

Tagging the TAUGs: Making SDTM TA Content Easier to Find and Use

Introduction

Therapeutic Area User Guide (TAUG) content is making SDTM Bigger and Better than Ever

More content

- New Domains
- New Variables

More support

- Concept maps
- Examples



Knowledge of TAUG content is essential!

- **SDTM of Tomorrow:** TAUGs preview provisional domains and variables, showcasing the direction SDTM is likely to follow
- **Context:** TAUGs provide scientific and technical background information not often covered in detail in the protocol
- **Not Just Metadata:** Useful examples that illustrate SDTM mappings of difficult concepts, using a best practice strategy

Purpose

With Growth Comes Operational Challenges

These operational challenges can be simply stated as

- How do we help make sure people can find applicable content?
- How can we guide the use of that content?

Tagging the TAUGs can make it easy for people to find and use what they need

Methodology

Cross-referenced Inventories make it easier to find applicable content

Provide a Map, not Instructions

- The inventories point to the applicable content but they do not unnecessarily repeat it
- Searchable, so applicable content can be quickly located
- Provide alternative methods for submissions that need to be compliant with current standards
- Break out content by topic. Based on end-user feedback, we currently support 5 related tabs:
1) **TAUG Inventory**, 2) **New Domains**, 3) **New Variables**, 4) **New Use Cases** and 5) **Examples**.
- Representative content for each tab is below.

MAINTENANCE REQUIRED

The inventory needs to be updated on a regular basis

- TAUGs get revised
- TAUGs become supported by the FDA
- SDTM IG gets revised
- New TAUGs are released
- Plan for quarterly updates

TAUG Inventory Tab

TAUG	Version	Date	FDA?
Therapeutic Area Data Standards User Guide for Diabetes	Provisional 1.0	2014-08-01	Yes
Therapeutic Area Data Standards User Guide for Chronic Hepatitis C Virus Infection	Provisional 1.0	2015-04-25	Yes
Therapeutic Area Data Standards User Guide for Influenza	Provisional 1.0	2014-11-25	
Therapeutic Area Data Standards User Guide for Diabetes	Provisional 1.0	2014-08-01	Yes

New Variables Tab

Variable	Label	TAUG	IG Notes	Options
CEEVAL	Evaluator	Cardio.	--EVAL is an allowed variable for a Findings domain per SDTM Model 1.4/IG 3.2; however, it is not yet one for an Events domain. Proposed addition for future versions of SDTM.	Place in SUPPCE or FA
CEEVALID	Evaluator Identifier	Cardio.	--EVALID is an allowed variable for a Findings domain per SDTM Model 1.4/IG 3.2; however, it is not yet one for an Events domain. Proposed addition for future versions of SDTM.	Place in SUPPCE or FA

Examples Tab

Concept	TAUG	Notes	Examples
Cardiac Events	Cardio	CE is used instead of AE when the event is a study endpoint	ST elevation, myocardial infarction (STEMI); Ischemic Attack; Stroke;
Cardiac Biomarkers	Cardio	Includes SUPPLB examples for 99% upper reference limits (study endpoint)	
Modified Rankin Scale (MRS)	Cardio		
Liver Biopsy and Histopathology	Hep. C		Fibrosis scores: METAVIR, Ishak, Knodell, Batts Ludwig, Scheuer

Guidance for using provisional/draft content in a way that is compliant with the current IG

Conclusion

New Domains Tab

Domain	Domain Label	Domain Description	Class	Sources
AG	Procedure Agents	CRF data that captures the agents administered to the subject as part of a procedure or assessment.	Interventions	Asthma, Diabetes 1.0 (Prov.)
RE	Respiratory System Findings	A domain for physiological findings related to the respiratory system	Findings	Asthma 1.0 (Prov.)
PF	Pharmacogenomics Findings	Gene expression and genetic variation assessment data.	Findings	SDTM-IG PGx, Virol. 1.0 (Prov.)

New Use Cases

Concept	TAUG	Notes	Options
Cardiac Lesions	Cardio.	TU & TR - It's not just for oncology anymore! While not currently supported in the 3.2 IG, it is expected that the next version of the IG will have updated labels (to 'Tumor/Lesion' instead of 'Tumor'). Used when specific lesions are the focus of data collection.	Use a custom domain that looks very similar to TU or use FA
Drug Regimens	Hep. C	CMGRPID is used to group together individual treatments which make up regimens	Compatible with current model

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TAUGs have helped make SDTM bigger and better than ever. Tagging all that new content so it is easier to find and use takes time and effort. That effort pays dividends.

Based on user feedback, cross-referenced TAUG inventories have made it easier for people to leverage TAUG content and stay up to date with CDISC standards, resulting in higher-quality SDTM deliverables.