CBER-CDER Data Standards Program Action Plan

Version: 2.0

FY2025 Q3 update

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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

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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
Assessing Applicable Data Standards for Use in Submission of Real-World Data to FDA FDA is examining how to optimize data standards for Real-World Data (RWD) that is submitted as study data in applicable FDA submissions. This effort will help develop a roadmap to facilitate the development of such data standards.	**Q3:** Preparing the final report, including gap analysis and specific enhancements. The multi-year project will complete at the end of the FY25 Period of Performance (POP) and will not continue in FY26.	In Progress	In Progress	Pending	Pending	Pending	Pending	Pending

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 (2023-2025) and is a multi-HHS agency initiative, funded by HHS/Assistant Secretary for Planning and Evaluation (ASPE) Patient-Centered Outcomes Trust Fund (PCORTF).	**Q3:** Developed the protocol for the cancer use case in collaboration with the oncologists at CDER/OND. Developed a Fast Healthcare Interoperability Resources (FHIR)-based query for the CDER clinical question. Provided the clinical question conforming to the FHIR standard to 2 large academic medical centers, participating in this project, who ran the clinical query on their clinical data repository and provided the results conforming to the HL7 FHIR standard in HL7 FHIR format. Validated the HL7 FHIR model, that will be registered by NCI team. Validated the CDISC SDTM model, that will be registered by the NCI team in caDSR.	Complete	Complete	In Progress	In Progress	Pending	Pending	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:** We note that although Dataset-JSON is a new standard, it has undergone more testing than other CDISC standards via internal testing, hackathons, the PHUSE–CDISC–FDA pilot, and software vendor implementations. As a next step to the pilot, FDA will deliberate whether another round of testing via the industry should be pursued to confirm previous issues and those identified below have been addressed and identify any new issues to allow more companies to get involved.	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:** Continued testing eCTD software suite updates to support FC and working with eCTD vendor to resolve issues in the next version release scheduled for FY26Q1.	Not Applicable	Not Applicable	In Progress	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 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. 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:** We continued our collaboration with the European Medicines Agency (EMA) and the Uppsala Monitoring Centre (UMC) through the Global IDMP Working Group (GIDWG) to advance a harmonized global ISO IDMP implementation framework. Phase 2 of GIDWG's end-to-end testing has been successfully completed. This comprehensive test framework encompasses business rules, best practices, software solutions, and an operational model designed to support the global implementation and maintenance of ISO IDMP standards. The framework utilizes several well-known individual drug products as examples to demonstrate the practical application of global identifiers for marketed pharmaceuticals. A complete end-to-end demonstration of the Global IDMP framework has been published, showcasing its effectiveness. Additionally, the end-to-end testing report for the Pharmaceutical Product Identifier (PhPID) has been released. The finalized version 2.0 of the business rules for global PhPID was completed on May 1, 2025.	Complete	Not Applicable	Complete	In Progress	Pending	Not Applicable	Not Applicable

Project Title & Description	Project Status	REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
Pharmaceutical Quality/ Chemistry, Manufacturing, and Controls Data Standardization 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.	**Q3:** This project has been canceled.	Complete	Complete	Pending	Pending	Pending	Pending	Pending

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:** One (1) test initiated for supplements covering these instruments: - Rising From Floor v1.0 One (1) test continuing from Q2 for supplements covering these instruments: - Richmond Agitation-Sedation Scale (RASS) v1.0 - SDS Four (4) tests completed for the supplement covering this instrument: - Acute Physiology and Chronic Health Evaluation II (APACHE-II) v1.0 – ADaM - Hamilton Depression Rating Scale 17 (HAMD-17) v1.0 – ADaM - Richmond Agitation-Sedation Scale (RASS) v1.0 - SDS - Rising From Floor v1.0	**Not Applicable**

Project Title & Description	Project Status	REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
SPL FHIR FDA is working towards replacing Structured Product Labeling (SPL) with HL7 FHIR. The FDA has created a proof-of-concept system that can receive labeling information using either SPL or FHIR standard (Dual Submission) in addition to a draft Implementation Guide (IG).	**Q3:** The FY25 POP has been successfully completed and the final report delivered. The FY26 award is pending efficiency review.	Complete	Complete	Complete	Complete	Pending	Pending	Pending

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:** **Ongoing Tests:** - CDISC SENDIG v4.0 - CDISC SDTMIG v4.0 - CDISC SDTM v3.0 - CDISC ADaM v3.0 - AEDNCA PK Data - Business Rules for SEND - CDISC Medical Device Domain Pilot - CDISC ADaMIG for NCA Input Data v1.0 **Initiated Tests:** - CDISC HL7-FHIR FRN - CDISC ADaM ADA IG v1.0 - Remove non-useful validation rules from FDA.gov **Completed Tests:** - ADNCA PK Data - CDISC Medical Device Domain Pilot - CDISC SENDIG v4.0 (Internal CDISC Development stage, feedback sent) - CDISC ADaMIG for NCA Input Data v1.0 (Review final comment delta)	**Not Applicable**

Project Title & Description	Project Status	REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
356H Modernization This project will be assessing feasibility and working towards development of a machine-readable approach for receiving the data requested in Form FDA 356h.	**Q3:** No updates in Q3.	In Progress	Pending	Pending	Pending	Pending	Pending	Pending

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 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:** The BEST platform has been deployed On-Prem (in the HVIE environment) to facilitate FDA SMEs access to the BEST IM Platform and started the authorization to operate (ATO) process. -Continued development and enhancement of the BEST platform. -Continued adverse event phenotype studies in BEST platform production. -Collaborated with 2 large academic medical centers and eHealth Exchange to pull FHIR resources for computable phenotypes. -Performed validation of large language model-enhanced computable phenotype algorithms employing FHIR resources for myocarditis and pericarditis.	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**

Project Title & Description	Project Status	REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
Post Approval Changes Rulemaking & Submission Standards This CBER-CDER project is focused on improving the usability of post approval submissions data.	**Q3:** The rulemaking proposal is listed in the Spring 2025 Unified Agenda of Regulatory and Deregulatory Actions with an action date of 05/00/2026 for a Notice of Proposed Rulemaking.	Complete	Not Applicable	In Progress	Not Applicable	Not Applicable	Not Applicable	Pending

Project Title & Description	Project Status	Project Stages
Study Data Technical Conformance Guide (sdTCG)	**Q3:** No updates in Q3.	**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 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 activities:

Program Operations	Updates
Action Plan	FY2025 Q1 published March 27, 2025.
Annual Assessment	2024 Annual Assessment publication is on hold.
eCTD Submission Standards	No updates.
Outreach Opportunities, Public Meetings & Educational Activities	FDA Webinars are planned to focus on various data standards topics.

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
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
SPL	Structured Product Labeling

Acronym	Definition
sdTCG	Study Data Technical Conformance Guide
TAUG	CDISC Therapeutic Area User Guide
TCG	Technical Conformance Guide
UMC	Uppsala Monitoring Centre
UNII	Unique Ingredient Identifier