2025 CDISC + TMF EUROPE INTERCHANGE

GENEVA

CONFERENCE & EXPO: 14-15 MAY | TRAININGS: 12, 13, 16 MAY

ARS Implementation Journey & Benefits

Presented by   Mayank Bhatia,   Head of Product Strategy & Management,   TATA Consultancy Services

Meet the Speaker

Mayank Bhatia

Title: Head of Product Strategy and Management

Organization: Tata Consultancy Services

Mayank has more than 22 years of experience in clinical domain. His expertise span across building products, leading cross functional teams, bringing operational excellence, and driving change for transformational programs to bring efficiency at scale. Successfully led and delivered many large scale and highly critical transformational programs

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.*

Agenda

1. ARS Scope, Functionalities and initially defined Target Benefits
2. ARS Mockup Mapped to ARDS Tables
3. ARS Implementation Journey
4. Benefits

ARS Implementation Journey

Data Standards maintenance scope and objectives

ARS Standards

SCOPE	FUNCTIONALITY	BENEFITS

❑ List of Reports
   ➢ Reporting Event, Categories
   ➢ List of Report and Analyses
❑ Report Metadata
   ➢ Population Definition
   ➢ Report Analysis Definition
   ➢ Layout Content Definition
   ➢ Data Derivation Definition
❑ Supporting
   ➢ Reference Document, Programing metadata
	❑ Create/Maintain Metadata for TFL
	❑ Design new TFL with easy-to-use Designer
	❑ Set up study reports metadata
	❑ Metadata driven report creation
		❑ Central Repository for analysis result metadata in standard format
		❑ TFL Designer
		❑ Single source of truth
		❑ End to End Lineage & Traceability
		❑ Downstream Automation
		   ➢ Study Setup
		   ➢ Automated TFL Creation

Table of Contents	Layout	Report Content	Content Derivation	Data Massaging	Programming Metadata

ARS – Sample TFL Mockup

Table 14.1.1
Summary of Demographics
Safety Population

Characteristics	Treatment X (N=XX)	Treatment Y (N=XX)	Total (N=XX)
Primary Race, n (%)			
American Indian or Alaska Native	XX (XX.X)	XX (XX.X)	XX (XX.X)
Asian	XX (XX.X)	XX (XX.X)	XX (XX.X)
Black or African American	XX (XX.X)	XX (XX.X)	XX (XX.X)
Native Hawaiian or Other Pacific Islander	XX (XX.X)	XX (XX.X)	XX (XX.X)
White	XX (XX.X)	XX (XX.X)	XX (XX.X)
Multiple	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Reported	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unknown	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)
Height (cm)			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	QX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX

Source dataset: adsl, Generated on: DDMONYYYY:HH:MM
Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM

TFL Mockup mapped to ARDS Tables

Summary of Demographics –Safety Population

Characteristics	Treatment X (N=XX)	Treatment Y (N=XX)	Total (N=XX)
Primary Race — n (%)			
American Indian or Alaska Native	XX (XX.X)	XX (XX.X)	XX (XX.X)
Asian	XX (XX.X)	XX (XX.X)	XX (XX.X)
Black or African American	XX (XX.X)	XX (XX.X)	XX (XX.X)
Native Hawaiian or Other Pacific Islander	XX (XX.X)	XX (XX.X)	XX (XX.X)
White	XX (XX.X)	XX (XX.X)	XX (XX.X)
Multiple	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not reported	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unknown	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)
Height (cm)			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX

a
b
c
d

Content Derivation

a. Treatment Variable, Analysis Method
b. Display Format
c. Variable and Label Corresponding to ADSL.RACE, ADSL.HEIGHTBL
d. Analysis Group

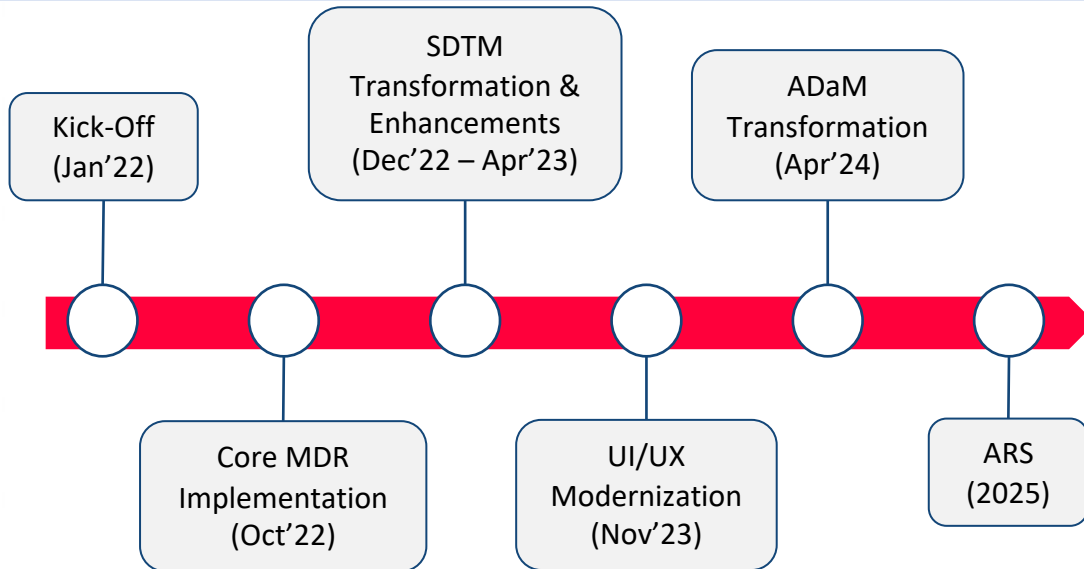### Report Content – Operation

Layout–Display
Title, Label Header, Footnote

Source dataset: adsl, Generated on: DDMONYYYY:HH:MM
Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM

ARS Real Life Case Studies

Case Study : ARS Implementation Journey

**A Next Generation , Interoperable, end-to-end(SDTM, ADaM, ARDS) Metadata Driven Process**

Kick-Off (Jan'22)

SDTM Transformation & Enhancements (Dec'22 – Apr'23)

ADaM Transformation (Apr'24)

Core MDR Implementation (Oct'22)

UI/UX Modernization (Nov'23)

ARS (2025)

Current State with SDTM, ADaM Automated

➢ **Implemented metadata repository** for all standards including data collection, SDTM, ADAM, and Analysis Results Datasets (ARDS) including study-level specifications

➢ **Study Build, SDTM, ADAM Automated**:
  - ➢ Robust programming process, Granular transformation metadata
  - ➢ Utilize metadata to dynamically create code
  - ➢ Enable study teams to insert code for study-specific variables.
  - ➢ Automated 95-97% SDTM variables
  - ➢ Automated ~70% ADaM variables
  - ➢ Consistency across studies.

ARDS Implementation Pilot Highlights

✓ **Metadata Management for ARS**(TFL metadata) in machine readable format
  - ➢ Similar metadata driven automation approach in ARDS as in SDTM/ADaM.
  - ➢ Process change: ARDS becomes input to TFLs.
✓ **End to End traceability** from Data Collection to SDTM to ADaM to TFL
✓ Set up Study CSR deliverables(TFL) using standard metadata
✓ **Metadata driven TFL** generation, **>90% automation** in generation of ARDS.
✓ Significant reduction in timeline as ARDS is automated via MDR & no programming needed for TFLs
✓ **TFL become cosmetic display** step(with no analysis) enabling GUI tools to be used

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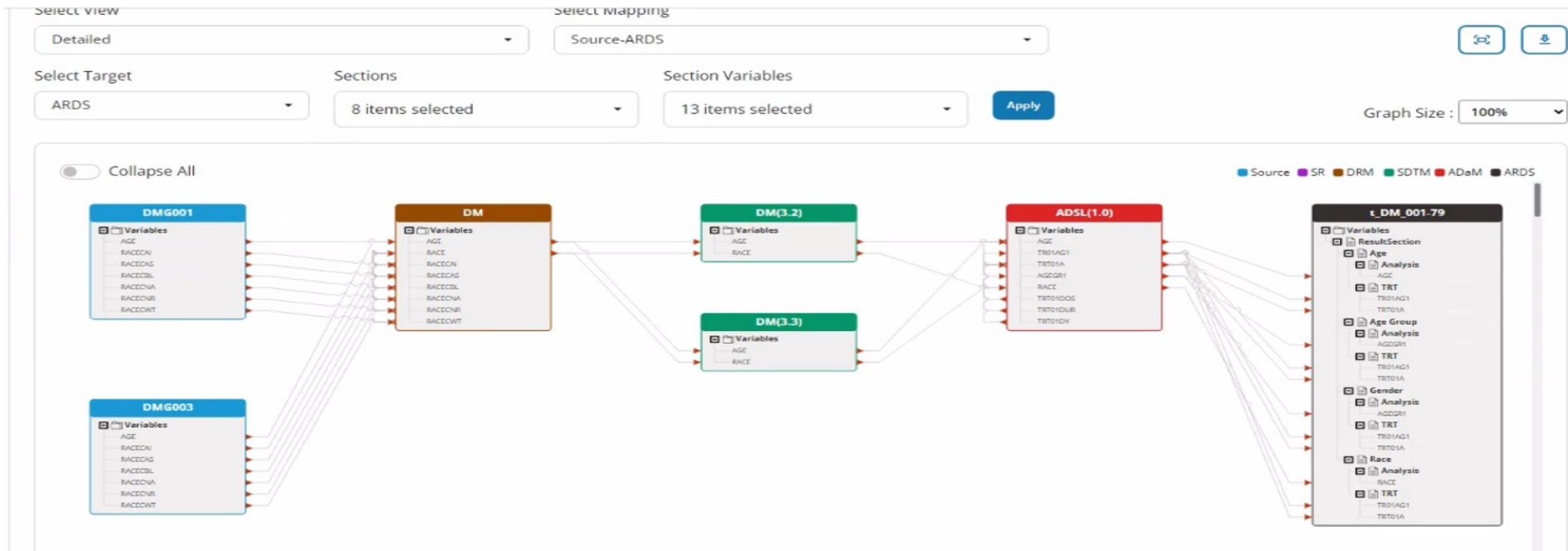# Connected Standards In Reality (1/2)
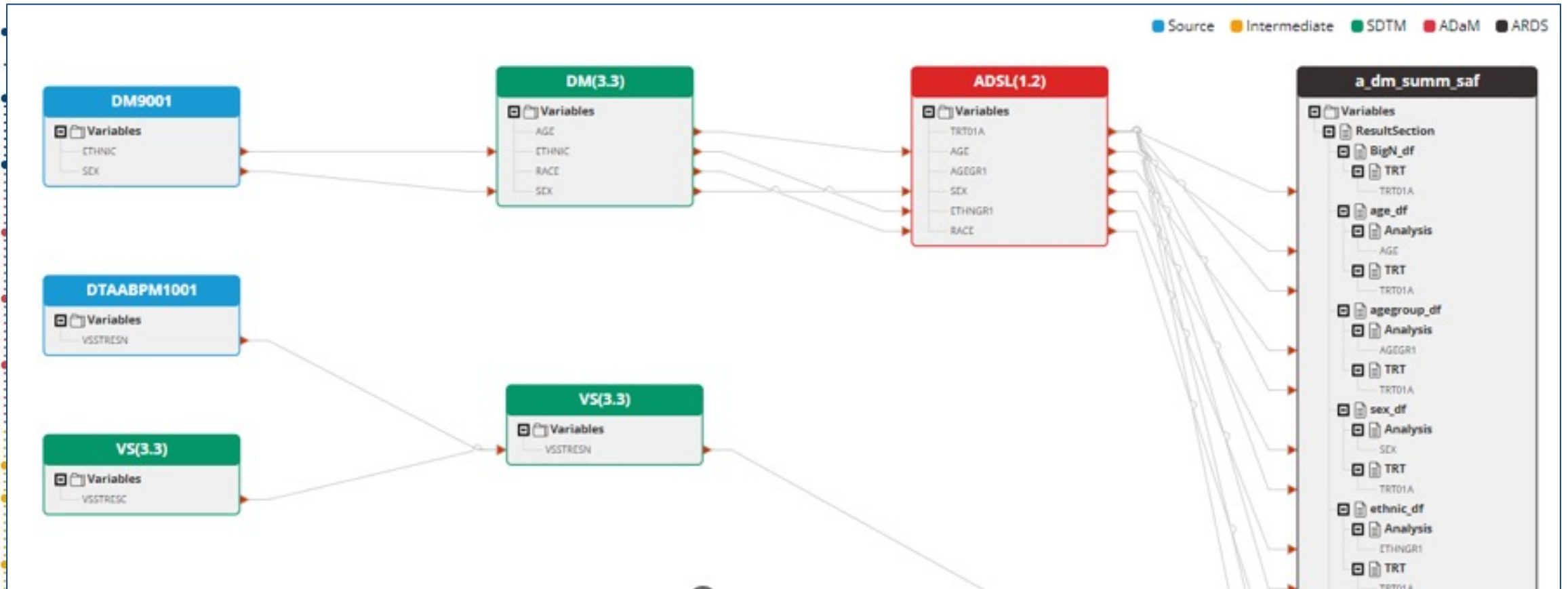
End to End Data Lineage

Source to SDTM to ADaM to ARDS

Content Derivation

Connected Standards In Reality (2/2)

QnA

Thank You!

Let's standardize, harmonize and automate!!

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