CBER-CDER Data Standards Program 2023 Annual Assessment

March 2024

Table of Contents

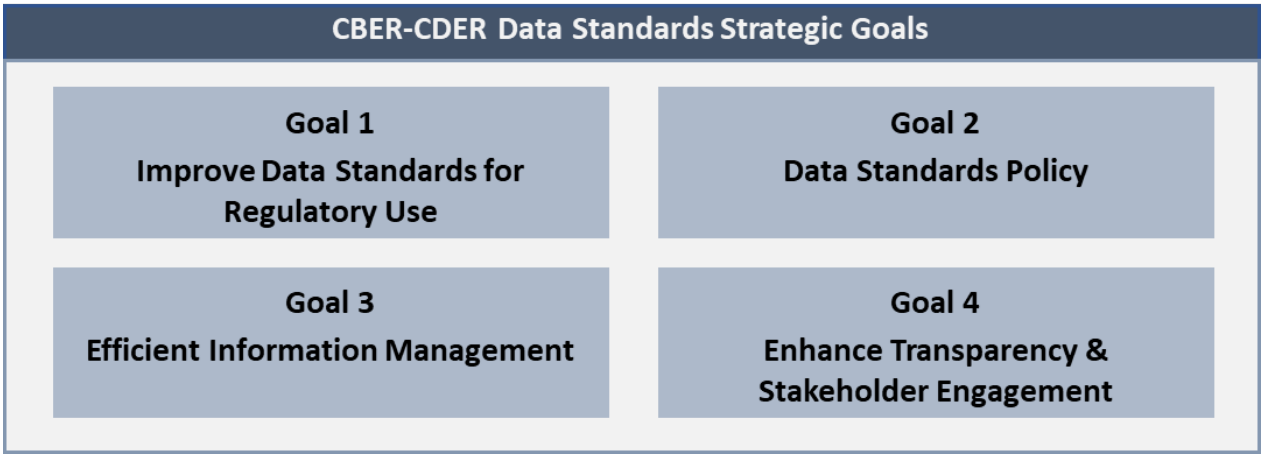
List of Figures

1 Introduction

FDA publishes an Annual Assessment for CBER-CDER's Data Standards Program (DSP) to provide a progress update to stakeholders reflecting the last calendar year. The previous year's assessment is available on the CDER DSP website. Further information for most projects referenced throughout this Annual Assessment is available in the Action Plan.

2 CBER-CDER Data Standards Program at a Glance

This assessment highlights the projects and ongoing efforts that cover the identification of need, development, testing, adoption, implementation, and maintenance of study data standards required for the efficient and effective review of regulatory submissions. The Annual Assessment is organized to align with the Data Standards Strategy and as of FY23, is now mapped to the four major areas of regulatory business activity of the CBER-CDER Strategic Plan (pictured below). The following sections highlight the program's accomplishments.



2023 Summary of Accomplishments

- SPL on FHIR (Structured Product Labeling) (Fast Healthcare Interoperability Resources) participated in HL7 Connectathon track exploring EMA electronic Product Information (ePI) FHIR IG and SPL-FHIR IG.
- Completed the eCTD v4.0 Technical Pilot, as well as continued to update regional specifications as needed (IG, CV, Validations, CTOC, TCG) and test updates provided in eCTD Software.
- Completed Submission Data Standards Assessment to establish a catalog of all data areas and associated regulatory submission standards in eCTD modules.
- Pharmaceutical Quality/Chemistry, Manufacturing, and Controls (PQ/CMC) continued its development of Phase 2 domains and published an FRN in May 2023 to announce progress and solicit comments; the project also published on FDA's PQ/CMC webpage, new chapters listing the latest PQ/CMC data elements and terminologies in September of 2023.

- Continued collaborating with EMA and WHO-UMC through the Global IDMP Working Group and successfully participated in a HL7 Connectathon FHIR IDMP message with Cross-Border Prescription use cases.
- Continued assessment of data requirements to support submission of study data derived from real world data sources and began to review prioritized data elements for feedback with internal stakeholders.
- Completed FAERS (FDA Adverse Event Reporting System) II E2B R3 Industry Testing Phase I and published two guidance documents in January 2023.
- Biologics Effectiveness and Safety (BEST) Innovative Methods (IM) initiative onboarded 12 partners and completed two eHealth Exchange Pilot studies.
- Published 6 updates to the Study Data Technical Conformance Guide (sdTCG).
- Published "Guidance for Industry: Identification of Medicinal Products – Implementation and Use".
- Published "Data Standards for Drug and Biological Product Submissions Containing Real-World Data".

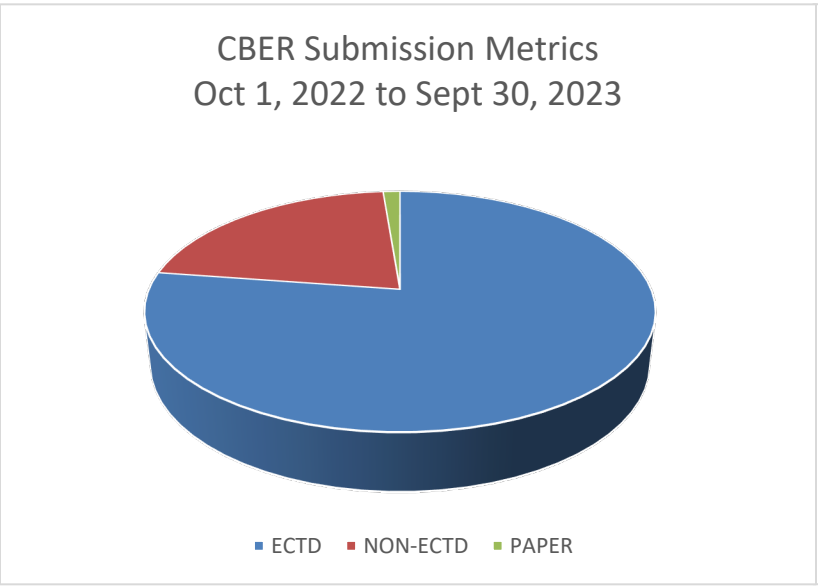
3 Impact of Requiring Standards

FDA continues to implement data standards for study data and submissions and requires applications to use these standards as defined in the FDA Data Standards Catalog. The Data Standards Program's strategic goal areas and objectives were identified as part of an Agency assessment to evaluate the degree of implementation of electronic submissions and data standards, the readiness of data standards, effectiveness of electronic review tools and training, and impact of standards and electronic submission on the review environment.

4 2023 Electronic Submission Metrics

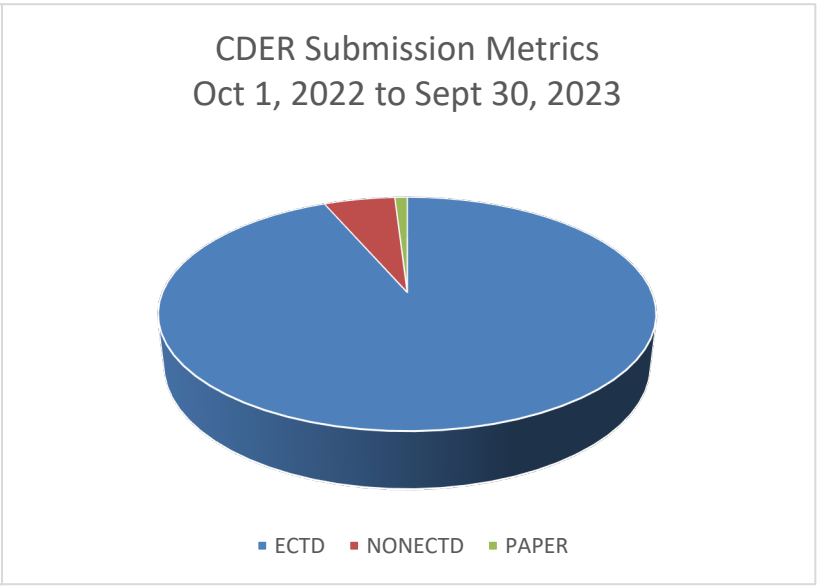
Analysis of FY 2023 data indicated that 94% of all submissions to CDER were in eCTD format, 5% in other electronic formats, and 1% paper. There was near 100% compliance with application types required in eCTD. For CBER, more than 77% of all submission were in eCTD format, with 21% in non-eCTD formats and approximately 1% paper submissions. CBER's metrics include submissions that are not subject to the eCTD requirement.

Figure 1. Percent of All Submissions to CBER and CDER by Electronic Format (FY 2023)



38,245 Total Submissions

ECTD	77%
NON ECTD	21%
PAPER	1%



354,000 Total Submissions

ECTD	94%
NON ECTD	5%
PAPER	1%

In 2020, FDA expanded electronic options for transmitting non-eCTD submissions. CDER's NextGen Portal began accepting non-eCTD submissions to Research IND and DMF Type III applications. Utilizing NextGen or ESG provides an easier and faster way to transmit a non-eCTD submission compared to paper or physical media (i.e., CD/USB Drive).

5 2023 Data Standards Program (DSP) Year in Review

In 2023, CBER and CDER's DSP continued to make significant progress in multiple fronts including, but not limited to, updates to the FDA Data Standards Catalog and the Study Data Technical Conformance Guide, publishing multiple guidances in the areas such as Real-World Data and Identification of Medicinal Products (IDMP). The PQ/CMC project reached another significant milestone with the completion of the development for the first iteration of a PQ/CMC Proof of Concept (POC) system that enabled end-to-end testing of the PQ/CMC FHIR Implementation Guide (IG). The Agency also contributed to the completion of all five IDMP pilot projects. The Global IDMP Implementation Working Group (GIDWG) finalized the global PhPID business rules that are expected to publish in 2024, with collaboration from EMA, ANVISA, Health Canada, SwissMedic, and WHO-UMC. The Agency continued to expand the development of its SPL-FHIR POC system in 2023. This development includes testing additional use cases which aims to ultimately enable dual submissions in both SPL and FHIR. Details on all major data standards program initiatives are highlighted in the sections below. Furthermore, FDA participated in a new PHUSE project aimed at evaluating Dataset-JSON as an alternative transport format for the Agency to receive electronic submissions for study data.

5.1 Goal 1: Improve Data Standards for Regulatory Use

5.1.1 Objective 1: Enhancement of Submission Formatting and Review

Data Standards and Real-World Data

Per mandates under the 21st Century Cures Act and the Food and Drug Omnibus Reform Act of 2022 has issued guidance about the use real-world data (RWD) to support regulatory decisions. RWD is data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Some of the most prominent sources of RWD are EHR systems used by the vast majority of hospitals and primary care clinics in the United States and insurance claims databases used to document billing for medical care events. Many other sources of RWD also exist and continue to emerge. FDA's robust Real-World Evidence Program, in addition to facilitating the publication of a suite of guidances, includes continuing engagement and collaboration with interested parties to explore continuing advances in this space. Part of these efforts including considerations relating to the use of RWD and currently accepted data standards at FDA and the opportunities for supporting the needs of RWD use for research and regulatory submissions. Under this effort, in December 2023, FDA published the Final version of its guidance (originally published as Draft for comment in 2021)https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-drug-and-biological-product-submissions-containing-real-world-data regarding the use of data standards for the submission of study data derived from RWD. This guidance was published as part of a growing suite of guidances addressing various aspects of the use of RWD for research and regulatory submissions. FDA is also investigating approaches to better align data standards for submission to FDA with the many sources of RWD.

Dataset-JSON Standard

In 2023, FDA initiated participation in a new PHUSE project aimed at evaluating Dataset-JSON as an alternative transport format for the Agency to receive electronic submissions. In addition, FDA received several pilot submissions from industry containing the current XPT format and converted JSON file formats to capture data integrity. CBER and CDER representatives provided technical feedback to stakeholders on the ability to receive and accept these submissions. The FDA will continue evaluating Dataset-JSON as an alternative transport format with a final readout on PHUSE project results expected during the summer of 2024.

eCTD V4.0 Project – Phase 1

Phase 1 of CBER and CDER's implementation of eCTD v4.0 is the acceptance of new applications and subsequent submissions (e.g., amendments, supplements).

In 2023, an eCTD v4.0 Technical Pilot was completed. Eleven companies participated in the pilot and six companies submitted test submissions. The scope of the pilot was the submission of original eCTD v4.0 applications and subsequent submission with a focus on the eCTD v4.0 enhancements (e.g., document reuse, one-to-many and many-to-one lifecycle).

CBER and CDER performed testing on our eCTD software, upgraded the electronic submissions process, and started the systems integration enhancements to incorporate the eCTD v4.0 functionality.

In 2024, the plan is to start accepting original eCTD v4.0 applications.

Engagement with HL7

CBER and CDER continues to actively participate in the HL7 Biomedical Research and Regulation (BR&R) workgroup. The BR&R areas of interest encompass clinical and translational research, both regulated and non-regulated, and the subsequent regulatory submissions and information exchanges to bring new products to market and to ensure safe use throughout the product lifecycle. The BR&R facilitates the development of common standards and the maintenance and enhancement of the research-focused domain analysis model for clinical research information management across a variety of organizations, including national and international government agencies and regulatory bodies, private researchers, research organizations, sponsored research, CROs and other interested entities. A shared semantic view is essential if the clinical research community is to achieve computable semantic interoperability, both for itself and as part of the larger healthcare and life sciences communities. The BR&R will seek to assure that related or supportive standards produced by other HL7 groups are robust enough to accommodate their use in regulated clinical research through participation as appropriate. The group also monitors information interchange standards developed outside of HL7 and attempts harmonization of information content and representation of such standards with the HL7 standards.

As part of FDA's participation with HL7, the HL7 FHIR Accelerator program for clinical research was jointly created by academia, sponsors, regulatory and translational research organizations, including TransCelerate Biopharma, FDA, NIH, JHU, HL7, CDISC, as well as several large professional societies. CBER and CDER are actively involved in Vulcan, participating in its Steering Committee, Advisory Board, and Technical Expert group to ensure that the solution is aligned with our regulatory review needs. Since 2021, the Agency also participated in multiple Vulcan FHIR Connectathon tracks including those focusing on RWD (which FDA also co-leads) and adverse events.

ICH eCTD File Tag Controlled Terminology

In 2022, FDA submitted a proposal to ICH M8 to expand the controlled terminology list for their eCTD file tags. The proposed file tags would be specific to the business needs around regulatory review and would serve reviewers by helping them to efficiently locate materials within a submission package that have been properly tagged. ICH has accepted the proposal and as of August 2023 was finalizing the expanded list of file tags.

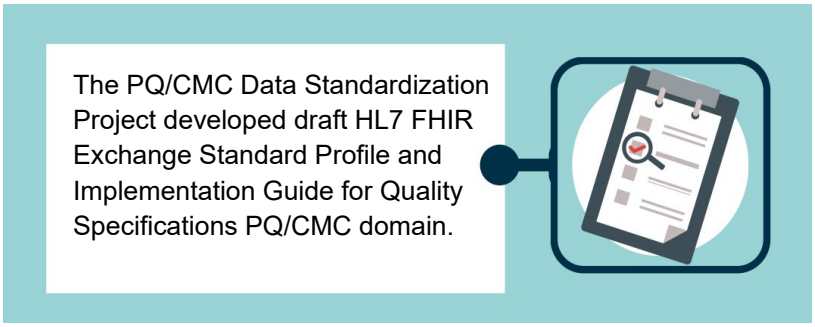
IDMP Project

As FDA focuses on the challenges of the global supply chain and foreign sourcing of medicinal products, the Agency continues to participate and promote conformance to international harmonized IDMP to foster the safety of medications throughout the world. FDA conducted a Global PhPID pilot with WHO-UMC to assess alternative solutions for ISO IDMP standards. The

findings and recommendations are included in the 2023 revision of ISO 11239 and TS20440. The Agency also collaborated with EMA and WHO-UMC to establish the GIDWG (Global IDMP Working Group) to assess and promote global implementation of ISO IDMP standards based on the success of Global PhPID project and Global Vaccine Initiative. GIDWG conducted five projects to further investigate solutions and processes to address identified gaps of ISO IDMP standards, and is working with ISO TC215 Working Group 6 to improve IDMP standards for global implementation. In Q4 2023, GIDWG completed a successful cross-border healthcare test case during HL7 Connectathon which demonstrated the benefit of using GIDWG global PhPID to identify like medicinal products in multiple jurisdictions. GIDWG will conduct end-to-end test cases on pharmacovigilance, product shortage, and cross-border healthcare care, and PhPID operating model in 2024 to further fine tune the global IDMP implementation framework.

Pharmaceutical Quality/Chemistry, Manufacturing, and Controls Data Standardization

The PQ/CMC Data Elements and Terminologies Data Standardization Project continued work related to characterizing data elements and terminologies for information used in support of Module 3 of eCTD-based drug applications. An overall goal of this initiative is the development of standardized, structured and computable data standards for PQ/CMC submissions, ensuring consistent representation of concepts. In 2022, the project finalized PQ/CMC Phase 1 requirements of FHIR resources and development of FHIR exchange standards, and all requirements for PQ/CMC Phase 1 data domains were included in the FHIR R5 ballot. In March 2022, FDA published an FRN [https://www.regulations.gov/document/FDA-2022-N-0297-0001] that provides the updated PQ/CMC Phase 1 Data elements and controlled terminology as well as Draft mappings [Data Elements & Terminologies Document] to HL7 FHIR. The focus of the 2022 FRN was to seek industry input on the FHIR mappings. In May 2023, FDA released another FRN requesting comments on further additions to data elements and terminology for PQ/CMC to support multi-layer products and manufacturing processes for solid oral products. The May 2023 FRN also established an open docket for further notices for comment about the PQ/CMC initiative. Additionally, work commenced in assessing the range of considerations to be addressed regarding regulation and guidance in order to ensure a successful implementation of PQ/CMC for submissions to FDA.



Questionnaires, Ratings and Scales (QRS) Assessment

It is a common practice for sponsors to collect data in support of a clinical trial using specific data collection instruments (I.e., questionnaires, ratings or scales (QRS)). Codifying data structures for study data that has been collected using an instrument is an effort undertaken by SDOs. Under the Data Standards Testing contract, CDER has been evaluating these codified data structures for suitability. These dataset structures can come from instruments qualified by the COA Project,

existing standards, or therapeutic area extensions. Well-defined dataset structures ensure that data submitted to the Agency is fit-for-purpose. The Agency collaborates with industry to develop these dataset structures through the QRS effort.

In 2023, the QRS effort has evaluated 8 QRS data structures or related artifacts. FDA has sent substantive comments back to the SDO during development which has resulted in data structures that are more fit for purpose.

Source Data Capture from EHRs: Using Standardized Clinical Research Data (OneSource)

Electronic Source (eSource) data refers to the use of electronically recorded information as a source of data directly transferred to data systems used for clinical trials. The device or system that records the original data can include many items such as wearable devices and mobile apps. One of the larger potential sources of eSource data are Electronic Health Record (EHR) systems. A large amount of clinical trials participant data, which needs to be entered in research electronic case report forms (eCRFs), already exists in healthcare provider's EHR systems. However, EHR and eCRF data are generally collected in separate, non-compatible formats and exist in separate systems. This results in patient information being manually re-entered into the eCRF system, significantly slowing down workflow and increasing the risk of inaccuracies due to duplicate entry. This is a major barrier to research on real-world use of drug and biological products.

A number of initiatives exist to help mitigate these challenges, including CDER's supported projects that aim to demonstrate approaches for collecting eCRF data, stored on research Electronic Data Collection (EDC) systems, directly from an EHR system in an FDA-compliant way. These automated approaches demonstrate relevant improvements in efficiencies and potential returns on investment versus the current manual methodology. The OneSource project is a CDER-led project in collaboration with the University of California San Francisco. This project uses EHRs as the electronic Source (eSource) in I-SPY 2.2 Breast Cancer Trial, conforming to open, consensus-based standards. Phase III of this project aims to accomplish the following: 1) enhance the adverse event detection and reporting process by implementing standards-based electronic Patient-Reported Outcome (PROs); and 2) identify key data elements from electronic case report forms for breast cancer trials, focusing primarily on the I-SPY 2 family of trials and provide the data elements to the HHS/Office of the National Coordinator for Health Information Technology (ONC) United States Core Data for Interoperability (USCDI), aimed at for broader sharing of electronic health information to support patient care.

OneSource platform originally developed for I-SPY Breast Cancer Trial, is being reused in I-SPY COVID Trial and has been implemented for eSource data capture of laboratory results and concomitant medications at 15 sites for the I-SPY COVID Trial.

SPL FHIR

FDA maintains and updates its data standards to ensure continuous support of critical regulatory functions in light of exchange standards technology enhancements and upgrades. For example, FDA has been proactively reviewing the technology behind the Structured Product Labeling (SPL) standard used to support a wide range of regulatory uses including labeling. SPL is the current

standard behind a range of information processed by FDA and public information systems and is implemented using the HL7 Version 3 standard. As HL7 is transitioning to the more advanced FHIR standard, FDA is conducting an assessment of the FHIR capability to support the full range of current functions and, potentially, new use cases in a more efficient, robust, and sustainable way. The FDA is creating a proof-of-concept intake system that would allow for the submission of the new FHIR standard as well as the SPL standard and will be working with industry on a pilot program to test the system.

Study Data Standards Testing and Evaluation

This project involves testing an external organization's study data standards, terminologies, exchange formats, or related technical documents (Properties) for their ability to meet FDA's regulatory review needs and identify potential areas of concern. Findings and results of this effort contributes to the Agency's decisions on standards adoption. Below is a list of completed assessments in 2023.

- CDISC SDTMIGv3.4
- CDISC PRO-CTCAEv1.0
- CDISC ADaMv2.1
- sdTCG Review for CDISC SEND Combination Studies
- Reviewed sdTCG for CDISC SENDIG DARTv1.2 potential contradictions.
- Reviewed sdTCG for General SEND notes based on CDISC feedback
- CDISC Lab Units Representation
- CDISC Rare Diseases TAUGv1.0
- CDISC Controlled Terminology Relationships-v1.0
- ADaM Metadata Submission Guidelines-v1.0
- SENDIG Genetox-v1.0
- SENDIG-DARTv1.2
- CDISC PASI Feldman-v1.0
- CDISC PASI Fredriksson-v1.0
- CDISC PASI Bozek-v1.0
- CDISC PASI EMAv1.0
- CDISC QRS Template
- CDISC KFSSv2.1
- Rutgeerts Score-v1.0 - Public Comment/QRS Instrument
- SF36V2.0 ACUTE - Public Comment/QRS Instrument
- Montreal Crohn's-v1.0 - Public Comment/QRS Instrument
- Columbia-Suicide Severity Rating Scale Already Enrolled Subjects (C-SSRS)v2.0- Public Comment/QRS Instrument
- Short Form 36 Health Survey Acute, US Version 2.0 (SF36 V2.0 STANDARD) v1.0- Public Comment/QRS Instrument

Submission Data Standards Assessment

CBER and CDER completed a joint assessment on the inventory of all data standards associated with regulatory submissions that reside within the eCTD. This effort aimed to accurately and thoroughly document both data and exchange standards for submission content, evaluate and determine whether current state of data and their associated standards are fit-for-purpose.

5.1.2 Objective 2: Improve Pre and Post Market Safety Surveillance Data

Biologics Effectiveness and Safety (BEST) Innovative Methods (IM)

In support of CBER's mission for post-market safety surveillance, in 2021, the Biologics Effectiveness and Safety (BEST) Innovative Methods (IM) initiative developed and tested the BEST platform, a proof-of-concept adverse events validation and reporting system. The BEST platform aims to utilize health information exchanges to improve the quality of adverse event reports submitted to CBER. The BEST platform uses the emerging HL7 FHIR standards to request and receive additional clinical data from health providers to enrich the reported cases of adverse events. In 2022, in collaboration with eHealth Exchange, the largest health information exchange network in the United States, the BEST platform launched a pilot to connect to production systems of early adopters. The BEST platform has the potential to improve the quality of information regarding adverse events reported to the FDA while minimizing the burden on providers and the public. The HL7 FHIR Implementation Guide: Profiles for ICSR Transfusion and Vaccination Adverse Event Detection and Reporting was updated in August 2023 to address comments received and the changes were approved by HL7. In addition, the Implementation Guide has been included under Adverse Event Reporting within the 2024 Interoperability Standards Advisory Reference Edition published by the Office of the National Coordinator for Health Information Technology.

FDA Adverse Event Reporting System (FAERS) II

FAERS is a mission critical system for FDA. FAERS supports CBER and CDER's post-marketing safety surveillance program for all marketed drug and therapeutic biological products. The FAERS II program was initiated to provide a modernized system for safety surveillance, including pre-market and post-market safety reports along with product quality defect reports. The goal for the system is to become a one-stop shop solution for intake, triage, and case processing. It will also allow for enhanced and unified data analytics and signal management lifecycle solution utilizing ICH E2B R3 standard.

To prepare for accepting ICH E2B R3 standard, industry testing was conducted. Six companies participated in testing and FAERS received 259 Pre & Post market files. The scope of the testing was to send appropriate acknowledgements to the companies once the files are received and for FAERS to process the test files. After the conclusion of industry testing, further updates and internal testing was conducted, and the system was deemed ready to start accepting ICH E2B R3 post market files.

To assist with testing, FDA provided the FDA E2B(R3) Validator tool to facilitate the validation of the E2B(R3) XML files generated from industry's safety database. This validator tool provides a web-based interface that enables submitters to submit an E2B(R3) XML file in a test environment

and check the validity or correctness of the file. The validation status and results are displayed to the user in real-time.

In 2024, FDA plans to start accepting E2B R3 files. Details will be posted on the FAERS Electronic Submission web page.

5.2 Goal 2: Data Standards Policy

Guidance Documents

In December 2023, FDA published the Final version of its guidance (originally published as Draft for comment in 2021) regarding the use of data standards for the submission of study data containing RWD.

FDA Data Standards Catalog

The FDA Data Standards Catalog lists the study data standards, exchange formats, and terminologies that FDA supports and requires for use in regulatory submissions. In 2023, the Agency published 5 updates to the FDA Data Standards Catalog.

IDMP

In March 2023, FDA published the “Identification of Medicinal Products – Implementation and Use” guidance, outlining the Agency's position and approach to support the development and global implementation of the ISO Identification of Medicinal Products (IDMP) standards. The harmonized global implementation of IDMP standards will improve the accuracy, completeness, and consistency in the international exchange of medicinal product information among stakeholders.

Real-World Data Guidance

FDA published the Final version of its guidance titled “Data Standards for Drug and Biological Product Submissions Containing Real-World Data” in December 2023. This guidance provides recommendations to sponsors for complying with section 745A(a) of the FD&C Act (21 U.S.C. 379k-1(a)) when submitting RWD as study data in applicable drug submissions.

Study Data Technical Conformance Guide (sdTCG)

To ensure that current information continues to be available, new versions of the technical specifications associated with Providing Regulatory Submissions in Electronic Format — Standardized Study Data guidance, specifically the Data Standards Catalog and sdTCG, were updated throughout 2023. The sdTCG provides specifications, recommendations and general considerations on how to submit standardized study data using the FDA Data Standards Catalog. In 2023, the Agency published 6 versions of the sdTCG (as opposed to the usual 2).

5.3 Goal 3: Efficient Information Management

The CDER Enterprise Data Governance project was initiated in 2022 with the goal of developing and implementing a data governance framework across CDER data domains such as Facilities Data and Products Data. In 2023, the project continued to refine the Data Governance operating model and collaborate with other enterprise level data governance efforts within CDER to improve

data management processes. Specifically, the CDER Enterprise Data Governance project helped mature data governance across people, process and technology.

The team introduced new key data governance roles and responsibilities and focused on operationalizing these roles at the office level.

The CDER Enterprise Data Governance project also created standard templates for key data governance artifacts that helped to define data expectations in a more consistent way, and also introduced common data quality dimensions such as data integrity, data consistency, data accuracy from which data quality rules could be defined.

For 2024, both Facility and Product Data control boards will work to integrate CDER Enterprise Data Governance practices and literacy, which in turn will promote consistency in the way artifacts are defined and further standardize CDER's data-related operations.

5.4 Goal 4: Enhance Transparency and 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 initiatives:

Program Operations	Updates
Outreach Opportunities, Public Meetings & Educational Activities	HL7 Weekly Calls, Work Group Meetings and Connectathon Vulcan FHIR Accelerator, co-leads and/or participants in multiple tracks IDMP/GIDWG & UNICOM TransAtlantic Meetings Monthly FDA/CDISC Technical Meetings ICH M8 Implementation Work Group Meetings PHUSE CSS Clinical Trials Transformation Initiative SBIA Presentations on IDMP, PQ/CMC, and the Data Standards Program

FDA actively engages with Clinical Data Interchange Standards Consortium (CDISC) to adopt and implement standards that enable the exchange of study data, further enhance data quality, and improve the consistency and reliability of clinical trial data submitted for regulatory review. The Agency ensures alignment with CDISC standards through collaborative discussions, and participations in workshops, public meetings, and other ongoing communications.

FDA maintains a collaborative relationship with the International Organization for Standardization (ISO), particularly regarding the global implementation of ISO IDMP and ICSR standards.

Through this collaboration the Agency aims to enhance global alignment of regulatory data management and medicinal product identification processes across international borders, which will ultimately improve global pharmacovigilance while enable more expeditious resolution of drug shortages.

FDA participates in the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), a global initiative involving regulatory authorities and industry representatives from multiple member countries. Through participation in ICH working groups and conferences, the Agency contributes expertise and insights to the development of guidelines that support harmonization of international regulatory practices with an aim to reduce duplication of efforts.

6 Moving Forward - 2024 CBER-CDER Data Standards Program Direction

With required electronic study data standards and electronic submissions in effect or coming into effect, respectively, CBER and CDER continues to focus on ensuring that the review environment is capable of supporting receipt, processing and review of all electronic data. Continued collaboration with SDOs and stakeholders to ensure long-term sustainability of supported data standards as well as the testing of new standards and terminologies, will be a key focus of the Data Standards Program.

To support communication of new technical specifications, conformance guides, and relevant standards information, the sdTCG will be updated in March and October of 2024 and posted on the CDER Data Standards Program webpage. FDA webpages (e.g., PDUFA VII Informatics page, Study Data Standards Resources, PQ/CMC, IDMP Webpage) will be updated throughout 2024. These updates will ensure a consistent external web presence, revised materials, and interactive tools for both internal and external stakeholders.

In addition to these project areas, FDA is committed to continuing support for demonstration efforts that highlight standards-based technology solutions for collection of related healthcare and clinical research information. Several projects of focus for CBER and CDER going into 2024 includes SPL on FHIR, PQCMC Standardization, and evaluation of Dataset-JSON for study data submissions. For updates on a comprehensive list of ongoing projects in 2024, see the DSP Action Plan published quarterly on the CDER Data Standards Program webpage.

Appendix A: Glossary of Acronyms

ANDA	Abbreviated New Drug Application
BEST - IM	Biologics Effectiveness and Safety - Innovative Methods
BLA	Biologics License Application
BR	Business Rules
BR&R	HL7 Biomedical Research and Regulation Group
BRIDG	Biomedical Research Integrated Domain Group
CBER	Center for Biologics Evaluation and Research
CCB	Change Control Board
CDER	Center for Drug Evaluation and Research
CDISC	Clinical Data Interchange Standards Consortium
CDM	Common Data Model
COA	Clinical Outcome Assessment
DSP	Data Standards Program
DSDG	Data Standards and Data Governance Board
eCRF	Electronic Case Report Form
eCTD	Electronic Common Technical Document
EDC	Electronic Data Collection
EHR	Electronic Health Record
EMA	European Medicines Agency
EUA	Emergency Use Authorization
FAERS	FDA Adverse Event Reporting System
FD&C Act	Federal Food, Drug, and Cosmetic Act
FHIR	Fast Healthcare Interoperability Resources
FRN	Federal Register Notice
FY	Fiscal Year
GSRS	Global Substance Registration System
IDMP	Identification of Medicinal Product
IND	Investigational New Drug
ISO	International Organization for Standardization
NCATS	National Center for Advancing Translational Sciences
NDA	New Drug Application
NIH	National Institutes of Health
PDUFA	Prescription Drug User Fee Act
PhUSE	Pharmaceutical Users Software Exchange
PQ/CMC	Pharmaceutical Quality/ Chemistry, Manufacturing, and Controls
RWD	Real World Data
SDO	Standards Development Organization
SEND	Standard for Exchange of Nonclinical Data
SENDIG	Standard for Exchange of Nonclinical Data Implementation Guide
SOP	Standard Operating Procedure
SPL	Structured Product Labeling
TA	Therapeutic Area
TCG	Technical Conformance Guide
TRC	Technical Rejection Criteria
WHO UMC	World Health Organization Uppsala Monitoring Centre