CBER-CDER Data Standards Program Action Plan

Version: 1.0

Document Date: March 1st, 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

Table of Contents

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.

1 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.

2 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 (i.e., the February 2023 report highlights work from October to December 2022). Previous Data Standard Action Plans may be found on the Data Standards Program Strategic Plan and Board webpage.

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
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.	**Q1:** CDISC SDTMIG v3.4 CDISC ADaM Examples of Traceability v1.0 CDISC Lab Units Representation Document CDISC ADaM v2.1 Review CDISC ADaM PopPK IG v1.0 CDISC RECIST v1.1 CDISC SENDIG-Genotoxicity v1.0 CDISC SEND Tumor Combinations PHUSE nSDRG - all versions CDISC SDTMIG v3.4 Decision Tree	**Not Applicable**						

Project Title & Description	Project Status	Project Stages						
		REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
Questionnaires, Ratings and Scales (QRS) Assessment This CDER project focus is on evaluations of standard 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.	**Q1:** CDISC PASI Feldman v1.0 QRS Instrument CDISC PASI Fredriksson v1.0 QRS Instrument PRO-CTCAE v1.0 QRS Instrument Logically Skipped vs Conditional Branching	**Not Applicable**						
eCTD v4.0 Project This CBER-CDER project focus is the development, testing, adoption, and implementation of the next major version of the electronic Common Technical Document (eCTD), version 4, which includes two-way communication. 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.	**Q1:** eCTD v4.0 Technical Pilot, test Lorenz Software, update regional specifications as needed (IG, CV, Validations, CTOC, TCG)	**Not Applicable**	**Not Applicable**	**Not Applicable**	**In Progress**	**In Progress**	**In Progress**	**Pending**

Project Title & Description	Project Status	Project Stages						
		REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
Submission Data Standards Assessment Establish a catalog of all data areas and associated regulatory submission standards in eCTD modules. Identify and prioritize opportunities for further standardization.	**Q1:** Finalized project activities plan. Completed preliminary information gathering. Refining questionnaires in preparation for CDER and CBER stakeholder interviews and surveys.	Complete	Not Applicable	In Progress	Not Applicable	Not Applicable	Pending	Not Applicable
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.	**Q1:** Continued development of Phase 2 domains: Manufacturing of Drug Products and Substances.	Complete	Complete	In Progress	Pending	Pending	Pending	Pending

Project Title & Description	Project Status	Project Stages						
		REQT	ALT	DEV	TEST	ADOPT	IMPL	POLICY
IDMP Project 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).	**Q1:** Continue working with EMA and WHO-UMC to conduct pilot projects to establish a framework from harmonized global implementation of ISO IDMP standards.	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
Assessing Applicable Data Standards for Use in Submission of Real-World Data to FDA 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.	**Q1:** Continued assessment of data requirements to support submission of study data derived from real world data sources.	In Progress	In Progress	Pending	Pending	Pending	Pending	Pending
Source Data Capture from EHRs: Using Standardized Clinical Research Data 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.	**Q1:** Continued development.	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
SPL FHIR 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.	**Q1:** Buildout of FHIR Implementation Guide to include early support for human prescription drug labelling.	Complete	Complete	In Progress	In Progress	Pending	Pending	Pending
Grant: Investigating Support for 21 CFR 11 Compliance Using HL7 FHIR 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).	**Q1:** Grantee planning further engagement with HL7 workgroups.	**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
FDA Adverse Event Reporting System (FAERS) II CDER and CBER project is receipt and processing of Investigational New Drug (IND) and post-market safety reports submission using E2B R3 standards.	**Q1:** Continued IT development for implementation.	Complete	Complete	Complete	Complete	Complete	In Progress	In Progress
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.	**Q1:** • Monitoring Biologically Derived Product Data Class for inclusion in USCDI v4 • eHealth Exchange Pilot launched in December 2021 is ongoing and expected to reach 11-16 participants by April 2023 • Prepared OMOP on FHIR for BEST population needs [Link]	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
Post Approval Changes Rulemaking & Submission Standards This CBER-CDER project is focused on improving the usability of post approval submissions data.	**Q1:** Rulemaking proposal is currently undergoing internal agency review	Complete	Not Applicable	In Progress	Not Applicable	Not Applicable	Not Applicable	Pending
Study Data Technical Conformance Guide (sdTCG)	**Q1:** Updates throughout to align with existing guidance documents.	**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 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
eCTD Submission Standards	eCTD v4.0 Validation Specifications v1.2 posted October 2022 eCTD v3.2.2 Technical Conformance Guide v4.7 posted November 2022
Technical Specifications and Conformance Guide Updates	Study Data Technical Conformance Guide (sdTCG) v5.0 posted October 2022
Action Plan	Q4 FY22 was published October 17, 2022
Annual Assessment	The next publication is scheduled for Q2 of FY23

Program Operations	Updates
Outreach Opportunities, Public Meetings & Educational Activities	FDA Webinars are planned to focus on various data standards topics HL7 Work Group Meetings and Connectathons IDMP/GIDWG Meetings CDISC Interchanges

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 projects 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

ADaM	Analysis Data Model
AE	Adverse Events
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
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
TAUG	CDISC Therapeutic Area User Guide
TCG	Study Data Technical Conformance Guide
UMC	Uppsala Monitoring Centre
UNII	Unique Ingredient Identifier