

APAC 2026

19–21 February

Novotel Hyderabad International Convention Centre

DS01

Embracing the Semantic Shift: SDTMIG 4.0 and Intelligent Clinical Data Standards

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DISCLAIMER

I confirm that, the opinions and thoughts discussed in this presentation are subject to my own independent views and are not subject to the opinions of the organization that I represent.



Today's Speaker



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Multiple Subject Instance

Demographics for Multiple Participations — supports multiple screenings/enrollments or repeated demographic collections

Non-Standard Variables (NSVs)

Horizontal NSV datasets are proposed instead of Supplementary datasets, removing the need of transposing them before appending to parent dataset.

CDISC 360i & Biomedical Concepts

Supports automation and traceability from protocol to SDTM
Reusable metadata definitions for clinical concepts

New Domains

Event Adjudication (EA)
Gastrointestinal System Findings (GI)

Metadata Restructuring – variables

Additional metadata columns in the domain specifications.

SDTM IG 4.0



SDTMIG 4.0 – Semantic Shift

From Dataset-
Centric to
Metadata-Driven
Clinical Standards

Embracing
Biomedical
Concepts &
CDISC 360 vision

Alignment with CDISC 360i and Biomedical Concepts
Metadata becomes the driver



Key Enhancements in SDTMIG 4.0

Major Structural Changes

FEATURE	SDTMIG 3.X	SDTMIG 4.0
Supplementary Data	SUPPQUAL datasets	NSV datasets
Metadata Format	Human-readable PDFs	Machine-readable via CDISC Library
Subject Instances	No standardized approach	DC domain introduced
Automation	Limited	Enhanced through semantic metadata



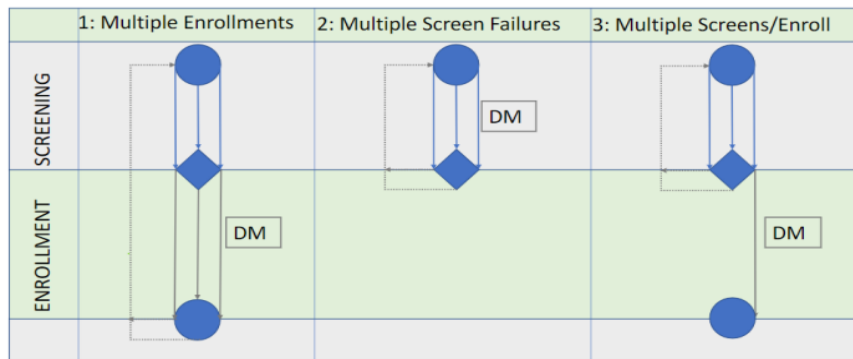
Multiple Subject Instances

Minimal guidance in earlier IG versions

- Inconsistent sponsor implementations

Why DC Matters

- Standardized guidance in IG 4.0
- Clear handling of re-screening and Multiple enrolments
- Improved traceability



STUDYID	USUBJID	SUBJID	RFSTDTC	RFXSTDTC	RFICDTC	RFENDTC	RFXENDTC	RFPENDTC	BRTHDTC	AGE	RACE	ARM	ACTARM	ARMNRS
ABC123	ABC12301001	1001	25-08-2006	25-08-2006	25-08-2006	12-9-2006	27-08-2006	12-09-2006	02-07-1950	56	ASIAN	Drug A	Drug A	
ABC123	ABC12301001	1001B	18-09-2006	18-09-2006	18-09-2006	28-10-2006	20-09-2006	28-10-2006	02-07-1950	56	ASIAN	Drug A	Drug A	
ABC123	ABC12302001	1001C	02-11-2006	02-11-2006	02-11-2006	02-12-2006	04-11-2006	15-12-2006	02-07-1950	56	ASIAN	Drug A	Drug A	

Multiple Enrollments

STUDYID	USUBJID	SUBJID	RFSTDTC	RFXSTDTC	RFICDTC	RFPENDTC	BRTHDTC	AGE	RACE	ARM	ACTARM	ARMNRS
ABC123	ABC12301001	1001			25-08-2006	13-09-2006	02-07-1941		WHITE			SCREEN FAILURE
ABC123	ABC12301001	01001B			18-09-2006	02-10-2006						SCREEN FAILURE
ABC123	ABC12301001	01001C			28-11-2006	20-12-2006						SCREEN FAILURE

Multiple screen failure and Never Enrolled

STUDYID	USUBJID	SUBJID	RFSTDTC	RFXSTDTC	RFICDTC	RFPENDTC	BRTHDTC	AGE	RACE	ARM	ACTARM	ARMNRS
ABC123	ABC12301001	1001			25-08-2006	13-09-2006	02-07-1950		ASIAN			SCREEN FAILURE
ABC123	ABC12301001	01001B			18-09-2006	02-10-2006						SCREEN FAILURE
ABC123	ABC12301001	01001C	02-11-2006	02-11-2006	02-11-2006	28-11-2006		64		Drug A	Drug A	

Multiple screening and Enrollment

NOTE: All the records will be included in the DC dataset, while only **Highlighted records** will be populated in DM dataset.



SUPP to NSV – Transformational Change

- SUPP relied on vertical structures
- NSV introduces horizontal, appendable datasets
- Direct integration with parent domains

Benefits of NSV

- Numeric NSVs supported
- Appropriate variable lengths
- Controlled terminology at variable level
- Simplified merging



Role of Biomedical Concepts

Normalized Abstraction Layer

Biomedical Concepts provide a standardized abstraction for clinical data ensuring consistent interpretation across studies.

Improved Data Interoperability

BCs enable uniform mapping to domains, codelists, and metadata, promoting interoperability and reducing redundancy

Support for FAIR Principles

Biomedical Concepts support Findable, Accessible, Interoperable, and Reusable data products enhancing regulatory review.

Automation of Clinical Workflows

Semantic approach drives automation, enabling tools to generate specifications and datasets from protocol concepts.



CDISC 360 Vision and Integration

Automated Interoperable Ecosystem

CDISC 360 creates a fully automated, interoperable clinical research ecosystem enhancing efficiency.

Semantic Metadata Integration

It enriches standards with semantic metadata enabling machine-executable data from design to analysis.

Global Standards Alignment

CDISC 360 aligns with global initiatives like HL7 FHIR and supports modern data exchange formats.

Improved Data Quality and Compliance

Enhances data quality, interoperability, and regulatory compliance in clinical trial management.



INTRODUCTION OF NEW DOMAINS

Enhanced the DV domain

Introduces one new variable, Classification of Protocol Deviation (DVCLASI) which may have values e.g. Important vs Non-Important.

Gastrointestinal Observations

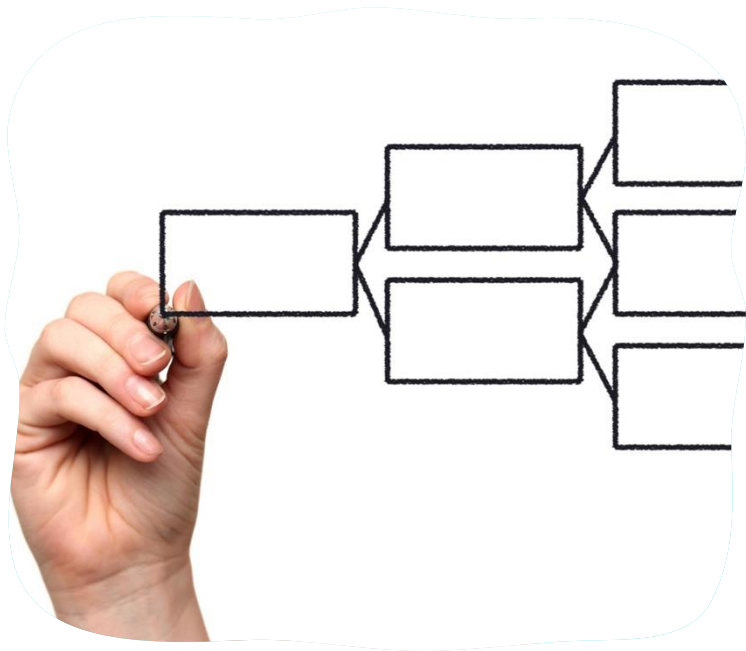
The GI domain captures both physiological symptoms and structural abnormalities related to the gastrointestinal system distinctly.

Event Adjudication Standardization

The EA domain standardizes adjudication data submission ensuring objective evaluation and traceability from events to outcomes.

Regulatory Compliance and Clarity

New domains improve data clarity and granularity supporting, regulatory guidance and enhancing global standards convergence.





Metadata Restructuring

Aligned with SDTM 3.0

Clear separation of metadata elements

Supports concept-driven standards

Key Metadata Updates



QUALIFIERS
REMOVED



NEW
VARIABLES
INTRODUCED



GROUPING
VARIABLES
ADDED



EXPLICIT
LINKING
PHRASES



Key Benefits of SDTMIG 4.0



Enhanced Traceability

SDTMIG 4.0 improves traceability from protocol concepts to datasets, boosting data integrity and regulatory confidence.



Automation and Efficiency

Machine-readable standards reduce manual programming, speeding up validation and study timelines.



Interoperability Across Standards

Seamless integration across SDTM, ADaM, and define.xml standards facilitates smooth data exchange.



Consistency through Biomedical Concepts

Standardized biomedical concepts minimize variability enabling better cross-study comparisons and data aggregation.





Thank You



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