CBER-CDER Data Standards Program Action Plan

Version: 2.4

FY2026 Q3 update

Document Date: September 17, 2026

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	• FDA Data Standards Catalog added to Goal 2 • IDMP Guidance added to Goal 2 • Technical Specifications and Conformance Guide Updates removed from Goal 4 • Appendix B updated
1.2	August 14, 2023	• IDMP Guidance removed from Goal 2
1.3	November 9, 2023	• Quarterly Project Updates
1.4	February 15, 2024	• Added 356H Modernization Project under Goal 1 Objective 1 • Removed Submission Data Standards Assessment Project from Goal 1 Objective 1 • Added Publication of Final Guidance for Industry “Data Standards for Drug and Biological Product Submissions Containing Real-World Data” Project under Goal 2 • Added “Dataset JSON” as its own project under Goal 1 Objective 1
1.5	May 8, 2024	• Added Common Data Model Harmonization (CDMH) under Goal 1 Objective 1

Version Number	Revision Date	Description of Change
		• Removed Source Data Captures from EHRs: Using Standardized Clinical Research Data from Goal 1 Objective 1 • Removed Publication of Final Guidance for Industry "Data Standards for Drug and Biological Product Submissions Containing Real-World Data" from Goal 2
1.6	August 9, 2024	• Removed Grant: Investigating Support for 21 CFR 11 Compliance Using HL7 FHIR from Goal 1 Objective 1
1.7	November 20, 2024	• Quarterly Project Updates
1.8	March 2025	• Quarterly Project Updates • Removed FDA Adverse Event Reporting System (FAERS) II Project • Removed eCTD v4.0 Project – Phase 1

1.9	August 2025	• Quarterly Project Updates
		• Reporting paused for the following projects:
		  ○ Study Data Standards Testing and Evaluation
		  ○ Post Approval Changes Rulemaking & Submission Standards

2.0	September 2025	• Quarterly Project Updates
2.1	December 2025	• Quarterly Project Updates • Removed the Pharmaceutical Quality/Chemistry, Manufacturing, and Controls Data Standardization Project
2.2	March 2026	• Quarterly Project Updates

Version Number	Revision Date	Description of Change
		• Removed the Assessing Applicable Data Standards for Use in Submission of Real-World Data to FDA Project • Removed the SPL FHIR Project • Removed the 356H Modernization Project
2.3	June 2026	• Quarterly Project Updates
2.4	September 2026	• Quarterly Project Updates • Removed Post Approval Changes Rulemaking & Submission Standards Project

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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 Coordination (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	REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
Common Data Model Harmonization (CDMH) This project aims to build a data infrastructure for conducting patient-centered outcomes research using Real-World Data (RWD) derived from the delivery of health care in routine clinical settings. This project started in 2017, is currently in Phase III (2023-2026) and is a multi-HHS agency initiative, funded by HHS/Assistant Secretary for Planning and Evaluation (ASPE) Patient-Centered Outcomes Trust Fund (PCORTF).	**Q3:** Continued to review and validate mappings from 16 HL7 Fast Healthcare Interoperability Resources (FHIR) US Core profiles to Clinical Data Interchange Consortium (CDISC) Study Data Tabulation Model (SDTM) standard. Continued to analyze de-identified Electronic Health Record (EHR) data from Nebraska Health Information Exchange. The final report for the project is under review by HHS/ASPE.	Complete	Complete	Complete	Complete	Complete	Complete	Pending

Project Title & Description	Project Status	REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
Dataset-JSON Exchange Format This CBER-CDER project is a continuation of the collaboration with PHUSE and CDISC to test the use of CDISC Dataset-JSON as a potential replacement for XPT v5.	**Q3:** No updates in Q3.	Complete	Complete	In Progress	In Progress	Pending	Pending	Pending
eCTD v4.0 Project – Phase 2 (Forward Compatibility) This CBER-CDER project is focused on the development, testing, adoption, and implementation of Forward Compatibility (FC). FC enables any dossier that started in eCTD v3.2.2 to transition to eCTD v4.0.	**Q3:** Development completed and User Acceptance Testing initiated. FDA is working with the eCTD vendor to check functionality and resolve any potential issues. Technical pilot with industry is in progress and FDA is scheduled to have support for FC in production, in Fall 2026.	Not Applicable	Not Applicable	Complete	In Progress	Pending	Pending	Pending

Project Title & Description	Project Status	REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
IDMP Project The International Organization for Standardization (ISO) Identification of Medicinal Products (IDMP) standards aim to harmonize specifications for the identification and exchange of medicinal product data between regulatory agencies, pharmaceutical companies, and manufacturers. This project has multiple use cases focused on the adoption of ISO 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. 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). Additionally, the Global IDMP Working Group (GIDWG) has been engaged with ISO and other regulators to ensure the standards are fit for global implementation.	**Q3:** IPRP (International Pharmaceutical Regulators Programme) — IPRP/IDMP SMEs are preparing FAQ Version 8.0 document intended to support implementation of the ISO IDMP standards. IDMP/PhPID concepts were adopted within the FDA Substance Registration System as part of the FDA's Unique Ingredient Identifier (UNII) framework. Recent IDMP meetings selected priority of IDMP use cases globally including 1) Global IDMP implementation best practices led by the International Federation of Pharmaceutical Manufacturers & Association (IFPMA), 2) IDMP implementation leveraging IFPMA IDMP ontology, including promotion of IDMP ontology training, 3) introducing automated packaging and production from NOMA (Norwegian Medicines Agency), and 4) Improving Global Pediatric safety monitoring through CTADHL (Citadel, a non-profit organization). European Directorate for the Quality of Medicine and Healthcare (EDQM) standards are recognized as equivalent to ISO standards 11239 and are applied in the FDA AEMS. IDMP working group is developing an IDMP implementation guide and best practices use cases to support global IDMP implementation.	Complete	Not Applicable	Complete	In Progress	Pending	Not Applicable	Not Applicable

Project Title & Description	Project Status	Project Stages
Questionnaires, Ratings and Scales (QRS) Assessment This CDER project is focused on evaluations of proposed standardized data structures (supplements) that capture the information from Questionnaires, Ratings, and Scales (instruments) administered to subjects during a clinical study and prioritize the instruments indicated in the Clinical Outcomes Assessment (COA) area.	**Q3:** Six (6) tests initiated for supplements covering these instruments: - Modified Alcohol Use Disorders Identification Test-Consumption: Self-Report Version 2001 (MODIFIED AUDIT-C: Self-Report Version 2001) – SDS - Modified Alcohol Use Disorders Identification Test-Consumption: Interview Version 2001 (MODIFIED AUDIT-C: Interview Version 2001) – SDS - ADaM Modified Alcohol Use Disorders Identification Test-Consumption (MODIFIED AUDIT-C) - ADaM PTSD Checklist for DSM-5 (PCL-5) - ADaM Patient Health Questionnaire - 9 (PHQ-9) - ADaM Work Productivity and Activity Impairment Questionnaire - Specific Health Problem (WPAI-SHP v2.0) One (1) test completed for the supplement covering this instrument: - ADaM PTSD Checklist for DSM-5 (PCL-5)	**Not Applicable**

Project Title & Description	Project Status	Project Stages
Study Data Standards Testing and Evaluation This CBER-CDER project tests new and updated study data standards and standards adjacent properties to establish FDA support and requirements.	**Q3:** CDISC provided feedback to FDA regarding March 2026 sdTCG.	**Not Applicable**

OBJECTIVE 2: Improve Pre and Postmarket Safety Surveillance Data

Project Title & Description	Project Status	REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
Biologics Effectiveness and Safety (BEST) Innovative Methods (IM) Leverages Artificial Intelligence, Machine Learning, FHIR standards, and Substitute Medical Applications, Reusable Technologies (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.	**Q3:** Completed validation of post-CAR-T hypogammaglobulinemia computation phenotype. Initiated development of post-blood product transfusion anaphylaxis computational phenotype with use of a large language model for feature extraction. Engaged with six Health Information Exchanges (HIEs) for participation in post blood product transfusion anaphylaxis phenotype development with two HIEs opting to participate in the project. One of the aims of the surveillance project is to evaluate data connection to collect adequate EHR data, through HIEs/ HDUs. Three HIEs have tentatively opted in to this study.	Complete	Complete	Complete	Complete	Complete	In Progress	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 biological 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
FDA Data Standards Catalog	**Q3:** No updates in Q3.	**Ongoing Updates**
Study Data Technical Conformance Guide (sdTCG)	**Q3:** Published a corrected version of the sdTCG v.6.2.1 (March Edition).	**Ongoing Semi-Annual Publications**

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 continue 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 activities:

Program Operations	Updates
Action Plan	FY2026 Q2 Action Plan published June 29, 2026.
Annual Assessment	2025 Annual Assessment published on June 30, 2026.
eCTD Submission Standards	No updates in Q3.
Outreach Opportunities, Public Meetings & Educational Activities	FDA Webinars are planned to focus on various data standards topics. FDA participated in the Small Business and Industry Assistance (SBIA) Regulatory Education for Industry (REDI) forum in May to communicate updates related to eCTD, CDER NextGen Portal, and its Prescription Drug User Fee Act (PDUFA) VII demonstration project for IR modernization.

Appendix A: Project Stage Definitions

Stage Name	Stage Description
Requirements	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.
Analyze Alternatives	A project's approach to the identification and analysis of alternatives to solve a data standards problem.
Development	The approach to address approved changes to data standards or data standards policy.
Test	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.
Determine Data Standard Adoption (Adoption)	The project is approved and proceeds towards the adoption.
Implement Standard (Implementation)	The advancement to implementing an approved data standard need or change.
Policy	FDA may publish an FRN or guidance, as well as relevant technical specifications or technical conformance guides, as needed.

Appendix B: Glossary of Acronyms

Acronym	Definition
ADaM	Analysis Data Model
AE	Adverse Events
AEMS	Adverse Event Monitoring System
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 Application
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

Acronym	Definition
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