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Single Day Event

SDTM SmartView Analysis Dashboard (SSAD)

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Agenda

- Introduction
- Challenges
- Importance of Visualization
- Planned Model
- Workflow
- SSAD Dashboard
- Value Opportunity
- Q&A

Introduction

Imagine a world where accessing, validating, analyzing and projecting data quality score happens seamlessly on a Single Platform:

No more juggling between different systems, tools and output files.

Let's have a look at this concept where in a web-based or desktop application that integrates R Shiny, Python, and Tableau to manage and analyze SDTM (Study Data Tabulation Model) datasets to streamline data issue and improving data analysis to project on smart view dashboard.

Challenges

- Dependency on multiple reports and files to figure out data issues and to trace the issue origin.
- Missing out on potential issues.
- Lack of clear solution to fix the issues which impacting data analysis/rejections.
- Lack of user options and accessibility to systems (standards compliance check/decision making guidance).

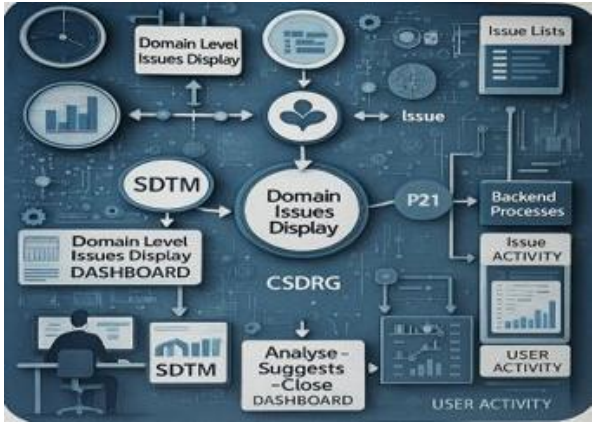
Resolution: **Smart Visualization - Need of the hour!!!!**

"**ONE size fits all**" analogy – SDTM smart dashboard to address all the above listed concerns.

Why Visualization Matters?

A Unified Platform:

- Single platform that visually tracks, analyzes and displays data issues to reduce manual task.



Issue Identification:

- Streamlined Issue identification for users
- Mockup of the visual interface

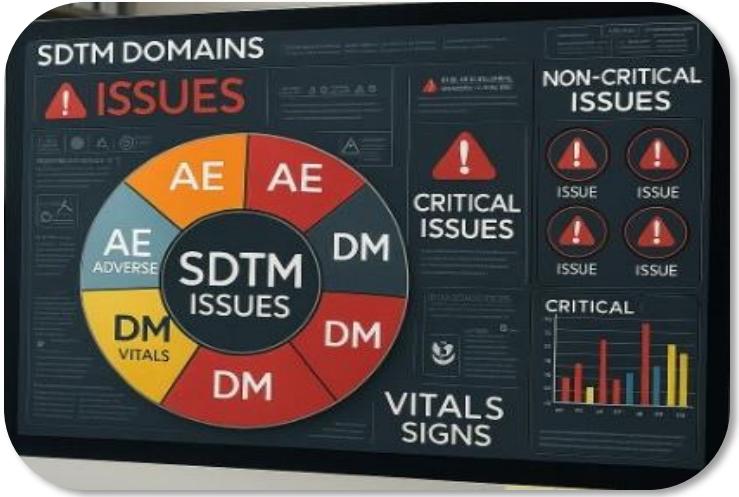
Automation of Reviewer Comments:

- Automate and track the manual review comments.
- User can pick auto-generated comments/resolution text based on issue type detected.
- High precision red-flags: Displays data module that needs attention prior to submission milestone.

Why Visualization Matters?

Benefits of the Platform:

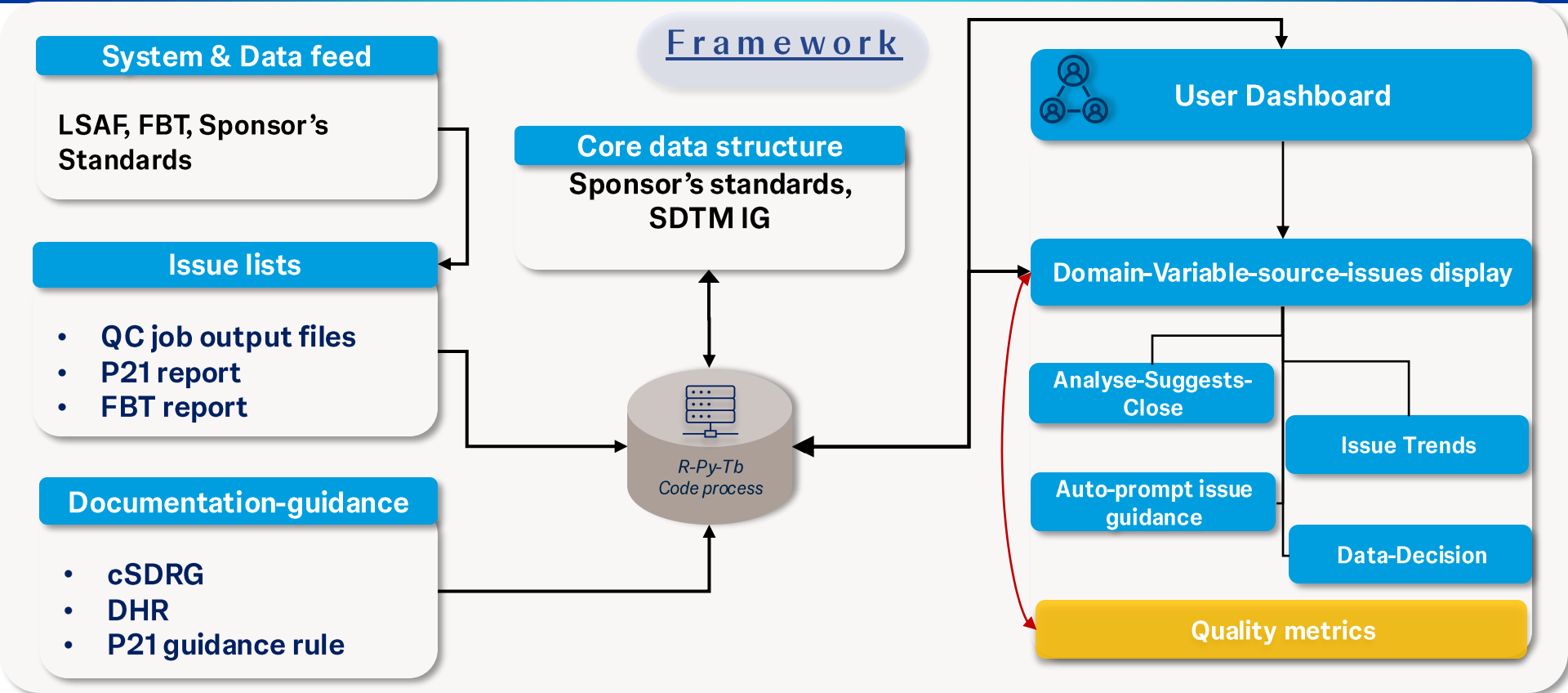
- Streamlined process to reduces manual effort.
- Enhanced accuracy and efficiency in data handling.
- Improved user experience and faster decision-making.
- Issue trending and auto-query



Central Dashboard Features:

- Central hub to monitor ongoing data uploads/transfer files.
- Real time issue flagging as per submission compliance check.
- Smart identification of problematic datasets (*missing key variables data/domains*).

Planned Model



Workflow

Data Feeds:

- SDTM data, study QC output files (formats: xlsx, txt, csv, work. But not limited!!)

Framework:

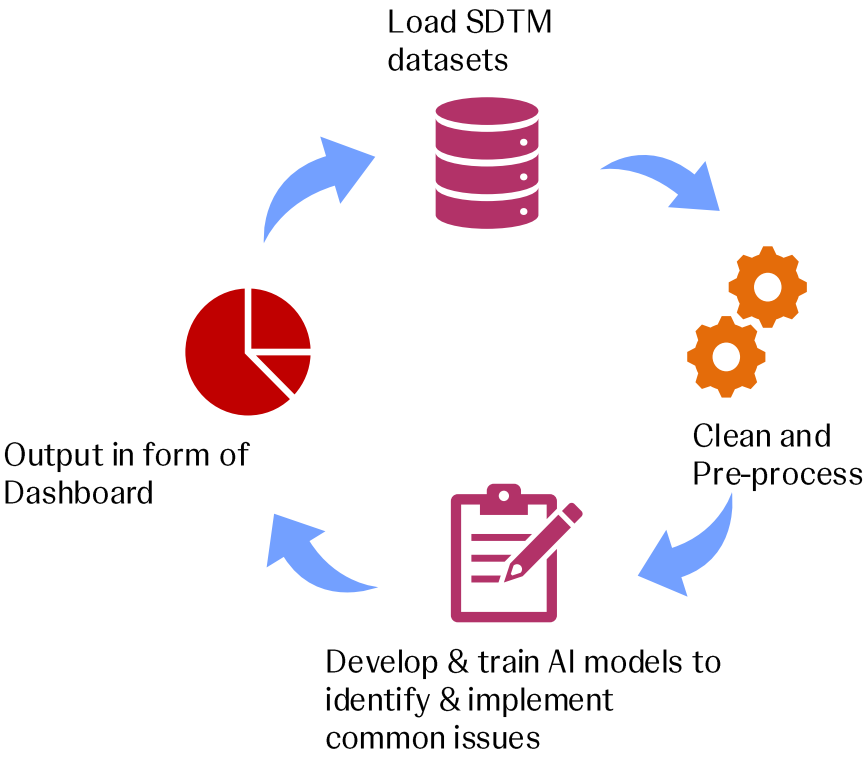
- SDTM IG, QC validation rules (J&J), cSDRG, P21 rules, SRI guidelines (J&J) incl. FDA/PMDA/MHRA

Tools / Systems involved:

- R Shiny, Python, Tabluae, Streamlite modules

Output:

- Issues in form of charts & Graphs



SSAD Dashboard

StudyID	Domain# 35	Issues: 120	Category	FDA/PMDA/EMA	Support-Document

Study Theme:

"Double blind, randomised, phase-2 ABC drug on blood cancer."

Metadata Configuration
SDTM-CT 2024-09-27
MedDRA 27.0
WHODD GLOBALB3Sep24
LOINC Not Configured
SNOMED 2024-09-01
UNII 2024-09-27
MED-RT 2024-10-08

Documents

aCRF	Define	cSDRG

Risk

Project Status

Open issues: 20
Non-critical: 30
Issue_Closed: 70
Total: 120

Data Standards Compliance

- SDTM Conformance: 95%
- Define.xml Validation: Passed
- cSDRG Status: In Progress
- CDISC Terminology Applied: Yes
- Pinnacle21 Validation: No critical errors

Data

AE	EC	LB
CE	EX	VS
MH	ML	PE
DS	CM	FA
DV	PR	QS

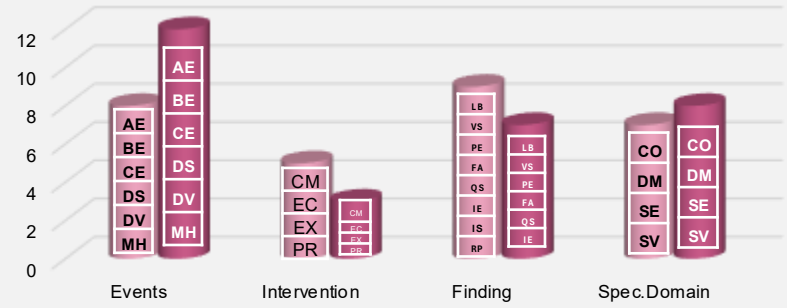
Summary

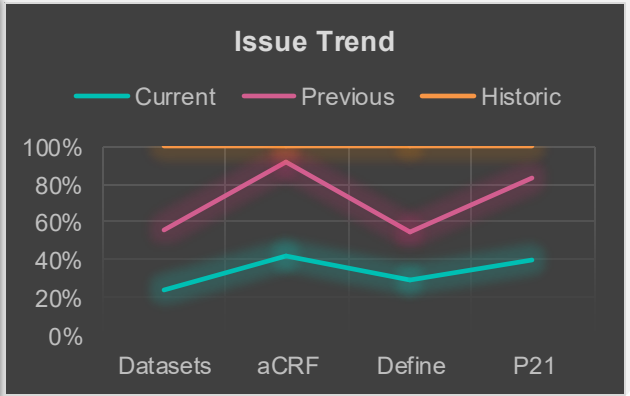
Data	Status
Subject Randomised	30
Drug Exposed	20
Death	5
Completed	22

User search field

Dashboard Prompts (AI chat)

Issue progress





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aCRF | Define | cSDRG

Risk

VS=Vital Signs

[redacted] Version 6.00 20NOV2020 NW: All Forms

Project Name: [redacted]

Form: Vital Signs

Generated On: 17 Dec 2020 18:41:36

Were vital signs collected?	[NOT SUBMITTED]	Yes ☐ No ☐
	VSSTAT=NOT DONE when VSTESTCD=VSALL	
If Yes, was the collection date the same as the visit date?	[NOT SUBMITTED]	Yes ☐ No ☐
Date	VSDTC	
Height	VSTEST	cm ☐ in ☐
Weight	VSORRES, VSORRESU when VSTESTCD=WEIGHT	kg ☐ lb ☐
Pulse	Fixed Unit: beats/min	
	VSORRES when VSTESTCD=PULSE	
Pulse unit	VSORRESU when VSTESTCD=PULSE	beats/min
Systolic Blood Pressure	Fixed Unit: mmHg	
	VSORRES when VSTESTCD=SYSBP	
SBP unit	VSORRESU when VSTESTCD=SYSBP	mmHg
Diastolic Blood Pressure	Fixed Unit: mmHg	
	VSORRES when VSTESTCD=DIABP	
DBP unit	VSORRESU when VSTESTCD=DIABP	mmHg

aCRF Issue: Pg:6/99

Issue Note

- <VSTESTCD><missing>
- <VSCAT><missing>

User search field

Dashboard Prompts (AI chat)

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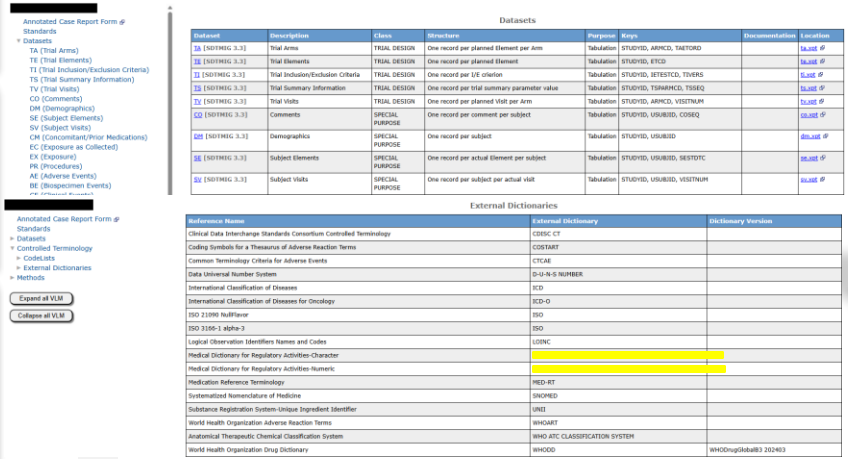

Define Issue: Section: 4.1

Issue Note

- <External_Dict><element#11> <missing>
- <External_Dict><element#12> <missing>

User search field

Dashboard Prompts (AI chat)

<elmt#11=> 27.1
<elmt#12=> 27.1

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Risk

1.3 Study Data Standards and Dictionary Inventory

Standard or Dictionary	Versions Used
SDTM	SDTM IG v3.2; SDTM v1.4
Controlled Terminology	CDISC controlled terminology version 2018-06-29 was used, supplemented with terminology from newer versions and sponsor defined terminology. For LB, the sponsor defined LUDWIG 2 dictionary has been used for the following variables: LBTEST/LBTESTCD/LBCAT/LBSPEC/LBMETHOD/LBORRESU/LBSTRESU.
Data Definitions	Define.xml v2.0.0
Medications Dictionary	
Medical Events Dictionary	

2. Protocol Description

cSDRG Issue: Section: 1.3

Issue Note

- <MedDRA.v.x><missing>
- <WHODD.v.x><missing>

User search field

Dashboard Prompts (AI chat)

<MedDRA= 27.1>

<WHODD=B3 202506 >

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Risk

4. Data Conformance Summary

4.1 Conformance Inputs

Was a validator used to evaluate conformance?

If yes, specify the version(s) of the validation rules:

Pinnacle 21 Enterprise v 4.2.1, Validation Rules for SDTM-IG v3.2, SDTM-CT 2018-06-29

Were sponsor-defined validation rules used to evaluate conformance? YES

If yes, describe any significant sponsor-defined validation rules:

N/A

Were the SDTM datasets evaluated in relation to define.xml? YES

Was define.xml evaluated?

Provide any additional compliance evaluation information:

N/A

Bookmarks

Study [redacted]

1. Introduction
2. Protocol Description
   - 2.2 Protocol Design
   - 2.3 Trial Design Datasets
3. Subject Data Description
4. Data Conformance Summary
   - 4.1 Conformance Inputs

cSDRG Issue: Section: 4.1

Issue Note

- <element#1/10><missing>
- <element#8/10 ><missing>

User search field

Dashboard Prompts (AI chat)

<elmt#1/10= Y/N>

< elmt#8/10= Y/N >

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aCRF | Define | cSDRG

Risk

4.2 Issues Summary

The following is a summary of issues within the conformance report that could not be resolved.

Issues with SDTM datasets:

Dataset	P21 Rule ID	Diagnostic Message	Impact	Type	Severity	Count	Explanation
AE	CT2001	AEACN value not found in 'Action Taken with Study Treatment' non-extensible codelist	High	Error		10,252	According to the CDISC guidance, 'MULTIPLE' is used in case multiple responses are available. This should not be considered as an error. As there are multiple study treatments, AEACN = MULTIPLE and the action taken per study treatment is mapped to SUPPAE.

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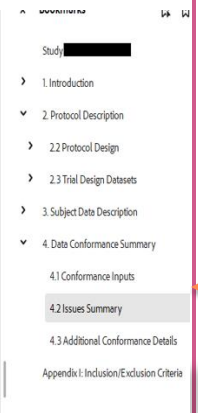
Study [redacted] Clinical Study Data Reviewer's Guide

Dataset	P21 Rule ID	Diagnostic Message	Impact	Type	Severity	Count	Explanation
AE	SD0021	Missing End Time-Point value	High	Warning		2,272	[redacted]
AE	SD0080	AE start date is after the latest Disposition date	High	Warning		786	This is expected as not all subjects will have a trial disposition as some will continue into Open label extension and to long term extension phase.
AE	SD0091	AEOUT is not 'FATAL', when AESDTH='Y'	High	Error		3	[redacted]



cSDRG Issue: Section: 4.2

Issue Note

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- <element#4/110 ><missing>
- <element#8/110 ><missing>
- <element#30/110 ><missing>
- <element#65/110 ><missing>
- <element#66/110 ><missing>
- <element#89/110 ><missing>

User search field

Dashboard Prompts (AI chat)

<elmt#2/110=>

This is expected as not all subjects will have a trial disposition as some will continue into Open label extension and to long term extension phase.

SSAD Dashboard

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Issue Note

- <element#2/110><missing>
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- <element#30/110 ><missing>
- <element#65/110 ><missing>
- <element#66/110 ><missing>
- <element#89/110 ><missing>

User search field

Dashboard Prompts (AI chat)

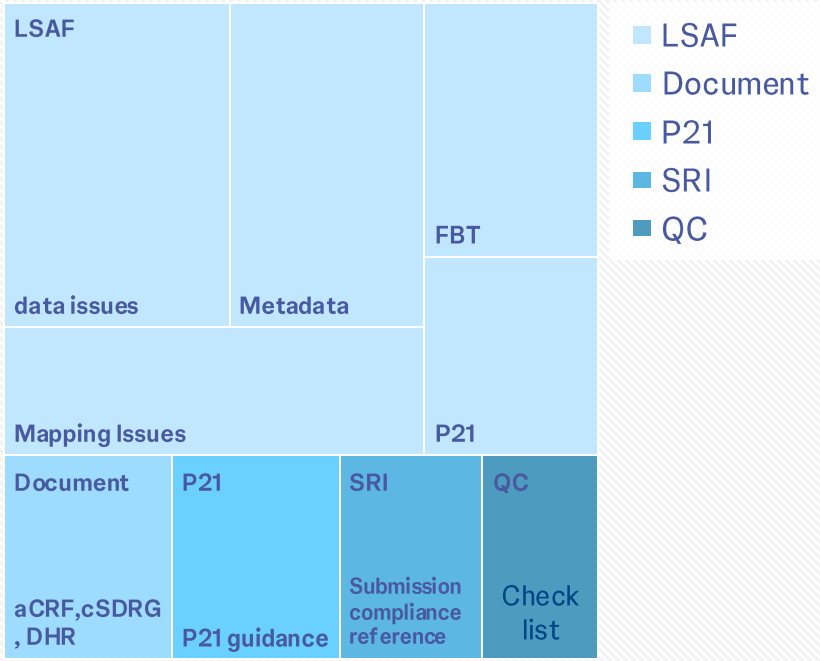
<elmt#4/110=>

Per data entry: the outcome has been entered as 'NOT RECOVERED/NOT RESOLVED' where the adverse events are also marked as leading to death.

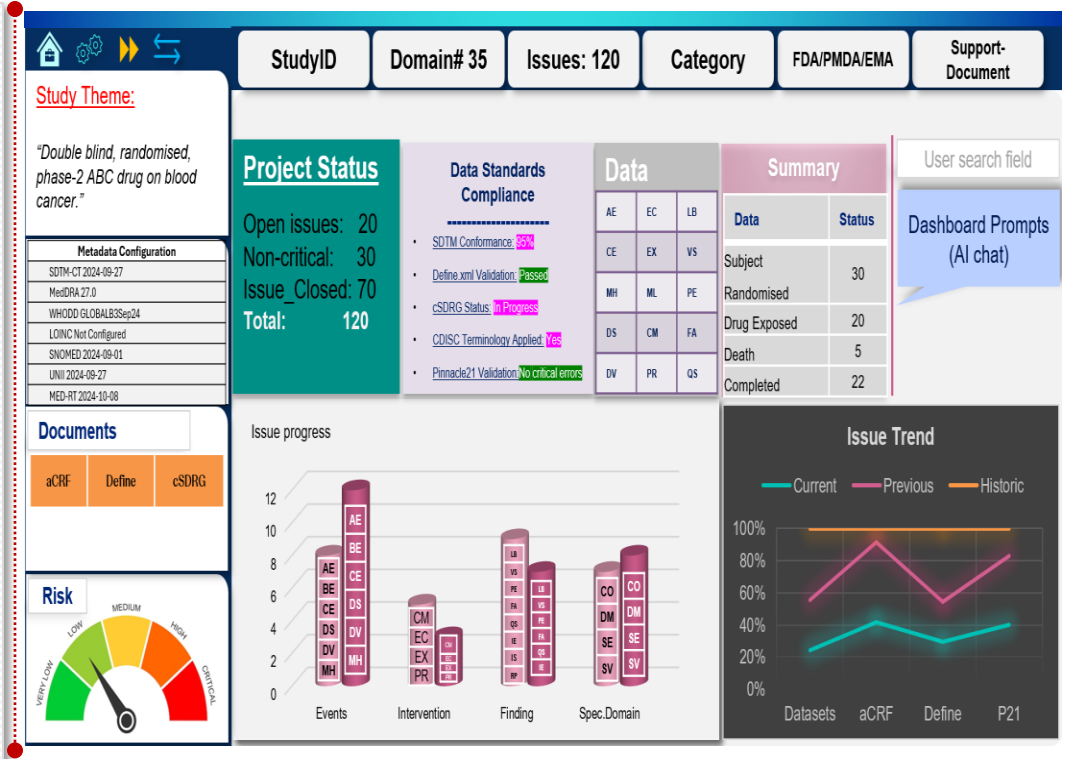
Value Opportunity

Current Model

Data-Systems & Volume-time



SSAD Model



Value Opportunity

SSAD Hyperview

Outcome	• Opportunity to deep-dive into core SDTM: source-to-analysis. • Optimizing comparison with conventional method. (i.e. reduces manual effort)
Efficiency	• Direct Impact in terms of processing time. • Easy submission QC
Dependency	• Minimizes dependency on no.of QC output files • On-Screen easy interpretations & simplified data visuals.

"Transforming data issues into value driving factors" time spent on issues identification, analyzing key data, automating and resolving issues.

Thank you

The Global Healthcare Data Science Community

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