

# SDTM v3.0 and SDTMIG v4.0: Public Review Preview

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*What Statistical Programmers Need to Know About the Biggest SDTM Update in Years*

## The Biggest SDTM Overhaul Since 2004

CDISC is preparing to release the most significant update to its foundational tabulation standards since the model was first published over two decades ago. SDTM v3.0 and SDTMIG v4.0 have completed internal review and are expected to enter public review in early 2026, with final publication planned alongside SENDIG v4.0 in 2026. The SDTMIG for Medical Devices (SDTMIG-MD v2.0) will follow shortly after.

For the statistical programming community, these updates bring changes that will reshape daily workflows: supplemental qualifier datasets are being replaced, new domains are being introduced, several familiar variables are being deprecated, and the model itself is being enriched with metadata structures designed to support machine-readable standards and automation.

This article summarizes the key changes across both documents and highlights what programmers should start preparing for now.

## Timeline and Release Strategy

SDTM v3.0 and SDTMIG v4.0 were developed in tandem to ensure alignment. Unlike previous minor releases (SDTM v2.1 was a narrow update for the Tobacco Implementation Guide), v3.0 is a full major version. Key milestones include:

Milestone	Status / Timing
Internal review	Completed (SDTM 3.0, SDTMIG 4.0, and SENDIG 4.0 reviewed together)
Public review	Expected late 2025
Final publication	

Planned 2026 (SDTM 3.0, SDTMIG 4.0, SENDIG 4.0 re-leased together)

SDTMIG-MD v2.0

To follow shortly after the main release

*Note: The public review period is your opportunity to provide feedback. CDISC posts all comments and resolutions publicly to show how feedback shaped the final standard.*

## SDTM v3.0: Model-Level Changes

### Goodbye SUPP, Hello NS

The single most impactful change for programmers is the replacement of Supplemental Qualifier datasets (SUPP--) with Nonstandard Variables datasets (NS--). This is not a cosmetic rename. It is a fundamental structural change:

SUPP-- (Previous)	NS-- (SDTM v3.0+)
Vertical: one row per nonstandard variable value	Horizontal: one row per parent record with any NS variable populated
QVAL is always character	NS columns can be character or numeric
IDVARVAL is character (requires char-to-num conversion)	IDVARVLN is numeric; merge without conversion
Requires transposing before merge	Direct merge with parent dataset
Value-level metadata in Define-XML for QVAL	Standard variable-level metadata in Define-XML

**Practical impact:** Every program that currently builds, reads, or merges SUPP-- datasets will require updates. The good news is that the NS-- structure is simpler, and the merge logic that programmers have complained about for years becomes straightforward.

### Simplified Qualifier Roles

In the Role column of variable metadata tables, a single "Qualifier" designation now replaces the separate Grouping, Result, Synonym, Variable, and Record Qualifier roles. The former "Variables Qualified" column has been removed entirely. These sub-types were always informative and are not part of submission metadata, so this change reduces complexity without affecting data content.

## Variable Groups and Variable Relationships

SDTM v3.0 introduces two new structural concepts to the model:

- **Variable Groups:** Each root variable is now assigned to a named group (e.g., "Dose Amount" includes --DOSE, --DOSTOT, --DOSTXT, --DOSU). Group definitions are part of the model and support machine-readable consumption.
- **Variable Relationships:** Each table of variables is now followed by a table of relationships between variables, described in both natural language and controlled terminology. For example, --DECOD "is a dictionary-derived term for the value in" --TERM. These relationship tables are designed to enable automated processing.

## Root Variable Enhancements

All root variable definitions have been completed (v2.0 definitions were incomplete). Definitions are now managed as controlled terminology, and every root variable carries a C-code. This means LBDTC, AEDTC, and EGDTC are all formally recognized as instances of the root variable --DTC, with a shared definition and code.

## SDTMIG v4.0: Implementation-Level Changes

### New Domains

Code	Domain Name	Purpose
DC	Demographics for Multiple Participations	Captures demographic data when a subject participates in a trial more than once. Required when at least one subject has multiple participations; prohibited otherwise.
EA	Event Adjudication	Standardizes the submission of adjudicated event data, such as cardiovascular endpoint committees or independent review boards.
GI	Gastrointestinal System Findings	A new Findings domain for gastrointestinal assessments and endoscopic results.

The DC domain is particularly noteworthy. It includes FOCID (supporting study designs with distinct treatments to multiple body parts), DCSEQ (aligning with other special-purpose domains that allow multiple records per subject), and collected race/ethnicity variables (CRACE, CETHNIC). The DM domain itself remains largely unchanged but also gains CRACE and CETHNIC.

## Enhanced Protocol Deviations (DV)

The DV domain gains a new classification variable (--CLASSI) to distinguish categories such as important vs. non-important protocol deviations. This update was driven by the need to better support Bioresearch Monitoring (BIMO) activities.

## Key Variable Changes Across Observation Classes

Scope	Change	Detail
All Datasets	SUBJID added to identifiers	Supports multiple subject participations across all classes
DM / DC	AGELO and AGEHI replace AGETXT	Separate low/high age variables replace the free-text age range
DM / DC	CRACE, CETHNIC added	

		Collected race/ethnicity values as originally reported by the subject
Events	--CLASSI added	Classification of Protocol Deviation (restricted to DV domain)
Interventions	--TRTCD added	Standardized Intervention Code associated with --DECOD
Findings	--CBRFL added	Conditionally Branched Item Flag (restricted to QRS domains)
Findings	--RESCNT added	Result Count (restricted to EG domain)
Findings	--BLFL, --MODIFY, --BODSYS removed	Deprecated from the Findings observation class
Findings	--PTFL, --PDUR reclassified	Moved from Timing to Findings class variables
Trial Design	TIRL removed from TI	Trial Inclusion/Exclusion Rule removed from the TI domain

*The removal of --BLFL from Findings is significant. Baseline flags in SDTM have long been a source of confusion. Programmers should watch the public review materials closely for guidance on how baseline identification will be handled going forward.*

## Restructured Documentation

Beyond data-level changes, the SDTMIG v4.0 document itself has been significantly reorganized. Introductory sections on SDTM fundamentals, conformance, and general assumptions have been updated and restructured. Metadata tables now include variable definitions and standardized documentation of variable relationships, aligning with the model-level enhancements in SDTM v3.0.

## What This Means for Statistical Programmers

## Immediate Action Items

- **Audit your SUPP-- code.** Every macro, program, and validation check that creates or consumes SUPP-- datasets will need to be rewritten for the NS-- horizontal structure. Begin inventorying these now.
- **Assess --BLFL usage.** If your SDTM specifications include baseline flags in Findings domains, track the public review for replacement guidance and update your mapping specifications accordingly.
- **Prepare for new domains.** If your studies include event adjudication committees, GI assessments, or subjects with multiple participations, evaluate whether DC, EA, and GI domain programs will be needed.
- **Update Define-XML generation.** The shift from value-level metadata (for QVAL in SUPP--) to standard variable-level metadata (for NS-- columns) will require changes to your Define-XML tooling.

## Longer-Term Considerations

The introduction of variable groups and variable relationships in SDTM v3.0 is a clear signal that CDISC is building toward machine-readable, automation-friendly standards. Combined with the USDM and 360i initiatives, the trajectory points toward a future where trial design metadata flows directly into SDTM specifications with minimal manual intervention. Programmers who understand these structural changes at the model level will be better positioned as the industry moves toward that vision.

## How to Participate in Public Review

When the public review opens, CDISC will post the draft documents on the CDISC Wiki. Reviewers submit comments via JIRA (the Wiki and JIRA share the same login credentials, which are separate from your cdisc.org account). All comments and resolutions are published afterward.

Given the scale of these changes, the statistical programming community should engage actively. This is particularly important for the SUPP-to-NS transition, variable deprecations, as these decisions will directly affect submission timelines and program libraries.

## Key Resources

Resource	URL
SDTM Standards Page	<a href="https://cdisc.org/standards/foundational/sdtm">cdisc.org/standards/foundational/sdtm</a>
SDTMIG Standards Page	<a href="https://cdisc.org/standards/foundational/sdtmig">cdisc.org/standards/foundational/sdtmig</a>

CDISC Standards Timeline	<a href="https://cdisc.org/standards/timeline">cdisc.org/standards/timeline</a>
Standards in Development	<a href="https://cdisc.org/standards/in-development">cdisc.org/standards/in-development</a>
CDISC Wiki (for Public Review)	<a href="https://wiki.cdisc.org">wiki.cdisc.org</a>
2025 US Interchange Program	<a href="https://cdisc.org/events/interchange/2025-cdisc-tmf-us-interchange/program">cdisc.org/events/interchange/2025-cdisc-tmf-us-interchange/program</a>

**Bottom line:** SDTM v3.0 and SDTMIG v4.0 represent a generational update to the standards that define our daily work. The transition from SUPP to NS alone justifies early preparation. Start reviewing your program libraries, engage in the public review, and plan your migration strategy now, well before the FDA Data Standards Catalog is updated to reference these new versions.