Data Standards Program Action Plan

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REVISION HISTORY

Version Number	Revision Date	Description of Change
1.0	February 21, 2013	Initial Document
1.1	July 29, 2013	Quarterly Update
1.2	October 23, 2013	Quarterly Update
1.3	February 5, 2014	Quarterly Update
1.4	May 30, 2014	Quarterly Update
1.5	October 2, 2014	Quarterly Update
1.6	January 21, 2015	Quarterly Update
1.7	April 8, 2015	Quarterly Update
1.8	July 8, 2015	Quarterly Update
2.0	October 14, 2015	Update to reflect Data Standards Strategy v2.0 and quarterly project update
2.1	February 3, 2016	Quarterly Update
2.2	May 25, 2016	Quarterly Update
2.3	August 31, 2016	Quarterly Update
2.4	November 18, 2016	Quarterly Update
2.5	March 15, 2017	Quarterly Update
2.6	June 29, 2017	Quarterly Update
2.7	December 26, 2017	Quarterly Update
3.0	February 28, 2018	Update to reflect Data Standards Strategy FY2018-2022 and quarterly project update
3.1	April 30, 2018	Quarterly Update Identification of Medicinal Product (IDMP) Project description was updated to reflect the use cases for the adoption of the IDMP standards (e.g., quality and safety of medicinal products).
3.2	July 18, 2018	Quarterly Update
3.3	October 25, 2018	Quarterly Update
3.4	January 18, 2019	Quarterly Update
3.5	April 17, 2019	Quarterly Update
3.6	July 31, 2019	Quarterly Update
3.7	November 6, 2019	Quarterly Update
4.0	February 12, 2020	Project stages updated as applicable to each project Appendix A: Updated to reflect internal project stages Quarterly Update
4.1	April 22, 2020	Quarterly Update
4.2	July 29, 2020	Quarterly Update
4.3	October 21, 2020	Quarterly Update
5.0	January 29, 2021	Quarterly Update

5.1	May 25, 2021	Quarterly Update
5.2	August 27, 2021	Quarterly Update
5.3	October 26, 2021	Quarterly Update
5.4	February 9, 2022	Quarterly Update

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1 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, and are resourced and funded, and have a scope that is primarily standards related.

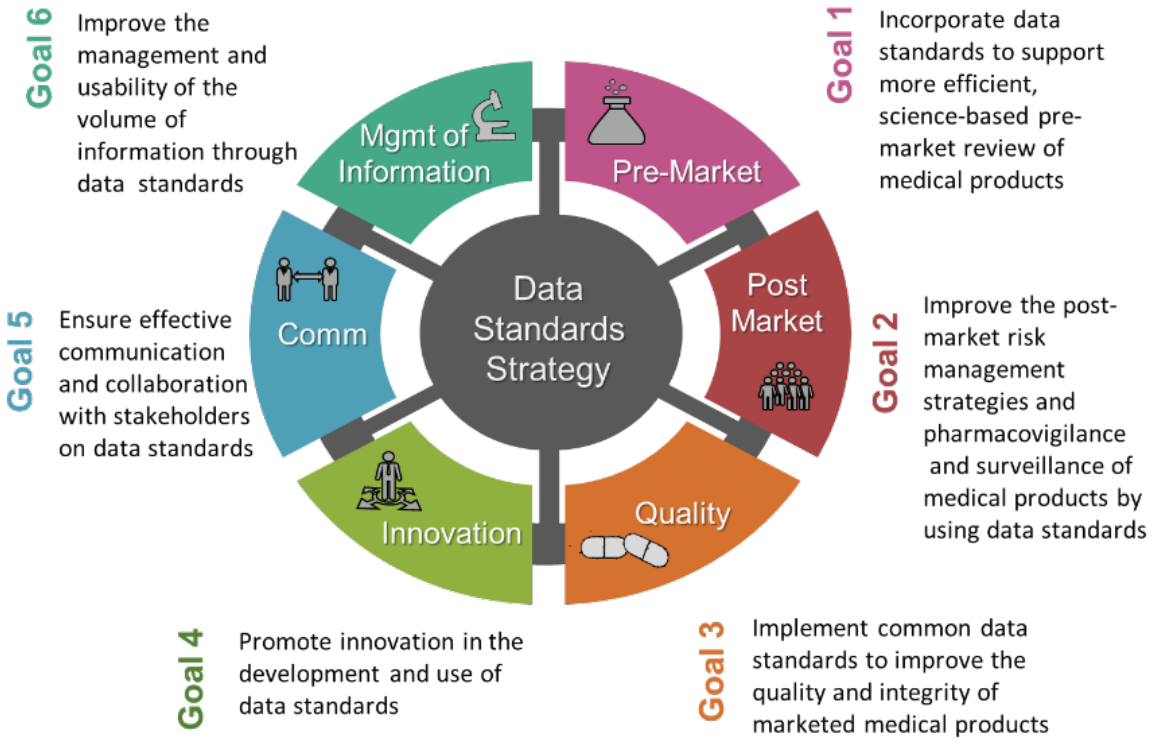
2 Purpose

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.

3 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. Projects in this section are organized by the goals outlined in the CBER-CDER Data Standards Strategy and shown below in **Figure 1.**

Figure 1. Data Standards Strategy Goals



For each project in this section, a project title, description, update, and project stage are provided. The project update reflects work done in the previous quarter (i.e., the February 2018 report highlights work from October to December 2017). 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. Completed or planned stages are shown in gray, stage(s) in progress are in green and have an asterisk, and stage(s) that do not apply to a project are marked with diagonal stripes. The definitions of the project stage are defined in **Appendix A**.

Goal 1: Incorporate Data Standards to Support More Efficient, Science-Based Pre-Market Review of Medical Products

Projects under Goal 1 generally address pre-market and submission standards. These include collaboration with stakeholders and Standards Development Organizations (SDO), and testing standards to be used for submission, content, and storage. Projects that highlight participation in initiatives focused on the harmonization of healthcare and clinical research data standards are highlighted here and further addressed in Goal 4.

Table 1. Pre-Market Projects

Project Title and Description	Project Status	Project Stage
Study Data Standards Testing This CBER-CDER project tests new and updated study data standards and standards adjacent properties to establish FDA support.	Q1: Evaluating the following for inclusion into the Data Standards Catalog • ADaMIGv1.3 and OCCDSv1.1 • SDTMIG v3.4	**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.	Q1: FDA received an eCTD v4.0 vendor software update and will begin testing in FY22 Q2. ICH M8 posted an updated eCTD v4.0 Q&A document.	Req Definition | Alt Analysis | Development | Testing | Adoption* | Implementation | Policy

Project Title and Description	Project Status	Project Stage
E2B IND Safety Report This CDER and CBER pilot project is testing the receipt and processing of Investigational New Drug (IND) safety reports submission using E2B standards.	Q1: Pilot project has concluded, and Technical Spec also published. This project has ended, all new developments are merged into the FAERS II program.	Req Definition | Alt Analysis | Development | Testing | Adoption | Implementation* | Policy*
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: Demonstration of current iteration of development.	**Not Applicable**
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: FDA is aligning the work being done in the QRS space to better support the work being done in the COA space. We are doing a needs assessment and gap analysis to determine the most efficient path forward.	**Not Applicable**

Project Title and Description	Project Status	Project Stage
Transferring Harmonized Laboratory Data from Healthcare Institutions to Registries Using FHIR Protocol Develop and pilot test lab data exchange from EHRs to registries using FHIR. Share FHIR Implementation Guide, lessons, recommendations. Help advance lab data interoperability, the aims of SHIELD, and ultimately improve registry capabilities for disease surveillance, quality assessment, and research.	Q1: Assessed requirements and readiness with user-centered design. Developing draft FHIR Implementation Guide. Developing app client software to extract relevant lab data via FHIR. Initial pilot test lab exchange: synthetic data via "simulated EHR" to registry.	**Not Applicable**
Evaluation of Modernization of Submission File Transport The project focus is to evaluate the technical capability to enable the enhanced capability for electronic transport of regulatory submissions. Exploring the IT infrastructure impact of transitioning from SAS Transport V5 to SAS V8 or other potential interim systems.	Q1: Completed requirements gatherings and exploring Standards Alternatives (JSON, SAS V8, XML, CSV) in context of FDA requirements.	

Goal 2: Improve the postmarket risk management strategies and pharmacovigilance & surveillance of medical products by using data standards

Projects for Goal 2 address standards identification and use in FDA's mission to protect public health through medical product safety and postmarketing surveillance. Projects that highlight the communication of essential risk evaluation and mitigation strategies and standards for electronic transmission of individual case safety reports with external stakeholders are highlighted here.

Table 2. Postmarket Projects

Project Title and Description	Project Update	Project Stage						
		Req Definition	Alt Analysis	Development*	Testing	Adoption	Implementation	Policy
Grant Project: 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 has developed early draft implementation guide as a proposed approach to representing audit trail events in FHIR data. Grantee continuing work with relevant HL7 FHIR workgroups to determine if work is sufficient to engage as an HL7 project.			■				
Biologics Effectiveness and Safety (BEST) Innovative Methods (IM) Leverages Artificial Intelligence (AI), Machine Learning (ML), FHIR standards and SMART-on-FHIR to develop a semi-automated adverse event 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 adverse events (AEs) accurately and efficiently, which is critical to strengthen the postmarket active surveillance program of CBER-regulated products.	Q1: FHIR IG is officially published as STU 1 Ballot (https://build.fhir.org/ig/HL7/fhir-icsr-ae-reporting/branches/main/index.html).				■			

Goal 3: Implement common data standards to improve the quality and integrity of marketed medical products

Projects for Goal 3 address medical product quality and identification of contamination and other production failures with common data standards. Projects that highlight the development and implementation of data standards that describe manufacturing and testing of medical products, International Standards Organization (ISO) standards implementation, and complete essential facility and manufacturing information through submission requirements are highlighted here.

Table 3. Quality Projects

Project Title and Description	Project Update	Project Stage						
		Req Definition	Alt Analysis	Development*	Testing*	Adoption	Implementation	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.	Q1: Began data standards development for Phase 2 data domains. Developing a public facing PQ/CMC webpage to provide an overview of all current project activities.							
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: Continued pursuing global harmonization in IDMP implementation via EU/FDA collaboration, ISO, and EU UNICOM project, and newly established Global IDMP Working Group (GIDWG) with EMA and WHO-UMC. • Dose form documents, ISO 11239 and TS 20440, have been revised and are being balloted. • Conducted two meetings of the GIDWG and established resources to work on 5 pilots in 2022. • Conducted a public webinar on the GIDWG activities for stakeholders							

Project Title and Description	Project Update	Project Stage
Post Approval Changes Rulemaking & Submission Standards This CBER-CDER project is focused on improving the usability of post approval submissions data.	Q1: The project is in the proposed rule stage and is undergoing internal agency review.	Req Definition* / Alt Analysis / Development / Testing / Adoption / Implementation / Policy

Goal 4: Promote innovation in the development and use of data standards

Projects for Goal 4 address research and development in pursuit of innovation to keep pace with advances in medical science and regulatory review. Projects that highlight implementation of new data standards, encourage the use of electronic health records to support clinical trials, and evaluation of the feasibility of representing real world data in an electronic standardized format are highlighted here.

Table 4. Innovation Projects

Project Title and Description	Project Update	Project Stage
Common Data Model Harmonization Project: Phase II This CDER project is focused on leveraging nearly all aspects of the previous phase of work to expand the utility of a real-world evidence research tool which, in addition to support queries across four distinct Common Data Models (FDA's Sentinel Program, the Observational Health Data Sciences and Informatics program, the National Patient-Centered Clinical Research Network, and the Accrual of Patients to Clinical Trials network), will support querying HL7 FHIR-compliant data sets, making it useable in a wide variety of research settings. For the phase of work, FDA is coordinating with its partner the National Institutes of Health National Center for Advancing Translational Sciences.	Q1: FDA development work on CDMH phase 2 architecture has finished. NIH/NCATS development work is sill ongoing in collaboration with FDA. FDA is finalizing work with data partners to execute queries with phase 2 implementation.	Req Definition; **Alt Analysis***; Development; Testing; Adoption; Implementation; 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: Evaluation of existing submissions for examples of RWD questions to determine (via multiple iterations of assessment and analyses) core RWD needs in FDA submissions.	Req Definition; **Alt Analysis***; Development; Testing; Adoption; Implementation; Policy

Project Title and Description	Project Update	Project Stage
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: Early draft FHIR implementation guide and internal proof of concept developed.	Req Definition | **Alt Analysis*** | Development | Testing | Adoption | Implementation | Policy

Goal 5: Ensure effective communication and collaboration with stakeholders on data standards

Program operations for Goal 5 execute CBER and CDER's communication and collaboration with internal and external stakeholders for the successful development, implementation, and use of data standards to support regulatory review of medical products. Document updates that report progress towards meeting FDA goals are highlighted here.

Table 5. Communication Efforts

Program Operations	Updates
Webpage Updates	The following webpages were updated with documents referenced below: • CDER Data Standards Program • Electronic Common Technical Document (eCTD) • Study Data Standards Resources • Study Data for Submission to CDER and CBER • eCTD v4 • Electronic Submission Presentations
Federal Register Notices (FRNs)	The below FRNs were published FY2022 (Q1): • No Data Standards related FRNs were published during FY2022 Q1.
eCTD Submission Standards	FY2022 (Q1) October 2021: • File Format Specifications, v7.0 • eCTD Technical Conformance Guide v1.6
Technical Specifications and Conformance Guide Updates	• The Study Data Technical Conformance Guide (sdTCG) v4.7 was published in April 2021, v4.7.1 was published in June 2021, v4.7.2 was published in August 2021, v4.8 was published in September 2021, and v4.8.1 was published in October 2021. • Submitting Nonclinical Datasets for Evaluation of Rodent Carcinogenicity Studies of Pharmaceuticals, Guidance for Industry, Technical Specifications Document v.1.0 (May 2021). • FDA Data Standards Catalog updated to reflect content in sdTCG and updates to the eStudy Data Guidance, September 2021.

Program Operations	Updates
Action Plan	The Data Standards Action Plan v5.3 was published October 28, 2021.
Outreach Opportunities, Public Meetings & Educational Activities	FY2022 (Q1) FDA Webinars are planned to focus on various data standards topics October 2021: • Annual Pharmaceutical Regulatory Operations & Submissions Conference: eCTD Guidance and Specifications Updates Nov 2021: • CDISC SEND F2F Conference: Study Data Technical Rejection Criteria • AAM GRx+Biosims Conference: FDA Technical Rejection Criteria for Study Data • R/Pharma Conference: Submitting Data to CDER: Requirements for your Application

Goal 6: Improve the management and usability of the volume of information through data standards

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 also continues to define and enhance ways to better capture information created internally to support continued knowledge management activities. Progress towards the Goal 6 objectives will be highlighted annually in the Data Standards Program Annual Assessment and not tracked quarterly.

Appendix A. Project Stage and Description

Table 6. Standard Development Project Stages

Stage Name	Stage Description
Define Scope and Requirement (Req Definition)	A plan is developed that can include a description of the data standard need, impact on tools, processes, and information technology infrastructure, high-level concept of operations, future state benefits, and high level requirements. For study data-related projects, FDA subject matter experts and document resources (e.g., case report forms, guidance documents) are used to develop requirements for study data standards development.
Analyze Alternatives (Alt Analysis)	If needed, FDA can conduct alternative analyses to assess options and recommendations for addressing the data standards need defined in the business case. Stakeholder input is a critical part of this effort and could include a request for public comment or input in addition to planned communications.
Development	The FDA subject matter experts conduct an iterative process of data element identification (e.g., elements needed to describe the study primary endpoint), definition, and validation, and conduct a review with defined expert groups.
Test Standards (Testing)	A project may be required to test that all identified factors are assessed (e.g., scale, impact, suitability for FDA regulatory review needs, compatibility with FDA infrastructure) and that all policy, regulatory, guidance, and technical specification needs are identified.
Determine Data Standard Adoption (Adoption)	If needed, policy, regulatory, guidance, and technical specification needs that were identified for a given data standards change are addressed to support implementation.
Implement Standard (Implementation)	The data standard change is being implemented into the FDA environment. This phase includes all the steps to make this part of the regulatory review process. Implementation is considered complete when data can be successfully processed, reviewed, and archived utilizing the new standard.
Policy	FDA may publish an FRN or guidance, as well as post relevant technical specifications or technical conformance guides, as needed.

Appendix B: Project to Goals/Objectives Mapping

The following table maps the projects listed in the tables above to the objectives outlined for each goal in the CBER-CDER Data Standards Strategy. Some projects may align to more than one goal and objective.

Table 7. Project Mapping

			PROJECT STATUS						
Projects			**Req Definition**	**Alt Analysis***	**Development**	**Testing**	**Adoption**	**Implementation**	**Policy**
	GOAL								
Study Data Standards Testing	1								
eCTD v4.0 Project	1							X	X
Source Data Capture from EHRs: Using Standardized Clinical Research Data	1								
E2B IND Safety Report	1							X	X
Questionnaires, Ratings and Scales Assessment	1								
Transferring Harmonized Laboratory Data from Healthcare Institutions to Registries Using FHIR Protocol	1								
Evaluation of Modernization of Submission File Transport	1								
Grant Project: Investigating Support for 21 CFR 11 Compliance Using HL7 FHIR	2				X				
Biologics Effectiveness and Safety (BEST) Innovative Methods (IM)	2					X			
Pharmaceutical Quality (PQ)/, Chemistry, Manufacturing, and Controls (CMC) Data Standardization	3				X	X			
IDMP Project	3				X	X			
Post Approval Changes Rulemaking & Submission Standards	3		X						

Common Data Model Harmonization Project: Phase II	4			X					
Assessing Applicable Data Standards for Use in Submission of Real World Data to FDA	4			X					
SPL FHIR	4			X					

Appendix C: Glossary of Acronyms

ADaM	Analysis Data Model
AI	Artificial Intelligence
API	Applied Program Interfaces
BR&R	HL7 Biomedical Research and Regulation Group
BRIDG	Biomedical Research Integrated Domain Group
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDISC	Clinical Data Interchange Standards Consortium
COA	Clinical Outcomes Assessment
DF	Dosage Form
eCTD	Electronic Common Technical Document
EDC	Electronic Data Capture
EDQM	European Directorate for Quality Medicines
EHR	Electronic Health Record
FHIR	Fast Healthcare Interoperability Resources
FRN	Federal Register Notices
FY	Fiscal Year
GSRS	Global Substance Registration System
HCT/P	Human Cells, Tissues and Cellular and Tissue-Based Products
HL7	Health Level Seven
ICH	International Council for Harmonisation
ICSR	Individual Case Safety Report
IDMP	Identification of Medicinal Product
IND	Investigational New Drug
ISO	International Organization for Standardization
ML	Machine Learning
MPID	Medicinal Product Identifier
MSG	Metadata Submission Guideline
NDC	National Drug Codes
PCORTF	Patient-Centered Outcomes Research Trust Fund
PDUFA	Prescription Drug User Fee Act
PhPID	Pharmaceutical Product Identifier
PQ/CMC	Pharmaceutical Quality/ Chemistry, Manufacturing, and Controls
REMS	Risk Evaluation and Mitigation Strategies
RoA	Route of Administration
SDO	Standards Development Organization
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
SME	Subject Matter Expert
SPL	Structured Product Labeling
TA	Therapeutic Area
TAUG	CDISC Therapeutic Area User Guide
TCG	Study Data Technical Conformance Guide
UMC	Uppsala Monitoring Centre

UNICOM	Up-scaling the global univocal identification of medicines
UNII	Unique Ingredient Identifier
UoM	Units of Measure
USCDI	United States Core Data for Interoperability
WHO	World Health Organization