TOBACCO IMPLEMENTATION GUIDE (TIG) V1.0: A NEW STANDARD FOR REGULATORY SUBMISSION

Presented by
Chrissie Cai
Data Quality Management Team Supervisor
Division of Regulatory Science Informatics
Office of Science, CTP, FDA

Presented by
Christine Connolly
Head of Standards Projects, CDISC

24 April 2024

CENTER FOR TOBACCO PRODUCTS

CTP Data Standards

- Updated Vision and Mission
- New 5-year Strategic Plan
- Standards and Data Standards
- Grant Program
- Benefits

CDISC Data Standards

- Tobacco Implementation Guide (TIG v1.0)
- Innovation Highlights

Learning Together

CTP DATA STANDARDS

ABOUT CTP

The U.S. Department of Health and Human Services (HHS) U.S. Food and Drug Administration (FDA) Center for Tobacco Products (CTP) is responsible for implementing the Family Smoking Prevention and Tobacco Control Act (FSPTCA), which Congress passed in 2009. The FSPTCA provides broad authority to regulate the **manufacturing, distribution, and marketing** of tobacco products.

As a public health regulatory entity, CTP takes a cohesive, comprehensive approach to reduce the negative health effects caused by tobacco use. This approach helps achieve the center's goals of preventing people from **starting to use tobacco products**, encouraging **people who use tobacco products to quit**, and **reducing the harm** caused by tobacco product use.

ABOUT CTP

VISION

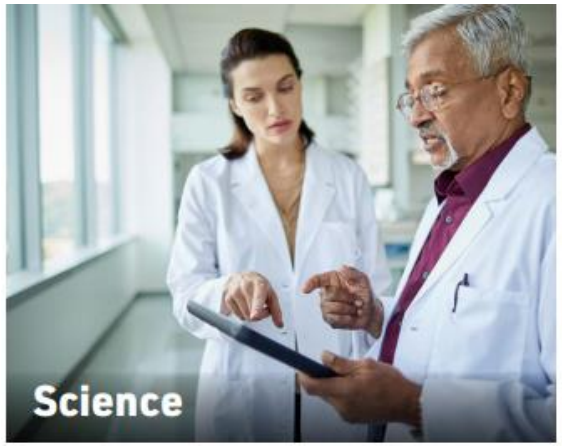
To make tobacco-related death and disease part of our nation's past by ensuring a healthier future and advancing health equity for those living in the United Sates.

MISSION

To protect the public health of the U.S. population from tobacco-related death and disease by comprehensively regulating the manufacture, distribution, and marketing of tobacco products; educating the public, especially youth, about the dangers of using tobacco products; and promoting and supporting strategies that ensure an equitable chance at living a healthier life for everyone.

CTP'S NEW FIVE-YEAR STRATEGIC PLAN

CTP's Strategic Plan defines five goals, 10 outcomes, and several corresponding objectives. These goals are reinforced by **four cross-cutting themes** that are emphasized throughout the plan:



Maintaining our commitment to use **data and evidence** driven approaches to inform CTP decision-making

Pursuing the highest level of health for all people by integrating health equity into CTP's programmatic, regulatory, policy, and operational activities

Continuously striving to optimize engagements with interested parties both external and internal to FDA, including other federal agencies

Promoting understanding of tobacco regulation through clear, consistent, and comprehensive communication

ABOUT STANDARDS

Standards are an invaluable resource for industry and FDA. For decades, FDA has **supported and benefited** from the development and use of standards to support the Agency's **mission in protecting and promoting the public health.**

Effective and meaningful **participation** in standards development organizations (SDOs) for the products FDA regulates are critically important.

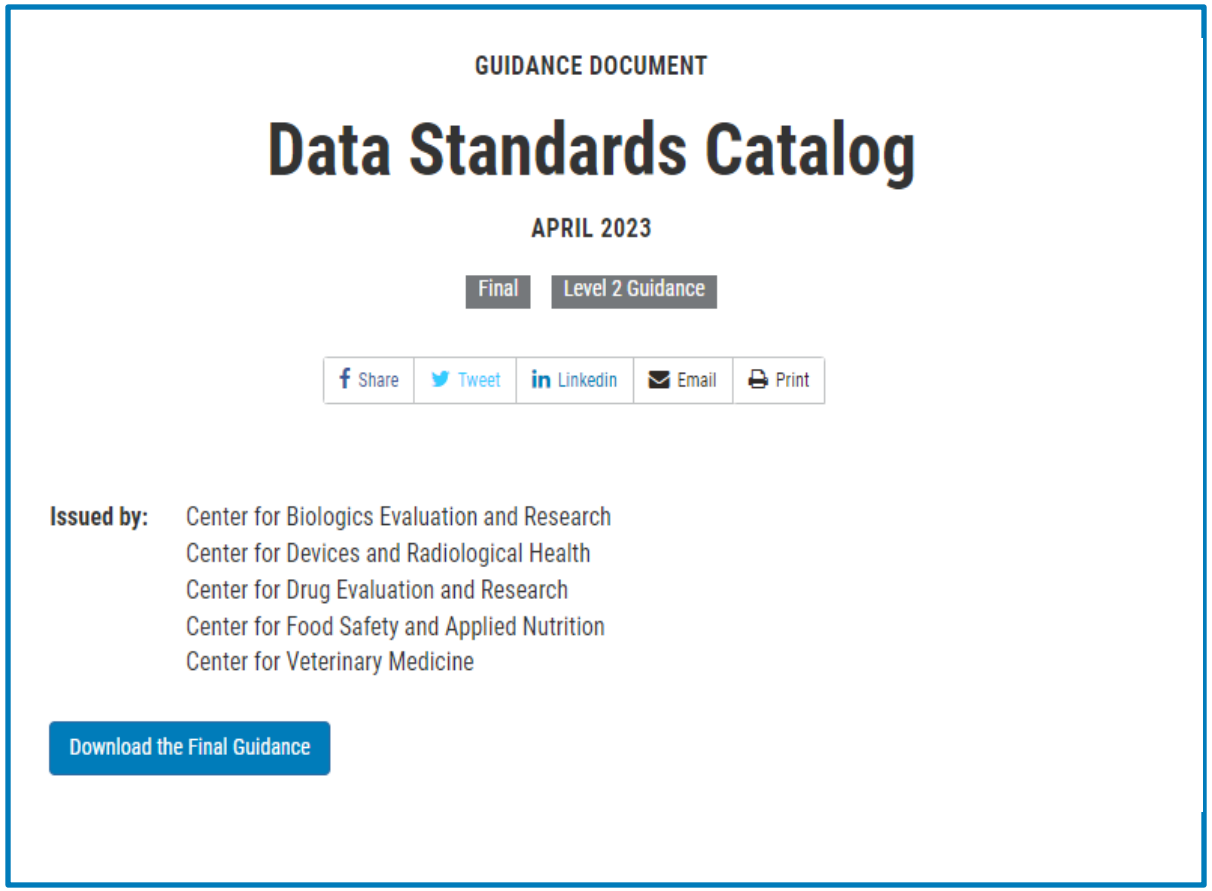
The use of standards can **increase predictability**, **streamline** premarket review, and facilitate market entry and use for safe and effective regulated products.

WHAT IS A DATA STANDARD?

Data standards provide a consistent general framework on how a particular type of data should be **structured, defined, formatted**, or **exchanged** between **computer systems.**

There are standards for everything, from how blood pressure is collected to how regulatory materials are submitted electronically to FDA.

Only some standards are required. See the **FDA Data Standards Catalog** (located on the Study Data Standards Resources page) for a list of standards currently supported or required by FDA.


GUIDANCE DOCUMENT

Data Standards Catalog

APRIL 2023

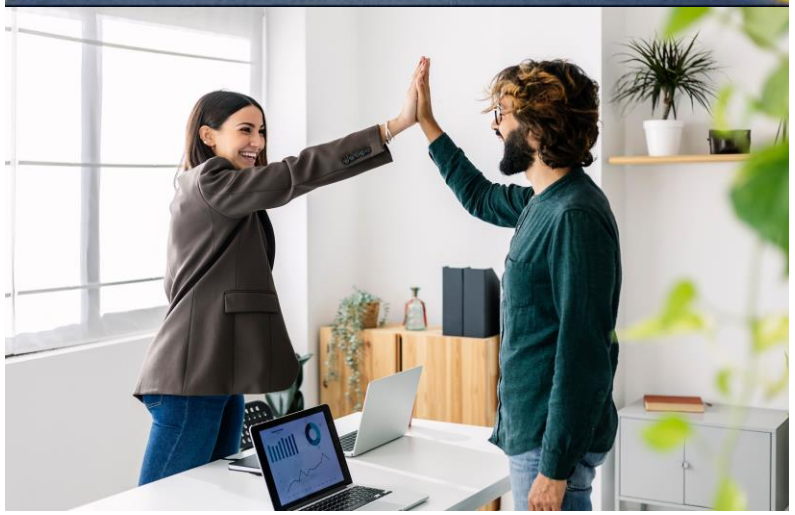
Final | Level 2 Guidance

Share | Tweet | Linkedin | Email | Print

Issued by: Center for Biologics Evaluation and Research
Center for Devices and Radiological Health
Center for Drug Evaluation and Research
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine

Download the Final Guidance

CTP DATA STANDARDS STRATEGY



CTP Data Standards Strategy 2021-2025

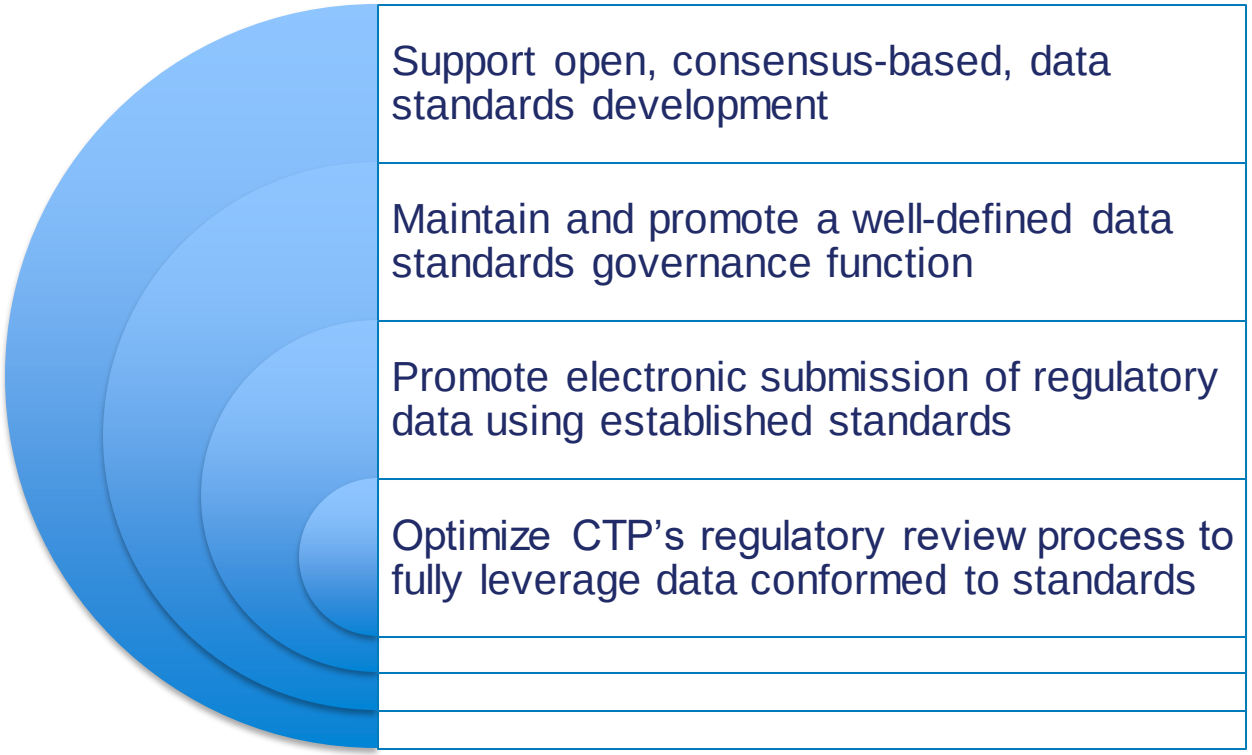
- Outlines strategies for the development and dissemination of data standards to better support the programs of CTP through better, more meaningful data
- Supports CTP's public health mission through predictable, consistent, and high-quality data standards
- Areas that are included
  - **Electronic Data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

CTP DATA STANDARDS GRANT PROGRAM

The Grant program was published for public participation under RFA-FD-22-002

This is a **Cooperative Agreement** grant which is a support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, FDA scientific or program staff will assist, guide, coordinate, or participate in project activities.

Strategic Goals



DATA STANDARDS BENEFITS

Reduce time in finding data

Ensure the same words mean the same thing *(Controlled Terminology)*

Reinforce validations *(Conformance Rules)*

Empower search and automation capabilities

Re-use data is easier

Enhance transparency & Stakeholder **E**ngagement

CDISC DATA STANDARDS

Clinical Data Interchange Standards Consortium

TOBACCO IMPLEMENTATION GUIDE (TIG) V1.0

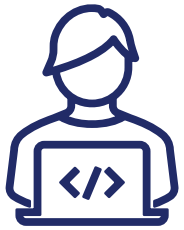
A single, comprehensive implementation guide designed for use cases unique to tobacco studies

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*)

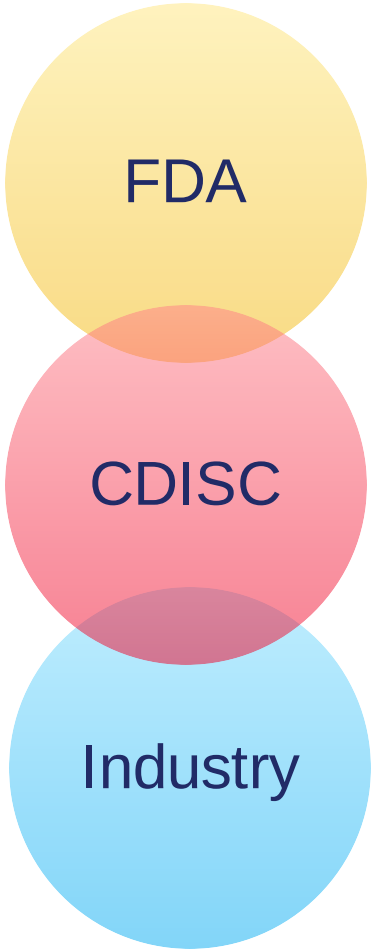
Education and Outreach (including *webinars*, *formal training*)

THE TIG PROJECT

Tobacco Implementation Guide (TIG) v1.0 standards are:

- The culmination of a collaborative project commenced by CTP and CDISC in 2021
  - Undertaken by **FDA-CTP, CDISC, and industry** stakeholders
- Designed to support the CTP Data Standards Strategy with standards to facilitate tobacco research, scientific review, harm reduction, and information exchange
- Non-proprietary, consensus-based, vendor-neutral, platform-independent submission data standards for tobacco product data to be freely available in **2024**

THE TIG PROJECT



Goal: A comprehensive resource for the collection, tabulation, analysis, and exchange of tobacco product data for submissions to FDA-CTP.

Team Formation
December 2021

Scoping
Start March 2022

Development
Start April 2022

Internal Review
Start April 2023

Public Review
Start October 2023

Publication
May/June 2024

INNOVATION

The TIG v1.0 is a new, stand-alone CDISC **foundational standard**.

Not all foundational standards are shown.

Focused on implementation for tobacco product submission use cases:

- Product Description
- Nonclinical
- Individual Health
- Population Health

SUBMISSION USE CASE EXAMPLE

Product Description

- Tobacco Product Identifiers and Descriptors (TO)
  - A study reference dataset that provides a mechanism for uniquely identifying a tobacco product

to.xpt

Draft Pending Permission for Publication

Row	STUDYID	DOMAIN	SPTOBID	TOSEQ	TOPARMCD	TOPARM	TOCAT	TOSCAT	TOVAL
1	TOB07	TO	CIG01a	1	TBPRDCAT	Tobacco Product Category	NEW PRODUCT	PRODUCT IDENTIFIER	Cigarettes
2	TOB07	TO	CIG01a	2	TBPRSCAT	Tobacco Product Subcategory	NEW PRODUCT	PRODUCT IDENTIFIER	Filtered
3	TOB07	TO	CIG01a	3	MANUF	Manufacturer	NEW PRODUCT	PRODUCT IDENTIFIER	Joes Cigs USA
4	TOB07	TO	CIG01a	4	TRADENAM	Trade Name	NEW PRODUCT	PRODUCT IDENTIFIER	Treetop Menthol King Size
5	TOB07	TO	CIG01a	5	PACKTYP	Package Type	NEW PRODUCT	PRODUCT DESCRIPTOR	HARD PACK

INNOVATION

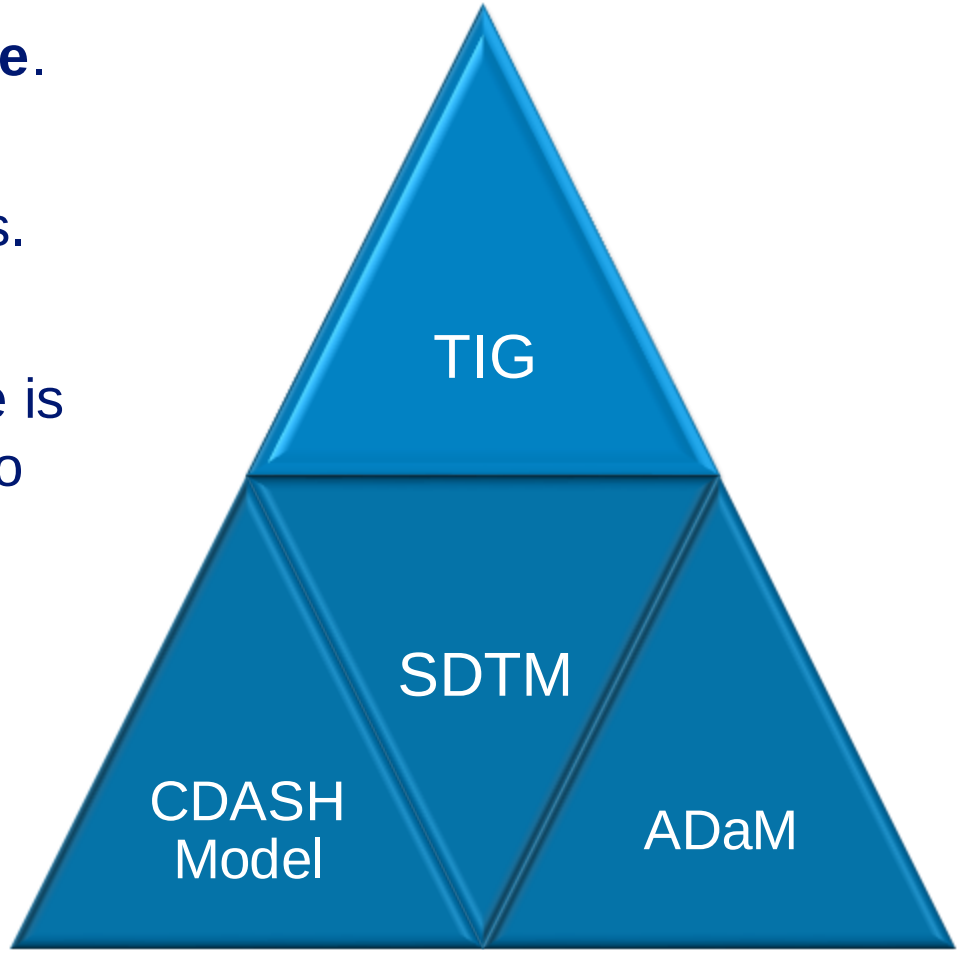
The TIG v1.0 is CDISC's first **hybrid implementation guide**.

Guidance is oriented to 1) Data, 2) Users, and 3) Standards.

End-to-end standardization for each submission use case is achieved by implementing foundational models applicable to the data flow for each use case in a **single guide**.

Additional standards and resources are referenced; e.g.:

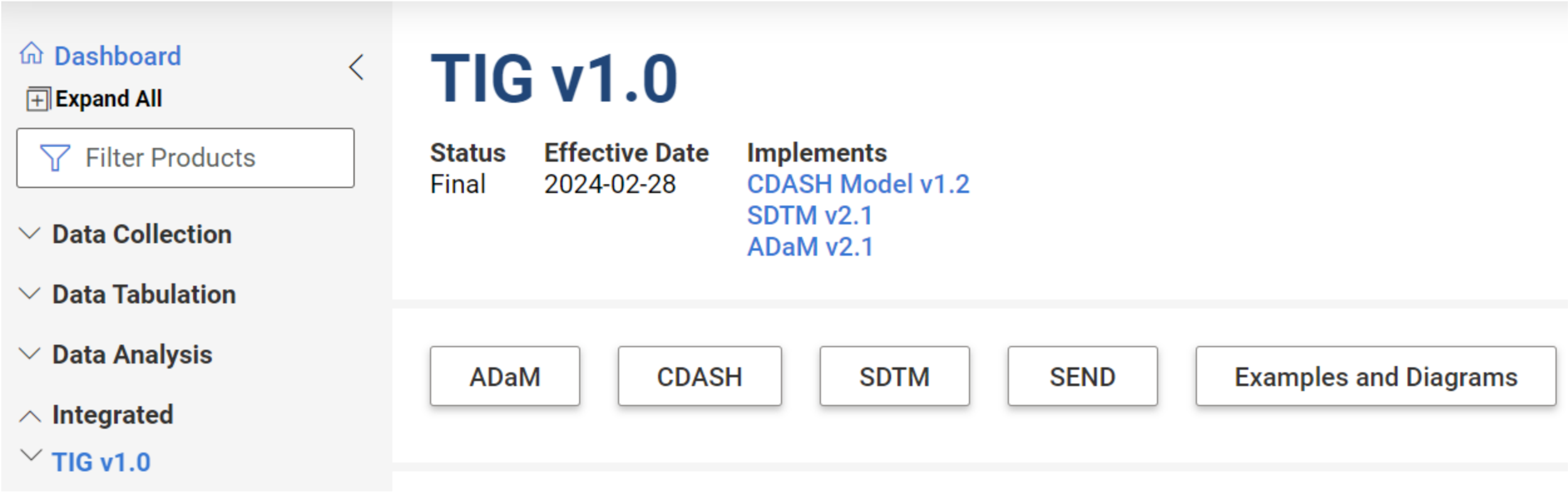
- Define-XML v2.1
- CDISC eCRF Portal



INNOVATION

cdisc LIBRARY Data Standards Browser

- Informative content (e.g., domain assumptions and examples)
- Biomedical Concepts
- ODM-XML representations of case report forms



LEARNING TOGETHER

FDA, CDISC, and Industry

LEARNING TOGETHER

1	2	3	4	5
The Tobacco Implementation Guide (TIG) v1.0	Government-led Initiatives	Open and Consensus-based	Controlled Terminology	Standards Harmonization
Is the culmination of a two-year project	CTP plays a central role in establishing data standards	Your voice is heard!	May take a few rounds to reach a common definition	Tobacco vs. Drug

Fostering Collaboration and Innovation

THANK YOU

- We welcome your questions and feedback!