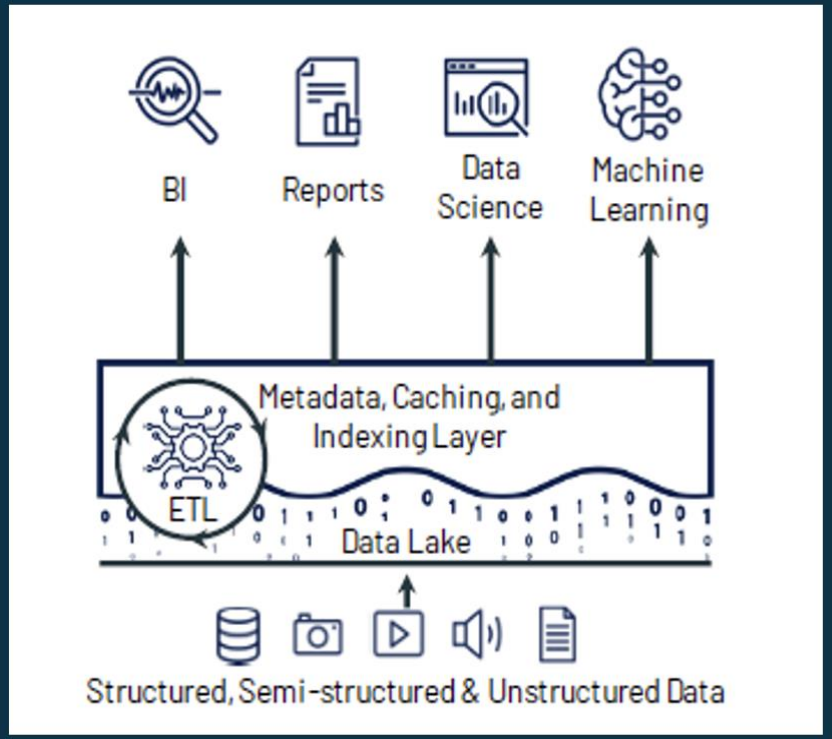
Adapting Clinical Systems to the Changing Nature of Trials

Architectural Challenges



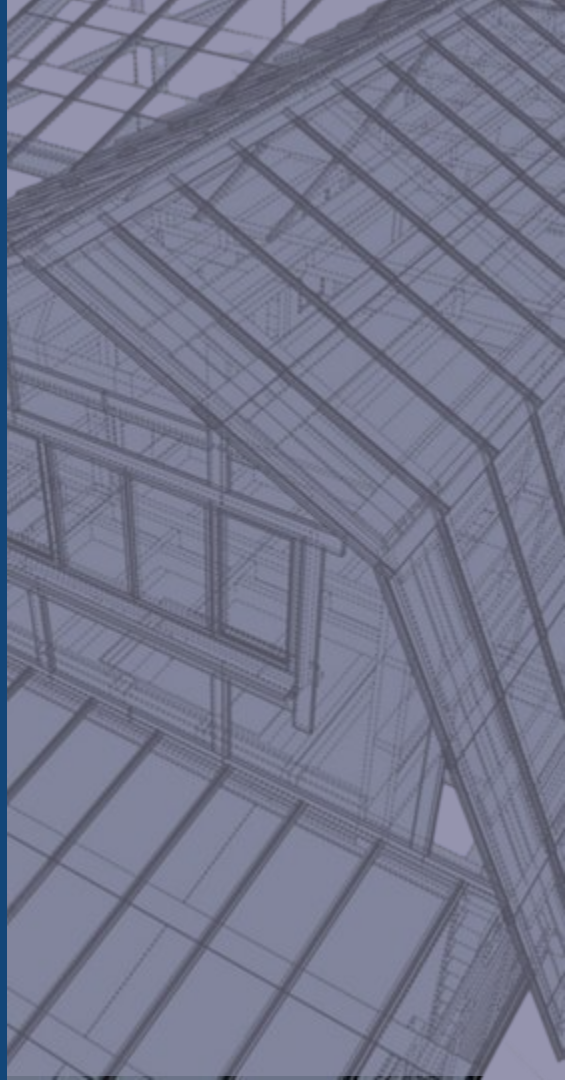
New Architectural Approaches

Michael Armbrust, Ali Ghodsi, Reynold Xin, Matei Zaharia
11th Annual Conference on Innovative Data Systems Research (CIDR '21), January 11–15, 2021, Online.

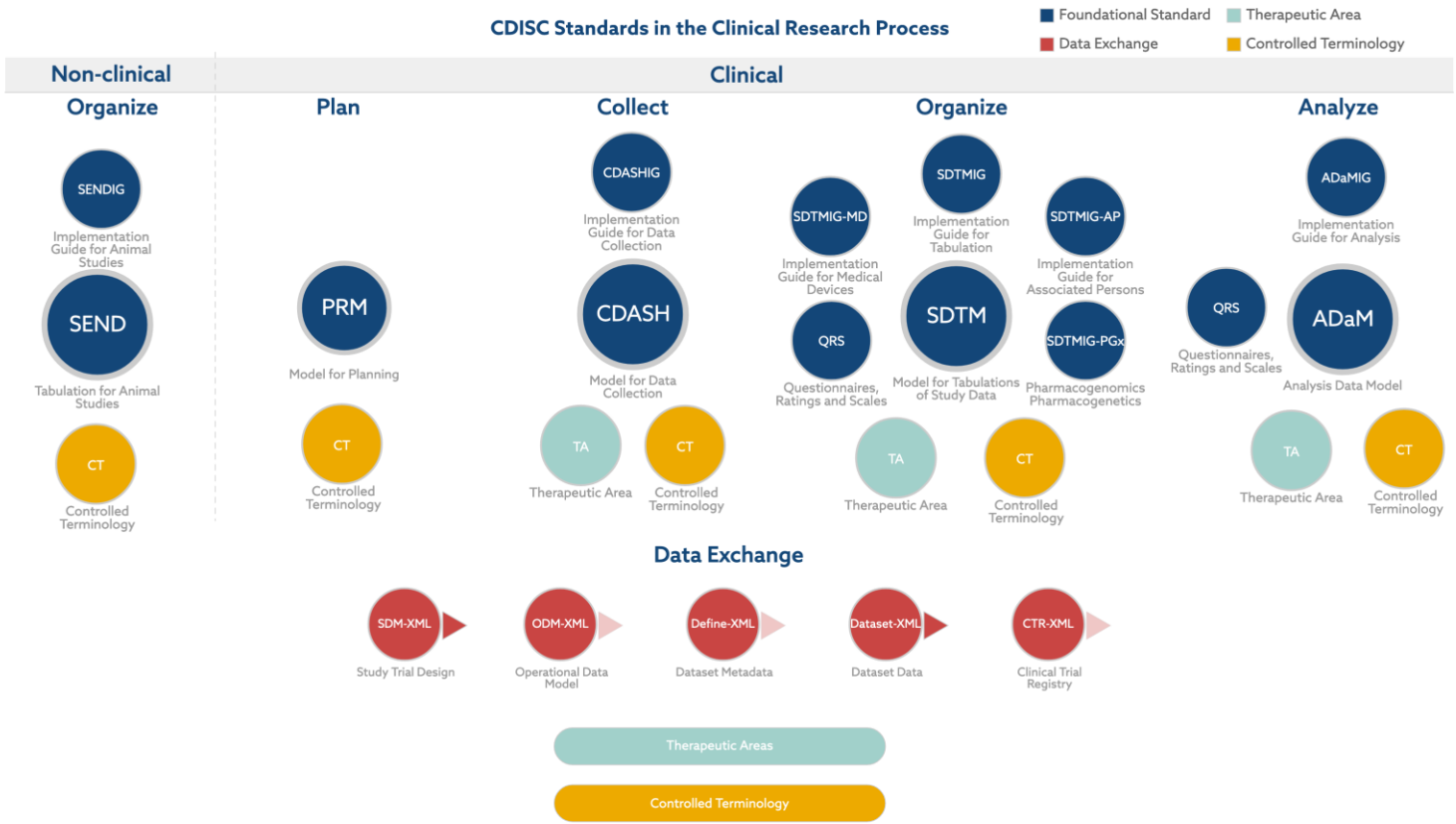


The Digital Blueprint: Structural Plans

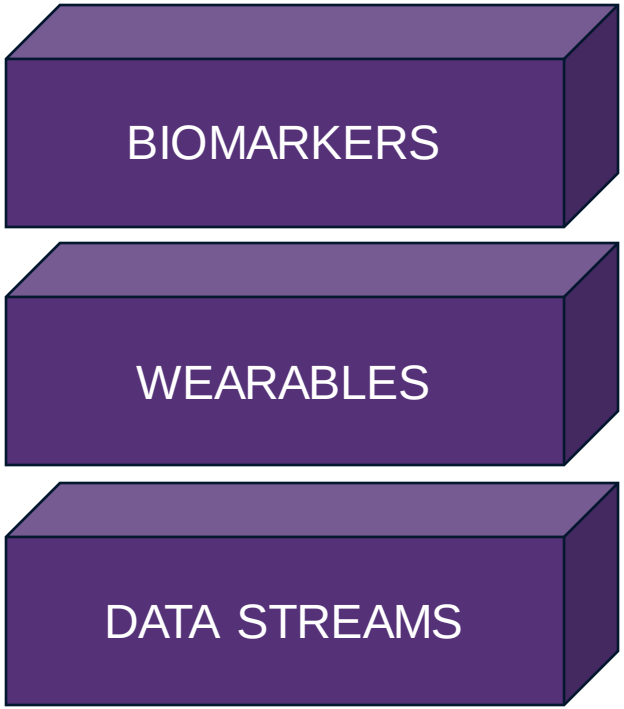
Can Standardization Address the Clinical Data Problem



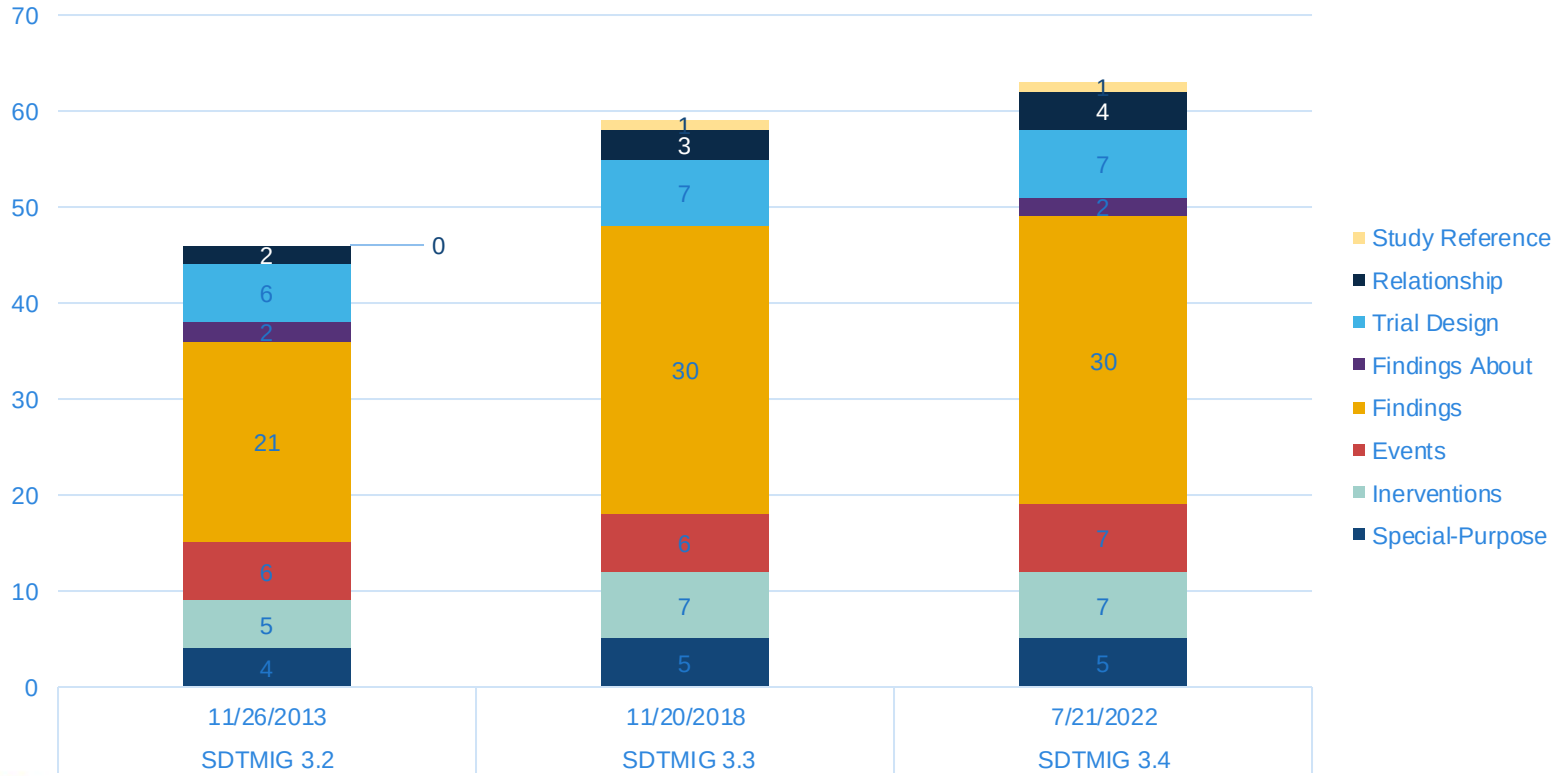
Standards to the Rescue



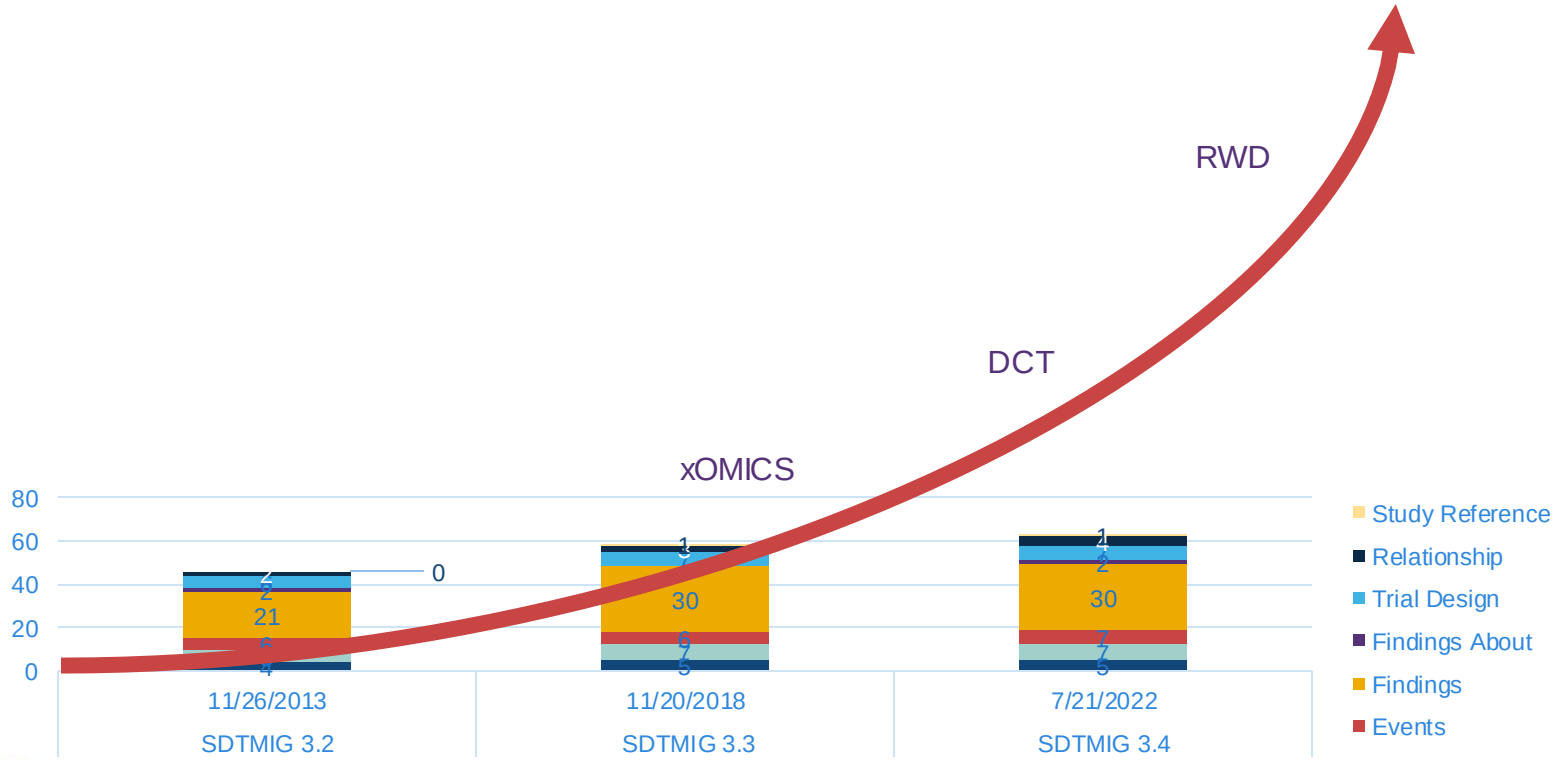
Challenges to Collection Standards



Pace of Growth in Number of SDTM Domains



Pace of Growth in Modern Trials



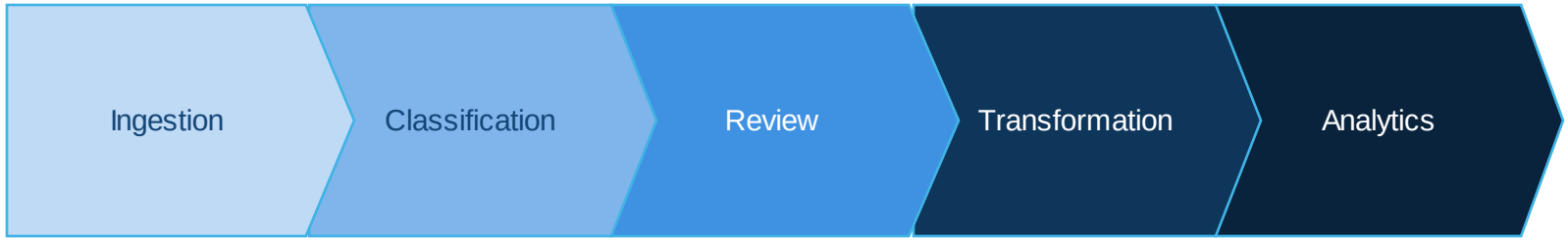
Standards as Part of the Solution

- Can we develop new standards at pace with the growth in variety and complexity of data?
- Can we rapidly adapt standards to accommodate new types of non-CRF data?
- Can we rapidly adapt new data sources to a domain-based tabulation model?

The Digital Blueprint: Engineering Plans

How Automation and Advanced Analytics are Driving Solutions

Automated Data Workflow



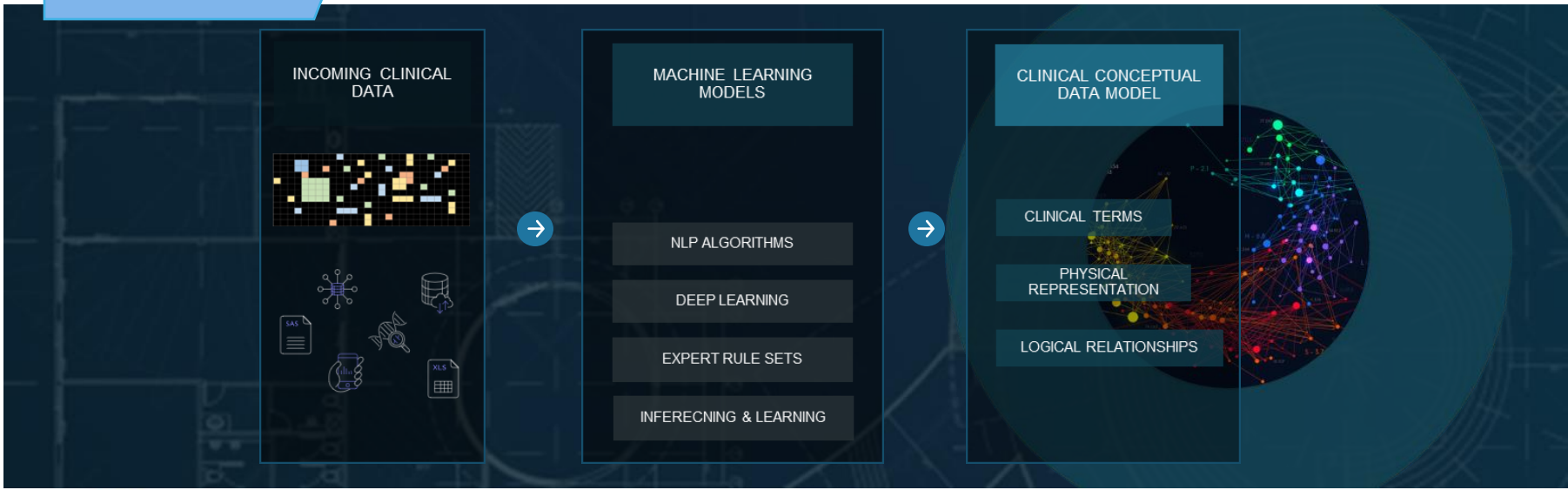
Automated Data Workflow: Ingestion

- Read from multiple sources
  - File storage (S3, OneDrive, SFTP, Box)
  - Database (Cloud SQL, DynamoDB, MongoDB)
  - Data Warehouse (Redshift, Snowflake)
  - API-based Connectors
- Scheduled or Triggered Refresh
- Compliant Traceability
- Downstream Notifications

Automated Data Workflow: Classification

Classification

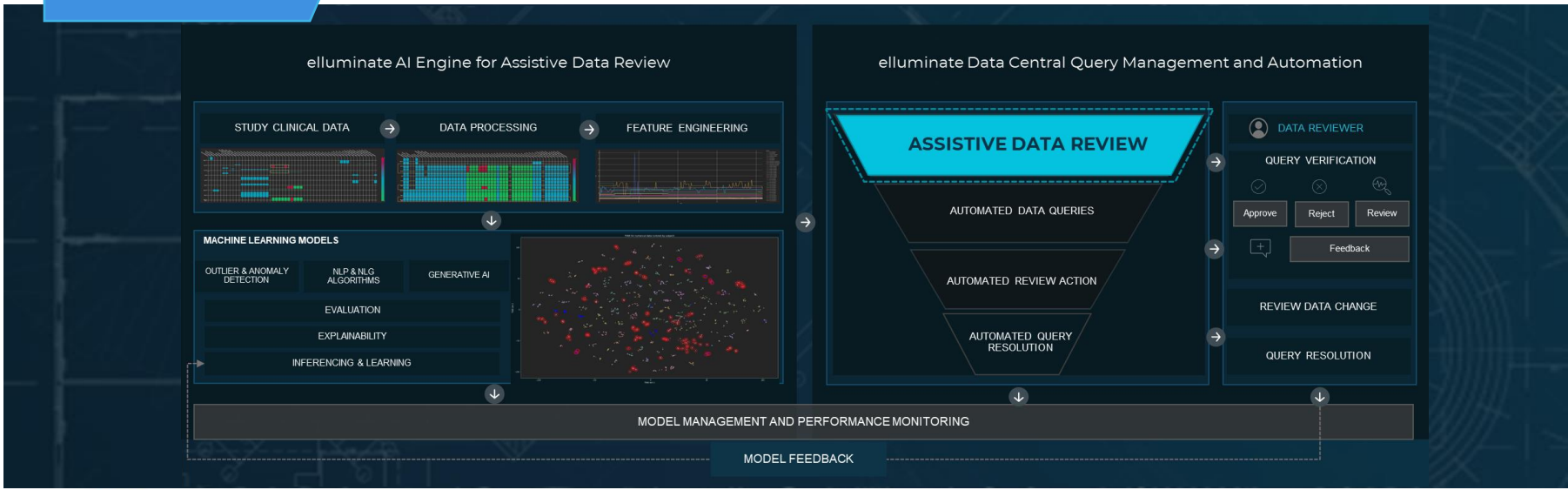
- ML Models to Automatically Classify Incoming Data



Automated Data Workflow: Review

Review

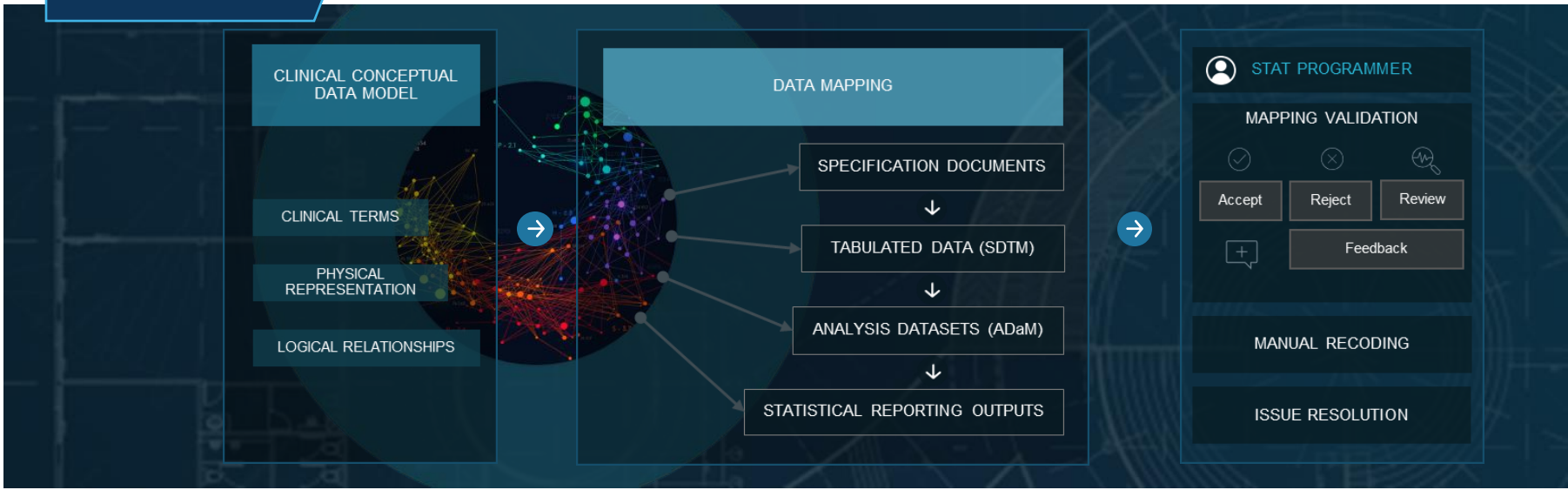
- AI-augmented Data Review and Cleaning



Automated Data Workflow: Transformation

Transformation

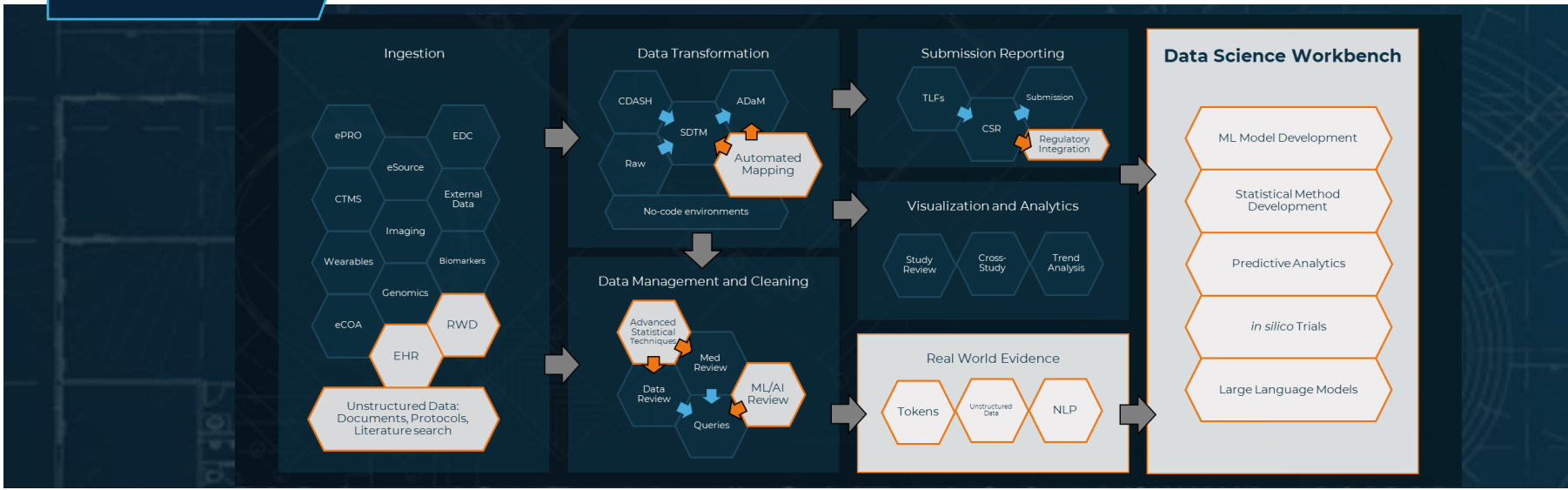
- Automated Specification Creation
- Automated Mapping Code Generation



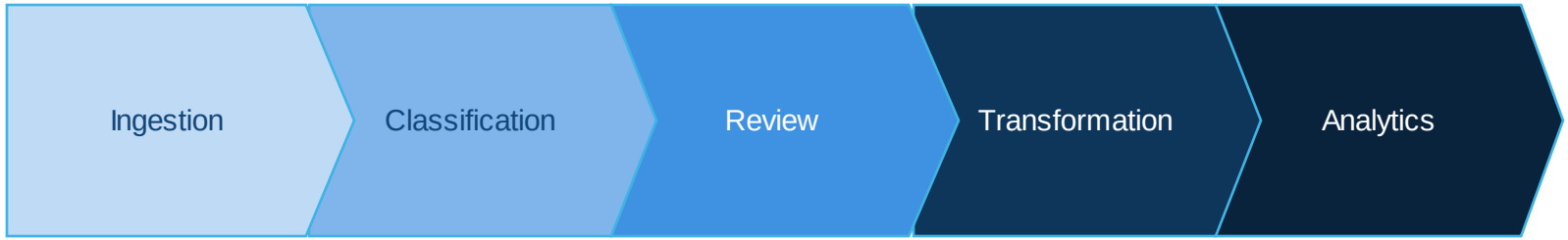
Automated Data Workflow: Analytics

Analytics

- Availability of all data across lifecycle
- Computational tools for advanced analytics

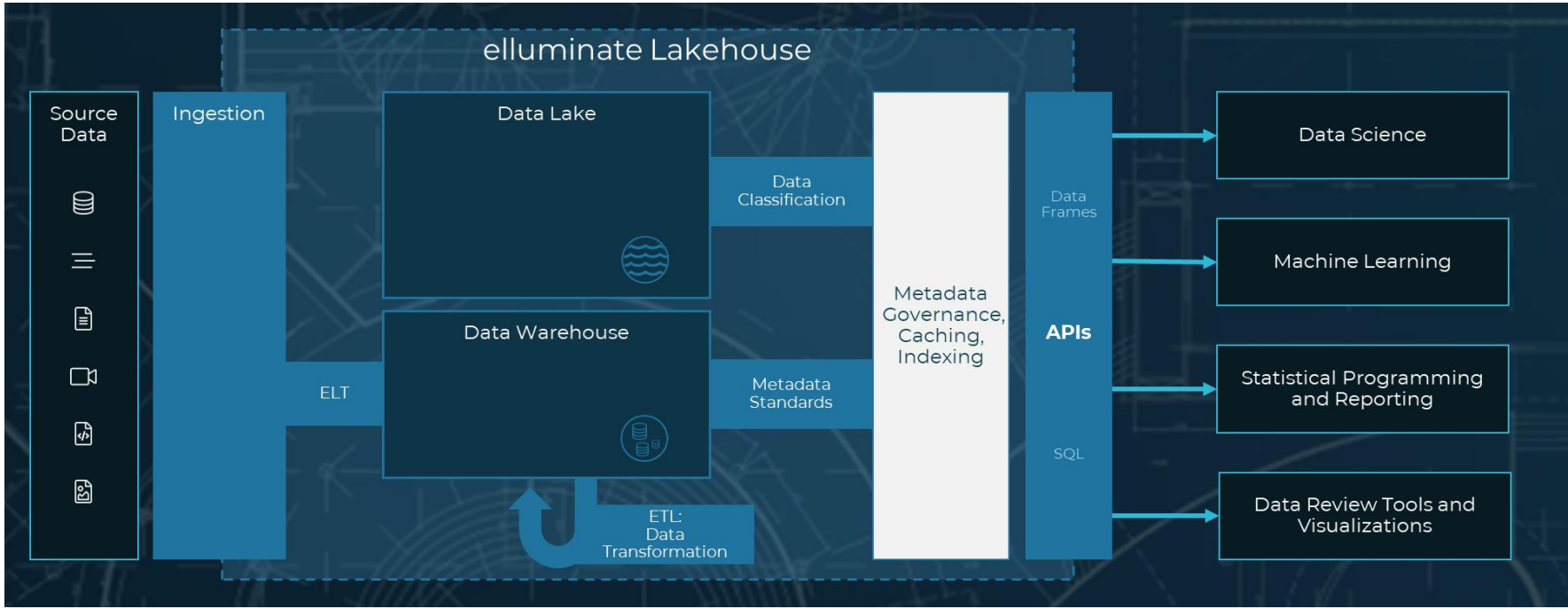


Automated Data Workflow



Case Study

Case Study: elluminate Clinical Data Cloud



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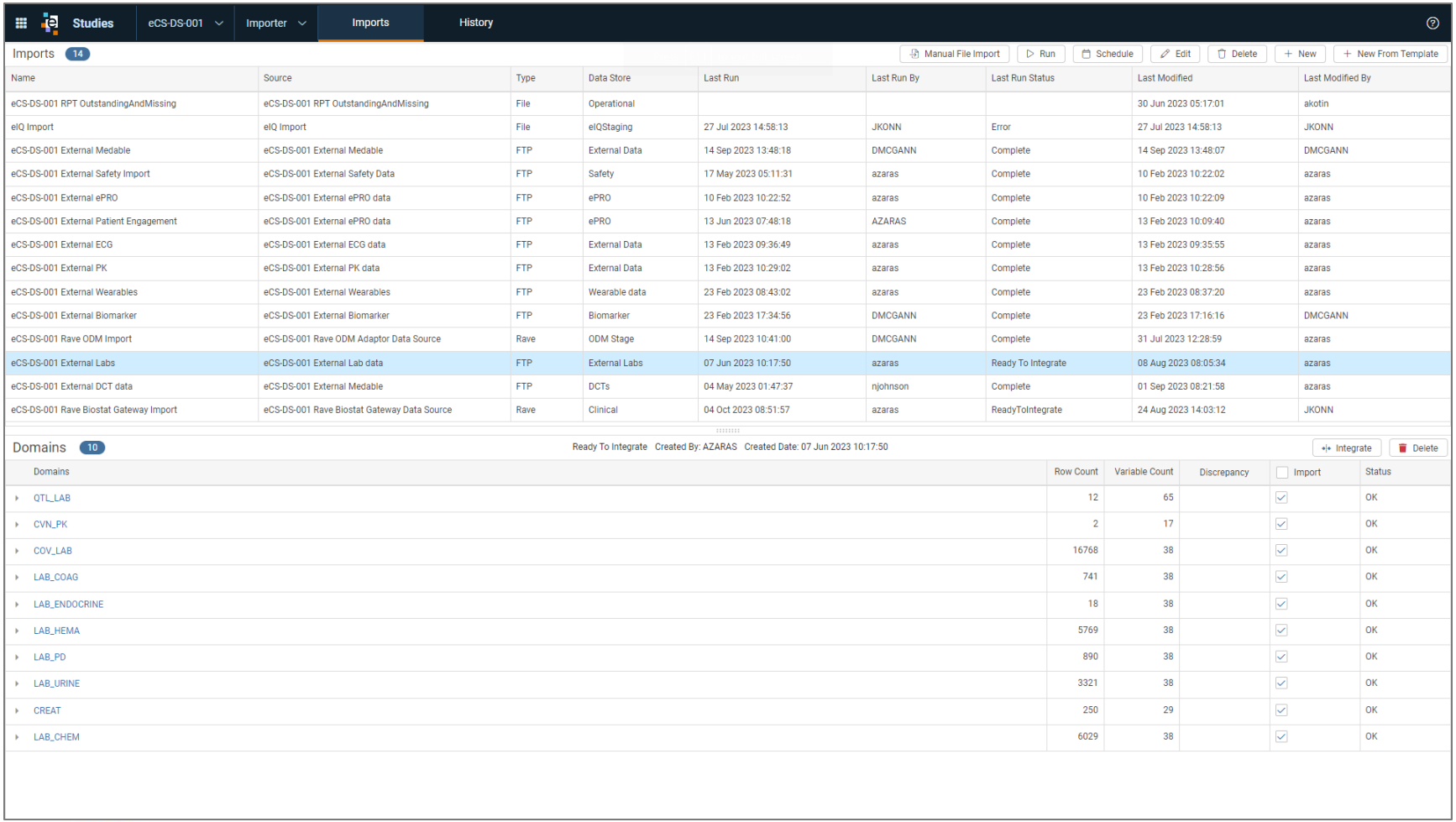
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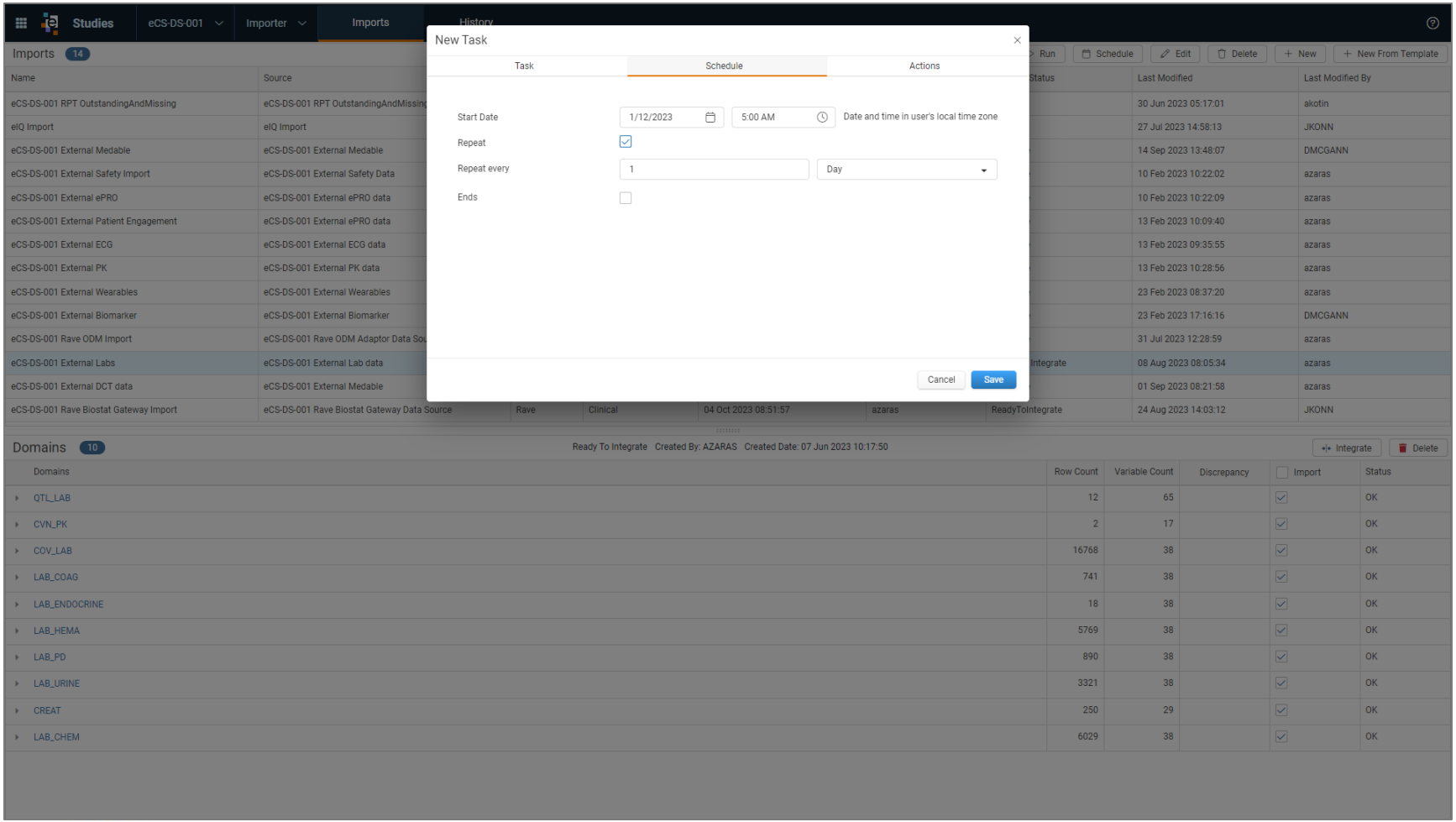
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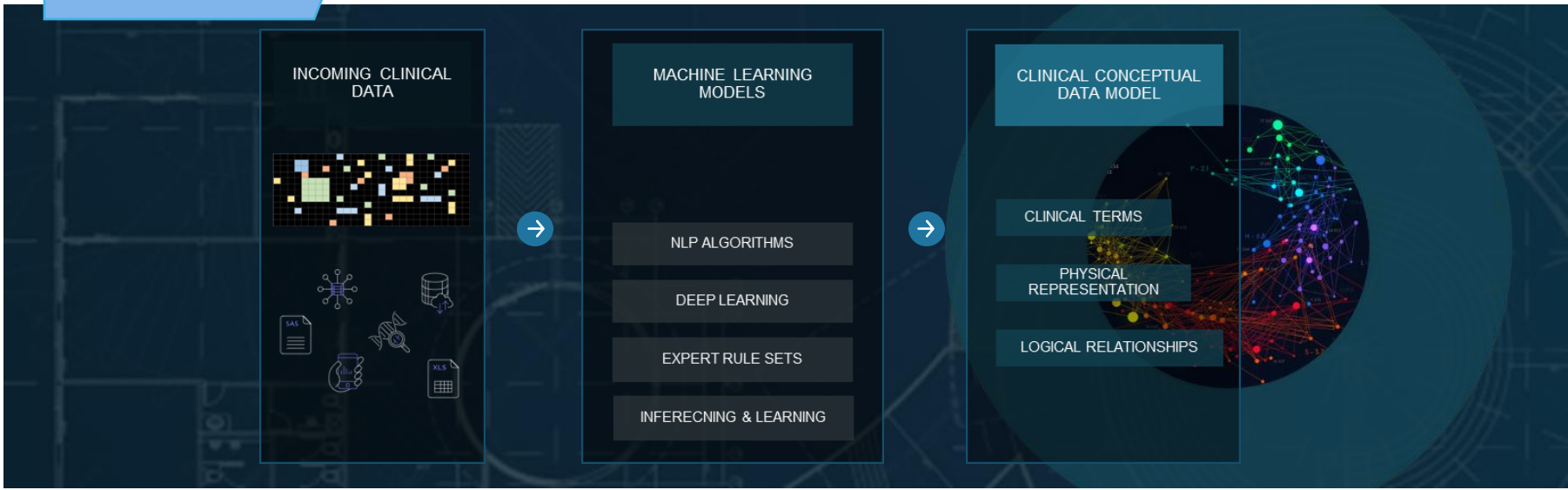
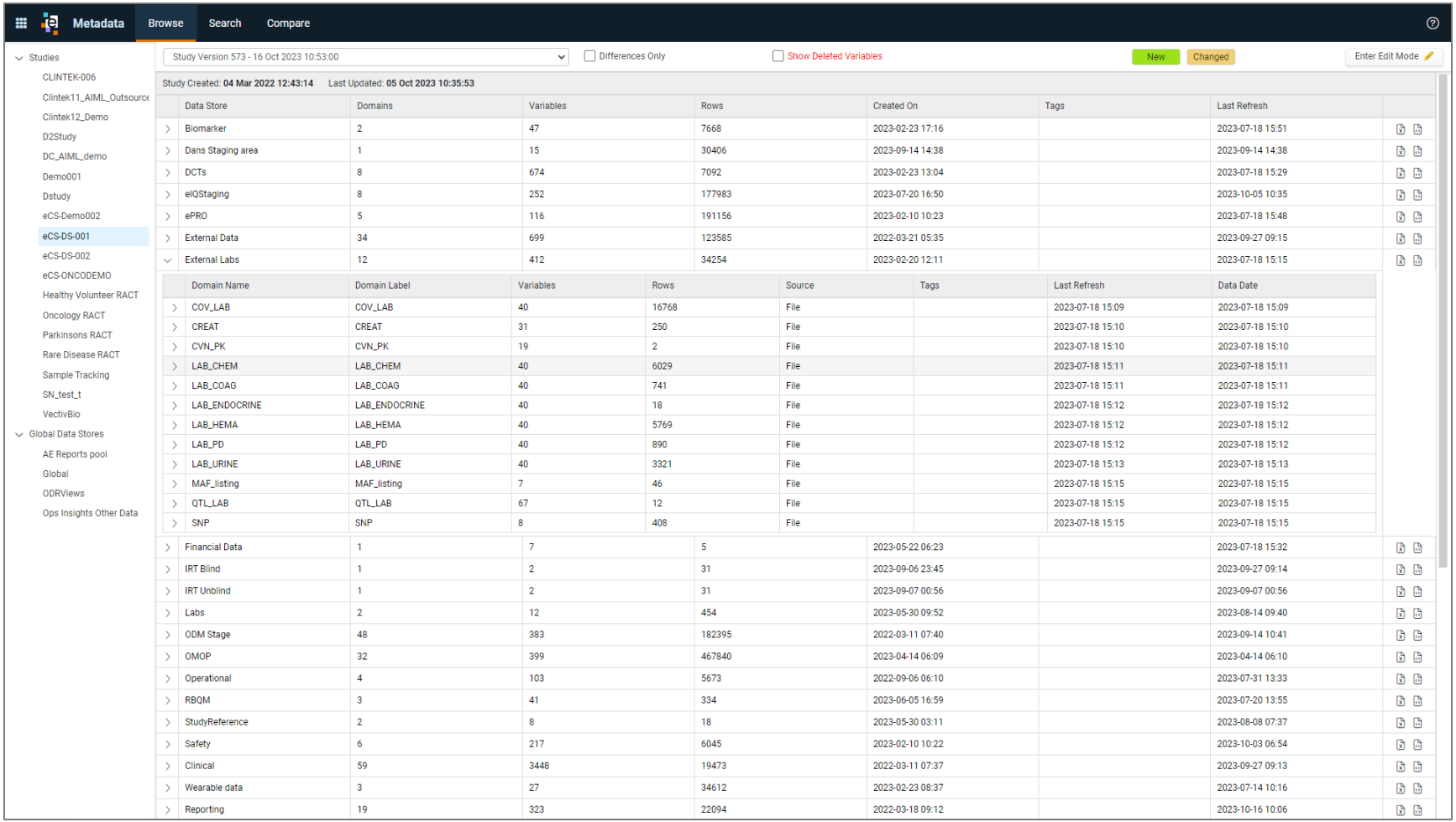
Automated Data Workflow: Classification

Classification

- ML Models to Automatically Classify Incoming Data

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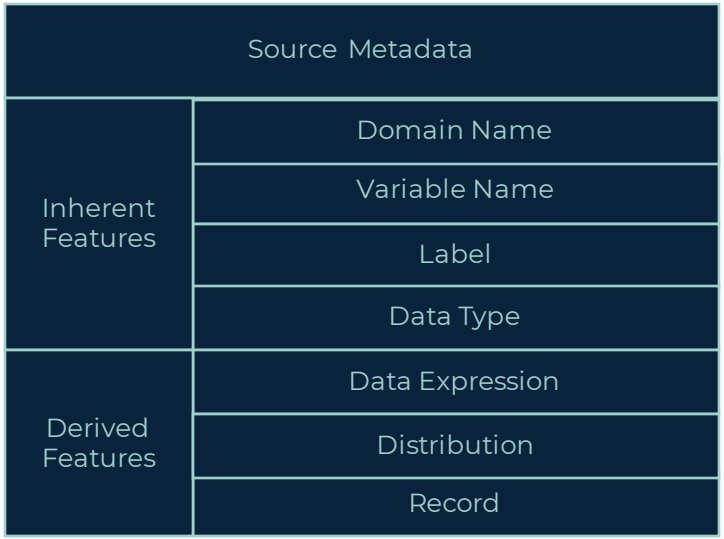
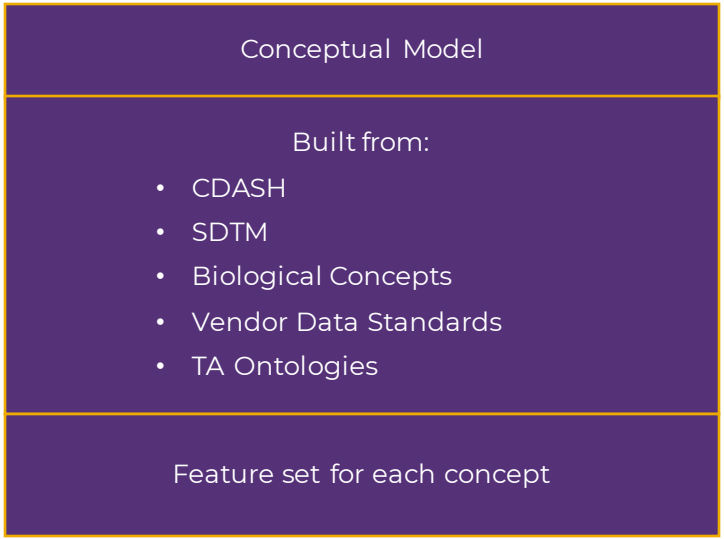
Automated Data Classification





Automated Data Classification

Source Metadata		
Inherent Features	Domain Name	ADV
	Variable Name	OUTCOME
	Label	“Outcome of Event”
	Data Type	Character
Derived Features	Data Expression	string; mixed case
	Distribution	Value Set
	Record	One record per Subject, per Event

→ Fatal
Not Recovered
Resolved
Recovering

Automated Data Classification

Source Metadata		
Inherent Features	Domain Name	ADV
	Variable Name	OUTCOME
	Label	“Outcome of Event”
	Data Type	Character
Derived Features	Data Expression	string; mixed case
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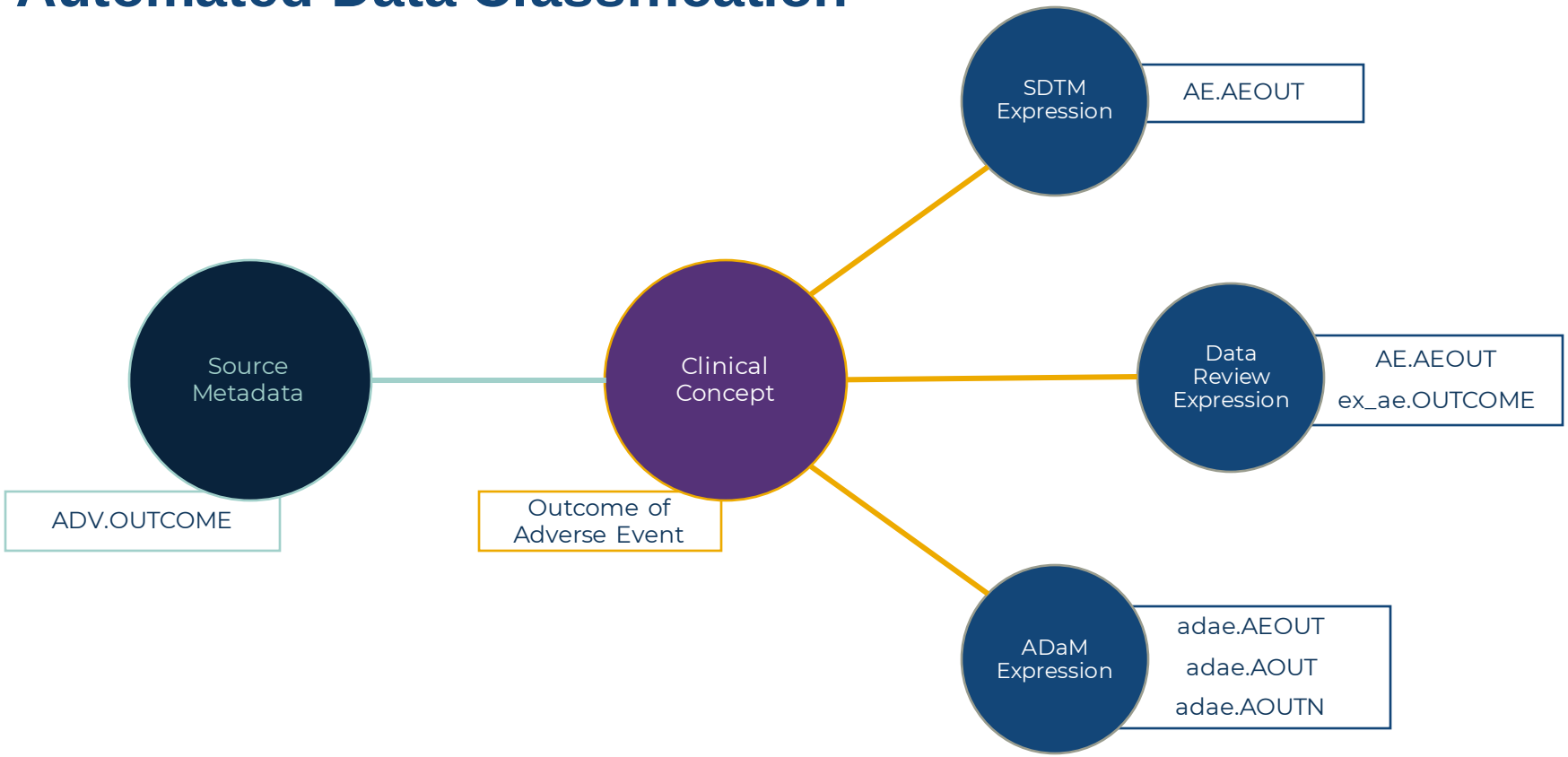
	Record	One record per Subject, per Event

Clinical Concept
Outcome of Adverse Event

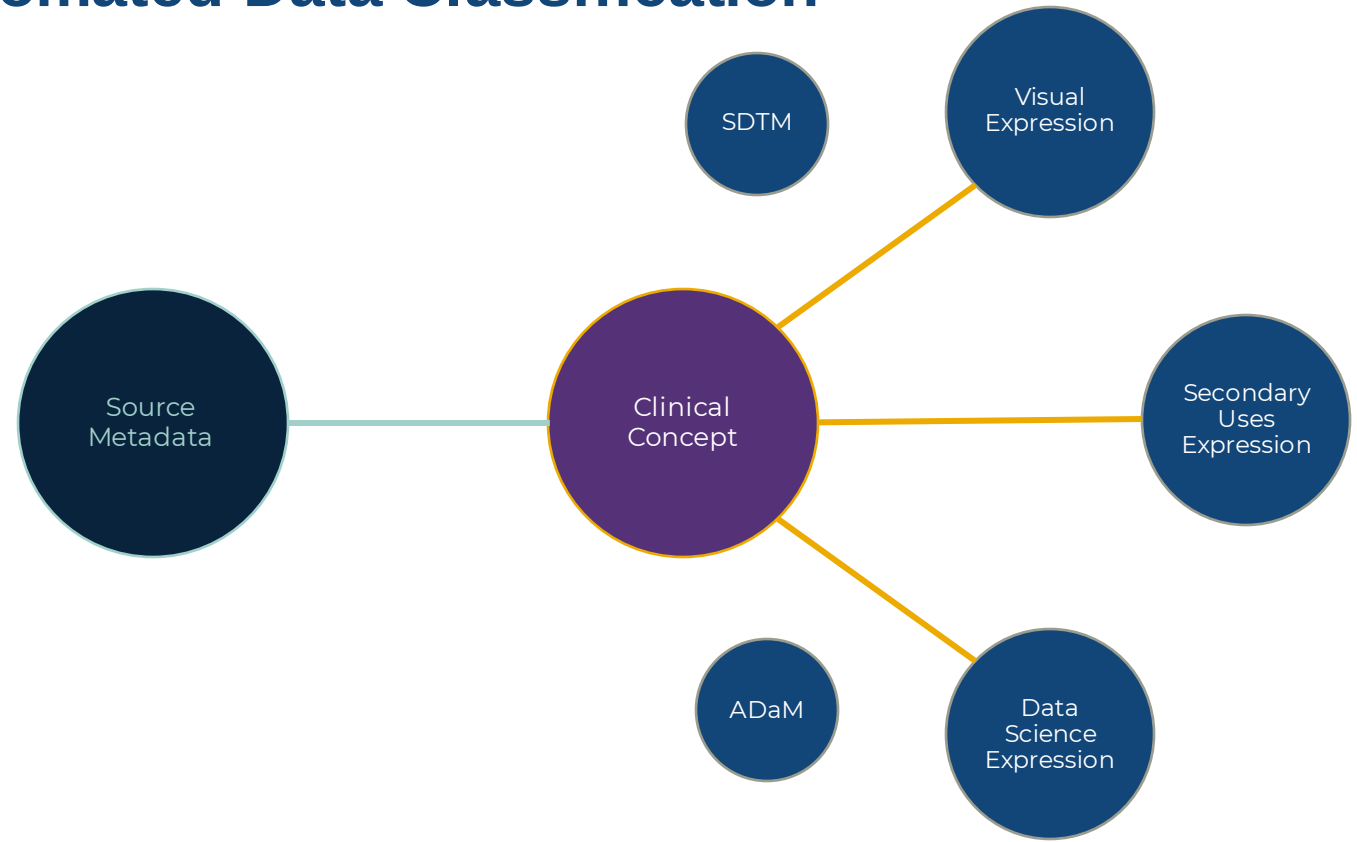
→

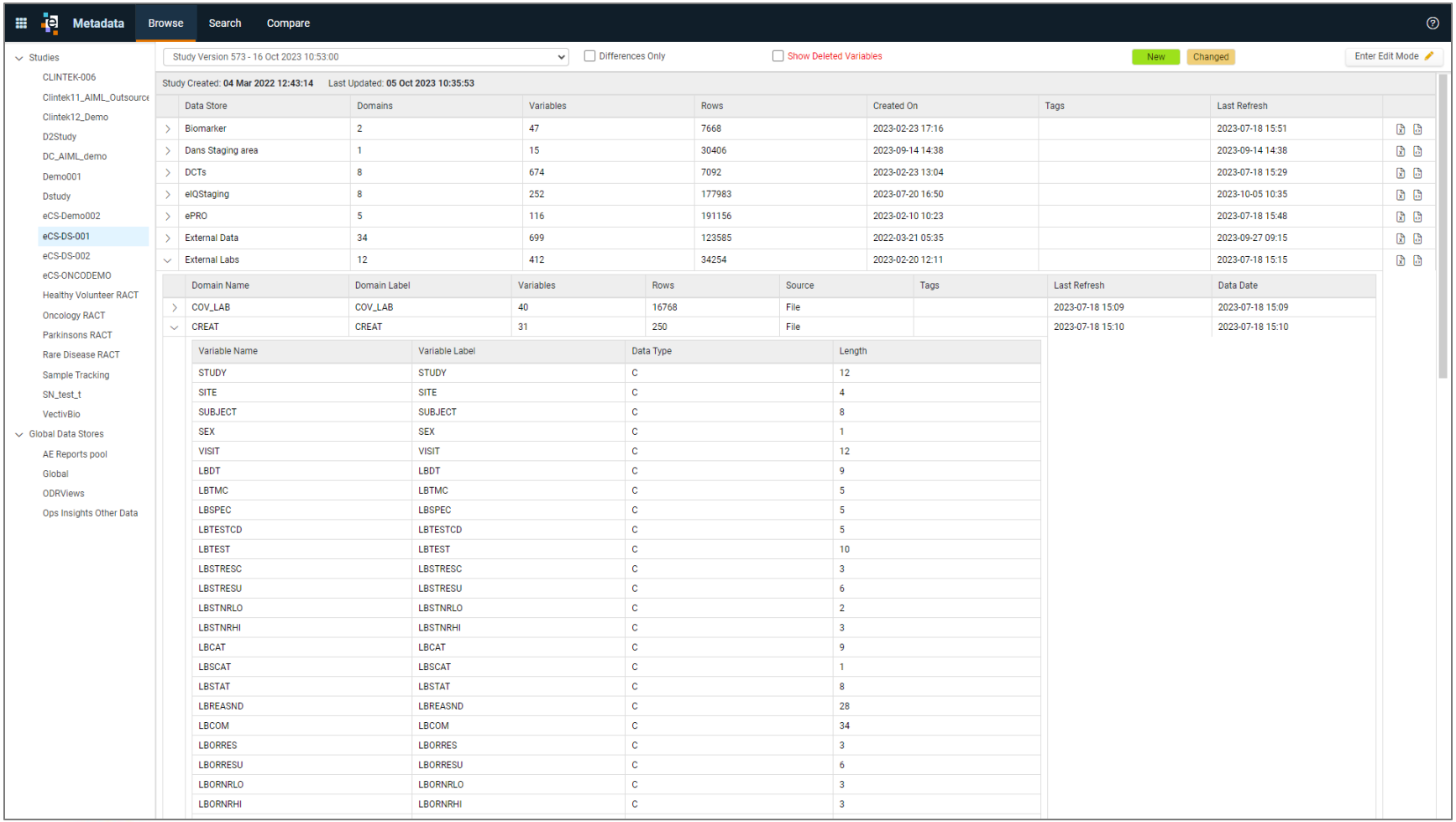
- Fatal
- Not Recovered
- Resolved
- Recovering

Automated Data Classification



Automated Data Classification

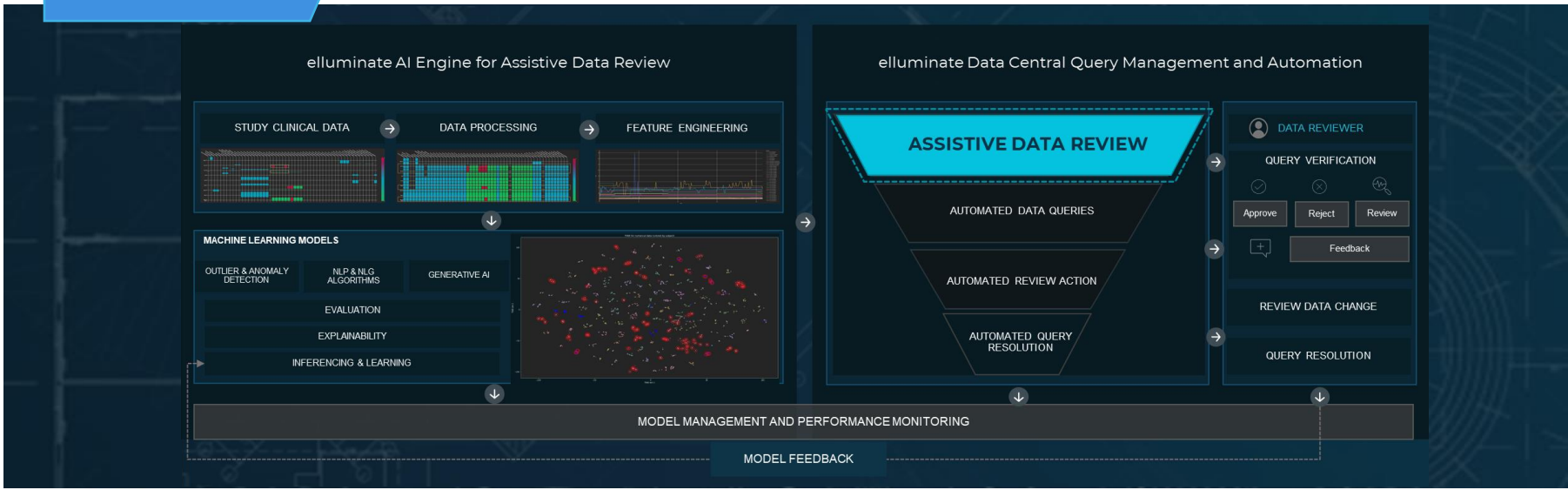


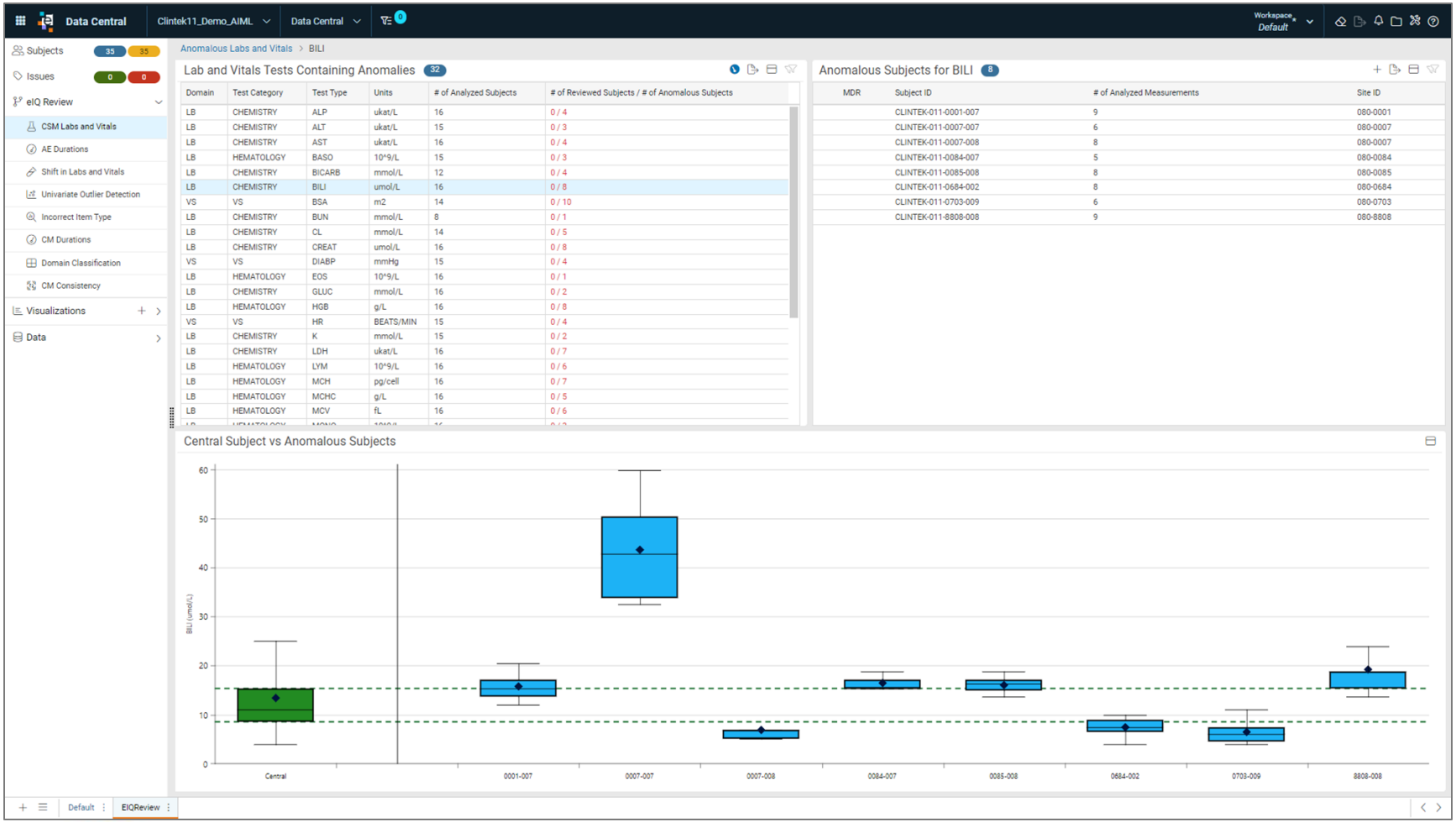

Metadata
Browse
Search
Compare
Studies
CLINTEK-006
Clintek11_AIML_Outsource
Clintek12_Demo
D2Study
DC_AIML_demo
Demo001
Dstudy
eCS-Demo002
eCS-DS-001
eCS-DS-002
eCS-ONCODEMO
Healthy Volunteer RACT
Oncology RACT
Parkinsons RACT
Rare Disease RACT
Sample Tracking
SN_test_t
VectivBio
Global Data Stores
AE Reports pool
Global
ODRViews
Ops Insights Other Data
Study Version 573 - 16 Oct 2023 10:53:00
Differences Only
Show Deleted Variables
New
Changed
Enter Edit Mode
Study Created: 04 Mar 2022 12:43:14
Last Updated: 05 Oct 2023 10:35:53
Data Store
Domains
Variables
Rows
Created On
Tags
Last Refresh
Biomarker 2 47 7668 2023-02-23 17:16 2023-07-18 15:51
Dans Staging area 1 15 30406 2023-09-14 14:38 2023-09-14 14:38
DCTs 8 674 7092 2023-02-23 13:04 2023-07-18 15:29
elQStaging 8 252 177983 2023-07-20 16:50 2023-10-05 10:35
ePRO 5 116 191156 2023-02-10 10:23 2023-07-18 15:48
External Data 34 699 123585 2022-03-21 05:35 2023-09-27 09:15
External Labs 12 412 34254 2023-02-20 12:11 2023-07-18 15:15
Domain Name
Domain Label
Variables
Rows
Source
Tags
Last Refresh
Data Date
COV_LAB COV_LAB 40 16768 File 2023-07-18 15:09 2023-07-18 15:09
CREAT CREAT 31 250 File 2023-07-18 15:10 2023-07-18 15:10
Variable Name
Variable Label
Data Type
Length
STUDY STUDY C 12
SITE SITE C 4
SUBJECT SUBJECT C 8
SEX SEX C 1
VISIT VISIT C 12
LBDT LBDT C 9
LBTMC LBTMC C 5
LBSPEC LBSPEC C 5
LBTESTCD LBTESTCD C 5
LBTEST LBTEST C 10
LBSTRESC LBSTRESC C 3
LBSTRESU LBSTRESU C 6
LBSTNRLO LBSTNRLO C 2
LBSTNRHI LBSTNRHI C 3
LBCAT LBCAT C 9
LBSCAT LBSCAT C 1
LBSTAT LBSTAT C 8
LBREASND LBREASND C 28
LBCOM LBCOM C 34
LBORRES LBORRES C 3
LBORRESU LBORRESU C 6
LBORNRLO LBORNRLO C 3
LBORNRHI LBORNRHI C 3

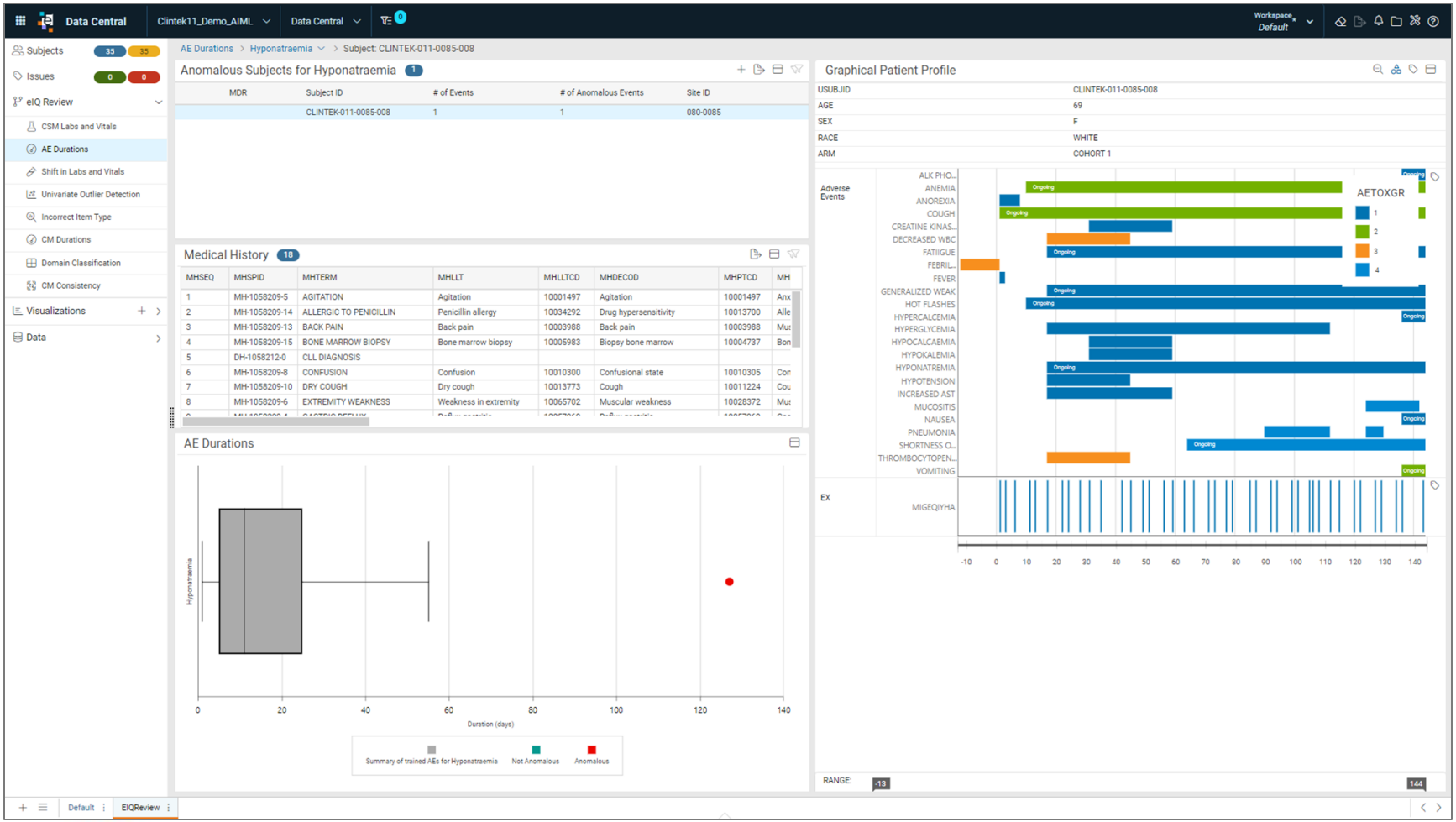
Automated Data Workflow: Review

Review

- AI-augmented Data Review and Cleaning



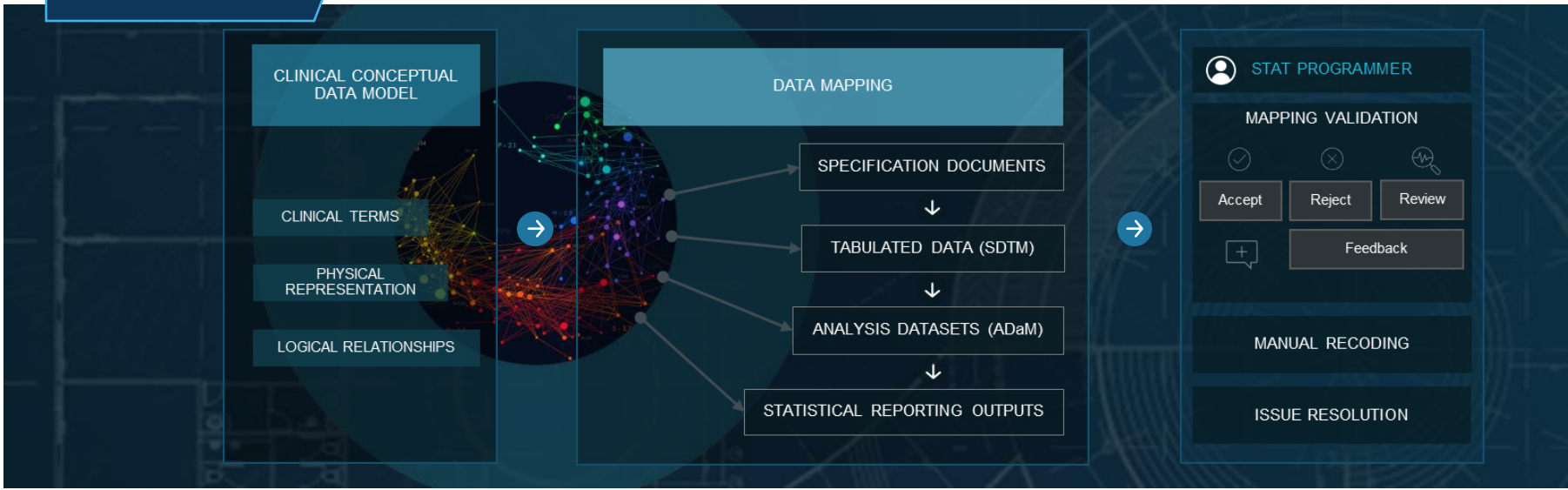

Data Central
Clintek11_Demo_AIML
Data Central
Workspace
Default
Subjects 35 35
Issues 0 0
eIQ Review
CSM Labs and Vitals
AE Durations
Shift in Labs and Vitals
Univariate Outlier Detection
Incorrect Item Type
CM Durations
Domain Classification
CM Consistency
Visualizations
Data
Anomalous Labs and Vitals > BILI
Lab and Vitals Tests Containing Anomalies 32
Domain | Test Category | Test Type | Units | # of Analyzed Subjects | # of Reviewed Subjects / # of Anomalous Subjects
LB | CHEMISTRY | ALP | ukat/L | 16 | 0 / 4
LB | CHEMISTRY | ALT | ukat/L | 15 | 0 / 3
LB | CHEMISTRY | AST | ukat/L | 16 | 0 / 4
LB | HEMATOLOGY | BASO | 10^9/L | 15 | 0 / 3
LB | CHEMISTRY | BICARB | mmol/L | 12 | 0 / 4
LB | CHEMISTRY | BILI | umol/L | 16 | 0 / 8
VS | VS | BSA | m2 | 14 | 0 / 10
LB | CHEMISTRY | BUN | mmol/L | 8 | 0 / 1
LB | CHEMISTRY | CL | mmol/L | 14 | 0 / 5
LB | CHEMISTRY | CREAT | umol/L | 16 | 0 / 8
VS | VS | DIABP | mmHg | 15 | 0 / 4
LB | HEMATOLOGY | EOS | 10^9/L | 16 | 0 / 1
LB | CHEMISTRY | GLUC | mmol/L | 16 | 0 / 2
LB | HEMATOLOGY | HGB | g/L | 16 | 0 / 8
VS | VS | HR | BEATS/MIN | 15 | 0 / 4
LB | CHEMISTRY | K | mmol/L | 15 | 0 / 2
LB | CHEMISTRY | LDH | ukat/L | 16 | 0 / 7
LB | HEMATOLOGY | LYM | 10^9/L | 16 | 0 / 6
LB | HEMATOLOGY | MCH | pg/cell | 16 | 0 / 7
LB | HEMATOLOGY | MCHC | g/L | 16 | 0 / 5
LB | HEMATOLOGY | MCV | fL | 16 | 0 / 6
Anomalous Subjects for BILI 8
MDR | Subject ID | # of Analyzed Measurements | Site ID
CLINTEK-011-0001-007 | 9 | 080-0001
CLINTEK-011-0007-007 | 6 | 080-0007
CLINTEK-011-0007-008 | 8 | 080-0007
CLINTEK-011-0084-007 | 5 | 080-0084
CLINTEK-011-0085-008 | 8 | 080-0085
CLINTEK-011-0684-002 | 8 | 080-0684
CLINTEK-011-0703-009 | 6 | 080-0703
CLINTEK-011-8808-008 | 9 | 080-8808
Central Subject vs Anomalous Subjects
BILI (umol/L)
60
50
40
30
20
10
0
Central
0001-007
0007-007
0007-008
0084-007
0085-008
0684-002
0703-009
8808-008
Default
EIQReview

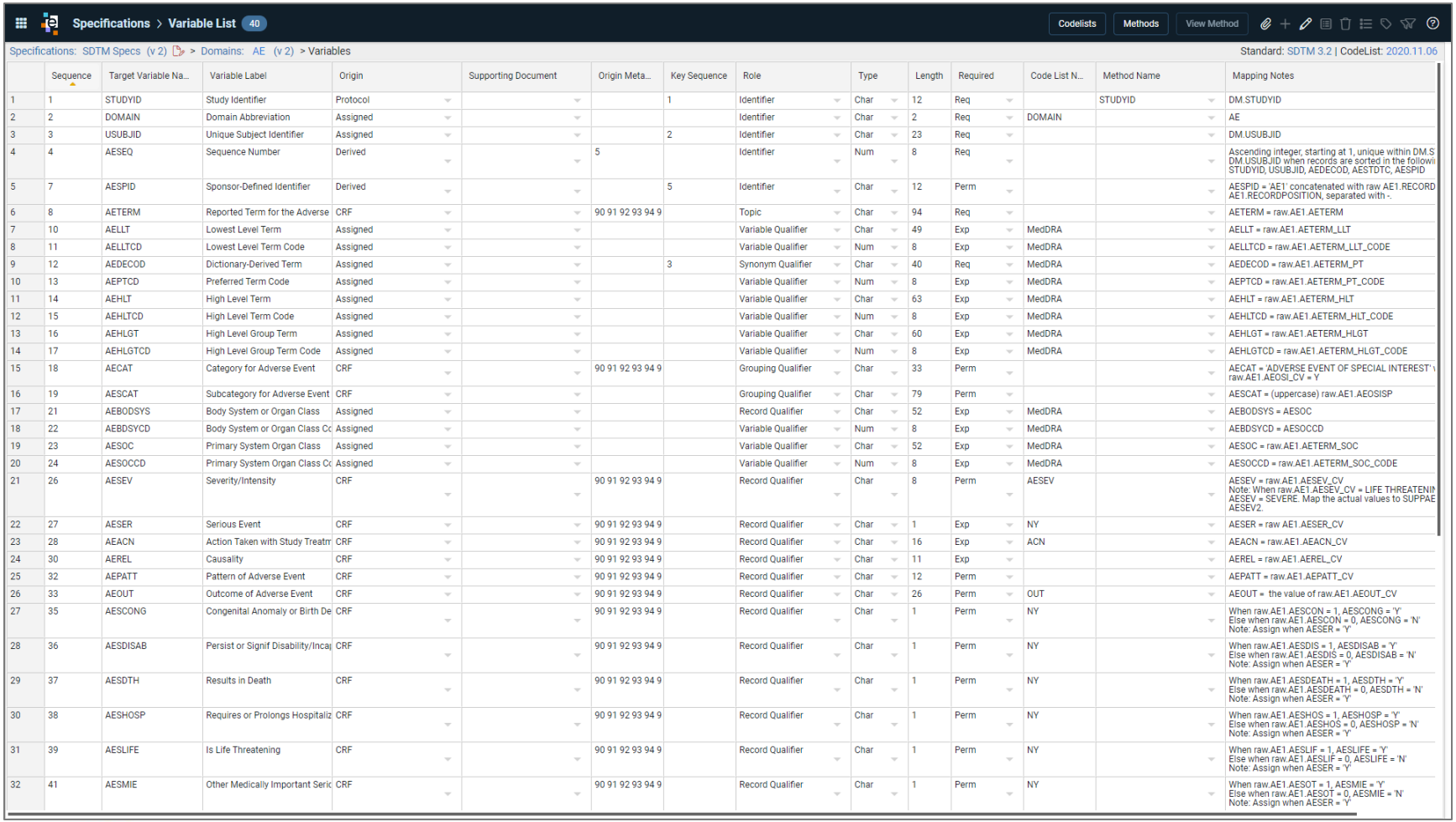

Data Central
Clintek11_Demo_AIML
Data Central
Workspace
Default
Subjects 35 35
Issues 0 0
eIQ Review
CSM Labs and Vitals
AE Durations
Shift in Labs and Vitals
Univariate Outlier Detection
Incorrect Item Type
CM Durations
Domain Classification
CM Consistency
Visualizations
Data
AE Durations > Hyponatraemia > Subject: CLINTEK-011-0085-008
Anomalous Subjects for Hyponatraemia 1
MDR
Subject ID
# of Events
# of Anomalous Events
Site ID
CLINTEK-011-0085-008
1
1
080-0085
Medical History 18
MHSEQ
MHSPID
MHTERM
MHLLT
MHLLTCD
MHDECOD
MHPTCD
1 MH-1058209-5 AGITATION Agitation 10001497 Agitation 10001497
2 MH-1058209-14 ALLERGIC TO PENICILLIN Penicillin allergy 10034292 Drug hypersensitivity 10013700
3 MH-1058209-13 BACK PAIN Back pain 10003988 Back pain 10003988
4 MH-1058209-15 BONE MARROW BIOPSY Bone marrow biopsy 10005983 Biopsy bone marrow 10004737
5 DH-1058212-0 CLL DIAGNOSIS
6 MH-1058209-8 CONFUSION Confusion 10010300 Confusional state 10010305
7 MH-1058209-10 DRY COUGH Dry cough 10013773 Cough 10011224
8 MH-1058209-6 EXTREMITY WEAKNESS Weakness in extremity 10065702 Muscular weakness 10028372
AE Durations
Hyponatraemia
0 20 40 60 80 100 120 140
Duration (days)
Summary of trained AEs for Hyponatraemia
Not Anomalous
Anomalous
Graphical Patient Profile
USUBJID CLINTEK-011-0085-008
AGE 69
SEX F
RACE WHITE
ARM COHORT 1
Adverse Events
ALK PHO...
ANEMIA
ANOREXIA
COUGH
CREATINE KINAS...
DECREASED WBC
FATIGUE
FEBRIL...
FEVER
GENERALIZED WEAK
HOT FLASHES
HYPERCALCEMIA
HYPERGLYCEMIA
HYPOCALCAEMIA
HYPOKALEMIA
HYPONATREMIA
HYPOTENSION
INCREASED AST
MUCOSITIS
NAUSEA
PNEUMONIA
SHORTNESS O...
THROMBOCYTOPEN...
VOMITING
Ongoing
AETOXGR
1
2
3
4
EX
MIGEQIYHA
-10 0 10 20 30 40 50 60 70 80 90 100 110 120 130 140
RANGE: -13 144
Default
EIQReview

Automated Data Workflow: Transformation

Transformation

- Automated Specification Creation
- Automated Mapping Code Generation ⊕





Specifications > Variable List 40

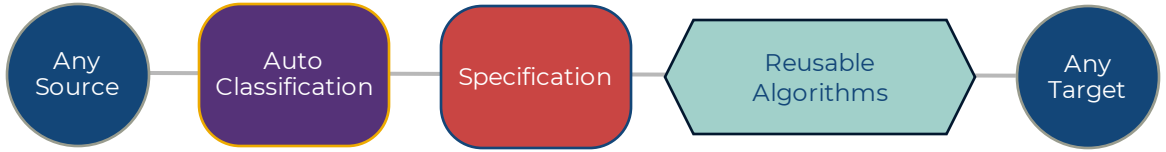
Codelists | Methods | View Method

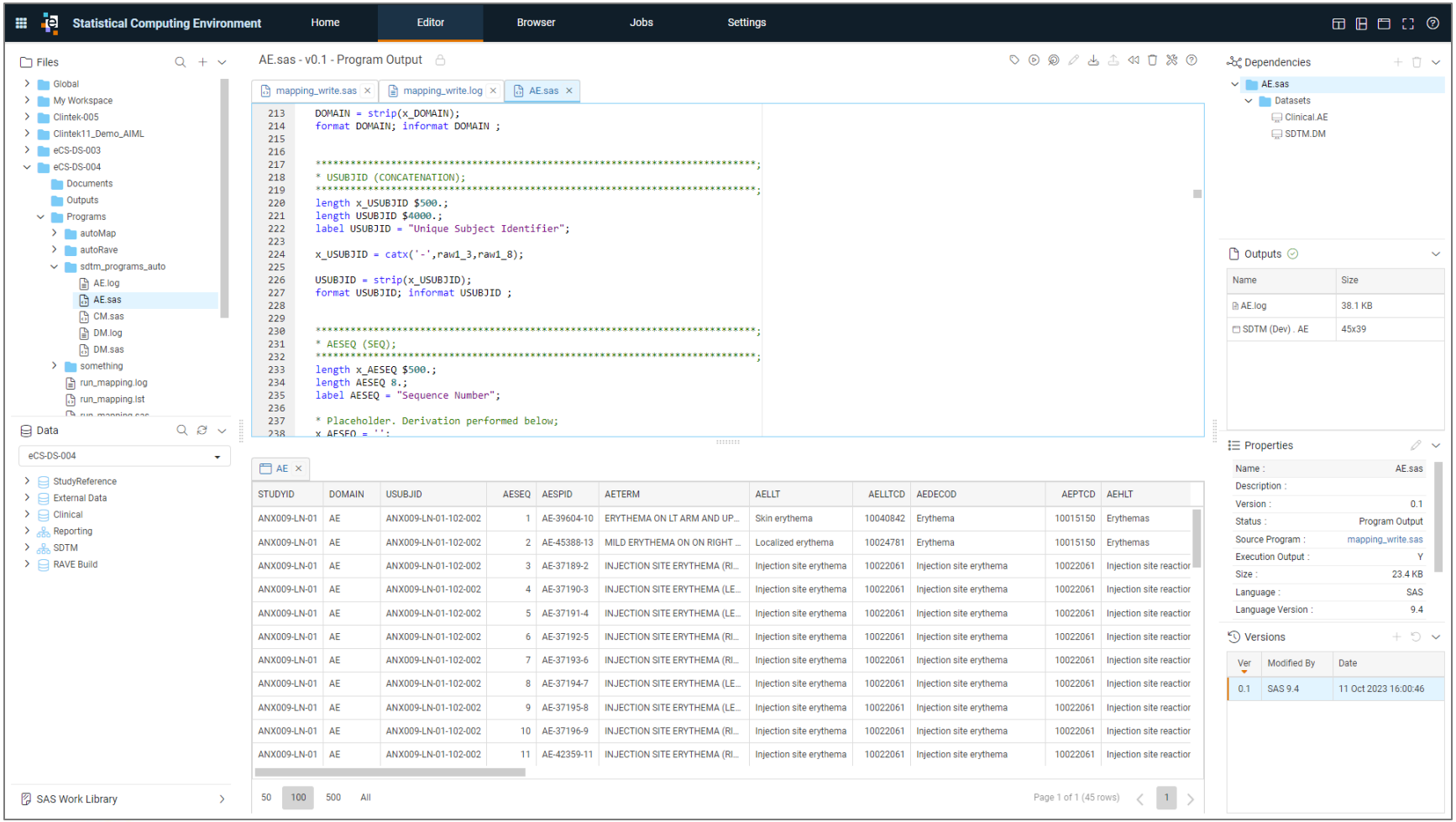
Specifications: SDTM Specs (v 2) > Domains: AE (v 2) > Variables

Standard: SDTM 3.2 | CodeList: 2020.11.06

	Sequence	Target Variable Na...	Variable Label	Origin	Supporting Document	Origin Meta...	Key Sequence	Role	Type	Length	Required	Code List N...	Method Name	Mapping Notes
1	1	STUDYID	Study Identifier	Protocol			1	Identifier	Char	12	Req		STUDYID	DM.STUDYID
2	2	DOMAIN	Domain Abbreviation	Assigned				Identifier	Char	2	Req	DOMAIN		AE
3	3	USUBJID	Unique Subject Identifier	Assigned			2	Identifier	Char	23	Req			DM.USUBJID
4	4	AESEQ	Sequence Number	Derived		5		Identifier	Num	8	Req			Ascending integer, starting at 1, unique within DM.S DM.USUBJID when records are sorted in the followi STUDYID, USUBJID, AEDECOD, AESTDTC, AESPID
5	7	AESPID	Sponsor-Defined Identifier	Derived			5	Identifier	Char	12	Perm			AESPID = 'AE1' concatenated with raw AE1.RECORD AE1.RECORDPOSITION, separated with -.
6	8	AETERM	Reported Term for the Adverse	CRF		90 91 92 93 94 9		Topic	Char	94	Req			AETERM = raw.AE1.AETERM
7	10	AELLT	Lowest Level Term	Assigned				Variable Qualifier	Char	49	Exp	MedDRA		AELLT = raw.AE1.AETERM_LLT
8	11	AELLTCD	Lowest Level Term Code	Assigned				Variable Qualifier	Num	8	Exp	MedDRA		AELLTCD = raw.AE1.AETERM_LLT_CODE
9	12	AEDECOD	Dictionary-Derived Term	Assigned			3	Synonym Qualifier	Char	40	Req	MedDRA		AEDECOD = raw.AE1.AETERM_PT
10	13	AEPTCD	Preferred Term Code	Assigned				Variable Qualifier	Num	8	Exp	MedDRA		AEPTCD = raw.AE1.AETERM_PT_CODE
11	14	AEHLT	High Level Term	Assigned				Variable Qualifier	Char	63	Exp	MedDRA		AEHLT = raw.AE1.AETERM_HLT
12	15	AEHLTCD	High Level Term Code	Assigned				Variable Qualifier	Num	8	Exp	MedDRA		AEHLTCD = raw.AE1.AETERM_HLT_CODE
13	16	AEHLGT	High Level Group Term	Assigned				Variable Qualifier	Char	60	Exp	MedDRA		AEHLGT = raw.AE1.AETERM_HLGT
14	17	AEHLGTCD	High Level Group Term Code	Assigned				Variable Qualifier	Num	8	Exp	MedDRA		AEHLGTCD = raw.AE1.AETERM_HLGT_CODE
15	18	AECAT	Category for Adverse Event	CRF		90 91 92 93 94 9		Grouping Qualifier	Char	33	Perm			AECAT = 'ADVERSE EVENT OF SPECIAL INTEREST' raw.AE1.AEOSI_CV = Y
16	19	AESCAT	Subcategory for Adverse Event	CRF				Grouping Qualifier	Char	79	Perm			AESCAT = (uppercase) raw.AE1.AEOSISP
17	21	AEBODSYS	Body System or Organ Class	Assigned				Record Qualifier	Char	52	Exp	MedDRA		AEBODSYS = AESOC
18	22	AEBDSYCD	Body System or Organ Class Cc	Assigned				Variable Qualifier	Num	8	Exp	MedDRA		AEBDSYCD = AESOCCD
19	23	AESOC	Primary System Organ Class	Assigned				Variable Qualifier	Char	52	Exp	MedDRA		AESOC = raw.AE1.AETERM_SOC
20	24	AESOCCD	Primary System Organ Class Cc	Assigned				Variable Qualifier	Num	8	Exp	MedDRA		AESOCCD = raw.AE1.AETERM_SOC_CODE
21	26	AESEV	Severity/Intensity	CRF		90 91 92 93 94 9		Record Qualifier	Char	8	Perm	AESEV		AESEV = raw.AE1.AESEV_CV Note: When raw.AE1.AESEV_CV = LIFE THREATENI AESEV = SEVERE. Map the actual values to SUPPAE AESEV2.
22	27	AESER	Serious Event	CRF		90 91 92 93 94 9		Record Qualifier	Char	1	Exp	NY		AESER = raw AE1.AESER_CV
23	28	AEACN	Action Taken with Study Treatm	CRF		90 91 92 93 94 9		Record Qualifier	Char	16	Exp	ACN		AEACN = raw.AE1.AEACN_CV
24	30	AEREL	Causality	CRF		90 91 92 93 94 9		Record Qualifier	Char	11	Exp			AEREL = raw.AE1.AEREL_CV
25	32	AEPATT	Pattern of Adverse Event	CRF		90 91 92 93 94 9		Record Qualifier	Char	12	Perm			AEPATT = raw.AE1.AEPATT_CV
26	33	AEOUT	Outcome of Adverse Event	CRF		90 91 92 93 94 9		Record Qualifier	Char	26	Perm	OUT		AEOUT = the value of raw.AE1.AEOUT_CV
27	35	AESCONG	Congenital Anomaly or Birth De	CRF		90 91 92 93 94 9		Record Qualifier	Char	1	Perm	NY		When raw.AE1.AESCON = 1, AESCONG = 'Y' Else when raw.AE1.AESCON = 0, AESCONG = 'N' Note: Assign when AESER = 'Y'
28	36	AESDISAB	Persist or Signif Disability/Incap	CRF		90 91 92 93 94 9		Record Qualifier	Char	1	Perm	NY		When raw.AE1.AESDIS = 1, AESDISAB = 'Y' Else when raw.AE1.AESDIS = 0, AESDISAB = 'N' Note: Assign when AESER = 'Y'
29	37	AESDTH	Results in Death	CRF		90 91 92 93 94 9		Record Qualifier	Char	1	Perm	NY		When raw.AE1.AESDEATH = 1, AESDTH = 'Y' Else when raw.AE1.AESDEATH = 0, AESDTH = 'N' Note: Assign when AESER = 'Y'
30	38	AESHOSP	Requires or Prolongs Hospitaliz	CRF		90 91 92 93 94 9		Record Qualifier	Char	1	Perm	NY		When raw.AE1.AESHOS = 1, AESHOSP = 'Y' Else when raw.AE1.AESHOS = 0, AESHOSP = 'N' Note: Assign when AESER = 'Y'
31	39	AESLIFE	Is Life Threatening	CRF		90 91 92 93 94 9		Record Qualifier	Char	1	Perm	NY		When raw.AE1.AESLIF = 1, AESLIFE = 'Y' Else when raw.AE1.AESLIF = 0, AESLIFE = 'N' Note: Assign when AESER = 'Y'
32	41	AESMIE	Other Medically Important Seric	CRF		90 91 92 93 94 9		Record Qualifier	Char	1	Perm	NY		When raw.AE1.AESOT = 1, AESMIE = 'Y' Else when raw.AE1.AESOT = 0, AESMIE = 'N' Note: Assign when AESER = 'Y'

Automated Mapping Code Generation: Similar Conceptual Approach

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Home
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My Workspace
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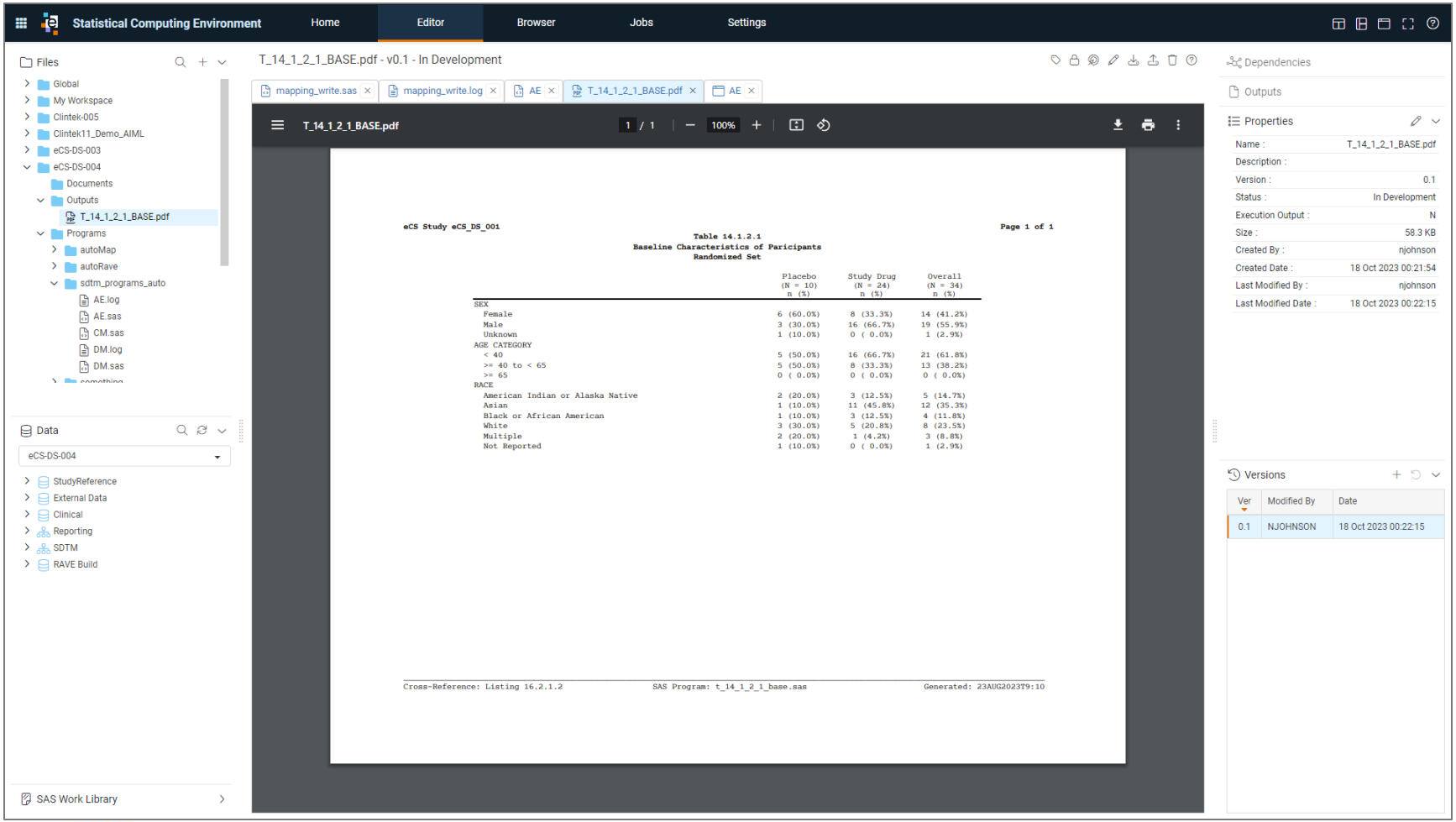
eCS-DS-004
Documents
Outputs
Programs
autoMap
autoRave
sdtm_programs_auto
AE.log
AE.sas
CM.sas
DM.log
DM.sas
something
run_mapping.log
run_mapping.lst
Data
eCS-DS-004
StudyReference
External Data
Clinical
Reporting
SDTM
RAVE Build
SAS Work Library
AE.sas - v0.1 - Program Output
mapping_write.sas
mapping_write.log
AE.sas
213 DOMAIN = strip(x_DOMAIN);
214 format DOMAIN; informat DOMAIN ;
215
216
217 **;
218 * USUBJID (CONCATENATION);
219 **;
220 length x_USUBJID $500.;
221 length USUBJID $4000.;
222 label USUBJID = "Unique Subject Identifier";
223
224 x_USUBJID = catx('-',raw1_3,raw1_8);
225
226 USUBJID = strip(x_USUBJID);
227 format USUBJID; informat USUBJID ;
228
229
230 **;
231 * AESEQ (SEQ);
232 **;
233 length x_AESEQ $500.;
234 length AESEQ 8.;
235 label AESEQ = "Sequence Number";
236
237 * Placeholder. Derivation performed below;
238 x_AESEQ = '';
AE
STUDYID DOMAIN USUBJID AESEQ AESPID AETERM AELLT AELLTCD AEDECOD AEPTCD AEHLT
ANX009-LN-01 AE ANX009-LN-01-102-002 1 AE-39604-10 ERYTHEMA ON LT ARM AND UP... Skin erythema 10040842 Erythema 10015150 Erythemas
ANX009-LN-01 AE ANX009-LN-01-102-002 2 AE-45388-13 MILD ERYTHEMA ON ON RIGHT ... Localized erythema 10024781 Erythema 10015150 Erythemas
ANX009-LN-01 AE ANX009-LN-01-102-002 3 AE-37189-2 INJECTION SITE ERYTHEMA (RI... Injection site erythema 10022061 Injection site erythema 10022061 Injection site reaction
ANX009-LN-01 AE ANX009-LN-01-102-002 4 AE-37190-3 INJECTION SITE ERYTHEMA (LE... Injection site erythema 10022061 Injection site erythema 10022061 Injection site reaction
ANX009-LN-01 AE ANX009-LN-01-102-002 5 AE-37191-4 INJECTION SITE ERYTHEMA (LE... Injection site erythema 10022061 Injection site erythema 10022061 Injection site reaction
ANX009-LN-01 AE ANX009-LN-01-102-002 6 AE-37192-5 INJECTION SITE ERYTHEMA (RI... Injection site erythema 10022061 Injection site erythema 10022061 Injection site reaction
ANX009-LN-01 AE ANX009-LN-01-102-002 7 AE-37193-6 INJECTION SITE ERYTHEMA (RI... Injection site erythema 10022061 Injection site erythema 10022061 Injection site reaction
ANX009-LN-01 AE ANX009-LN-01-102-002 8 AE-37194-7 INJECTION SITE ERYTHEMA (LE... Injection site erythema 10022061 Injection site erythema 10022061 Injection site reaction
ANX009-LN-01 AE ANX009-LN-01-102-002 9 AE-37195-8 INJECTION SITE ERYTHEMA (LE... Injection site erythema 10022061 Injection site erythema 10022061 Injection site reaction
ANX009-LN-01 AE ANX009-LN-01-102-002 10 AE-37196-9 INJECTION SITE ERYTHEMA (RI... Injection site erythema 10022061 Injection site erythema 10022061 Injection site reaction
ANX009-LN-01 AE ANX009-LN-01-102-002 11 AE-42359-11 INJECTION SITE ERYTHEMA (RI... Injection site erythema 10022061 Injection site erythema 10022061 Injection site reaction
50 100 500 All
Page 1 of 1 (45 rows)
1
Dependencies
AE.sas
Datasets
Clinical.AE
SDTM.DM
Outputs
Name Size
AE.log 38.1 KB
SDTM (Dev) . AE 45x39
Properties
Name : AE.sas
Description :
Version : 0.1
Status : Program Output
Source Program : mapping_write.sas
Execution Output : Y
Size : 23.4 KB
Language : SAS
Language Version : 9.4
Versions
Ver Modified By Date
0.1 SAS 9.4 11 Oct 2023 16:00:46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Clintek11_Demo_AIML
eCS-DS-003
eCS-DS-004
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External Data
Clinical
Reporting
SDTM
RAVE Build
SAS Work Library
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mapping_write.sas
mapping_write.log
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T_14_1_2_1_BASE.pdf
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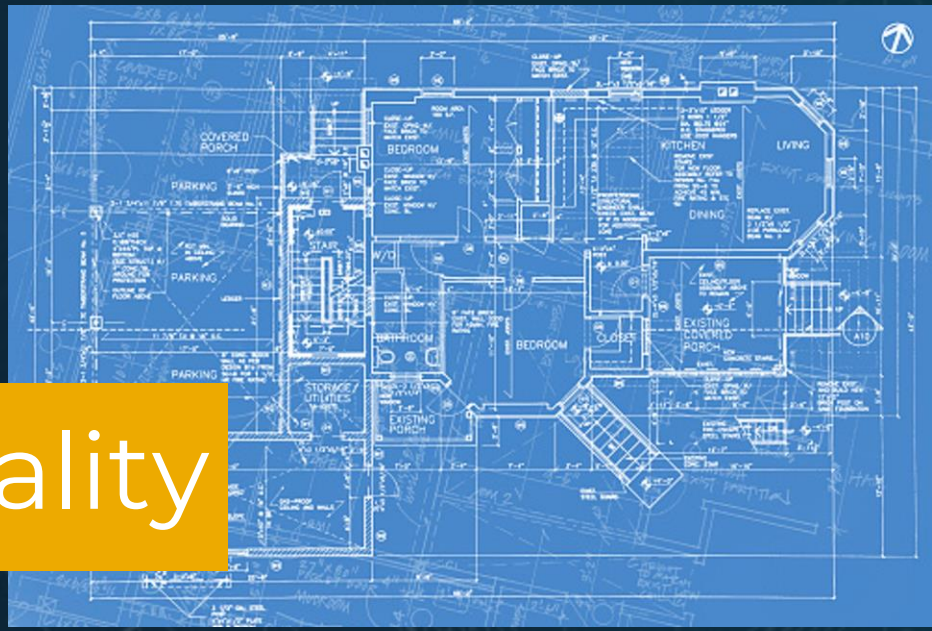
T_14_1_2_1_BASE.pdf
1 / 1
100%
eCS Study eCS_DS_001
Page 1 of 1
Table 14.1.2.1
Baseline Characteristics of Paricipants
Randomized Set
Placebo (N = 10) n (%)
Study Drug (N = 24) n (%)
Overall (N = 34) n (%)
SEX
Female 6 (60.0%) 8 (33.3%) 14 (41.2%)
Male 3 (30.0%) 16 (66.7%) 19 (55.9%)
Unknown 1 (10.0%) 0 (0.0%) 1 (2.9%)
AGE CATEGORY
< 40 5 (50.0%) 16 (66.7%) 21 (61.8%)
>= 40 to < 65 5 (50.0%) 8 (33.3%) 13 (38.2%)
>= 65 0 (0.0%) 0 (0.0%) 0 (0.0%)
RACE
American Indian or Alaska Native 2 (20.0%) 3 (12.5%) 5 (14.7%)
Asian 1 (10.0%) 11 (45.8%) 12 (35.3%)
Black or African American 1 (10.0%) 3 (12.5%) 4 (11.8%)
White 3 (30.0%) 5 (20.8%) 8 (23.5%)
Multiple 2 (20.0%) 1 (4.2%) 3 (8.8%)
Not Reported 1 (10.0%) 0 (0.0%) 1 (2.9%)
Cross-Reference: Listing 16.2.1.2
SAS Program: t_14_1_2_1_base.sas
Generated: 23AUG2023T9:10
Dependencies
Outputs
Properties
Name : T_14_1_2_1_BASE.pdf
Description :
Version : 0.1
Status : In Development
Execution Output : N
Size : 58.3 KB
Created By : njohnson
Created Date : 18 Oct 2023 00:21:54
Last Modified By : njohnson
Last Modified Date : 18 Oct 2023 00:22:15
Versions
Ver
Modified By
Date
0.1
NJOHNSON
18 Oct 2023 00:22:15

Conclusions

The Digital Blueprint

Vision

Reality



Thank You!

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