



Tobacco Implementation Guide (TIG) eSubmission Pilot

Informational and Call for Volunteers Webinar

Christine Connolly, Head of Standards Projects, CDISC

Chrissie Cai, Center for Tobacco Products, FDA

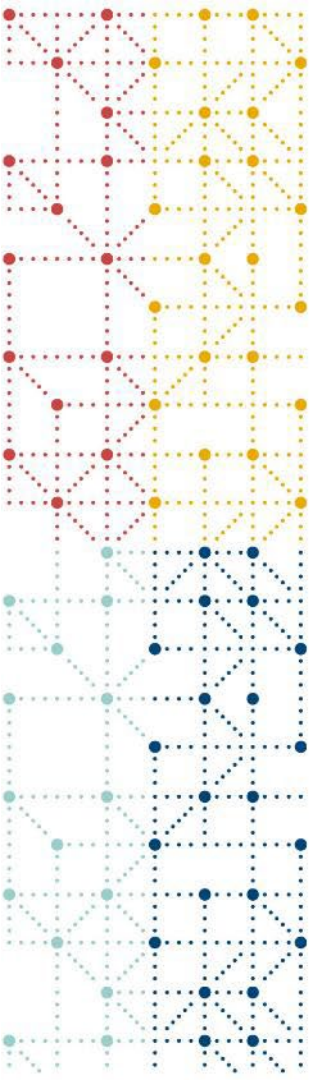
16 January 2025, 11am - 12:30pm EST





Agenda

- What is the Tobacco Implementation Guide (TIG)?
- TIG eSubmission Pilot Project
- Call for Volunteers
- Questions & Answers Session



What is the Tobacco Implementation Guide (TIG)?

About FDA Center for Tobacco Products (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 States.

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.

About CDISC

CDISC is a global, nonprofit standards development organization (SDO).

- Founded in 2000 (www.cdisc.org)
- Freely available research data standards
- Consensus-based development process
- Supporting research world-wide (e.g., Americas, Europe, Japan, China, India, Korea, other regions)
- Standards downloaded in 90+ countries

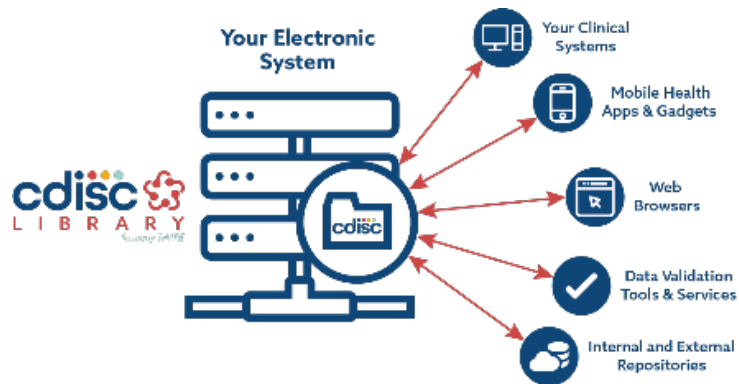
Community Need



CDISC Team & Volunteers



Standards & Resources



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**.



The image shows the cover of a guidance document titled "Data Standards Catalog". At the top, it says "GUIDANCE DOCUMENT". The title "Data Standards Catalog" is in a large, bold font. Below the title, it says "SEPTEMBER 2024". There are two buttons: "Final" and "Level 2 Guidance". Below these are social media sharing options: "Share", "Post", "LinkedIn", "Email", and "Print". Underneath, it lists the issuing organizations: Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Center for Drug Evaluation and Research, Human Foods Program, and Center for Veterinary Medicine. At the bottom, there is a blue button that says "Download the Final Guidance".

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

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog>



Tobacco Implementation Guide (TIG)

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 published and freely available as of **June 2024**

<https://www.cdisc.org/standards/foundational/tobacco-implementation-guide/tobacco-implementation-guide-v1-0>

Tobacco Implementation Guide (TIG) v1.0

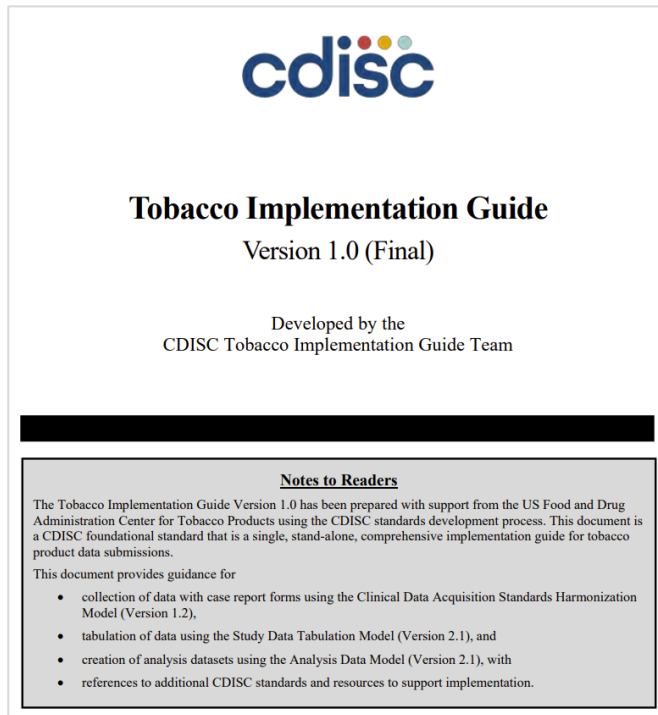
The TIG guides the use of CDISC standards and resources for the organization, structure, and format of tobacco product data.

The TIG describes how to use CDISC standards 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) 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 Challenge

Data variability that is not based on science.

Name for
Subject ID is not
the same

Name for
dataset varies

Gender or Sex -
do these mean
the same thing!?

Study #1 – demog.xpt

SUBJID	SEX
0001	M
0002	F
0003	F
0004	M
0005	F

Study #2 – dmgl.xpt

ID	GENDER
A1	Male
A2	Male
A3	Female
A4	Female
A5	Male

Study #3 – dmglph.xpt

PTID	GENDER
0001	1
0002	1
0003	2
0004	2
0005	1

Study #4 – axd222.xpt

USUBID	SEX
00011	0
00012	1
00013	1
00014	0
00015	1

Is it Male or Female,
M or F, 1 or 2, or 0 or 1?

What do these
numeric codes
mean?

Tobacco Implementation Guide (TIG) v1.0

Without unnecessary variability, science is the focus.

Study #1 – dm.xpt

USUBJID	SEX
0001	M
0002	F
0003	F

Study #2 – dm.xpt

USUBJID	SEX
A1	M
A2	M
A3	F

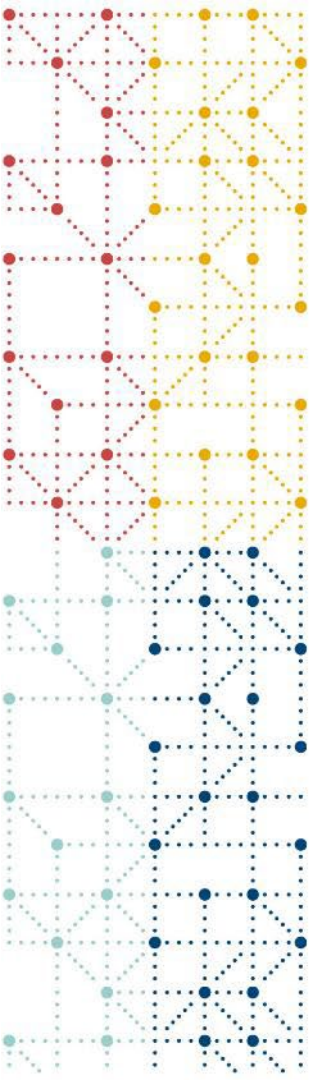
Study #3 – dm.xpt

USUBJID	SEX
0001	M
0002	M
0005	F

Study #4 – dm.xpt

USUBJID	SEX
00011	M
00012	F
00015	F

- The tables above represent TIG v1.0 standardized demographic data for four different studies.
- Data are structured, defined, and formatted consistently, ready for sharing and use.



TIG eSubmission Pilot Project

Project Basics

What

- This project is a continuation of the collaboration formed to develop the TIG v1.0 with the goal to support adoption and stakeholder realization of efficiencies.

How

- This project enables standards adoption and efficiencies through hands-on experience and subject matter expert support.

When

- Two years, 2024 June through 2026 June

Who

- CDISC will engage FDA CTP, tobacco industry subject matter experts, and other relevant stakeholders through project duration

Stakeholder Adoption & Efficiencies Through Hands-on Experience



Initiate

- Adopt TIG data standards through electronic submission experience



Educate

- Educate for consistent use of standards for submissions to CTP



Future State

- Develop a framework for long-term collaboration and support

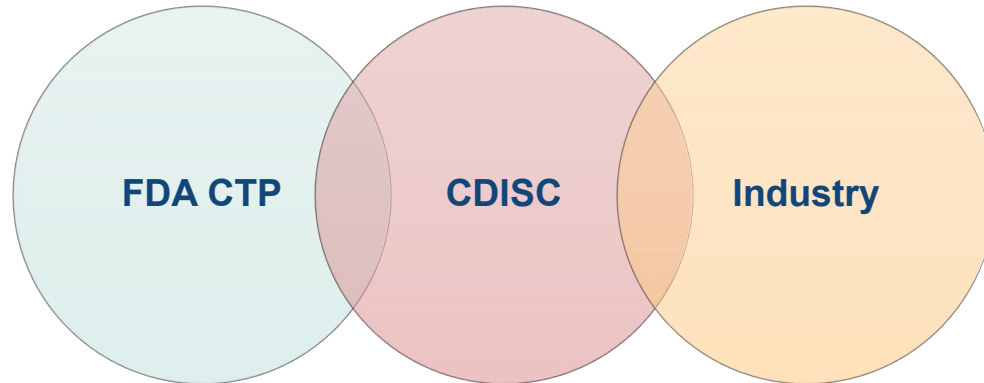


Community Benefit

A **standing volunteer team** will be formed support, manage, and refine TIG standards over time.

- Comprised of FDA CTP, tobacco industry, and CDISC subject matter experts,
- To act as a support forum for industry applicants and FDA CTP reviewers; and
- To continue after project close for future TIG standards direction and development.

CDISC Tobacco Implementation Guide (TIG) Team



Community Benefit

This project gives participants the ability to:



Practice eSubmission of standardized data with support and training



Design education resources to address community needs



Build a shared framework for long-term collaboration post project



Participation

This is a **dynamic and collaborative** project to pilot the TIG v1.0 together!

Requirements

Industry members must actively adopt TIG v1.0 standards within their organizations during the project adoption and stakeholder realization of efficiencies

CTP and industry team members must complete the TIG online education curriculum at the project's start

Engagement

Please participate actively,

Communicate openly, and;

Drive this project per your expertise and organizational needs



Participation

Our focus is stakeholder **adoption and efficiencies**, not actual product submissions.

Expectations

Data and supporting information shared as part of this project will not be used by FDA CTP for regulatory purposes.

Participants will not receive study or product related feedback from FDA CTP for shared data and supporting information.

Participation in this project and related data entry will not have any bearing on current and future regulatory decisions.

Data entry and related information shared as part of this project does not constitute a cross referenceable document for future regulatory product submission.

Project Aims

Initiate

- Begin stakeholder adoption and further refinement of TIG v1.0 standards for submissions to FDA CTP via an electronic submission (eSubmission) pilot

Educate

- Provide and create educational content to promote understanding of the value of data standards in research and to support consistent implementation of TIG v1.0 standards for submissions to FDA CTP

Future State

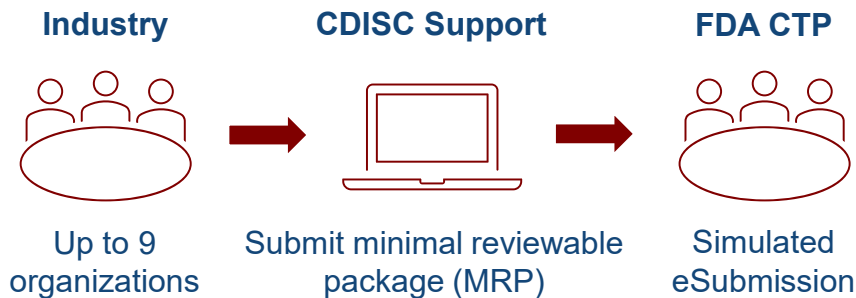
- Develop a documented framework for long-term collaboration, support, and refinements to TIG v1.0 standards for subsequent eSubmissions and other data standardization needs

TIG eSubmission Pilot Project

Initiate

Adopt TIG standards through eSubmission experience

- Industry application of TIG v1.0 standards in the context of an eSubmission to CTP
- CTP receipt and processing of standardized data as part of an eSubmission
- CTP reviewer understanding of standardized data in a way that facilitates of product review



Submission Types and Data

- Premarket Tobacco Product Application for ENDS with associated e-liquid(s)
- Substantial Equivalence Report for combustible product(s)



Standards Adoption and Refinement

This project will focus on adoption of the:

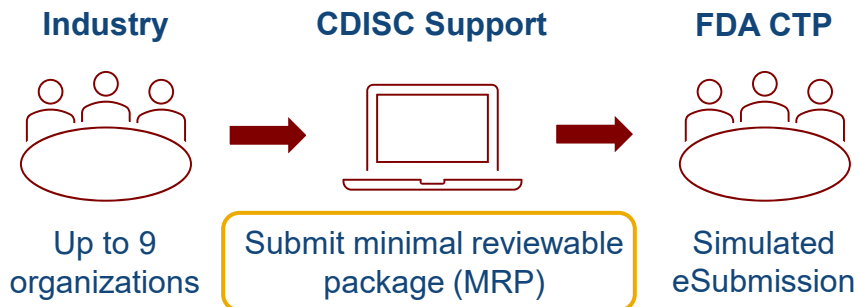
- Tobacco Implementation Guide (TIG) v1.0
- TIG Conformance Rules v1.0
- CDISC Controlled Terminology

Draft standards for project use may developed if gaps are identified and will be considered for publication in future versions of the TIG.

Gaps may also be addressed through education.

- <https://www.cdisc.org/standards/foundational/tobacco-implementation-guide/tobacco-implementation-guide-v1-0>
- <https://www.cdisc.org/standards/terminology/controlled-terminology>

Minimal Reviewable Package (MRP)



Data must be a reasonable facsimile of actual data and contribute to a reasonable representation of a hypothetical product

The MRP is comprised of:

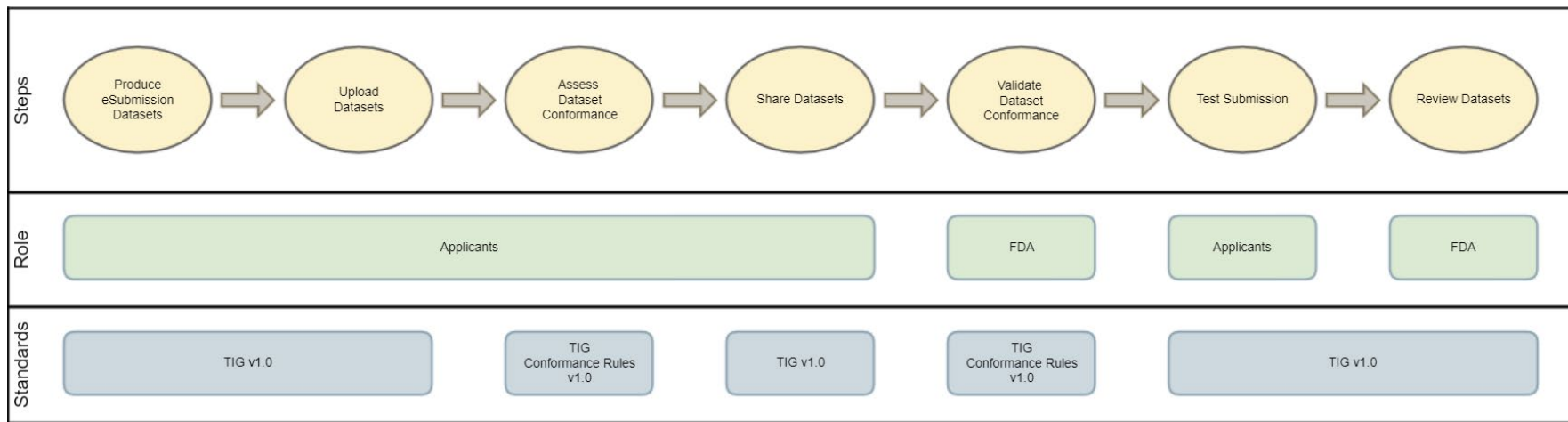
- Deidentified actual and/or dummy data
- In datasets standardized per the TIG v1.0 in SAS V5 Open Transport format
- With a summary of content within and across datasets

Conformance

Dataset conformance to TIG v1.0 standards will be assessed:

- Using TIG Conformance Rules v1.0
- An instance of the CDISC Open Rules Engine (CORE)

Simulated eSubmission Workflow



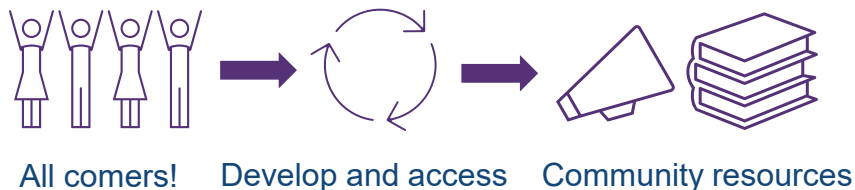
TIG eSubmission Pilot Project

Educate

Educate for consistent use of standards for submissions to CTP

- Promote community awareness and adoption of TIG v1.0 resources, and project progress
- Support consistent implementation of standards
- Enable use of applicable CDISC tools, technology, platforms, and tools by standards implementers

FDA CTP, Industry, & CDISC



A minimum set of education resources is already planned to support simulated eSubmission and adoption. Additional resources will be developed to support adoption based on needs.



Planned Education Resources

In addition to the full CDISC TIG online education curriculum, resources will be provided for the following topics:

- Controlled Terminology
- CDISC Library
- CDISC Open-Source Alliance (COSA)
- Conformance Rules
- FDA Reviewer Training

TIG eSubmission Pilot Project

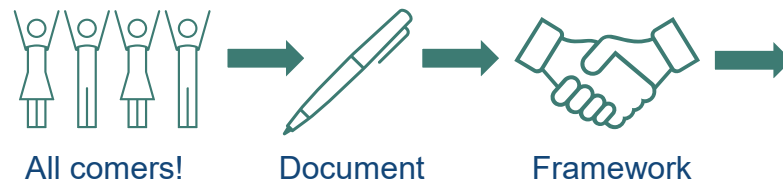
Future State

Develop a framework for long-term collaboration and support

- White paper to summarize experience with learnings and recommendations
- Framework to guide steps for long-term collaboration, support, and enhancements to standards

The white paper and long-term framework are intended as a foundation for future CTP, CDISC, and/or industry guidance.

FDA CTP, Industry, & CDISC





White Paper and Framework Development

The white paper and framework will be informed by the following reviewed and organized into key learnings and themes:

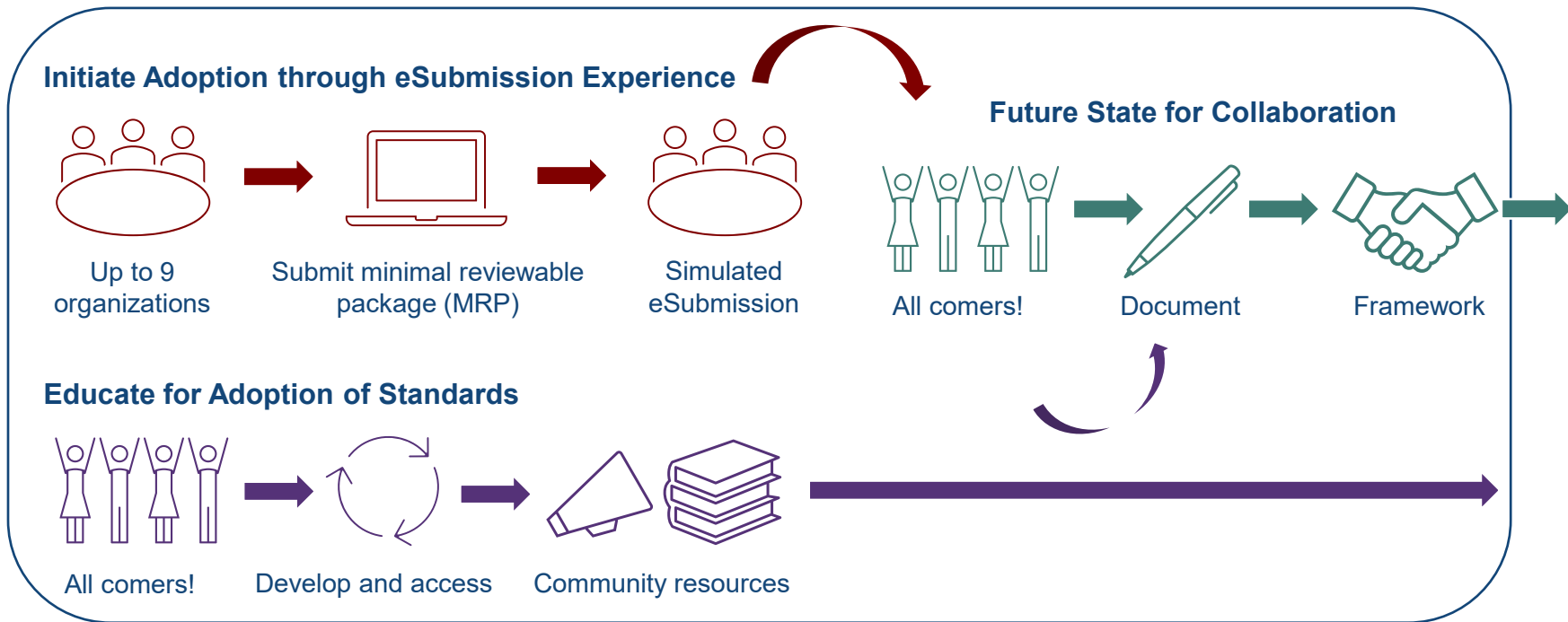
- All team member feedback and resolutions
- Draft standards developed to support stakeholder adoption
- Conformance rules findings
- Education developed to support stakeholder adoption

Additional topics may also be explored including:

- Machine-readable data dictionaries (i.e., CDISC Define-XML)
- CDISC Dataset-JSON formatted datasets

Project Work

The **CDISC Tobacco Implementation Guide (TIG) Team** will address aims in tandem over project duration.



Project Work and Timelines

The **TIG eSubmission Pilot Project** is in progress!



➤ With planning and development work to support upcoming activities



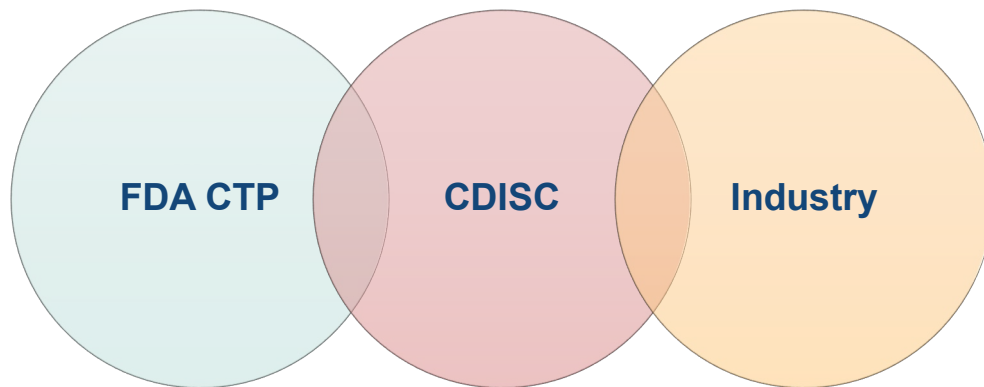
Project Scoping

Project activities began with a collaborative scoping exercise undertaken by CTP and CDISC to identify:

- Basic regulatory expectations for use of TIG v1.0 standards for simulated eSubmission
- Submission types and supporting data needed for piloting
- A basic subset of corresponding TIG v1.0 standards and conformance rules to be implemented for piloting

CDISC Tobacco Implementation Guide (TIG) Team Kick-off

- Our Kick-off meeting is planned for **early February**.
- Current volunteers will receive a poll this week to support scheduling.
- It is never too late to volunteer; new volunteers will be onboarded.



What comes next?

Feb 2025 –
May 2026

Initiate

Prepare for eSubmission

eSubmission and gap assessment

Develop resources as needed

Educate

Provide planned resources

Gap assessment

Develop resources as needed

Dec 2025 –
May 2026

Future State

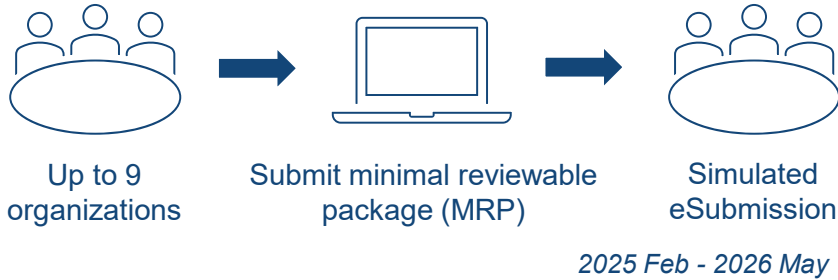
Assess project learnings and themes

Develop and finalize framework

TIG eSubmission Pilot Project

CDISC Tobacco Implementation Guide (TIG) Team

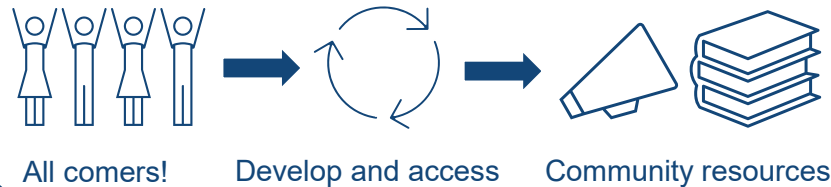
Initiate Adoption through eSubmission Experience



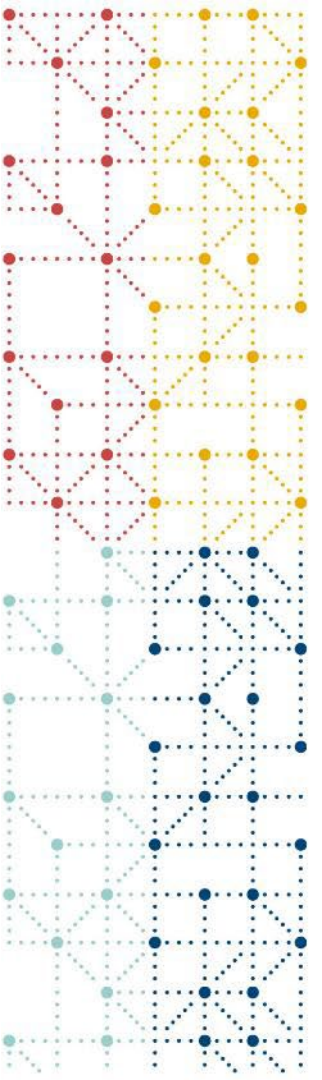
Future State for Collaboration



Educate for Adoption of Standards



Enable standards adoption and realization of efficiencies through hands-on experience & support.



Call for Volunteers

CDISC Tobacco Implementation Guide (TIG) Team

The project team, operating as a full team and through two workstreams, will meet monthly to review strategy, progress, and findings, with additional weekly workstream meetings (up to one hour, plus two hours of prep).

Simulated eSubmission Workstream

- Up to nine industry organizations will apply TIG v1.0 standards in project-specific eSubmissions to CTP

Education Workstream

- Open to all adopters to strengthen CTP and industry knowledge and adoption of TIG v1.0 through focused educational content



How can I volunteer?

We invite you to participate as part of a multi-disciplinary team with membership from CTP, industry, and CDISC.

Sign-up through the CDISC Website

- <https://www.cdisc.org/volunteer/form>

Reach out if you need help!

- Email: **Christine Connolly**, cconnolly@cdisc.org



Follow Project Progress

Project progress will be shared with the community regardless of participation.

Current information will be available any time via the:

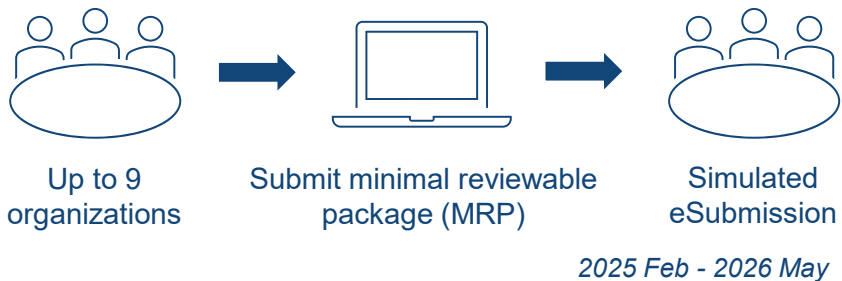
- CDISC website
 - <https://www.cdisc.org/tig-esubmission-pilot>
- CDISC TIG LinkedIn page
 - <https://www.linkedin.com/showcase/tobaccoimplementationguide>

Periodic in-person and virtual presentations via conferences, webinars, and workshops will be conducted to address community questions in real-time.

Please join us!

CDISC Tobacco Implementation Guide (TIG) Team

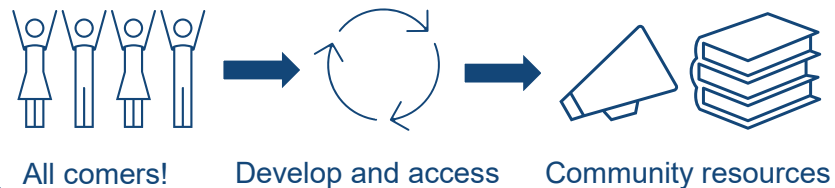
Initiate Adoption through eSubmission Experience



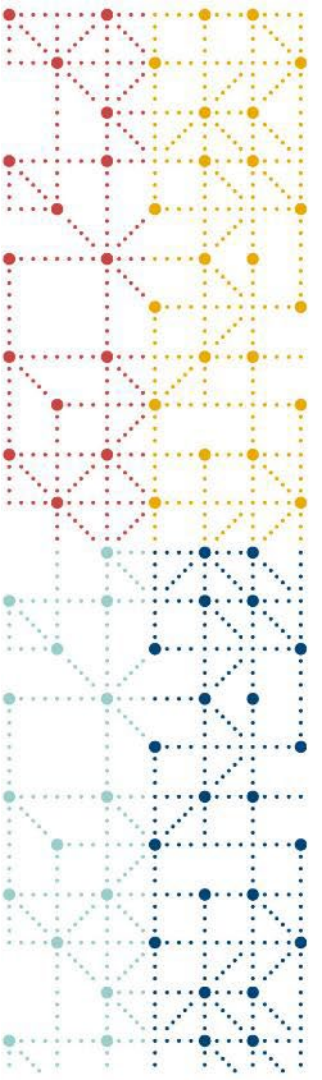
Future State for Collaboration



Educate for Adoption of Standards



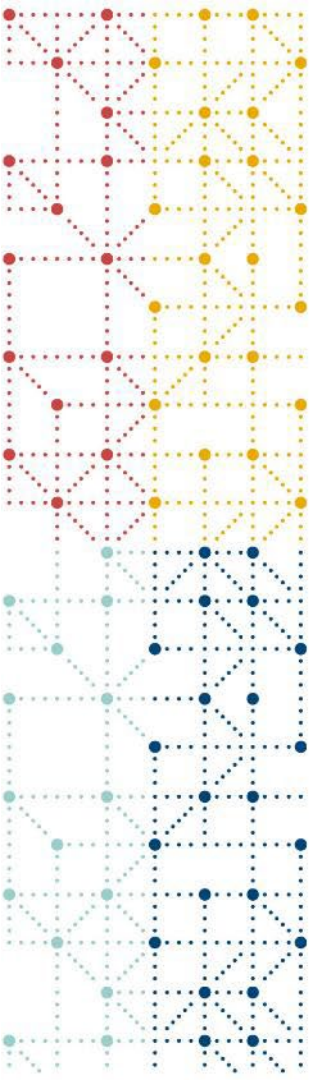
Enable standards adoption and realization of efficiencies through hands-on experience & support.



Questions & Answers Session

Audience Questions





Thank You!

cdisc