



# **CBER-CDER Data Standards Program Action Plan**

**Version: 1.3**

**FY2023 Q4 update**

**Document Date: 11/9/2023**

**REVISION HISTORY**

Version Number	Revision Date	Description of Change
1.0	January 25, 2023	Revision of document structure to align with FY23-FY27 CBER-CDER Data Standards Strategic Goals
1.1	May 9, 2023	<ul style="list-style-type: none"> <li>• FDA Data Standards Catalog added to Goal 2</li> <li>• IDMP Guidance added to Goal 2</li> <li>• Technical Specifications and Conformance Guide Updates removed from Goal 4</li> <li>• Appendix B updated</li> </ul>
1.2	August 14, 2023	<ul style="list-style-type: none"> <li>• IDMP Guidance removed from Goal 2</li> </ul>
1.3	November 9, 2023	<ul style="list-style-type: none"> <li>• Quarterly project updates</li> </ul>

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## Introduction

The purpose of the *CBER-CDER Data Standards Strategy* is to reinforce the ongoing commitment to the development, implementation, and maintenance of a comprehensive data standards program that will facilitate the pre- and post-market regulatory review process so that safe and effective medical products are available to patients.

This action plan aligns to the CBER-CDER Data Standards Strategy and reflects progress in CBER and CDER towards the defined goals and objectives. Projects selected for this action plan have started, are resourced and funded, and have a scope that is primarily standards related.

## Purpose

This action plan provides a quarterly update to internal and external stakeholders, with an overview and progress update of current data standards initiatives. The plan will continue to be updated quarterly to reflect progress of current projects, as well as initiation of new projects. For information on prior quarters, refer to previous versions of the [Action Plan](#).

## Program Goals and Initiatives

The program goals are derived from the major areas of regulatory business activities. A detailed description of these major areas can be found in the [CBER-CDER Data Standards Strategy](#).

The CBER-CDER Data Standards Program goals focus on four areas:

- Goal 1: Improve Data Standards for Regulatory Use
- Goal 2: Data Standards Policy
- Goal 3: Efficient Information Management
- Goal 4: Enhance Transparency and Stakeholder Engagement

The successful accomplishment of these goals may be achieved given sufficient resources, regulatory/legislative factors, and collaboration with stakeholders.

For each project in this section, the project title, description, update, and project stage(s) are provided. The project update reflects work done in the previous quarter (e.g., the FY2023 Q1 report highlights work from October to December 2022).

The project stage lists the typical stages a project might address during work for the project and are generally conducted in sequence from left to right. The definitions of the project stage are defined in **Appendix A**.

Project Stage
Requirements (REQT)
Analyze Alternatives (ALT)
Development (DEV)
Testing (TEST)
Adoption (ADOPT)
Implementation (IMPL)
Policy (POLICY)

Project Stage Status
In Progress
Pending
Complete
Not Applicable

### Goal 1: Improve Data Standards for Regulatory Use

Projects related to Goal 1 address our continued collaboration with Standards Development Organizations to improve data standards and support initiatives for the adoption and adaptation of new and existing standards

#### OBJECTIVE 1: Enhancement of Submission Formatting & Review

Project Title & Description	Project Status	Project Stages						
		REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
<p><b>Study Data Standards Testing and Evaluation</b></p> <p>This CBER-CDER project tests new and updated study data standards and standards adjacent properties to establish FDA support and requirements.</p>	<p><b>Q4:</b></p> <p>Review of Study Data Technical Conformance Guide (sdTCG) for impacts related to CDISC SEND.</p> <p>Initiated testing and pilot activities with Dataset-JSON standard.</p> <p>Initiated evaluation of gaps in regulatory submission standards for new data types.</p> <p>Public Comment Review:</p> <ul style="list-style-type: none"> <li>CDISC Controlled Terminology Relationships v1.0</li> </ul> <p>Final Published Review:</p> <ul style="list-style-type: none"> <li>SENDIG-DART v1.2</li> <li>SENDIG GENETOX v1.0</li> </ul>	<p><b>Not Applicable</b></p>						

Project Title & Description		Project Status		Project Stages						
				REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
<p><b>Questionnaires, Ratings and Scales (QRS) Assessment</b></p> <p>This CDER project is focused on evaluations of proposed standardized data structures that capture the information from Questionnaires, Ratings, and Scales administered to subjects during a clinical study and prioritize the data collection instruments indicated in the Clinical Outcomes Assessment (COA) area.</p>		<p><b>Q4:</b></p> <p>CDISC PASI Feldman v1.0                      CDISC PASI Fredriksson v1.0                      CDISC PRO-CTCAE v1.0                      CDISC PASI Bozek v1.0                      CDISC PASI EMA v1.0</p>		<p><b>Not Applicable</b></p>						
<p><b>eCTD v4.0 Project – Phase 1</b></p> <p>This CBER-CDER project is focused on the development, testing, adoption, and implementation of the next major version of the electronic Common Technical Document (eCTD), version 4 for new applications. FDA currently uses eCTD version 3.2.2. Note: A separate project to upgrade CDER parsing capability to consume eCTD v4.0 messages is planned.</p>		<p><b>Q4:</b></p> <p>Shared Lessons Learned from eCTD v4.0 Technical Pilot with participants. Continue to test updates provided in eCTD Software, update regional specifications as needed (IG, CV, Validations, CTOC, TCG). Continued work on FDA Implementation.</p>		<p><b>Not Applicable</b></p>	<p><b>Not Applicable</b></p>	<p><b>Not Applicable</b></p>	<p><b>In Progress</b></p>	<p><b>In Progress</b></p>	<p><b>In Progress</b></p>	<p><b>In Progress</b></p>

Project Title & Description		Project Status		Project Stages				
				REQT	ALT	DEV	TEST	ADOPT
<p><b>Submission Data Standards Assessment</b></p> <p>Establish a catalog of all data areas and associated regulatory submission standards in eCTD modules. Identify and prioritize opportunities for further standardization.</p>	<p><b>Q4:</b></p> <p>Delivered final work products, project complete.</p>	Complete	Not Applicable	In Progress	Not Applicable	Not Applicable	Pending	Not Applicable
<p><b>Pharmaceutical Quality/ Chemistry, Manufacturing, and Controls Data Standardization</b></p> <p>This CDER project with participation from CBER and CVM will identify and standardize data elements, terminologies, and data structures to enable automation of key analyses of Pharmaceutical Quality (PQ)/ Chemistry, Manufacturing, and Controls (CMC) data to support more efficient and effective regulatory decision-making.</p>	<p><b>Q4:</b></p> <p>Continued development of Phase 2 domains.</p>	Complete	Complete	In Progress	Pending	Pending	Pending	Pending



Project Title & Description	Project Status	Project Stages						
		REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
<p><b>IDMP Project</b></p> <p>This project has multiple use cases focused on the adoption of ISO Identification of Medicinal Product (IDMP) standards: 1. Medicinal Product ID (MPID), 2. Substance ID (SubID), 3. Pharmaceutical Product ID (PhPID), 4. Route of Administration, Dosage Form, and 5. Units of Measure.</p> <p>These ISO standards define medicinal product information for regional and global data sharing. Generally, the use cases focus on safety (e.g., ICSRs) and can support quality (e.g., PQ / CMC).</p>	<p><b>Q4:</b></p> <p>Continue working with EMA and WHO-UMC to pilot projects to establish a framework for harmonized global implementation of ISO IDMP standards. Participated in a successful HL7 Connectathon FHIR IDMP message with Cross-Border Prescription use cases.</p>	Complete	Not Applicable	Complete	In Progress	Pending	Not Applicable	Not Applicable

Project Title & Description	Project Status	Project Stages						
		REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
<p><b>Assessing Applicable Data Standards for Use in Submission of Real-World Data to FDA</b></p> <p>FDA is examining Real World Data (RWD) and data standards to support submission of RWD to FDA. This assessment will help determine a roadmap for applying data standards for RWD submission to FDA.</p>	<p><b>Q4:</b> Begin review of prioritized data elements with internal stakeholders to gather feedback.</p>	In Progress	In Progress	Pending	Pending	Pending	Pending	Pending
<p><b>Source Data Capture from EHRs: Using Standardized Clinical Research Data</b></p> <p>This CDER project is working to demonstrate an approach to collecting data for clinical trials that populates an electronic data capture (EDC) system directly from an electronic health record (EHR) system and document improvements to efficiency and accuracy compared to traditional methodologies.</p>	<p><b>Q4:</b> Continued development.</p>	Complete	Not Applicable	In Progress	Not Applicable	Not Applicable	Not Applicable	Not Applicable

Project Title & Description	Project Status	Project Stages						
		REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
<p><b>SPL FHIR</b></p> <p>FDA is examining HL7 FHIR as an alternative to Structured Product Labeling (SPL). Currently the SPL data exchange standard is a modified version of HL7 version 3 data standard. Since HL7 is sunsetting HL7 in favor of HL7 FHIR, FDA is working to determine if an HL7 FHIR can support the same functionality and use cases as the current SPL standard.</p>	<p><b>Q4:</b></p> <p>Continued buildout of FHIR IG including revisions reflecting FHIR version R4B. Participated in HL7 Connectathon track exploring EMA electronic Product Information (ePI) FHIR IG and SPL-FHIR IG.</p>	Complete	Complete	In Progress	In Progress	Pending	Pending	Pending
<p><b>Grant: Investigating Support for 21 CFR 11 Compliance Using HL7 FHIR</b></p> <p>As a use case for enabling implementation of audit trailing and provenance capabilities in Real World Data research, this grant is evaluating approaches to build out elements of the HL7 FHIR standard to support these capabilities. An initial use case is to add audit trail support to FHIR Resources used for recording Patient Reported Outcomes (PROs).</p>	<p><b>Q4:</b></p> <p>Grantee planning further engagement with HL7 workgroups.</p>	Not Applicable						

**OBJECTIVE 2: Improve Pre and Postmarket Safety Surveillance Data**

Project Title & Description	Project Status	Project Stages						
		REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
<p><b>FDA Adverse Event Reporting System (FAERS) II</b></p> <p>CDER and CBER project is receipt and processing of Investigational New Drug (IND) and post-market safety reports submission using E2B R3 standards.</p>	<p><b>Q4:</b></p> <p>FAERS II E2B R3 Industry Testing Phase I completed. Minor enhancements and defects are being developed in preparation for Industry Testing Phase II.</p>	Complete	Complete	InProgress	InProgress	In Progress	In Progress	In Progress

Project Title & Description	Project Status	Project Stages						
		REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
<p><b>Biologics Effectiveness and Safety (BEST) Innovative Methods (IM)</b></p> <p>Leverages Artificial Intelligence, Machine Learning, FHIR standards and SMART-on-FHIR to develop a semi-automated adverse event (AE) reporting system from EHRs. The system uses such innovative methods to detect exposures/outcomes of biologics and facilitates validation and reporting of flagged cases to the FDA. Project goals include development of tools, methods and techniques needed to reduce the burden on providers to report AEs accurately and efficiently, which is critical to strengthen the post market active surveillance program of CBER regulated products.</p>	<p><b>Q4:</b></p> <p>Updated IG: <u>v1.0.1</u> to address concerns about nomenclature.</p> <p>Completed two eHealth Exchange Pilot studies. These two studies explored both implementation of standards, and put forward recommendation on scalability</p> <ul style="list-style-type: none"> <li>• AE reports validation (assessed data quality for regulatory purposes).</li> <li>• Semi-automated detection using computable phenotypes developed by the BEST team.</li> </ul>	Complete	Complete	Complete	In Progress	Pending	Pending	Pending

## Goal 2: Data Standards Policy

Projects aligned under Goal 2 provide governance and expertise for the development and revision of data standards policies related to the regulation of human drugs and biologic products. The continued implementation and refining of governance processes ensure proper oversight during the development, publication, and maintenance of guidance documents detailing the use of data standards, terminologies, and exchange formats for regulatory submissions.

Project Title & Description		Project Status		Project Stages						
				REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
<p><b>Post Approval Changes Rulemaking &amp; Submission Standards</b></p> <p>This CBER-CDER project is focused on improving the usability of post approval submissions data.</p>	<p><b>Q4:</b></p> <p>Rulemaking proposal is currently undergoing internal agency review.</p>	Complete	Not Applicable	In Progress	Not Applicable	Not Applicable	Not Applicable	Pending		
<p><b>Study Data Technical Conformance Guide (sdTCG)</b></p>	<p><b>Q4:</b></p> <p>Preparing updates for the October sdTCG.</p>	Ongoing Semi-Annual Publications								

Project Title & Description	Project Status	Project Stages						
		REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
FDA Data Standards Catalog	Q4: Version 10.0 under development.	Ongoing Updates						

### Goal 3: Efficient Information Management

Projects aligned under Goal 3 promote efficient review process because the data submitted is in a predictable and consistent format that can be more easily used by analytic systems.

As outlined in the [CBER-CDER Data Standards Strategy](#) document, technology is critically important and serves as an enabler for reviewers to access and use large amounts of data and information that is received and generated. Several data standards development projects are already underway, as highlighted earlier in this document, to promote access to high-quality, standardized data including the PQ/CMC Standardization and IDMP projects. CDER and CBER also continues to define and enhance ways to better capture information created internally to support continued knowledge management activities. Progress towards the Goal 3 objectives will be highlighted annually in the Data Standards Program Annual Assessment and not tracked quarterly.

### Goal 4: Enhance Transparency and Promote Stakeholder Engagement

Efforts supported under Goal 4 enhance transparency and promote stakeholder engagement in its decision-making regarding adoption of new standards, especially required standards. In addition, these efforts are promoted through the following objectives:

Program Operations	Updates
<b>eCTD Submission Standards</b>	No updates in Q4.
<b>Action Plan</b>	FY2023 Q3 published August 18, 2023.
<b>Annual Assessment</b>	Published February 17, 2023.
<b>Outreach Opportunities, Public Meetings &amp; Educational Activities</b>	FDA Webinars are planned to focus on various data standards topics HL7 Weekly Calls, Work Group Meetings and Connectathon Vulcan FHIR Accelerator, co-leads and/or participants in multiple tracks IDMP/GIDWG & UNICOM TransAtlantic Meetings Monthly FDA/CDISC Technical Meetings ICH M8 Implementation Work Group Meetings PHUSE CSS Clinical Trials Transformation Initiative



## Appendix A: Project Stage Definitions

Stage Name	Stage Description
<b>Requirements</b>	A project with the objective of developing a standard, or utilizing an existing standard for the receipt, processing, review, and archive of data used in regulatory review is considered a data standards project.
<b>Analyze Alternatives</b>	A projects approach to the identification and analysis of alternatives to solve a data standards problem.
<b>Development</b>	The approach to address approved changes to data standards or data standards policy.
<b>Test</b>	A project may be required to test (CDER) study data standards that is adaptable based on the situation. Provides a process to determine if a standard meets the needs of the FDA and should be accepted by the FDA.
<b>Determine Data Standard Adoption (Adoption)</b>	The project is approved and proceeds towards the adoption.
<b>Implement Standard (Implementation)</b>	The advancement to implementing an approved data standard need or change.
<b>Policy</b>	FDA may publish an FRN or guidance, as well as relevant technical specifications or technical conformance guides, as needed.

## Appendix B: Glossary of Acronyms

ADaM	Analysis Data Model
AE	Adverse Events
Catalog	FDA Data Standards Catalog
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDISC	Clinical Data Interchange Standards Consortium
COA	Clinical Outcomes Assessment
eCTD	Electronic Common Technical Document
EHR	Electronic Health Record
FHIR	Fast Healthcare Interoperability Resource
FRN	Federal Register Notice
FY	Fiscal Year
GSRS	Global Substance Registration System
HL7	Health Level Seven
ICH	International Council for Harmonization
ICSR	Individual Case Safety Report
IDMP	Identification of Medicinal Product
IND	Investigational New Drug
ISO	International Organization for Standardization
PDUFA	Prescription Drug User Fee Act
PQ/CMC	Pharmaceutical Quality/ Chemistry, Manufacturing, and Controls
QRS	Questionnaires, Ratings, and Scales
SDTM	Study Data Tabulation Model
SDTMIG	Study Data Tabulation Model Implementation Guide
SEND	Standard for Exchange of Nonclinical Data
SENDIG	Standard for Exchange of Nonclinical Data Implementation Guide
SENDIG-AR	Standard for Exchange of Nonclinical Data Implementation Guide: Animal Rule
SPL	Structured Product Labeling
sdTCG	Study Data Technical Conformance Guide
TAUG	CDISC Therapeutic Area User Guide

TCG	Technical Conformance Guide
UMC	Uppsala Monitoring Centre
UNII	Unique Ingredient Identifier