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

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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.

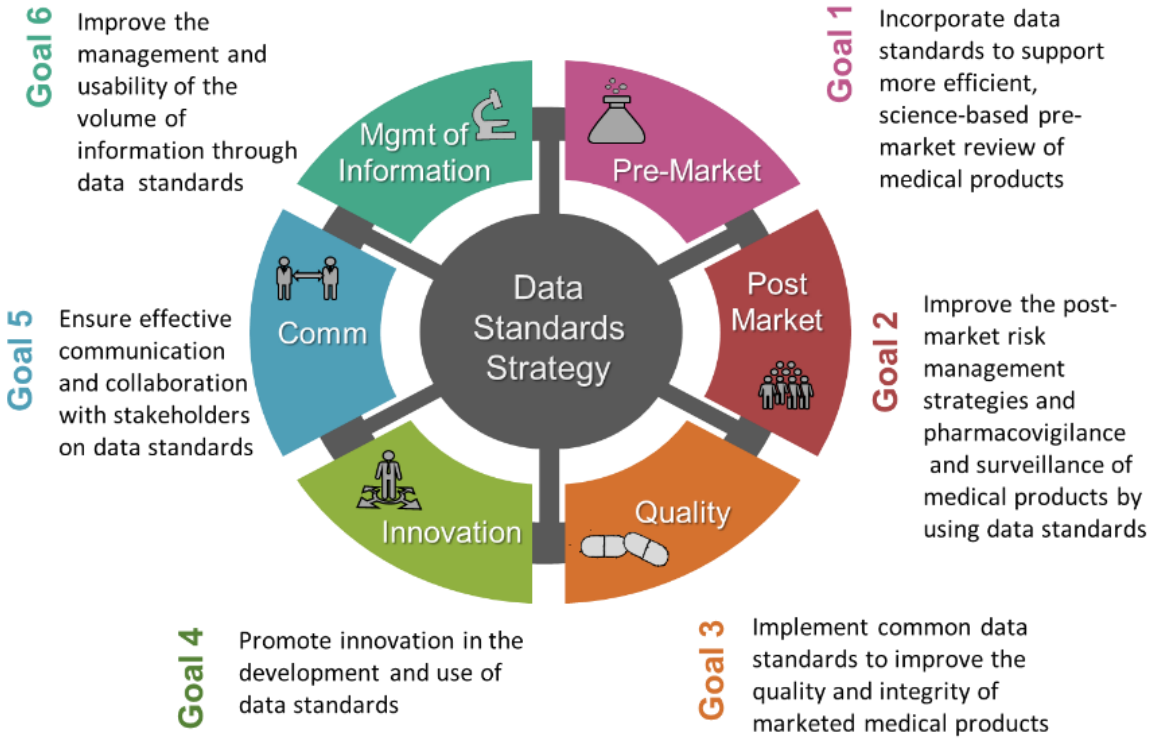
2 Purpose

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 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. Q2: No updates this quarter.							

Project Title and Description	Project Update	Project Stage						
		Req Definition	Alt Analysis	Development	Testing*	Adoption	Implementation	Policy
Study Data Standards Testing 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 Q1: • Lung Cancer v.1.0 Q2: The following therapeutic areas were added to the Study Data Technical Conformance Guide and will be published in April, 2019: • COPD v.1.0 • Colorectal Cancer v.1.0 • Huntington Disease v.1.0				*			
BRIDG Architecture Review This CDER project is focused on the architectural review of the Biomedical Research Integrated Domain Group (BRIDG) model. The three project objectives are (1) Map BRIDG to Fast Healthcare Interoperability Resources (FHIR), (2) Formalize the modeling-by-reference approach, and (3) Develop a plan to reorganize BRIDG as a collection of different "views" which show only the BRIDG classes relevant to a particular purpose or use case.	Final report being developed and is expected to be delivered in FY19 Q3.			*				

Project Title and Description	Project Update	Project Stage						
		Req Definition	Alt Analysis	Development	Testing	Adoption*	Implementation	Policy
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: 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. Q2: No updates this quarter.					✓		
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.	In Q2, the effort had its multi-party kickoff and is currently working to implement the EDC-to-EHR solution at multiple sites.		✓					
Transforming Research Through eSource & Standards This CDER project is developing and testing an implementation approach which employs multiple standards synergistically to enable the use of EHRs for eSource data collection. The work aims to highlight increased efficiencies in many points of the end-to-end work flow of clinical healthcare and research.	In FY19 Q1, the project completed development on its proof of concept and analysis and prepared a set of reports for delivery in FY19 Q2. In Q2 the reports were delivered and will be revised in Q3.		✓					

Project Title and Description	Project Update	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.	In Q1, the project plan and target production dates confirmed: • IND Safety Report scheduled to be in production by the end of October 2019 for voluntary submission using E2B(R2) format. • FAERS II implementation will support IND Safety Report in both E2B(R2) and E2B(R3) formats in early 2020. In Q2: • First ePrompt meetings held in March, 2019.The next meeting is planned for July 2019.	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
Integrating REMS Information into SPL 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. Q2: Activities to finalize the guidance are underway.	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
Grant Projects for Therapeutic Areas & Animal Efficacy and Natural History Studies This CDER project provides program and subject matter expertise to awarded grant projects.	The following Clinical TA grants are in progress: • Clinical Data Interchange Standards Consortium (CDISC) Therapeutic Area User Guide (TAUG) for Lung Cancer is in the development stage. • CDISC TAUG for Clostridium Difficile Associated Diarrhea is currently under CDISC review. • CDISC TAUG for Treatment of HIV is currently under CDISC review. 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. 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 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.	In FY19 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.			■				

Project Title and Description	Project Update	Project Stage						
		Req Definition	Alt Analysis	Development	Testing	Adoption	Implementation*[1]	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).	Established IDMP work streams and working groups for each of the five ISO standards. • FDA has now become a-member of the EDQM Standard Terms Working Party. • Collaborating with EMA to develop FHIR resource for substance and medicinal products. • Global Substance Registration System (GSRS) v2.3.3 is in production.						■	
Post Approval Changes Rulemaking & Submission Standards 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.	In FY19 Q1, the project continues to assess and refine the proposed changes that are undergoing internal agency review. Q2: No updates this quarter.			■				

[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						
		Req Definition*	Alt Analysis	Development	Testing	Adoption	Implementation	Policy
Clinical Outcomes Assessment This CDER project is focused on the development and evaluation of clinical outcome assessments (COA) submitted in support of regulatory submissions.	In FY19 Q2, the following Questionnaires, Ratings, and Scales were returned to CDISC for publication: • Patient Global Instrument • Clinical Global Instrument							
Patient-Centered Outcomes Research Trust Fund (PCORTF) Common Data Harmonization Pilot Project 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.	In FY19 Q2, continued with architectural development and initiated testing with data partners.							
		Req Definition	Alt Analysis*	Development	Testing	Adoption	Implementation	Policy

Project Title and Description	Project Update	Project Stage
Evaluation of FHIR for Regulatory Applications 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.	In FY19 Q2: The project completed the following: • SPL document analysis. • Interviews of SPL agency experts to understand SPL business use cases. • Development of SPL data flow diagrams across FDA and external systems. • Documentation of data elements for each SPL document type.	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 the eCTD submission types and sub-types, technical rejection criteria, conformance guide, and action plan documents referenced below: • CDER Data Standards Program • Electronic Common Technical Document (eCTD)
Federal Register Notices (FRNs)	No relevant FRNs were published this quarter
eCTD Submission Standards	In January, the following documents were updated and published: • Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications • eCTD Validation Criteria • eCTD Submission Standards • Technical Rejection Criteria for Study Data • Self-Check Worksheet for Study Data Preparation
Technical Specifications and Conformance Guide Updates	The March update of TCG is complete and will be published in April 2019
Action Plan	The Data Standards Action Plan v3.4 was published on January 31, 2019

Outreach Opportunities, Public Meetings & Educational Activities	• **FDA Webinars**
	  ○ Webinars are planned to focus on various data standards topics
	• **Public Meetings**
	  ○ PDUFA VI, Electronic Submissions and Data Standards, scheduled for April 10, 2019.

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.

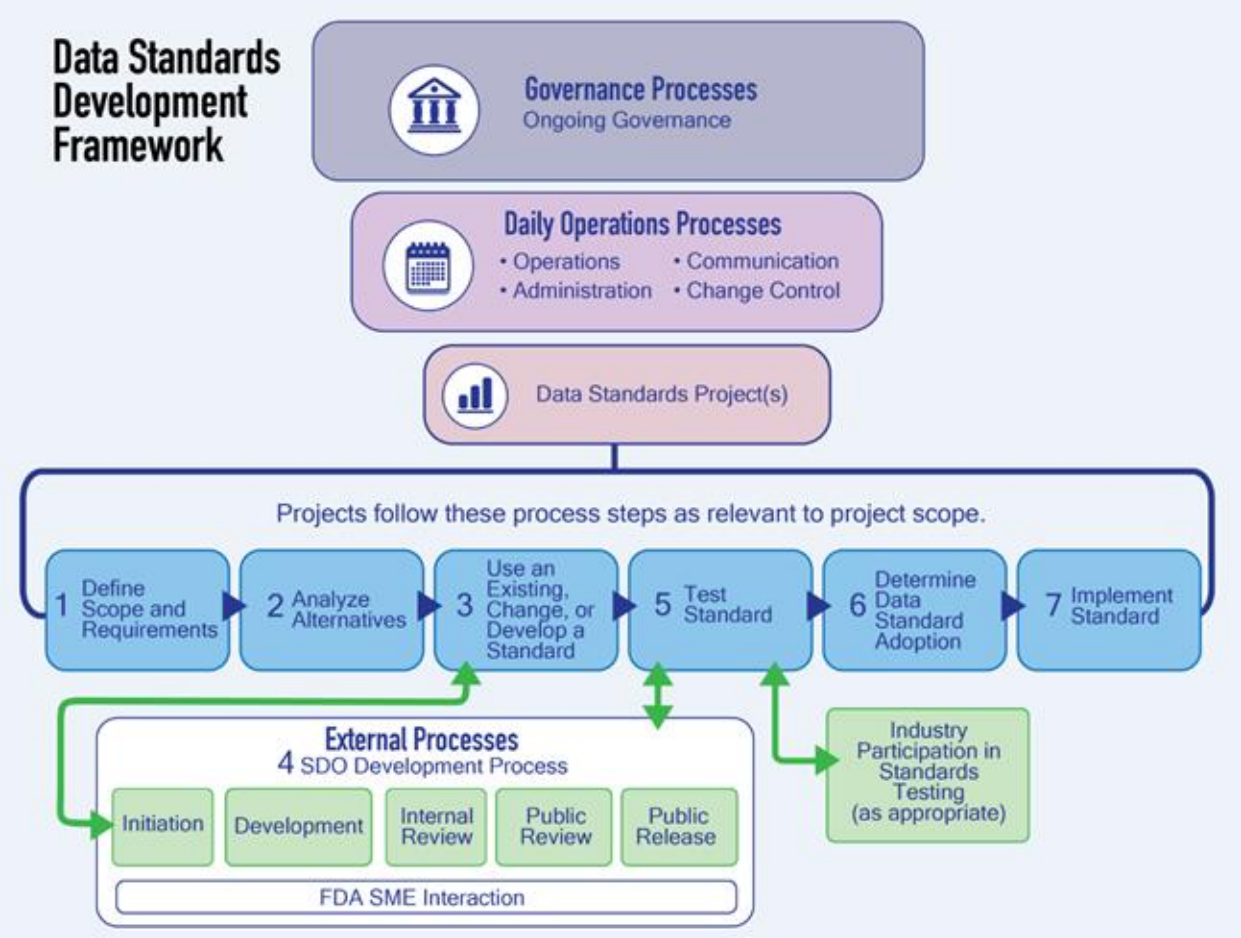
Table 6. Standard Development Project Stages

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. 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. 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