



Tobacco Implementation Guide (TIG) v1.0

Public Review Webinar

09 November 2023

cdisc

Tobacco Implementation Guide (TIG) v1.0

Welcome to this Public Review Webinar.

- The purpose of this webinar is to provide an overview of the Tobacco Implementation Guide v1.0 to support Public Review for this standard.

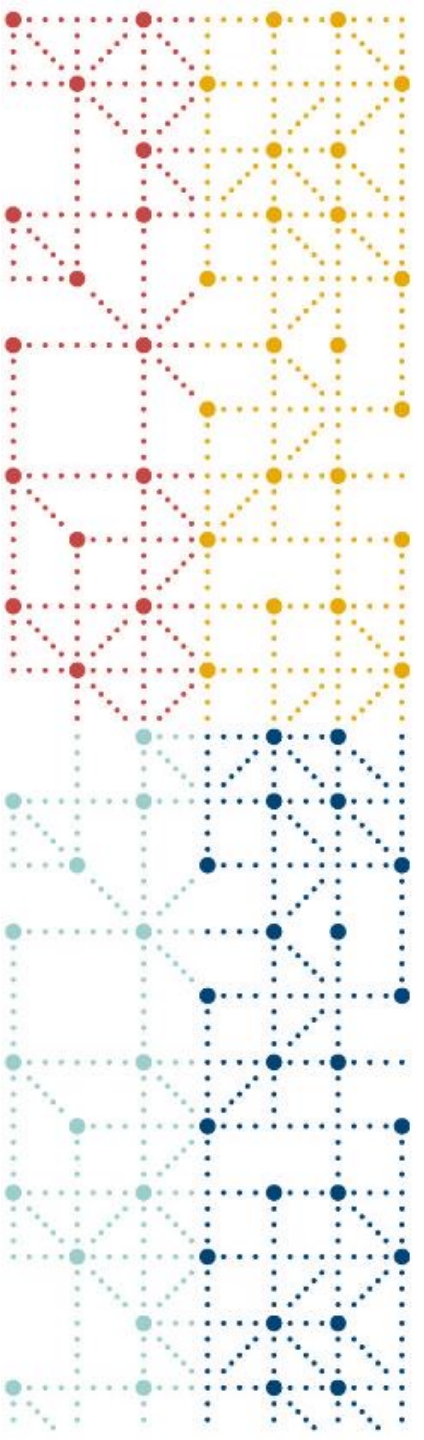
It takes a village to build a standard.





Agenda

- What are Tobacco Implementation Guide *data standards*?
- Tobacco Implementation Guide v1.0
- Discussion and Questions



Data Standards

When we say TIG *data standards*, what do we mean?



FDA Center for Tobacco Products (FDA-CTP)

Family Smoking Prevention and Tobacco Control Act

- Passed in 2009 giving FDA the authority to regulate the manufacture, marketing, and distribution of tobacco products **to protect public health**

Vision

- To make tobacco-related death and disease part of America's past, not America's future and, by doing so, ensure a healthier life for every family

Mission

- To protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others



FDA Center for Tobacco Products (FDA-CTP)

FDA's goal is to reduce the harm from all regulated tobacco products across the entire U.S. population.

Reducing the number of people who start using tobacco products

Encouraging more people to stop using these products

Reducing the adverse health impact for those who continue to use these products



FDA Center for Tobacco Products (FDA-CTP)

In general, FDA's tobacco regulatory authorities do not extend to:

- Setting tax rates for tobacco products
- Regulating therapeutic products, such as those marketed to treat tobacco dependence (regulated by other parts of FDA)
- Setting clean indoor air policies
- Regulating tobacco growing
- Requiring the reduction of nicotine yields to zero
- Providing cessation services
- Banning all cigarettes, smokeless tobacco products, little cigars, other cigars, pipe tobacco, or roll-your-own tobacco products
- Changing the minimum age of sale for tobacco products



FDA Center for Tobacco Products (FDA-CTP)

Data Standards Strategy 2021-2025

- Outlines strategies for the development and dissemination of data standards to better support the programs of CTP through better, more meaningful data
- Supports CTP's public health mission through predictable, consistent, and high-quality data standards
- Areas that are included
 - **Electronic Data Exchange Standards**
 - **Premarket and Postmarket Review**
 - Quality
 - Policy
 - Planning and Governance

Tobacco Implementation Guide (TIG) Project

CDISC in collaboration with the **FDA-CTP** is developing data standards, collectively referred to as the **CDISC Tobacco Implementation Guide Version 1.0**

- With funding from Cooperative Agreement Grant RFA-FD-22-002

Components of Participating Organizations	Center for Tobacco Products (CTP)
Funding Opportunity Title	Data Standards for Tobacco Research and Scientific Review Program (U24) Clinical Trial Not Allowed
Activity Code	U24 Resource-Related Research Projects – Cooperative Agreements

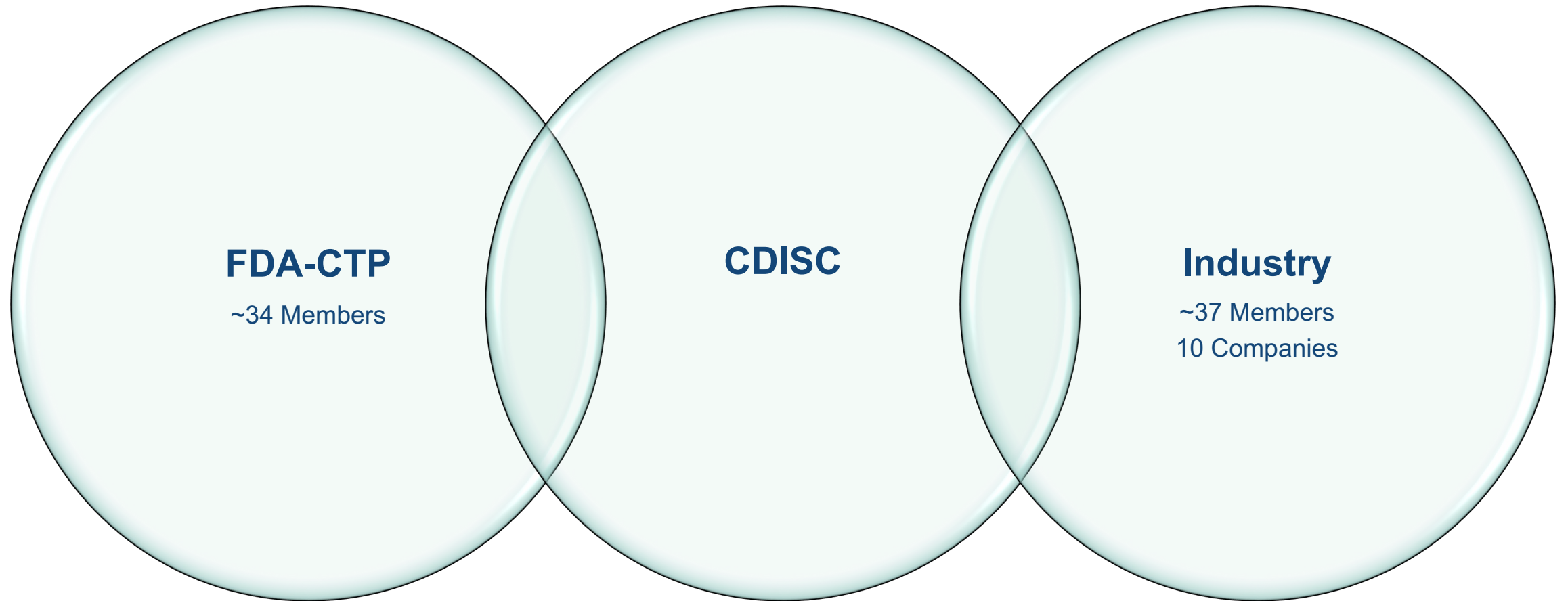
➤ <https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-22-002.html>



Tobacco Implementation Guide (TIG)

- Supports the CTP Data Standards Strategy 2021-2025 through provision of standards and terminologies to facilitate tobacco research, scientific review, harm reduction, and information exchange
- Is a collaborative initiative with FDA-CTP, CDISC, and industry stakeholders
- To develop non-proprietary, consensus-based, vendor-neutral, platform-independent submission data standards for tobacco product data
- Will develop a set of standards, collectively referred to as **TIG v1.0**, to be freely available on the CDISC website in 2024

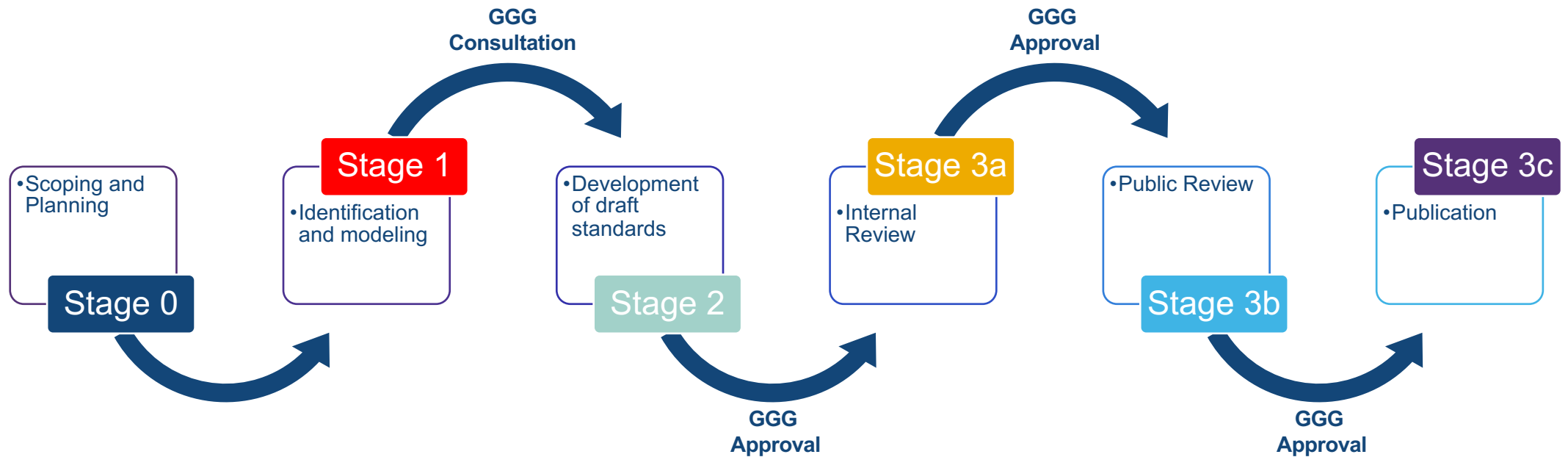
Multidisciplinary Team



CDISC Standards Development Process

The TIG Project follows the CDISC consensus-based development process:

- [CDISC Operating Procedure COP-001 \(cdisc.org\)](http://cdisc.org)



GGG is the CDISC Global Governance Group.

Tobacco Implementation Guide (TIG)

Three specific project aims:

Aim 1 **Standards Development**

Creating Standards Content
for product submissions

Aim 2 **Data Science**

Making Standards Accessible
to all stakeholders

Aim 3 **Education & Communication**

Building Awareness and Support
across stakeholders



Data Standards

The purpose of the TIG is to guide the use of CDISC standards for the organization, structure, and format of tobacco product data.

The TIG describes how to use CDISC standards and resources for the:

- Collection
- Representation; and
- Exchange of tobacco product data
- With examples to demonstrate intended use

The goal is FAIR data.

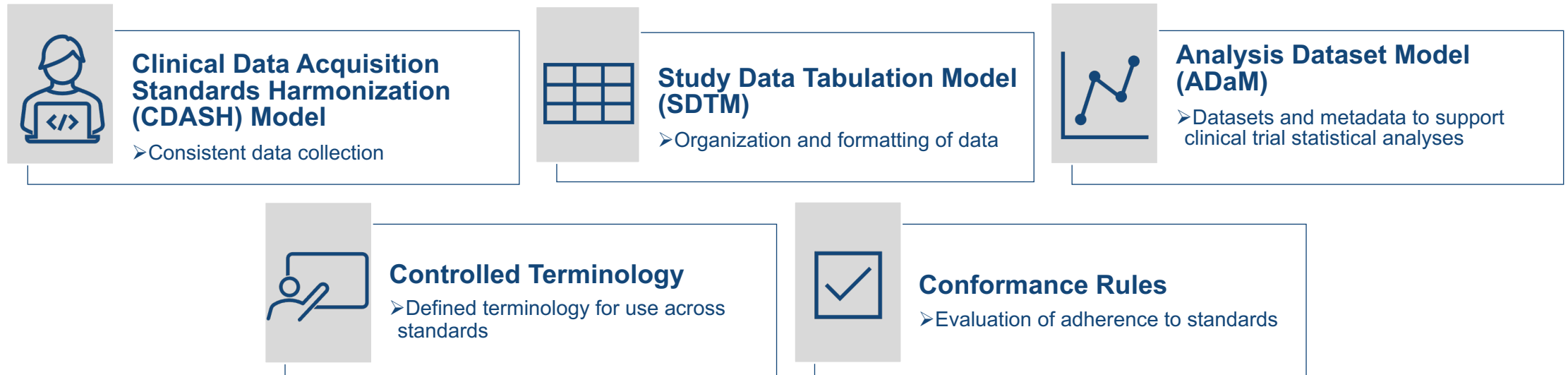
- Findable, Accessible, Interoperable, and Reusable

Tobacco Implementation Guide (TIG)

Addresses concepts for tobacco product data and translates them into CDISC standards; both:

- Established CDISC standards
- New standards to fill gaps identified by FDA-CTP and Industry SMEs

Standards you will see as part of this project include:



What do TIG data standards do?

Data Standards make a difference!

Study #1 – dm.xpt

USUBJID	SEX
0001	M
0002	F
0003	F

Study #2 – dm.xpt

USUBJID	SEX
A1	M
A2	M
A3	F

Study #3 – dm.xpt

USUBJID	SEX
0001	M
0002	M
0005	F

Study #4 – dm.xpt

USUBID	SEX
00011	M
00012	F
00015	F

Study #1 – demog.xpt

SUBJID	SEX
0001	M
0002	F
0003	F

Study #2 – dmng.xpt

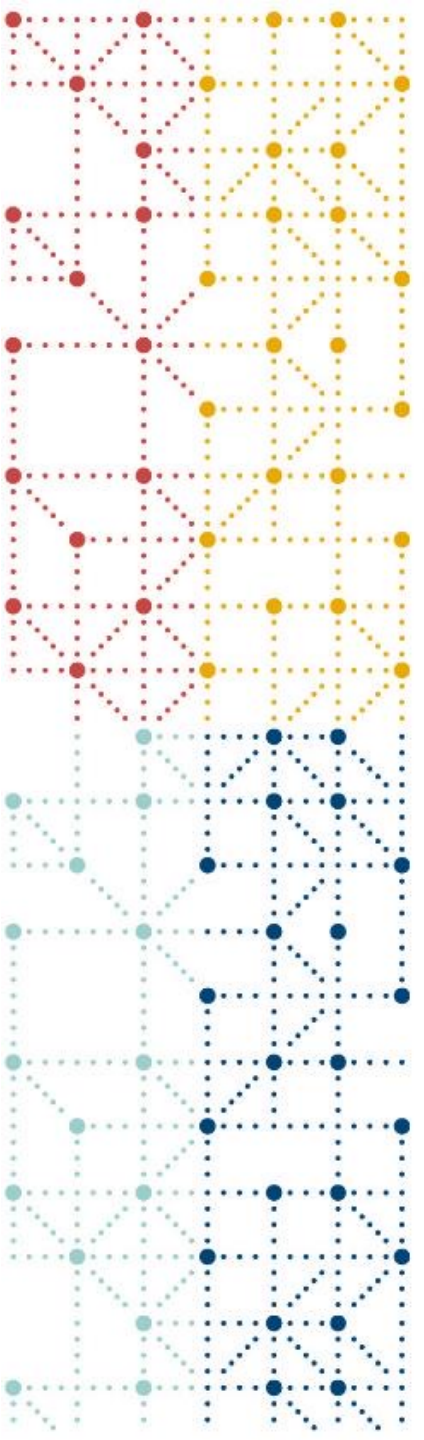
ID	GENDER
A1	Male
A2	Male
A3	Female

Study #3 – dmngph.xpt

PTID	GENDER
0001	1
0002	1
0005	2

Study #4 – axd222.xpt

USUBID	SEX
00011	0
00012	1
00015	1



Tobacco Implementation Guide (TIG) v1.0

- Overview
- Recommendations for Review
- Walkthrough

Tobacco Implementation Guide (TIG) v1.0 Overview



Tobacco Implementation Guide (TIG) v1.0

- The **first set of TIG standards** proactively designed to reflect use cases unique to tobacco product data
- A single, comprehensive **standards implementation guide** for tobacco product data submissions



An overview of standards and general implementation

With guidance by topics and use cases; e.g.

- Product Description
- Nonclinical
- Individual Health
- Population Health



Key scientific concepts and maps



Data Collection
(CDASH eCRFs, ODM-XML)



Data Tabulation
(SEND, SDTM Human Clinical, Define-XML)



Analysis
(ADaM, Define-XML)



Common Language (*Controlled Terminology*)



Measures of Adherence (*Conformance Rules*)



Accessible in platforms which optimize use (including *CDISC website, CDISC Library*)


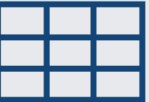



Education and Outreach (including *webinars, formal training*)



The TIG Implements CDISC Models

Models are toolkits to standardize data across the data life cycle.

Process	Model	Use
 Collection	Clinical Data Acquisition Standards Harmonization (CDASH)	A framework to collect information on Case Report Forms (CRFs)
 Tabulation	Study Data Tabulation Model (SDTM)	A conceptual model for representing tabulated data
 Analysis	Analysis Data Model (ADaM)	Principles for creating analysis datasets and associated metadata

The TIG is an Implementation Guide

Implementation guides apply CDISC models to data.

The following data are the focus of the TIG v1.0:

Identified by stakeholders as important in the context of tobacco product submissions

Use Case	Description
Product Description	Concepts used to characterize tobacco products (e.g., product specifications, HPHCs, stability, and ingredient listing)
Nonclinical	Concepts used to identify potential risks and effects on biological processes for tobacco products via in vitro and in vivo nonclinical studies
Product Impact on Individual Health	Concepts used to assess the impact of tobacco products on individuals
Product impact on Population Health	Concepts used to assess the impact of tobacco products on populations



The TIG is a Foundational, Hybrid Implementation Guide

TIG v1.0 is a stand-alone CDISC **foundational standard** that serves as a comprehensive resource for:

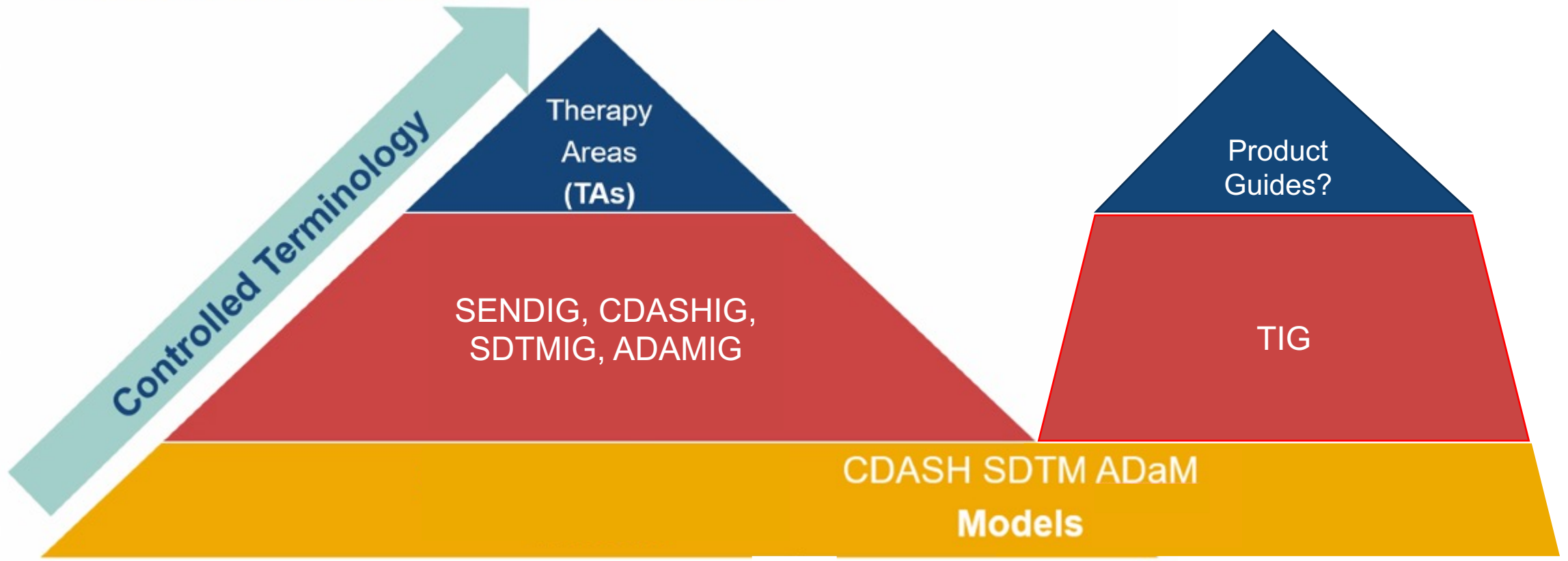
- Collection
- Tabulation
- Analysis; and
- Exchange of tobacco product data for submissions to FDA-CTP.

The TIG v1.0 is CDISC's first **hybrid** implementation guide.

- A data-focused, end-to-end implementation guide with standards for collection through analysis and data exchange.

The TIG is a Foundational, Hybrid Implementation Guide

Building on Foundational Standards



Philosophy for Development

- Adhere to [Plain Writing: It's the Law! | FDA](https://www.plainlanguage.gov/guidelines/) Suggested in team kick-off.
 - <https://www.plainlanguage.gov/guidelines/>, as much as possible
- Orient implementation guide to 1) Data, 2) Users, and 3) Standards - in this order
- Ensure guidance is simplified, concise, and organized from highest level concepts to detailed concepts
- Adhere to scope of implementation of standards only (i.e., an instruction manual)
- Limit content best described in other resources (e.g., other CDISC and regulatory documentation)

Controlled Terminology

TIG v1.0 standards use defined language, referred to as ***controlled terminology***.

Study #1 – dm.xpt

USUBJID	SEX
0001	M
0002	F
0003	F

Study #2 – dm.xpt

USUBJID	SEX
A1	M
A2	M
A3	F

Study #3 – dm.xpt

USUBJID	SEX
0001	M
0002	M
0005	F

Study #4 – dm.xpt

USUBID	SEX
00011	M
00012	F
00015	F



Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
Sex	F	Female	A person who belongs to the sex that normally produces ova. The term is used to indicate biological sex distinctions, or cultural gender role distinctions, or both. (NCI)
Sex	M	Male	A person who belongs to the sex that normally produces sperm. The term is used to indicate biological sex distinctions, cultural gender role distinctions, or both. (NCI)

Conformance

TIG v1.0 examples support conformance through further understanding of implementation guidance.

Ingredients and Additives Draft

it.xpt

Row	DOMAIN	STUDYID	SPTOBID	IGDCMPID	TPMF	ITSPECIF	ITIGDPLX	ITCURMTH
1	IT	TOB07	CIG01A	Tobacco Filler			COMPLEX INGREDIENT	
2	IT	TOB07	CIG01A	Burley Tobacco	MF5555555	NC 7LC	SINGLE INGREDIENT	Air
3	IT	TOB07	CIG01A	Bright Tobacco		CC 1063	SINGLE INGREDIENT	Flue
4	IT	TOB07	CIG01A	Oriental Tobacco		USDA Nicotiana Collection PI 552747	SINGLE INGREDIENT	Sun

Adherence to standards can be assessed using ***conformance rules***.

Data Exchange

Standards and resources for data exchange support sharing of metadata and data between parties and across different information systems.

- Conformant eCRFs for electronic data capture (EDC) tools
- Electronic data standards for automation
- Data definition files to describe the structure and contents of datasets





New to CDISC: Standards for Tobacco Product Characterization

Implementation of the SDTM with new domains:

- Tobacco Product Identifiers and Descriptors (TO)
- Product Design Parameters (PD)
- Tobacco Product Testing (PT)
- Tobacco Ingredients (IT)
- Non-Tobacco Ingredients (IN)
- Ingredient Quantities by Component (IQ)
- Environmental Storage Conditions (ES)

Implementation of a non-subject based ADAM OTHER dataset structure to support analyses



New to CDISC: Standards for Nonclinical In Vitro Testing

SEND implementation of the SDTM with new domains:

- Genetic Toxicology In Vitro Test Results (GT)
- Related References (RELREF)

New to CDISC: Standards for Population Modeling Input Parameters

Implementation of new ADaM REFERENCE dataset structure to designed to capture parameters used as inputs to population models

Example 1

This is an example of an ADaM dataset designed to capture the reference data describing historical transitional probabilities.

▼ rftransp.xpt

rftransp.xpt

Row	STRTM1	STRVAL1	STRTM2	STRVAL2	STRTM3	STRVAL3	STRTM4	STRVAL4	STRTM5	STRVAL5	STRTM6	STRVAL6	STRTM7	STRVAL7	INPRM	INPRMVAL	INPRMU
1	YEAR	2000	AGE	60	SEX	F	TRANSITION TYPE	INITIAL	PRODUCT	NEVER/NEVER	INITIAL STATUS	NEVER/NEVER	PRODUCT OF INTEREST	CIGARETTES/CIGAR	TRANSITION PROBABILITY	0.75	RATIO / 10 PER 1000
2	YEAR	2000	AGE	60	SEX	F	TRANSITION TYPE	INITIATE	PRODUCT	CIGARETTES/CIGAR	INITIAL STATUS	NEVER/NEVER	PRODUCT OF INTEREST	CIGARETTES/CIGAR	TRANSITION PROBABILITY	0.15	RATIO / 10 PER 1000
3	YEAR	2000	AGE	60	SEX	F	TRANSITION TYPE	QUIT	PRODUCT	CIGARETTES/CIGAR	INITIAL STATUS	NEVER/NEVER	PRODUCT OF INTEREST	CIGARETTES/CIGAR	TRANSITION PROBABILITY	0.03	RATIO / 10 PER 1000
4	YEAR	2000	AGE	60	SEX	F	TRANSITION TYPE	RELAPSE	PRODUCT	CIGARETTES/CIGAR	INITIAL STATUS	NEVER/NEVER	PRODUCT OF INTEREST	CIGARETTES/CIGAR	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000
5	YEAR	2000	AGE	60	SEX	F	TRANSITION TYPE	INITIATE	PRODUCT	CIGARETTES	INITIAL STATUS	NEVER/NEVER	PRODUCT OF INTEREST	CIGARETTES/CIGAR	TRANSITION PROBABILITY	0.01	RATIO / 10 PER 1000
6	YEAR	2000	AGE	60	SEX	F	TRANSITION TYPE	INITIATE2	PRODUCT	CIGARETTES/CIGAR	INITIAL STATUS	NEVER/NEVER	PRODUCT OF INTEREST	CIGARETTES/CIGAR	TRANSITION PROBABILITY	0.01	RATIO / 10 PER 1000



Updates to the SDTM

The SDTM has been updated, as SDTM v2.1, to

- Reflect *investigational products* rather than “treatments” in variable labels and definitions
- References to “animals” have been updated to *nonclinical*.

Public Review Recommendations





Public Review Materials

Public Review closes 18 December 2023 and reviewers are requested to provide comments in JIRA.

Review materials are:

- Tobacco Implementation Guide (TIG) v1.0
- TIG Conformance Rules v1.0
- Study Data Tabulation Model (SDTM) v2.1

Controlled terminology will be managed in a separate Public Review.

How can I best participate?

You are welcome to review the TIG in its entirety.

However, the scope of your review can be refined by:

- How you will use the TIG v1.0
- Your areas of subject matter expertise

From here, we will review the organization of the TIG v1.0 to help you determine the scope of your review.



How will I use the TIG v1.0?

In general, there will be two sets or “types” of TIG v1.0 users:

- Users who will produce data; i.e., applicants and implementers
- Users who will consume data; i.e., reviewers

Each set of users will have slightly different needs and may have different areas of expertise.



Subject Matter Expertise

Both data producers and consumers may have expertise in one or more areas:

- **Product Description**; concepts used to characterize tobacco products
 - e.g., Product specifications, HPHCs, stability, and ingredient listing
- **Nonclinical**; concepts used to identify potential risks and effects on biological processes for tobacco products via in vitro and in vivo nonclinical studies
- **Product Impact on Individual Health**; concepts used to assess the impact of tobacco products on individuals
- **Product Impact on Population Health**; concepts used to assess the impact of tobacco products on populations of individuals

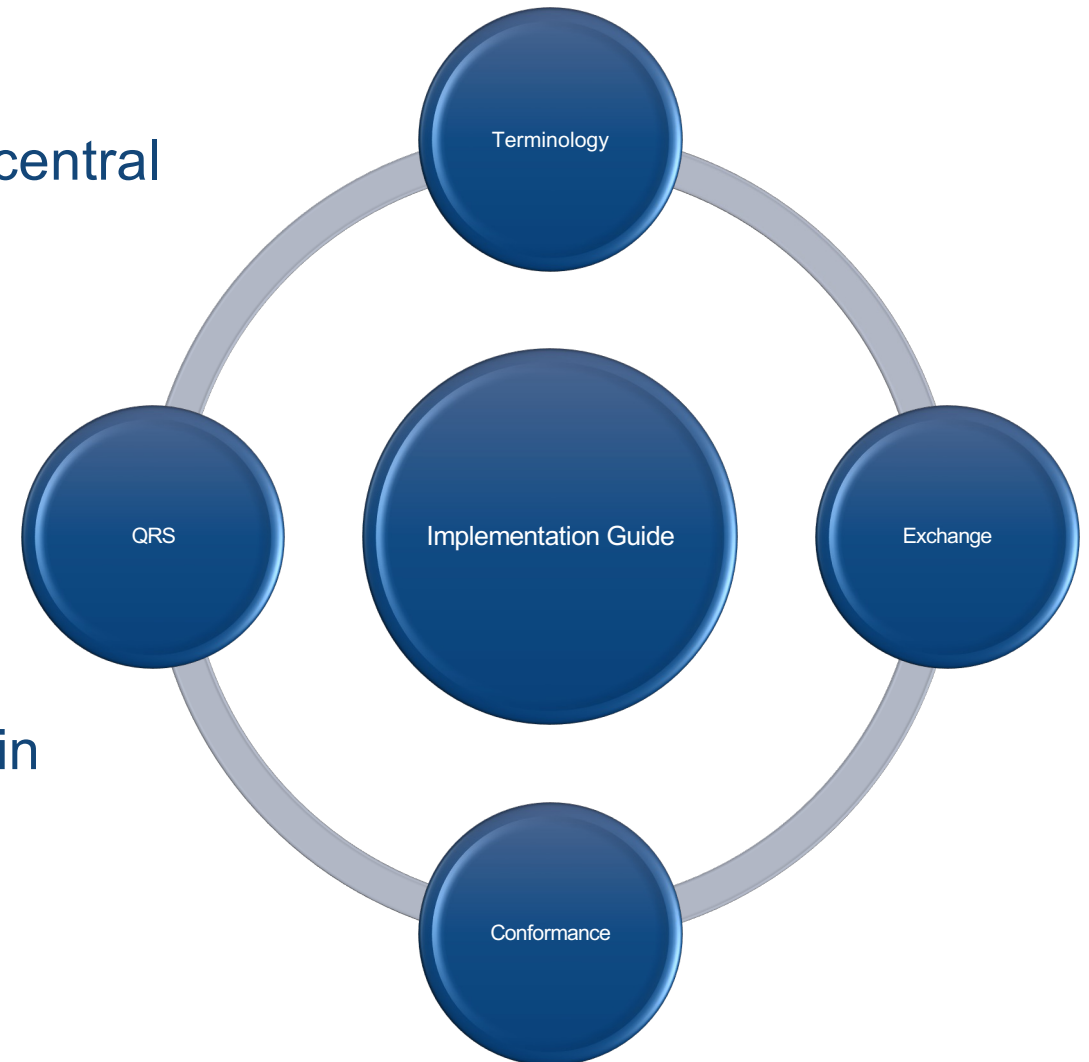
Tobacco Implementation Guide (TIG) v1.0

All standards are present or referenced in a central Implementation Guide for areas:

- Product Description
- Nonclinical
- Product Impact on Individual Health
- Product Impact on Population Health

Referenced standards are further described in additional resources.

QRS stands for Questionnaires, Ratings, and Scales



TIG v1.0 Organization

TIG v1.0 content is organized in four sections for ease of use:

Section	Description
1 Introduction	An overall introduction to the guide describing its purpose, organization, and relationship to other CDISC standards and resources
2 Standards for Tobacco Product Data	How to use CDISC standards and resources for the collection, representation, and exchange of tobacco product data
3 Examples	Examples to demonstrate the intended use of standards
Appendices	Additional background material and other materials to support implementation

- **TIG v1.0 conformance rules are referenced and stored in a separate Excel file.**

Standards for Tobacco Product Data

▼ 2 Standards for Tobacco Product Data

Draft

- 2.1 How To Determine Where Data Belong
- 2.2 How Standards Work Together
- 2.3 How to Use Controlled Terminology and Formats
- 2.4 About Questionnaires, Ratings, and Scales
- 2.5 Conformance to Standards
- 2.6 Guidance for Datasets
- › 2.7 Standards for Collection
- › 2.8 Standards for Tabulation
- › 2.9 Standards for Analysis
- 2.10 Standards for Data Exchange

- Provides instructions to apply standards for data producers
- Describes how data are standardized for data consumers
- Organized from highest level to detailed guidance

Examples

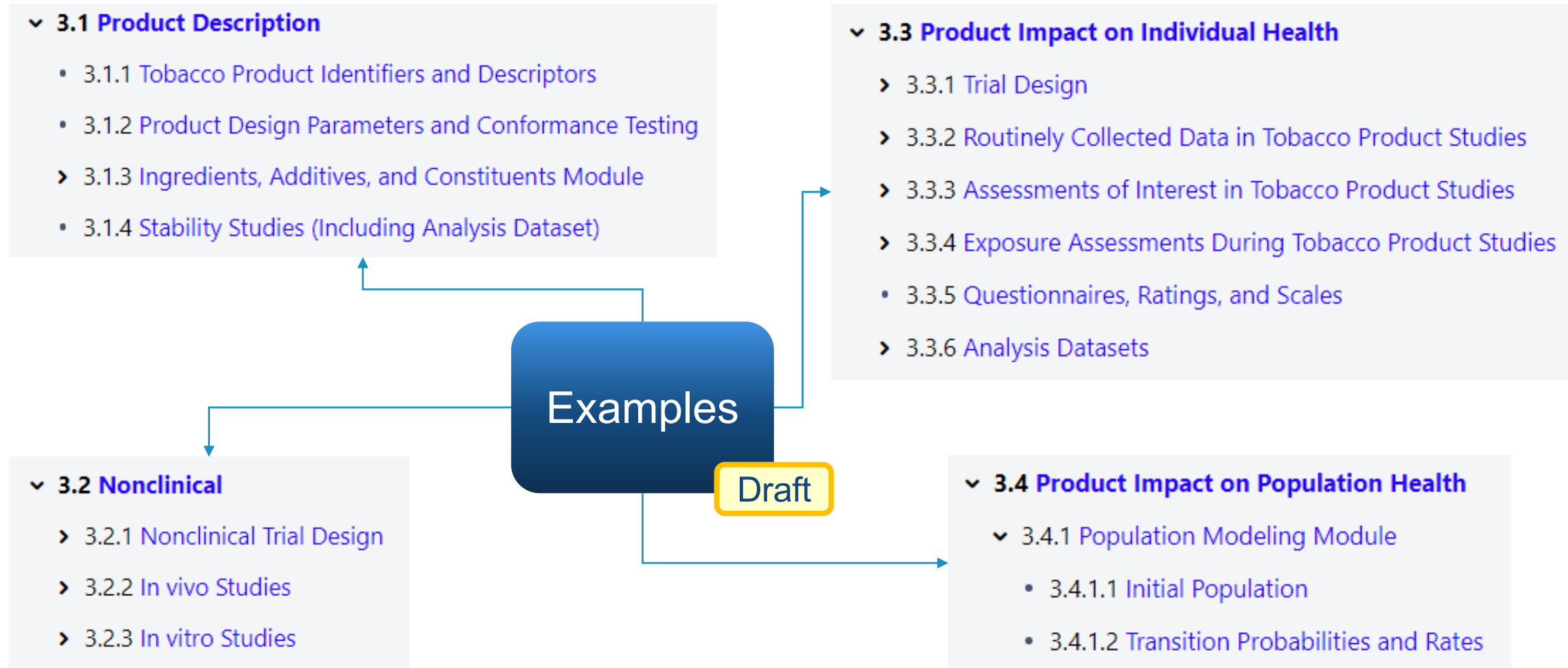
▼ 3 Examples

Draft

- › 3.1 Product Description
- › 3.2 Nonclinical
- › 3.3 Product Impact on Individual Health
- › 3.4 Product Impact on Population Health

- Provides real-world examples of standardized data when standards are used as intended
- Supports understanding of guidance for data producers
- Demonstrates standard representation of scientific concepts for data consumers

Examples



TIG v1.0 Conformance Rules

Conformance Rules are available for review in a separate Excel file.

TIG Conformance Rules v1.0

Created by Christine Connolly, last modified on Oct 05, 2023

Thank you for reviewing the TIG Conformance Rules v1.0, which encompasses all current conformance rules for TIG v1.0.

Please download the TIG Conformance Rule v1.0 catalog for your review.

File

>  [TIG Conformance Rules v1.0.xlsx](#)

Tobacco Implementation Guide (TIG) v1.0 Walkthrough



Tobacco Implementation Guide (TIG) v1.0

Please find the TIG v1.0 and TIG Conformance Rules v1.0 here:

➤ <https://wiki.cdisc.org/display/TATOBA/Tobacco+Implementation+Guide+Home>

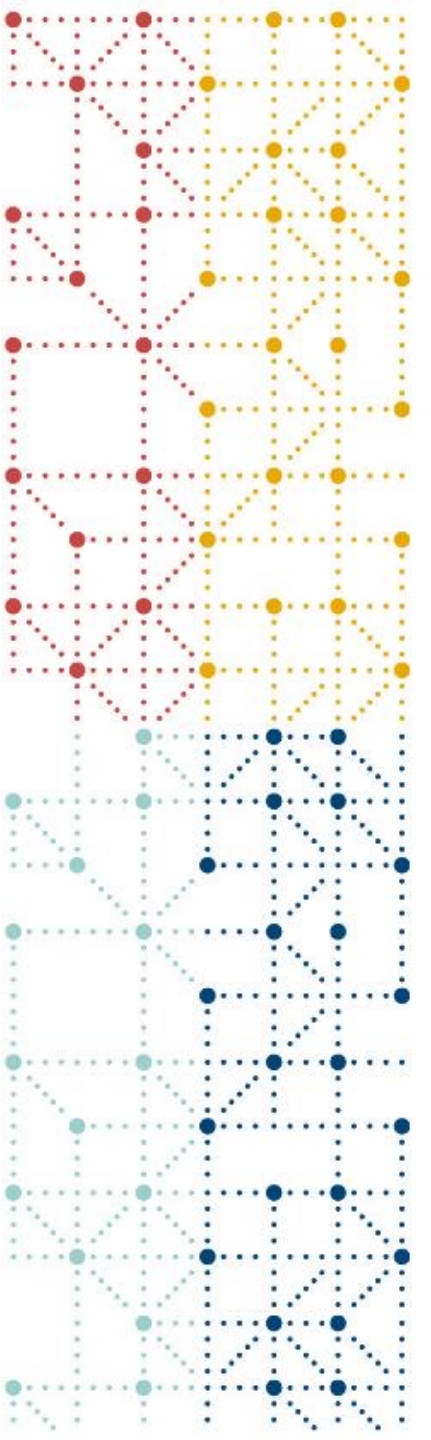
Tobacco Implementation Guide Home

Created by Joe Ben Clark, last modified by Christine Connolly on Oct 03, 2023

- **Read the document**
 - [TIG sections](#) — This displays each section on its own page and comprises the source of the content.
 - [Jump to a specific section:](#)
- **Read Conformance Rules**
 - [TIG Conformance Rules v1.0](#) - This is where the conformance rules catalog for the TIG v1.0 is located.
- **View the examples and figures**
 - [TIG examples](#) — This is where all examples used in the document are located.
 - [TIG diagrams](#) — This is where all figures used in the document are located.
- **Provide feedback**
 - [Instructions for Reviewers](#) — This is where to find detailed instructions for how to use JIRA to provide feedback on the document.

Status

This is a **DRAFT** standard, which means that it is still in development and not yet ready for provisional or general use.



Discussion and Questions

Tobacco Implementation Guide (TIG) v1.0

Thank you for your interest in the TIG v1.0 Public Review!

- Community driven standards development and reviews ensure publication of robust consensus-based standards that meet stakeholder needs.

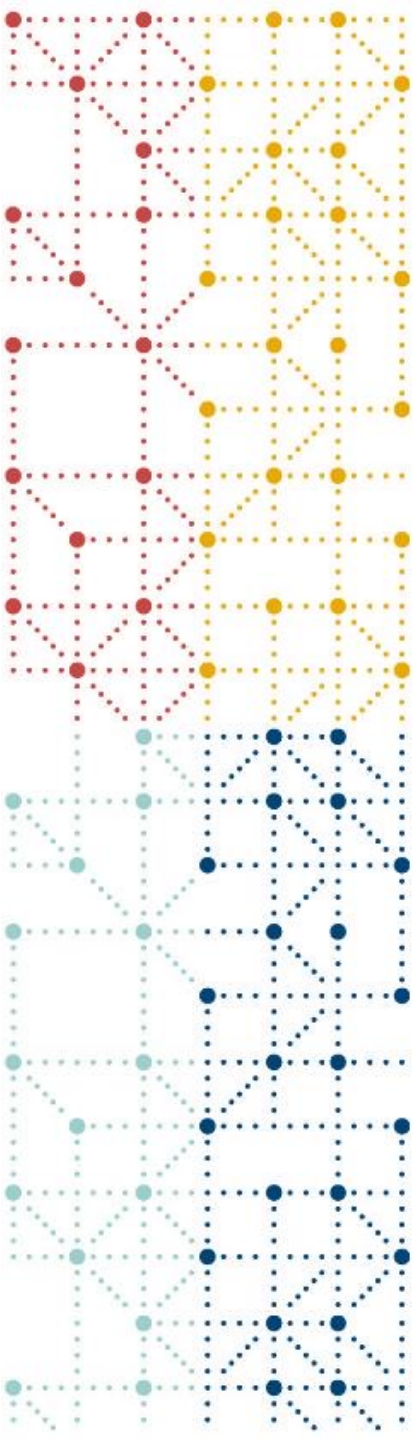
It takes a village to build a standard.



Questions

- What questions do you have?





Thank you!

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