

EVOLVING WITH SDTM-IG V3.4: WHAT CLINICAL DATA PROFESSIONALS NEED TO KNOW

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AGENDA

Evolving with SDTM-IG v3.4

- Why SDTM-IG v3.4 matters
- Key changes from SDTM-IG v3.3 to v3.4
- New domains introduced:
 - Genomics Findings (GF)
 - Cell Phenotype Findings (CP)
- Moving beyond SUPPQUAL: adoption of standardized variables
- Improved inter-domain traceability
- Enhanced metadata to support review readiness
- Conclusion

WHY SDTM-IG V3.4 MATTERS

Supports Precision Medicine: Enables capture of complex, detailed data required for personalized treatments.

Addresses Increasing Complexity: Introduces new domains for emerging data types like Genomics and Cell Phenotype.

Introduces New Variables: Expands domain variables to capture more detailed laboratory and immune response data.

Enhances Data Consistency: Reduces reliance on SUPPQUAL by adopting standardized variables for better clarity.

Improves Traceability: Strengthens inter-domain relationships to ensure seamless data linkage and review.

Ensures Regulatory Readiness: Provides stronger metadata guidance for efficient data management and faster approvals.



KEY CHANGES FROM SDTM-IG V3.3 TO V3.4

Aspect	SDTM-IG v3.3	SDTM-IG v3.4
Domains	No GF or CP domains	Added Genomics Findings (GF), Cell Phenotype (CP) domains
Supplemental Data	Heavy reliance on SUPPQUAL	Reduced SUPPQUAL, standardized variables introduced
Immune Response (IS)	Limited variables	Enhanced variables in IS and LB domains
Inter-domain Relations	Fragmented and unclear	Clear, explicit guidance
Metadata	Basic, inconsistent	Stronger, consistent, regulatory-ready

NEW DOMAINS INTRODUCED

SDTM-IG v3.3 lacked dedicated domains for complex molecular and cellular data.

Sponsors relied on workarounds (LB + SUPPQUAL, FA, or custom domains), leading to inconsistencies and traceability issues.

SDTM-IG v3.4 introduces **Genomics Findings (GF)** and **Cell Phenotype Findings (CP)** domains to standardize, streamline, and improve data clarity.

[SDTM-IG v3.3]



[LB + SUPPQUAL / FA]



(Inconsistent & Fragmented)



[SDTM-IG v3.4]



[GF / CP Domains]



(Standardized & Traceable)



GENOMICS FINDINGS (GF)

- Stores genomic data from clinical trials: gene variants, sequencing results, biomarkers.
- Captures structure, function, evolution, mapping, and editing of genomic material.
- Supports personalized medicine, biomarker discovery, pharmacogenomics, and regulatory submissions (FDA, PMDA).
- Enables standardized data collection and traceability, reducing reliance on workarounds like SUPPQUAL.

GENOMICS FINDINGS (GF): EXAMPLE

SDTM-IG v3.3 (LB + SUPPQUAL) - Before GF Domain:

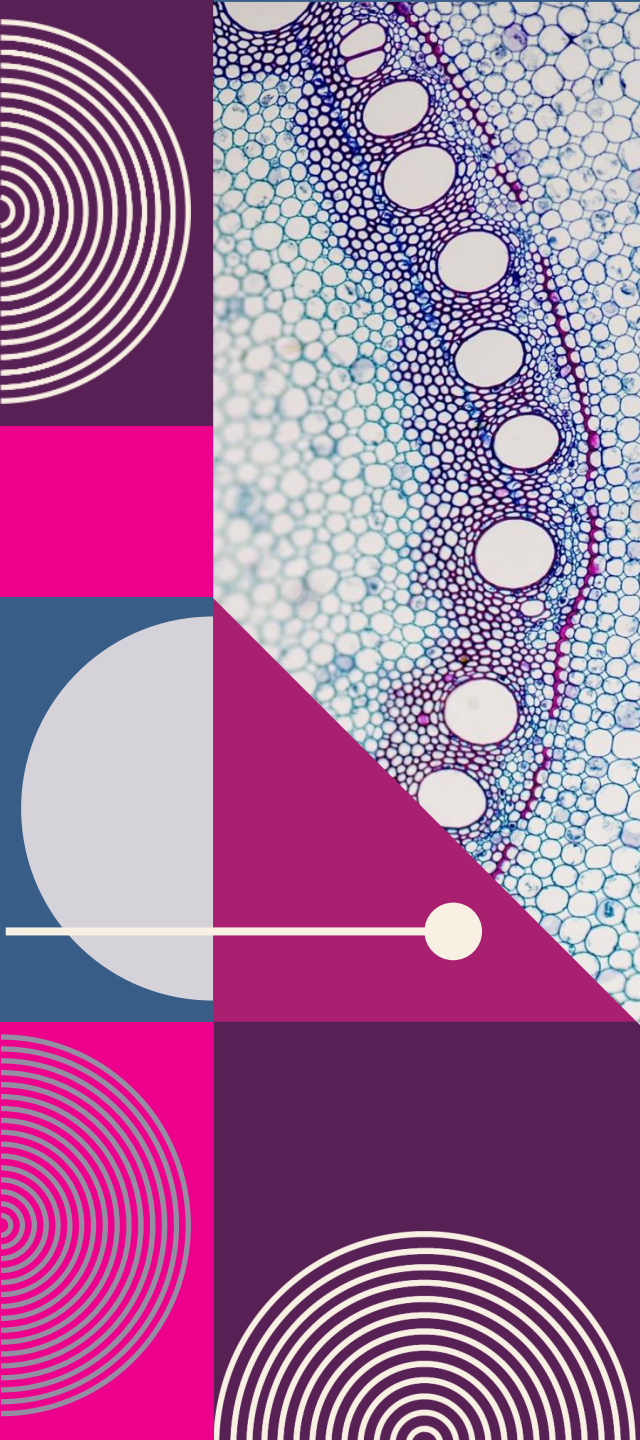
LB

- |—— LBTEST = BRAF Mutation Status
- |—— LBSTRESC = DETECTED
- |—— SUPPQUAL
- |—— GENE = BRAF
- |—— VARIANT = V600E

SDTM-IG v3.4 (GF) - After GF Domain:

GF

- |—— GFTEST = Variant Status
- |—— GFGENE = BRAF
- |—— GFVAR = V600E
- |—— GFSTRESC = DETECTED



CELL PHENOTYPE FINDINGS (CP)

- Captures cell phenotype, cell lineage, and function based on marker expression in single-cell or particle suspensions.
- Designed for disseminated tissue specimens (blood, body fluids, bone marrow aspirates).
- Not intended for solid tissue specimens, routine lab hematology, or microscopic/IHC assessments.
- Supports standardized marker-based cell phenotyping tests.

CELL PHENOTYPE FINDINGS (CP): EXAMPLE

Before SDTM-IG v3.4 (v3.3 Workaround) Example - CD4+ T-Cell Percentage (v3.3):

LB

- |—— LBTEST = CD4 Positive Cells
- |—— LBSTRESN = 35
- |—— LBSTRESU = %
- |—— SUPPQUAL
- |—— CELLTYPE = T-Cell
- |—— MARKER = CD4

After SDTM-IG v3.4 (CP Domain) Example - CD4+ T-Cell Percentage (v3.4):

CP

- |—— CPTEST = Cell Percentage
- |—— CPCELL = T-Cell
- |—— CPMARKER = CD4
- |—— CPSTRESN = 35
- |—— CPSTRESU = %



MOVING BEYOND SUPPQUAL: ADOPTION OF STANDARDIZED VARIABLES

- ❑ Limited standard variables in SDTM-IG v3.3 for emerging and complex data types (e.g., genomics, cell phenotype, detailed laboratory tests)
- ❑ SUPPQUAL was used to capture additional study-specific attributes not accommodated by standard domains
- ❑ Challenges in v3.3: data was fragmented, inconsistent, and difficult to interpret or compare across studies
- ❑ SDTM-IG v3.4 introduces standardized variables and expands parent domains to accommodate complex data
- ❑ Direct mapping to parent domains reduces reliance on SUPPQUAL and ensures consistency
- ❑ Key benefits: enhanced clarity, improved data consistency and traceability (CRF → SDTM → ADaM), faster review, and support for automation and data reuse

MOVING BEYOND SUPPQUAL: ADOPTION OF STANDARDIZED VARIABLES

Table 1: SDTM-IG v3.3 (SUPPQUAL):

VSTESTCD	VSORRES	VSSTRESN	QNAM (SUPPQUAL)	QVAL (SUPPQUAL)
SBP	140	140	XXCLSIG	Yes
SBP	140	140	XXREASOC	Hypertension

Table 2: SDTM-IG v3.4 (Standardized Variables):

VSTESTCD	VSORRES	VSSTRESN	VSCLSIG	VSREASOC
SBP	140	140	Yes	Hypertension



IMPROVED INTER-DOMAIN TRACEABILITY

- SDTM-IG v3.4 provides clear guidance on how domains relate, improving navigation of complex clinical datasets.
- v3.3 had fragmented relationships; linking findings, interventions, and events was sometimes scattered.
- Explicit links between parent domains and related findings (e.g., LB, IS, GF/CP → Subject or Specimen domains).
- Formal specification of cross-domain relationships (e.g., BE → BS → RELSPEC) enhances traceability.
- Supports better understanding, analysis, and regulatory review.



IMPROVED INTER-DOMAIN TRACEABILITY

Immunogenicity Data Modeling Example - v3.3 (Before SDTM-IG v3.4):

LBTESTCD	LBORRES	RELREC Link to EX
AVIDITY	High	Yes

Immunogenicity Data Modeling Example - v3.4 (After SDTM-IG v3.4):

ISTESTCD	ISORRES	ISBDAGNT
AVIDITY	High	COVID-19 S-Protein



ENHANCED METADATA TO SUPPORT REVIEW READINESS

- Provides precise metadata for consistent capture of complex clinical data.
- Introduces new standardized variables in domains like IS and LB.
- Standardizes biospecimen domains for traceable relationships.
- Corrects core variables and updates controlled terminology for accuracy.
- Enables seamless data integration and interoperability across studies.
- Supports regulatory-ready, reviewable, and transparent datasets.
- Facilitates automation, validation, and data reuse for efficiency.



ENHANCED METADATA TO SUPPORT REVIEW READINESS

Eliminates SUPPIS reliance, simplifying CRF → SDTM → ADaM traceability and regulatory review.

SDTM-IG v3.3 (SUPPIS)	SDTM-IG v3.4 (IS Domain)
QNAM = ISBDAGNT	ISBDAGNT = NUCLEAR AUTOANTIGENS
QLABEL = Binding Agent	—
QVAL = NUCLEAR AUTOANTIGENS	—



CONCLUSION

- ✓ The updates in SDTM-IG v3.4 streamline SDTM mapping and improve downstream processes such as ADaM specification, programming, and QC validation. Clearer domain definitions, standardized variables, and enhanced inter-domain relationships reduce ambiguity, improve data consistency, and make datasets more interpretable and traceable.
- ✓ By strengthening metadata guidance and promoting regulatory-ready standards, these changes simplify submission package preparation and review. Understanding and implementing SDTM-IG v3.4 is essential for ensuring compliance, supporting efficient data reuse, and future-proofing clinical data management strategies.





THANK YOU

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