

A ROBUST **FRAMEWORK** TO PROVIDE AND VALIDATE **REAL-TIME SDTM** DATA

EU Connect 2023
DH07

Bremer Louw

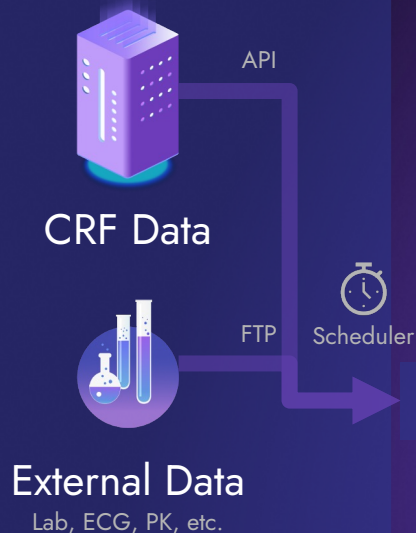
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THE FRAMEWORK

FRAMEWORK

Data Acquisition



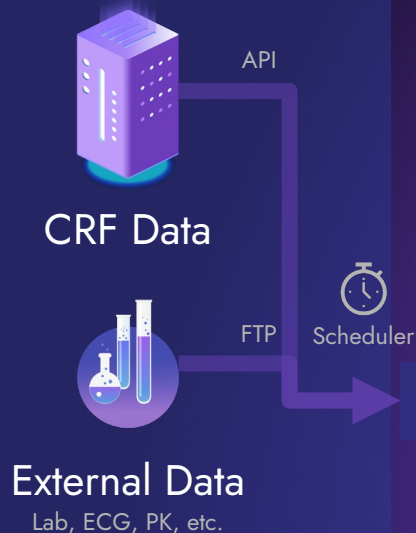
RAW Data



Data Storage

FRAMEWORK

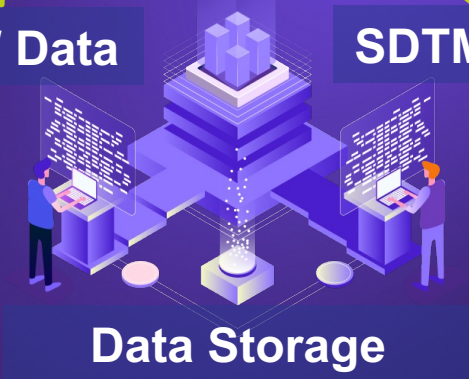
Data Acquisition



Data Processing

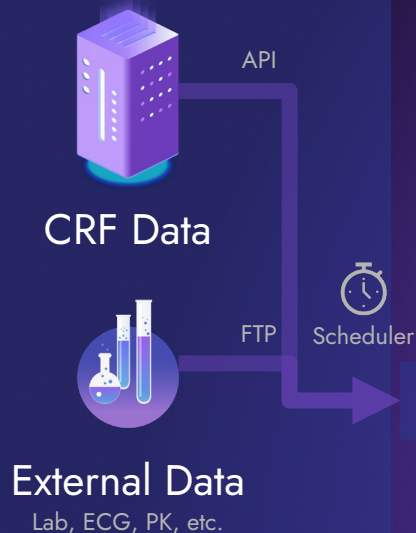


Data Storage



FRAMEWORK

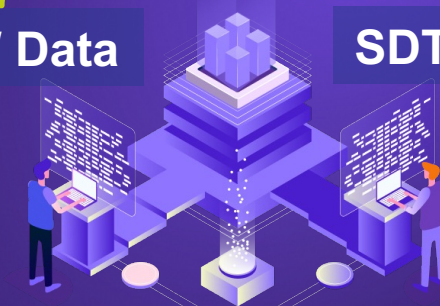
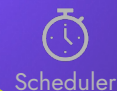
Data Acquisition



Data Processing

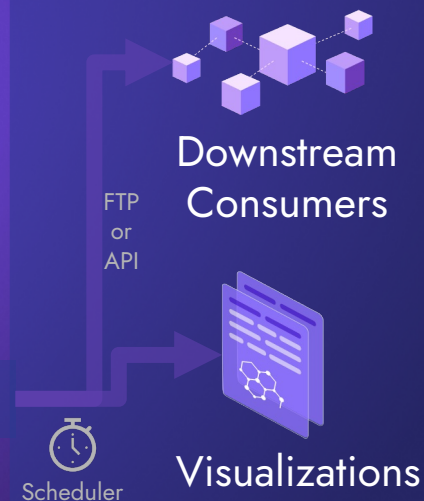
RAW Data

SDTM Data



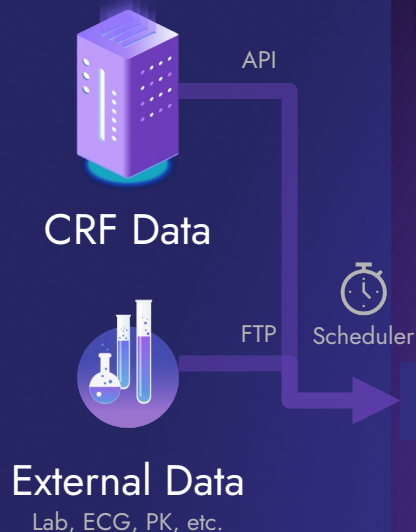
Data Storage

Data Publishing



FRAMEWORK

Data Acquisition



Data
Validation

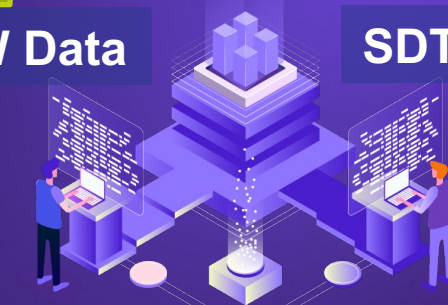
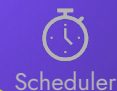
Issue
Detection

Data Issue
Handling

Data Processing

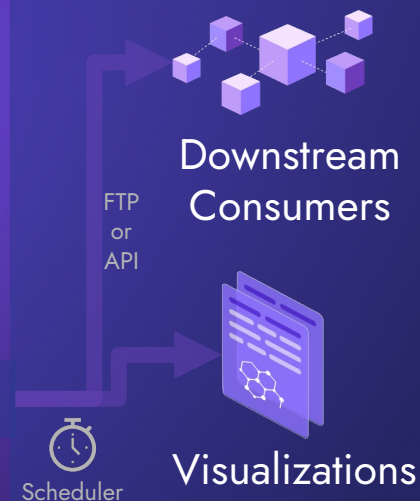
RAW Data

SDTM Data



Data Storage

Data Publishing



DATA STATUS REPORTING

DASHBOARD

Data Acquisition

Dataset	Last Refresh	Observations	Structure Change
DEMOG	02-JUL-2023	230 (+10)	No
ADVERSE	02-JUL-2023	482 (+10)	No
CONMED	01-JUL-2023	321 (+7)	No
EOS	02-JUL-2023	143 (-3)	No
LAB	02-JUL-2023	7863 (+686)	Yes  ALERT
ECG	02-JUL-2023	1024 (+155)	No

DASHBOARD

Data Processing

Dataset	Last Refresh	Observations	Structure Change	QC Compare Differences	Validation Rules
DM	02-JUL-2023	230 (+10)	No	Yes	No
AE	02-JUL-2023	482 (+10)	No	No	No
CM	01-JUL-2023	321 (+7)	No	No	No
DS	02-JUL-2023	143 (-3)	No	No	No
LB	02-JUL-2023	7863 (+686)	Yes	No	Yes
EG	02-JUL-2023	1024 (+155)	No	No	No

DASHBOARD

Data Publishing

Dataset	Destination	Last Refresh
DM	Analysis FTP	02-JUL-2023
AE	Analysis FTP	02-JUL-2023
CM	Analysis FTP	01-JUL-2023
DS	Visualizations	02-JUL-2023
LB	Visualizations	02-JUL-2023
EG	Visualizations	02-JUL-2023

DATA VALIDATION

LEGACY SDTM VALIDATION



Specification



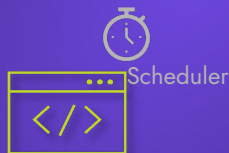
Independent
Review



**Conversion
Program(s)**



Data
Completeness
Tracking



Double
Programming



**Data
Validation**



Validation
Checks

Mapping Correctness

**SDTM
Conformance**

NEW SDTM VALIDATION



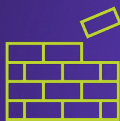
Specification



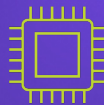
Review Module



**Conversion
Logic**



Data
Completeness
Tracking



Computer
System
Validation



**Data
Validation**



Real-Time
Validation Checks

Mapping Correctness

**SDTM
Conformance**

REVIEW MODULE

SDTM Variables 9

Variable Name	Mapping Logic	Modifications	Unique Values	Total Values
STUDYID	CONST		1	240
USUBJID	1 → 1		26	240
VSCAT	1 → 1		1	240
VSTEST	IF		1	240
VSTESTCD	IF		1	240
VSSTRESN	IF		121	240
VSORRESU	88 →		4	240
VSORRES	IF		121	240

Mapping Logic

SYS → VSORRES

SYS Not Null

Modifications

1st Scan Sub-String

Delimiter

-

Element

2nd

Mapping Name Source File Filter Records

BP Systolic VS_Scr (260) 2 Criteria 240/260

Mapping Filters 2

Test = "Systolic" | 260 Records

And

SYS is not NULL | 240 Records

VS

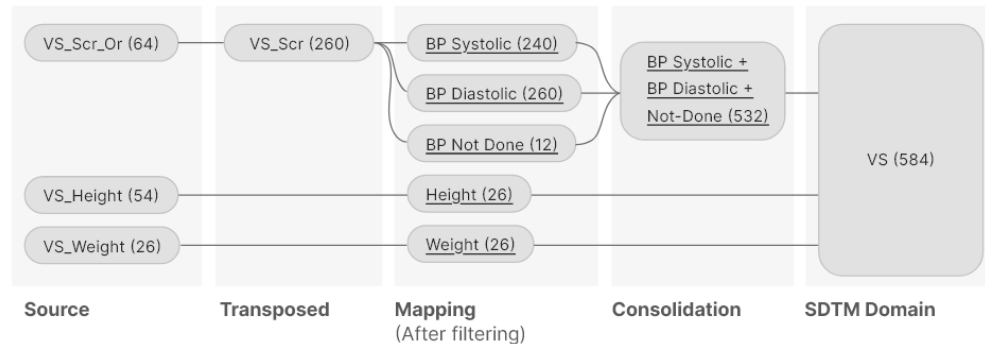
Vital Signs

Records 584

Subjects 26/26

Approved Mappings 1/5

Committed Mappings 3/5



Consolidation 12/12 Conflicts Resolved

REAL-TIME VALIDATION

Jet Convert Demo-ALS-1

Issue Management

Raw Data Review
SDTM Review
SDTM Conformance
Configuration

ALL
Issues: 30
Instances: 3,310

AE
Issues: 2
Instances: 4

CM
Issues: 1
Instances: 19

DM
Issues: 1
Instances: 1

DS
Issues: 3
Instances: 24

IR
Issues: 6
Instances: 2301

VS
Issues: 3
Instances: 117

VSTEST value not found in extensible codelist
Source: ID CT2002
Instances: 89

Description

Variable Should Be Populated With Terms From Its CDISC Controlled Terminology. New Terms Can Be Added As Long As They Are Not Duplicates, Synonyms Or Subsets Of Existing Terms.

USUBJID	VISIT	VSTESTCD	VSTEST	Is
(Distinct Count)	(Distinct Count)	(Distinct Count)	(Value)	
45	7	1	Toe Brachial Index	4

VSORRES value is populated, when VSSTAT is 'NOT DONE'
Source: ID SD1123
Instances: 27

VSORRES Type Mismatch VSORRES Numeric Instead Of String
Source: ID SD1073
Instances: 1

Results Tables

Vital Signs

STUDYID	DOMAIN	USUBJID	VSTEST	VSORRES	VSORRESU	VSSTAT	VISIT	VSC
Demo-ALS	VS	DEMO_ALS-5-000336	Toe Brachial Index	0.89			Screening	
Demo-ALS	VS	DEMO_ALS-5-000336	Toe Brachial Index	1.19			Day 1	
Demo-ALS	VS	DEMO_ALS-5-000336	Toe Brachial Index	0.79			Day 14	
Demo-ALS	VS	DEMO_ALS-5-000336	Toe Brachial Index	1.77			Day 30	
Demo-ALS	VS	DEMO_ALS-5-000336	Toe Brachial Index	0.11			Day 5	
Demo-ALS	VS	DEMO_ALS-5-000336	Toe Brachial Index	1.48			Day 60/Termination	
Demo-ALS	VS	DEMO_ALS-5-000336	Toe Brachial Index	1.95			Day 0 - Surgery	
Demo-ALS	VS	DEMO_ALS-5-000362	Toe Brachial Index	1.14			Screening	
Demo-ALS	VS	DEMO_ALS-5-000362	Toe Brachial Index	0.38			Day 0 - Surgery	
Demo-ALS	VS	DEMO_ALS-5-000391	Toe Brachial Index	1.86			Screening	
Demo-ALS	VS	DEMO_ALS-5-000391	Toe Brachial Index	0.96			Day 1	
Demo-ALS	VS	DEMO_ALS-5-000391	Toe Brachial Index	0.29			Day 14	
Demo-ALS	VS	DEMO_ALS-5-000391	Toe Brachial Index	0.51			Day 30	
Demo-ALS	VS	DEMO_ALS-5-000391	Toe Brachial Index	1.42			Day 5	
Demo-ALS	VS	DEMO_ALS-5-000391	Toe Brachial Index	1.33			Day 60/Termination	
Demo-ALS	VS	DEMO_ALS-5-000391	Toe Brachial Index	0.58			Day 0 - Surgery	
Demo-ALS	VS	DEMO_ALS-8-000409	Toe Brachial Index	0.56			Screening	
Demo-ALS	VS	DEMO_ALS-8-000409	Toe Brachial Index	0.56			Day 1	
Demo-ALS	VS	DEMO_ALS-8-000409	Toe Brachial Index	0.04			Day 14	
Demo-ALS	VS	DEMO_ALS-8-000409	Toe Brachial Index	0.71			Day 30	
Demo-ALS	VS	DEMO_ALS-8-000409	Toe Brachial Index	1.45			Day 5	
Demo-ALS	VS	DEMO_ALS-8-000409	Toe Brachial Index	1.44			Day 60/Termination	
Demo-ALS	VS	DEMO_ALS-8-000409	Toe Brachial Index	1.81			Day 0 - Surgery	
Demo-ALS	VS	DEMO_ALS-8-000415	Toe Brachial Index	1.53			Screening	
Demo-ALS	VS	DEMO_ALS-8-000415	Toe Brachial Index	1.79			Day 1	
Demo-ALS	VS	DEMO_ALS-8-000415	Toe Brachial Index	0.42			Day 14	
Demo-ALS	VS	DEMO_ALS-8-000415	Toe Brachial Index	0.66			Day 30	
Demo-ALS	VS	DEMO_ALS-8-000415	Toe Brachial Index	1.25			Day 5	
Demo-ALS	VS	DEMO_ALS-8-000415	Toe Brachial Index	0.35			Day 60/Termination	
Demo-ALS	VS	DEMO_ALS-8-000415	Toe Brachial Index	0.33			Day 0 - Surgery	
Demo-ALS	VS	DEMO_ALS-8-000416	Toe Brachial Index	0.63			Screening	
Demo-ALS	VS	DEMO_ALS-8-000416	Toe Brachial Index	1.53			Day 1	
Demo-ALS	VS	DEMO_ALS-8-000416	Toe Brachial Index	1.83			Day 14	
Demo-ALS	VS	DEMO_ALS-8-000416	Toe Brachial Index	1.99			Day 30	
Demo-ALS	VS	DEMO_ALS-8-000416	Toe Brachial Index	0.16			Day 5	
Demo-ALS	VS	DEMO_ALS-8-000416	Toe Brachial Index	1.12			Day 60/Termination	
Demo-ALS	VS	DEMO_ALS-8-000416	Toe Brachial Index	0.04			Day 0 - Surgery	
Demo-ALS	VS	DEMO_ALS-8-000417	Toe Brachial Index	0.69			Screening	
Demo-ALS	VS	DEMO_ALS-8-000417	Toe Brachial Index	1.25			Day 1	

DATA HEALTH

Measure the health of your data in ways never seen before...

Status Tracking



Data acquisition

When was data refreshed?



Issue Management

- Data Issues
- Reconciliation
- Unit Conversion



Medical Coding

Outstanding terms to be coded

Conformance



Validation Rules

- FDA (regulatory)
- Custom Rule Library



CT Monitoring

- Non-conformant CT
- New CT



Data Completeness

- Real-time tracking

Change Tacking



Data Changes Over Time

- Data source
- Form\dataset
- Variable
- Record count
- Unique values
- Specific datapoint changes

BENEFITS



Readily available SDTM data



Data health monitoring



Accurate and timely decisions



Reduction in cost (no human effort)

THANK YOU!

