
# Data Standards Program Action Plan

**Draft Version: 3.7**

**Document Date: November 6, 2019**

# 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<br>• 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 |

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

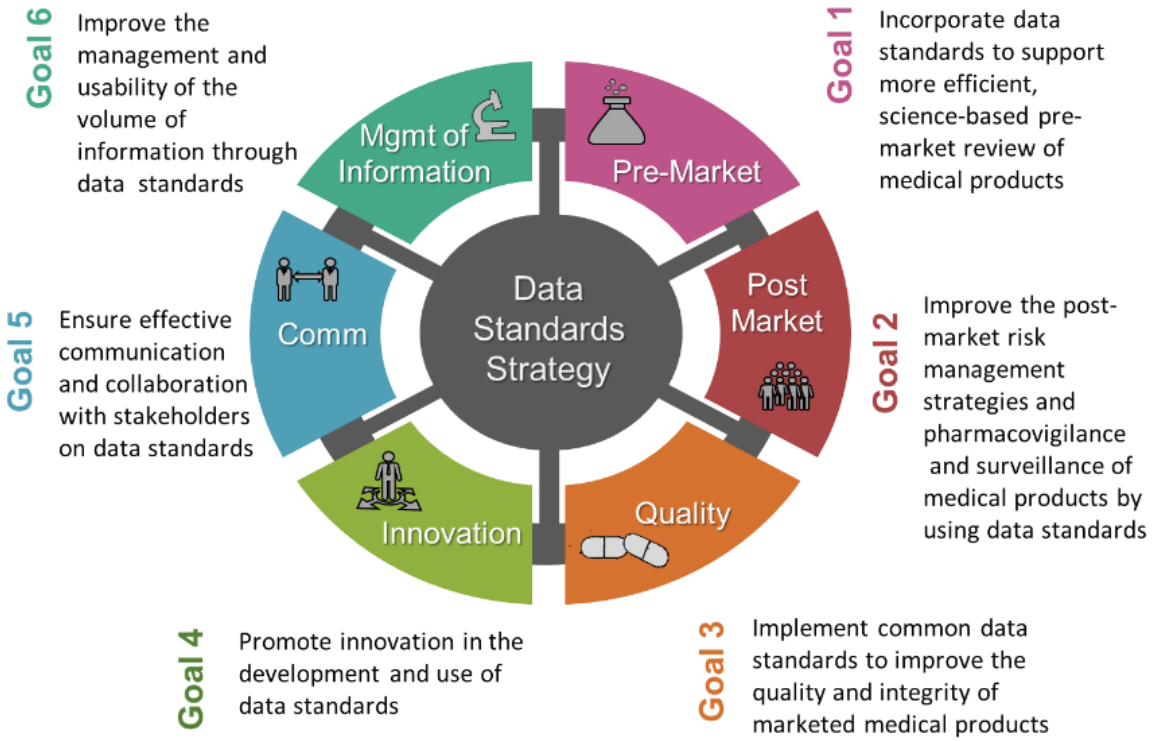
# 2 Purpose

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 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). 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 **Table 6**.

## 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 Update | Project Stage | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | Req Definition | Alt Analysis | Development | Testing* | Adoption | Implementation | Policy |
| **Evaluation and Testing of the SEND Standard for CBER**<br>The CBER project will evaluate and test the feasibility to support and require the Standard for Exchange of Nonclinical Data (SEND) standard to improve efficiency in the review process for nonclinical toxicology studies. | Q1: A sub-team under the Clinical Data Interchange Standards Consortium (CDISC) worked with CBER subject matter experts (SMEs) to review the existing SEND Implementation Guide (SENDIG) and perform gap analysis to assess any CBER specific data needs. Biweekly meetings have been going on.<br><br>Q2: No updates this quarter.<br><br>Q3: The CDISC SEND for CBER workgroup completed a gap analysis and is near completion of reviewing all domains included in SENDIG V3.1. A Proof-Of-Concept (POC) approach has been defined to test the inclusion of SEND in submissions to CBER offices. For the next step, the workgroup will request a toxicology study example from the public to support the POC implementation.<br><br>Q4: All the domain reviews have been completed. Request letter of study data donation from industry has been posted on FDA website and CDISC Wiki page. CBER will evaluate the proof-of-concept data after receipt. | | | | ■ | | | |

| Project Title and Description | Project Update | Project Stage |
|---|---|---|
| **Study Data Standards Testing**<br>This CBER-CDER project uses an established methodology to test new and version updates of study data standards to establish FDA support. | The following study data standards and TA extensions were tested during the public comment period in FY19<br>Q1:<br>• Lung Cancer v.1.0<br><br>Q2:<br>The following therapeutic areas were added to the Study Data Technical Conformance Guide and will be published in April, 2019:<br>• COPD v.1.0<br>• Colorectal Cancer v.1.0<br>• Huntington Disease v.1.0<br>Q3:<br>Post-Traumatic Stress Disorder (PTSD) therapeutic area will be added to the next Study Data Technical Conformance Guide.<br><br>Q4:<br>Assessed HIV and Define v2.1b | Req Definition<br>Alt Analysis<br>Development<br>**Testing***<br>Adoption<br>Implementation<br>Policy |

| Project Title and Description | Project Update | Project Stage |
|---|---|---|
| **eCTD v4.0 Project**<br>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: The FDA is finalizing the initial draft eCTD v4.0 Technical Conformance Guide for public comment. The International Council for Harmonisation (ICH) M8 group completed an update to the ICH eCTD v4.0 Implementation Package during the ICH June 2018 meeting. The updated implementation package (v1.3) was posted on the ICH eCTD v4.0 webpage in September 2018.<br><br>Q2: No updates this quarter.<br><br>Q3: ICH is currently reviewing the eCTD v4.0 implementation strategy based on limited Health Level Seven (HL7) version 3 messaging support and the development of HL7's Fast Healthcare Interoperability Resources (FHIR). A decision on the implementation strategy is anticipated by the end of this year.<br><br>Q4: No updates this quarter. | Req Definition \| Alt Analysis \| Development \| Testing \| **Adoption*** \| Implementation \| Policy |
| **Source Data Capture from EHRs: Using Standardized Clinical Research Data**<br>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. | Q3: The project continued to measure baseline metrics and implement the EDC-to-EHR solution at multiple sites.<br><br>Q4: Project completed. | Req Definition \| **Alt Analysis*** \| Development \| Testing \| Adoption \| Implementation \| Policy |

| Project Title and Description | Project Update | Project Stage | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | Req Definition | Alt Analysis | Development | Testing | Adoption* | Implementation* | Policy* |
| **E2B IND Safety Report**<br>This CDER and CBER pilot project is testing the receipt and processing of Investigational New Drug (IND) safety reports submission using E2B standards. | Q1: Project plan and target production dates confirmed:<br>• IND Safety Report scheduled to be in production by the end of October 2019 for voluntary submission using E2B(R2) format.<br>• FAERS II implementation will support IND Safety Report in both E2B(R2) and E2B(R3) formats in early 2020.<br>Q2: First ePrompt meetings held in March, 2019<br>Q3: Draft IND Safety Report Guidance under internal review<br>Q4: Second ePrompt held in July 2019, with additional meeting planned for Q2 FY2020. | | | | | | | |
| **Clinical Outcomes Assessment**<br>This CDER project is focused on the development and evaluation of clinical outcome assessments (COA) submitted in support of regulatory submissions. | Q4: FDA is providing a final review on Ten-Meter Walk, 4 Stair Ascend, 4 Stair Descend, Rise From Floor CDISC Supplements | Req Definition* | Alt Analysis | Development | Testing | Adoption | Implementation | Policy |

## 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* |
| **Integrating REMS Information into SPL**<br>The objective of this CDER project is to capture and submit structured information about Risk Evaluation and Mitigation Strategies (REMS) and official FDA-approved REMS Documents in Structured Product Labeling (SPL). | In FY18 Q1, the project published draft guidance (FDA-2017-E-4282) under 745A(a) on September 5, 2017 to move towards requiring REMS submissions in SPL format.<br><br>Q2: Activities to finalize the guidance are underway.<br><br>Q3: No updates this quarter.<br><br>Q4: No updates this quarter. | | | | | | | |
| **Grant Projects for Therapeutic Areas & Animal Efficacy and Natural History Studies**<br>This CDER project provides program and subject matter expertise to awarded grant projects. | Status of Clinical TA grants:<br>• Clinical Data Interchange Standards Consortium (CDISC) Therapeutic Area User Guide (TAUG) for Lung Cancer is complete.<br>• CDISC TAUG for Clostridium Difficile Associated Diarrhea is complete.<br>• CDISC TAUG for Treatment of HIV is complete.<br><br>The CDISC Improved Data Standards for Animal Efficacy Studies and Natural History Studies for Animal Rule project is in the development stage. The Standard for Exchange of Nonclinical Data Implementation Guide: Animal Rule (SENDIG-AR) was published for public comment in Feb, 2019.<br><br>To see the list of the grant projects underway, see CDER's Grant Program for Data Standards Development webpage. | | | | | | | |

## 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**<br>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. | Q2: the project completed a draft FHIR implementation guide (IG) for the PQ/CMC Proof-of-Concept (PoC), and is engaging industry participants to prepare for PoC testing. Testing is scheduled to begin in Q3.<br><br>Q3: Initiated PQ/CMC Proof-of-Concept (PoC) testing with seven PhRMA participants. The PoC tested PQ/CMC Data Exchange Standards for drug product specification using HL7 FHIR standard. PoC participants are currently developing test samples, several have been receieved by FDA.<br><br>Q4: Completed PQ/CMC Proof-of-Concept (PoC) testing with PhRMA industry participants. Demonstrated successful end-to-end creation, submission, and report generation using structured PQ/CMC data. | | | ■ | ■ | | | |

| Project Title and Description | Project Update | Project Stage | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | Req Definition | Alt Analysis | Development | Testing* | Adoption | Implementation[1] | Policy |
| **IDMP Project**<br>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).<br><br>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). | Established IDMP work streams and working groups for each of the five ISO standards.<br>• FDA has now become a member of the EDQM Standard Terms Working Party.<br>• Collaborating with EMA to develop FHIR resource for substance and medicinal products.<br>• Global Substance Registration System (GSRS) v2.3.3 is in production.<br>• At ISO meeting in April, FDA presented issues related to ISO 11239/TS 20440 and the use of regional vs central terminologies for dose form.<br>• US TAG/FDA provided comment on ISO on TS 20440 during its systematic review cycle; further discussion at upcoming ISO TC215 meeting in November 2019. Ongoing collaboration with stakeholders to identify dose form terminology for international IDMP. | | | | ■ | | | |
| **Post Approval Changes Rulemaking & Submission Standards**<br>This CBER-CDER project is focused on improving submission requirements to ensure that essential facility location, production information, and an up-to-date view of the CMC process are captured completely, and in a format that is conducive to electronic receipt, storage and usage. | Q4: The project continues to assess and refine the proposed changes that are undergoing internal agency review. | ■ | | | | | | |

[1] As reported in the Action Plan v2.7, IDMP (ISO 11238) was implemented as part of the GSRS and CDER implemented the Product Master Data domain that is referenced by other CDER applications, as appropriate.

## 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 |
|---|---|---|
| **Patient-Centered Outcomes Research Trust Fund (PCORTF) Common Data Harmonization Pilot Project**<br>This CDER project is focused on the development of a proof of concept solution to enable a researcher to make a single query usable across four distinct Common Data Model formats from 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. FDA is coordinating with its partners, the National Cancer Institute, National Library of Medicine, National Center for Advancing Translational Sciences, and the Office of the National Coordinator for Health Information Technology. | Q3: Wrap-up of PCOR-TF funded elements of projects is underway. Planning for new phases of work currently in progress.<br><br>Q4: Project complete. | Req Definition<br>**Alt Analysis***<br>Development<br>Testing<br>Adoption<br>Implementation<br>Policy |

| Project Title and Description | Project Update | Project Stage |
|---|---|---|
| **Evaluation of FHIR for Regulatory Applications**<br>The contract objective is to assess the application of HL7 FHIR by developing and presenting the proof-of-concept FHIR artifacts for selected SPL use cases. | Q3: The project completed the following:<br>• Roadmaps for transition of SPL information pathways to FHIR-based approaches<br><br>Q4: Project complete. The project has proposed a draft roadmap for a long-term transition from SPL to FHIR-based, including the mapping of data elements from SPL to FHIR, gaps analysis, and a proof-of-concept FHIR artifacts for an SPL establishment registration use case. It has prepared ground for the next phase, that will developed the architectural approach to the FHIR implementation of labeling data submission. | Req Definition<br>**Alt Analysis*** <br>Development<br>Testing<br>Adoption<br>Implementation<br>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 the eCTD submission types and sub-types, technical rejection criteria, conformance guide, and action plan documents referenced below:<br>• CDER Data Standards Program<br>• Electronic Common Technical Document (eCTD)<br>• Study Data Standards Resources |
| **Federal Register Notices (FRNs)** | No relevant FRNs were published this quarter. |
| **eCTD Submission Standards** | In August, the following documents were updated and published:<br>• eCTD Submission Standards<br>• File Format Specifications<br>• Promotional-Material-Type M1 v2.4 Attribute List<br>• TRC Self-Check Worksheet<br>• TRC Self-Check Worksheet Instructions |
| **Technical Specifications and Conformance Guide Updates** | Submitting Next Generation Sequencing Data to the Division of Antiviral Products v. 1.0 (July 2019) |
| **Action Plan** | The Data Standards Action Plan v3.6 was published on August 14th, 2019. |
| **Outreach Opportunities, Public Meetings & Educational Activities** | FDA Webinars are planned to focus on various data standards topics. |

## 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

The Stage Name column lists the stage name as outlined in **Figure 2** and a shortened name listed in the tables above. The rows highlighted in yellow***** are processes owned by SDOs; other rows are FDA owned processes. As discussed in the next section, there is variation in all data standards projects so not all processes are needed for every project.

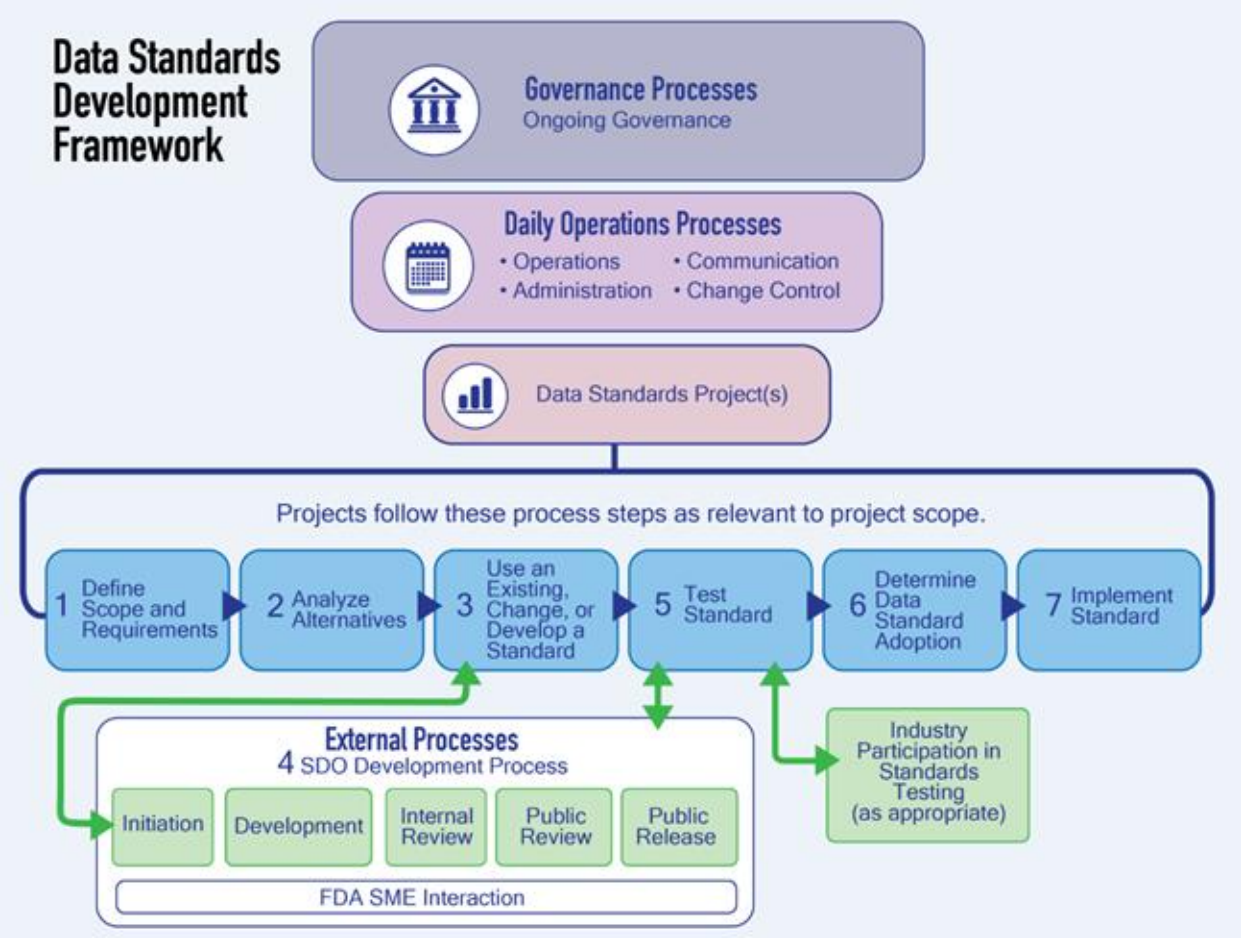
**Table 6. Standard Development Project Stages**

| 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.<br><br>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 (as outlined in the Communication Plan). |
| Initiation***** | The SDO, grantee, or other lead group working with the FDA and other subject matter experts defines the project scope (e.g., what is needed for regulatory review decision making), develops a charter to define the project and ensure available resources, develops a plan, and conducts a kick off of the project. |
| Development***** | The SDO, grantee, or other lead group conducts an iterative process of data element identification (e.g., elements need to describe the study primary endpoint), definition, validation, and conducts a review with defined expert groups. FDA's subject matter experts participate throughout the development phase. A key output is an implementation guide for the study data standard. |
| Internal Review***** | During this stage, the lead group conducts an internal review to ensure readiness for the public review period. |
| Public Review***** | The lead group facilitates a public review comment period. Comments are addressed per the lead group's process. |
| Public Release***** | An initial release of the study data standard is released for public use. |

| Stage Name | Stage Description |
|---|---|
| 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.<br>For study data, FDA may use converted or sample data sets to test the study data standard to simulate regulatory review decision making. Having the business rules and/or conformance checks available for a new or updated standard at time of SDO release will be important to FDA's testing efforts. |
| Determine Data Standard Adoption (Adoption) | If needed, policy, regulatory, guidance, and technical specification needs 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. |
| FRN/Guidance | FDA will issue a FRN (and guidance as needed) if the use of a new standard is required. |

The data standards development stages described above are shown graphically in **Figure 2**.

**Figure 2. Data Standards Development Framework**



## 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**

| Projects | Goal 1 | | | | Goal 2 | | Goal 3 | | | Goal 4 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1.1 | 1.2 | 1.3 | 1.4 | 2.1 | 2.2 | 3.1 | 3.2 | 3.3 | 4.1 | 4.2 | 4.3 | 4.4 |
| Evaluation and Testing of the SEND standard for CBER | x | | | | | | | | | | | | |
| Study Data Standards Testing | x | | | | | | | | | | | | |
| BRIDG Architecture Review | x | | | | | | | | | | | | |
| eCTD v4.0 Project | x | | | | | | | | | | | | |
| Source Data Capture from EHRs: Using Standardized Clinical Research Data | | | | x | | | | | | | | x | |
| Transforming Research Through eSource and Standards | | | | x | | | | | | | | x | |
| E2B IND Safety Report | x | | | | | | | | | | | | |
| Integrating REMS Information into SPL | | | | | x | | | | | | | | |
| Grant Projects for Therapeutic Areas & Animal Efficacy and Natural History Studies | x | | | | | | | | | | | | |
| Pharmaceutical Quality (PQ)/, Chemistry, Manufacturing, and Controls (CMC) Data Standardization | | | | | | | x | | | | | | |
| IDMP Project | | | | | | x | | X | | | | | |
| Post Approval Changes Rulemaking & Submission Standards | | | | | | | | | x | | | | |
| Clinical Outcomes Assessment | x | x | | | | | | | | | x | | |
| PCORTF Common Data Harmonization Pilot Project | | | | | | | | | | | | | x |
| Evaluation of FHIR for Regulatory Applications | | | | | | | | | | x | | | |

## Appendix C: Glossary of Acronyms

| | |
|---|---|
| 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 |
| MPID | Medicinal Product Identifier |
| 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 |
| SEND | Standard for Exchange of Nonclinical Data |
| 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 |
| UNII | Unique Ingredient Identifier |
| UoM | Units of Measure |