CBER-CDER Data Standards Program 2025 Annual Assessment

June 2026

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 as depicted in Figure 1 CBER-CDER Data Standards Strategic Goals. The following sections highlight the program's accomplishments.

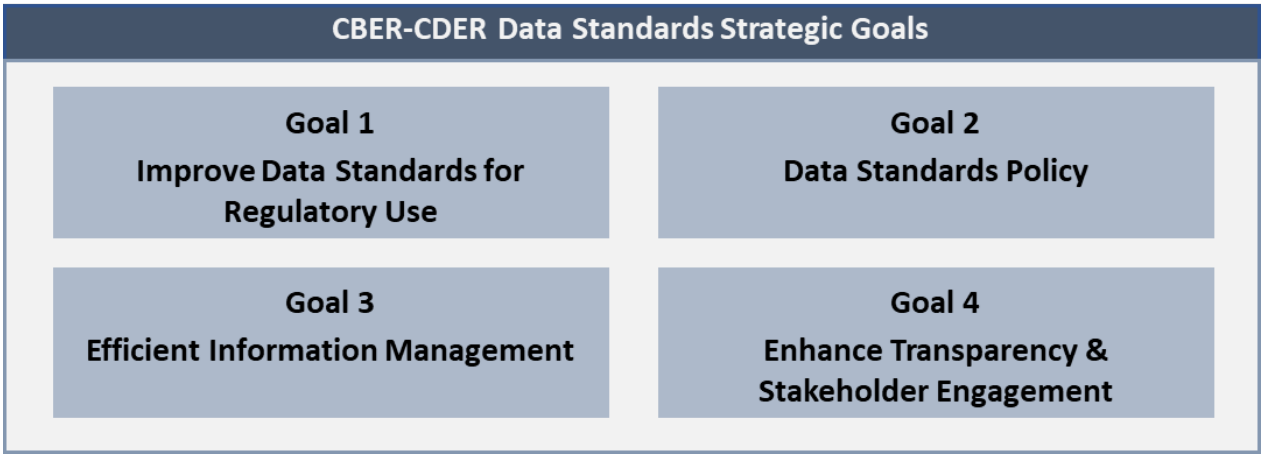

Figure 1 CBER-CDER Data Standards Strategic Goals

2025 Summary of Accomplishments

- Completed Phase 1 of the Electronic Common Technical Document (eCTD) v4.0 Project and initiated Phase 2 to enable Forward Compatibility which will allow industry to transition in flight eCTD v3.2.2 applications to eCTD v4.0.
- FDA Substance Registration System adopted Identification of Medicinal Products (IDMP) and Pharmaceutical Product Identification (PhPID) concepts as part of the FDA's Unique Ingredient Identifier (UNII) framework.
- The Data Standards Testing and Implementation team reviewed upcoming high-impact properties in the development phase at Clinical Data Interchange Standards Consortium (CDISC), including the Study Data Tabulation Model Implementation Guide (SDTMIG) v.4.0, SDTM v3.0, and the Standard for Exchange of Nonclinical Data Implementation Guide (SENDIG) v4.0.

- The Biologics Effectiveness and Safety (BEST) Innovative Methods (IM) project developed and validated Large Language Models (LLM) and Clinical Quality Language (CQL) methodologies for adverse event detection.
- FDA initiated daily publication of adverse event data from the FDA Adverse Event Monitoring System (AEMS) and launched the FDA AEMS Public Dashboard for Cosmetic Products.
- Completed 17 assessments of study data models, technical documents, and terminologies to evaluate suitability for regulatory review.
- Published one update to the FDA Data Standards Catalog (DSC) and two updates to the Study Data Technical Conformance Guide (sdTCG).

3 Impact of Requiring Standards

FDA continued to evaluate and 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 2025 Electronic Submission Metrics

Analysis of FY 2025 data, as depicted in Figure 2 Percent of All Submissions to CBER and CDER, indicated that 84% of all submissions to CDER were in eCTD format, 15.5% in other electronic formats, and 0.5% paper. Compliance with required application types in eCTD format was nearly 100%. For CBER, more than 76% of all submissions were in eCTD format, with 23% in non-eCTD formats and approximately 1% paper submissions. CBER's metrics include submissions that are not subject to the eCTD requirement.

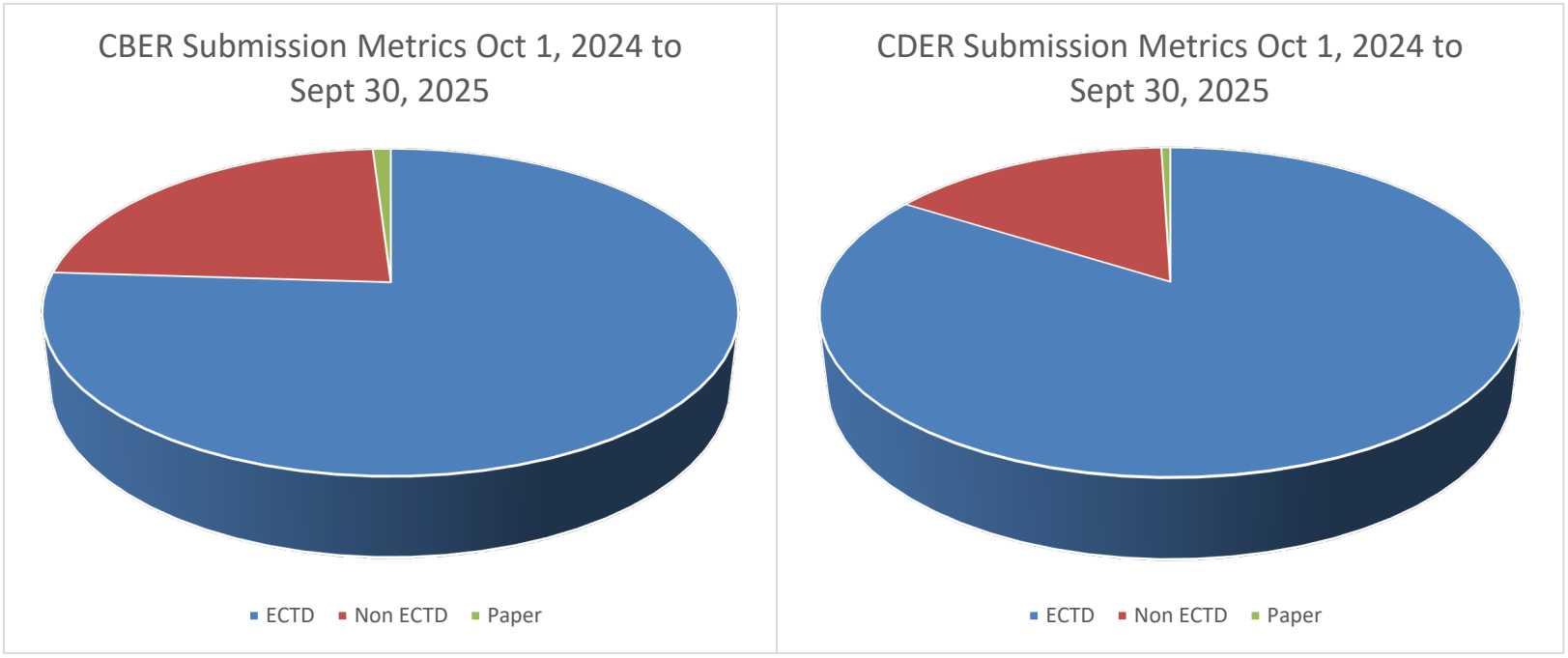

Figure 2 Percent of All Submissions to CBER and CDER

CBER - 46,827 Total Submissions

ECTD	76%
Non ECTD	23%
Paper	1%

CDER - 429,879 Total Submissions

ECTD	84%
Non ECTD	15.5%
Paper	0.5%

In 2020, FDA expanded electronic options for transmitting non-eCTD submissions. CDER's Electronic Submissions Gateway Next Generation (ESG NextGen) Portal began accepting non-eCTD submissions to Research Investigational New Drugs (IND) and Drug Master File (DMF) Type III applications. Utilizing ESG NextGen or the Electronic Submissions Gateway (ESG) provides an easier and faster way to transmit a non-eCTD submission compared to paper or physical media (e.g., CD/USB Drive).

In April 2024, the AEMS system began accepting IND safety reports utilizing the E2B(R3) format. Previously, commercial IND safety reports were only submitted to FDA in eCTD format. As of April 2026, FDA requires electronic submissions of premarketing (IND study) individual case safety reports (ICSRs) in electronic format using the E2B(R3) data standards. The requirement applies to commercial IND sponsors submitting ICSRs electronically to AEMS via ESG NextGen using database-to-database transmission (E2B(R3) data standards). In 2025, AEMS received 50,000+ E2B(R3) IND safety reports.

Overall, CDER received 99.5% of all submissions electronically with 96% following either eCTD or E2B(R3) data standard.

5 2025 Data Standards Program Year in Review

In 2025, CBER and CDER's Data Standards Program (DSP) continued to make significant progress on multiple fronts including, but not limited to, updates to the FDA Data Standards Catalog and the sdTCG, and conducted 17 assessments of study data models, technical documents, and terminologies to evaluate suitability for regulatory review.

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

Consistent with the 21st Century Cures Act and the Food and Drug Omnibus Reform Act of 2022, FDA has issued guidance about the use of 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 Electronic Health Record (EHR) systems used by hospitals and primary care clinics in the United States and insurance claims databases used to document billing for medical care events. 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 advances in this space. FDA's efforts to support submission of study data from RWD sources include evaluations by FDA comparing RWD to currently accepted data standards at FDA, clarifying the pertinent supported data standards for study data based on RWD sources, and supporting various projects addressing the needs of RWD use for research and regulatory submissions such as the OneSource project. In April 2025, FDA published a Federal Register Notice (FRN) seeking input on the potential use of Health Level Seven's (HL7) Fast Healthcare Interoperability Resources (FHIR) standards for submitting study data derived from real-world data sources to the Agency, as part of efforts to support interoperability and modernize regulatory data submissions.

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 2025, FDA/CDER engaged with industry volunteers for five clinical studies and three nonclinical studies to submit three versions of dataset packages: the original XPT v5 dataset packages, the converted JSON dataset packages, and the dataset packages converted back into their XPT v5 format. The goals were to confirm receipt of these dataset packages and that data integrity had been maintained across all three versions. Based on the testing results, FDA concluded that Dataset-JSON does not demonstrate superiority over existing processes and that premature adoption was found to risk negatively impacting reviewer and analyst productivity and efficiency. FDA will continue participating in future Dataset-JSON testing efforts, though specific dates have not yet been determined.

eCTD V4.0 Project – Phase 1

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

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

CBER and CDER completed Phase 1 and published an FRN announcing that support begins on September 16, 2024, for original eCTD v4.0 applications and subsequent submissions.

eCTD V4.0 Project – Phase 2

Phase 2 of CBER and CDER's implementation of eCTD v4.0 is enabling Forward Compatibility, the ability for industry to transition in-flight eCTD v3.2.2 applications to eCTD v4.0.

CBER and CDER performed testing on eCTD software and determined it requires further software revisions to complete the project. Phase 2 is scheduled to conclude near the end of FY26 and will be followed by a Technical Pilot to engage with industry.

Engagement with HL7

FDA's organizational membership in Health Level Seven International (HL7) is mission-critical to fulfilling the Agency's public health mandate. Through this membership, FDA actively participates in and benefits from the development of consensus-based data standards that form the foundation of national and global health information exchange infrastructure. These standards are integral to FDA's regulatory oversight, post-market safety surveillance, real-world evidence generation, and public health emergency response functions.

CBER and CDER as well as other organizations at FDA hold designated voting memberships within HL7 and are responsible for identifying, evaluating, and reviewing draft standards relevant to FDA's regulatory mission.

As part of FDA's participation with HL7, the HL7 FHIR Accelerator program for clinical research (Vulcan) was jointly created by academia, sponsors, regulatory and translational research organizations, including Taiwan Food and Drug Administration (TFDA), National Institutes of Health (NIH), TransCelerate Biopharma, HL7, CDISC, as well as several large professional societies. CBER and CDER are actively involved in Vulcan, serving as FDA representatives to Vulcan's steering and operations committees to ensure that the solution is aligned with regulatory review needs. In June 2025, CDER participated in the Vulcan Interoperability Bridge (VIB) and demonstrated a FHIR-based adverse event reporting to FDA from an academic medical center EHR system as well as directly from patients' Personal Health Records (PHRs).

CBER and CDER actively participated in the HL7 Biomedical Research and Regulation (BR&R) workgroup, contributing to the development and harmonization of common standards for clinical and translational research. This participation supported semantic interoperability across

regulatory bodies, research organizations, and the broader healthcare and life sciences communities, and helped ensure that HL7 and external information interchange standards are robust enough to accommodate regulated clinical research.

International Council for Harmonisation eCTD File Tag Controlled Terminology

The International Council for Harmonisation (ICH) accepted the proposal to expand the controlled terminology list of eCTD File Tags proposed by FDA and published the updated terminology list in May 2024. In 2025, FDA published updates to its eCTD specifications webpage, showing support for the new file tags as of February 2025.

IDMP Project

As FDA focuses on the challenges of the global supply chain and foreign sourcing of medicinal products, the Agency continued to participate and promote conformance to international harmonized IDMP to foster the safety of medications throughout the world. In June 2019, Version 7.0 of the IDMP FAQ document was published as a living document on the International Pharmaceutical Regulators Programme (IPRP) website, intended to support implementation of the International Organization for Standardization (ISO) IDMP standards and IPRP/IDMP. SMEs are currently preparing Version 8.0 of the IDMP FAQ. In addition, Version 2.0 of the business rules (EU IDMP implementation Guide version 2.0) was published by the European Medicinal Agency (EMA) in February 2025 for pharmaceutical companies and relevant medicinal professionals.

The FDA's guidance for industry, Identification of Medicinal Products (IDMP) – Implementation and Use, was published in March 2023 for sponsors, applicants, and registrants involved in the regulatory submission of medicinal product data. IDMP concepts were adopted within the FDA Substance Registration System as part of the FDA's UNII framework. FDA also adopted Medicinal Product Identification (MPID) using NDC (National Drug Code) as FDA's regional MPID in FDA electronic Vaccine Adverse Event Reporting System (eVAERS) and Adverse Event Monitoring System (AEMS).

Pharmaceutical Quality/Chemistry, Manufacturing, and Controls Data Standardization

The Pharmaceutical Quality/Chemistry, Manufacturing, and Controls Data (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. At the January 2024 HL7 Connectathon, FDA tested the first iteration FHIR Implementation Guide, encompassing "Stage 1" of PQ/CMC (product composition, general substance information, and multiple quality specification reports). The Implementation Guide was then balloted for HL7 review and comment and ultimately published as Release 1, Standard for Trial Use (STU) 1.0.0. The next iteration Implementation Guide added support for "Stage 2" concepts (additional substance information, batch formula, and

characterization of product impurities), and was tested at the September 2024 Connectathon and submitted in December for the January 2025 HL7 ballot cycle. The latest iteration of the PQ/CMC project has been completed. The upcoming ICH M16 Structured Product Quality Submissions (SPQS) initiative is expected to reflect the key PQ/CMC objective of developing an international guideline for structured product quality submissions for both original applications and post-approval changes. FDA is looking forward to developing a data pipeline to parse and further consume the structured CMC data.

Questionnaires, Ratings and Scales Assessment

It is common practice for sponsors to collect data in support of a clinical trial using specific data collection instruments such as questionnaires, ratings or scales (QRS). Codifying data structures for study data collected using an instrument is an effort undertaken by Standards Development Organizations (SDOs). CDER continued to evaluate codified data structures for suitability. 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 2025, the QRS effort evaluated 9 QRS data structures or related artifacts. FDA sent substantive comments to the SDOs during development which resulted in data structures more suited to the needs of the Agency.

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 sources of eSource data is EHR systems. A large amount of clinical trial 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.

The OneSource project is a CDER-led project in collaboration with the University of California San Francisco. This project uses EHRs as the eSource in I-SPY 2.2 Breast Cancer Trial, conforming to open, consensus-based standards. The project is currently in Phase III, which 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/Assistant Secretary for Policy Technology United States Core Data for Interoperability (USCDI), aimed at for broader sharing of electronic health information to support patient care.

Common Data Model Harmonization

This project aims to register mappings among several Common Data Models (CDMs) (e.g., OMOP, Sentinel, PCORNet, i2b2/ACT, and TriNetX) and between CDMs and data standards (FHIR US Core and CDISC SDTM). This project is a collaboration between FDA, National Cancer Institute (NCI), National Center for Advancing Translational Sciences (NCATS) and HHS Assistant Secretary for Technology Policy (ASTP). The CDMH project is currently in Phase III, with the goal to enhance data sharing, aggregation, and analysis by creating a solution that enables researchers to transform data consistently and accurately and to make new discoveries to improve patient and population health.

Structured Product Labeling Fast Healthcare Interoperability Resources

In 2024, FDA held its first pilot testing of the SPL-FHIR Implementation Guide with eight industry organizations. This was successful and provided significant feedback to help improve the quality and accuracy of the SPL-FHIR Implementation Guide. Exploratory work was successfully completed in 2025 and the next steps will be determined following the evolution of FDA's data standards strategy.

Study Data Standards Testing and Implementation

This project involves testing an external organization's study data models, technical documents, terminologies, or exchange formats, for their ability to meet FDA's regulatory review needs and identify potential areas of concern. Findings and results of this effort contribute to the Agency's decisions on standards adoption. The following assessments were performed in 2025.

1. CDISC SENDIG v4.0
2. CDISC SDTMIG v4.0
3. CDISC SDTM v3.0
4. CDISC ADaM v3.0 / ADaMIG v3.0
5. CDISC Define.xml v2.1.7
6. CDISC Dataset JSON v1.1 Public Review
7. CDISC Dataset JSON v1.1 Published Review
8. Considerations for the removal of CC data out of the RS domain
9. Considerations for CDISC deprecating the PP domain from SDTM
10. Assist OGD reviewers in evaluating gaps in PK data
11. CDISC Cardiac Imaging Supplement to the Duchenne Muscular Dystrophy TAUG v1.0
12. CDISC ADaMIG for NCA Input Data v1.0
13. FDA Business Rules for SEND
14. FDA Business Rules for Clinical Data
15. Investigate adding DVCLASI to SDTMIG v4.0
16. Investigate adding INVARVLN to SDTM v3.0 / SDTMIG v4.0
17. CDISC Define.xml v2.1.8
18. CDISC ADaM ADA IG v1.0
19. HL7-FHIR FRN
20. Perform Medical Device domain evaluation pilot

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

Biologics Effectiveness and Safety Innovative Methods

The BEST IM initiative supports CBER's post-market safety surveillance mission by utilizing health information exchanges to streamline adverse event (AE) detection and improve AE report quality. The platform leverages HL7 FHIR standards to request and receive clinical data from healthcare providers, enriching reported cases while minimizing provider burden. In 2025, BEST-IM successfully developed and validated Large Language Model (LLM) and clinical quality language (CQL) methodologies for adverse event detection, demonstrating excellent performance in identifying myocarditis/pericarditis cases from COVID-19 mRNA vaccines using HL7 FHIR data exchanged through eHealth Exchange from two major health systems. The team disseminated findings through presentations at the International Society for Pharmacoepidemiology (ISPE) 41st Annual Meeting, eHealth Exchange 2025 Annual Meeting, eHealth Exchange AI Participant call, and MITRE Real World Data Technical Exchange Meeting, with an upcoming presentation accepted at HIMSS26 in March 2026. Moving forward, BEST-IM plans to expand phenotype validation studies to additional CBER-regulated products beyond vaccines, including blood products, gene therapies, and cell therapies, while continuing to advance LLM and CQL methodologies and exploring partnerships with additional Qualified Health Information Networks (QHINs) and Health Information Exchanges (HIEs) to achieve broader national coverage.

FDA Adverse Event Monitoring System (AEMS)

AEMS is a mission-critical system for FDA. AEMS supports the Office of the Commissioner (OC), CBER and CDER's safety surveillance program for investigational products, marketed drugs, biological products, and cosmetics. The AEMS II program provides a modernized system for safety surveillance, including pre-market and post-market safety reports along with product quality defect reports making it a one-stop shop solution for intake, triage, case processing, reporting and analytics. The modernized AEMS Platform also allows for enhanced and unified data analytics and signal management lifecycle solution utilizing ICH E2B(R3) data standard.

In August 2025, the FDA initiated daily publication of adverse event data from the FDA AEMS, marking a transformative advancement in the agency's safety monitoring capabilities. This milestone represents a fundamental shift from periodic to real-time data dissemination, enabling healthcare professionals, researchers, and the public to access critical safety information with unprecedented timeliness. By transitioning to daily updates, the FDA has strengthened its commitment to proactive public health protection while establishing a new standard for regulatory transparency. This enhanced data accessibility supports more rapid identification of potential safety signals.

While the FDA AEMS Public Dashboard offers stakeholders many more ways of searching for and organizing data on adverse events reported to the FDA, there remain limitations to the data. For example, while AEMS contains reports on a particular drug or biological product, this does not mean that the drug or biological product caused the adverse event. Importantly, the AEMS

data themselves are not an indicator of the safety profile of a product. For example, there are many instances of duplicative reports, submission of a report does not mean that the information included in it has been confirmed (nor it is an admission from the reporter that the product caused or contributed the event), and the information in these reports cannot be used to estimate the incidence (occurrence rates) of the events reported.

In September 2025, the agency launched the FDA AEMS Public Dashboard for Cosmetic Products, an interactive platform that enables access to real-time adverse event data. This specialized dashboard addresses a critical need for dedicated cosmetic product safety monitoring by consolidating and streamlining data that was previously more difficult to access and analyze. The platform integrates two essential data streams: mandatory serious adverse event reports submitted by responsible persons under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), and voluntary reports contributed by healthcare professionals, consumers, salon professionals, cosmetologists, and other stakeholders. This dual-source approach ensures comprehensive safety surveillance while facilitating user-friendly queries and analysis. The dashboard exemplifies the FDA's commitment to leveraging technology to enhance public safety oversight and stakeholder engagement in the cosmetics sector.

5.2 Goal 2: Data Standards Policy

The Data Standards Policy goal supports the clear and consistent communication of policies that facilitate the effective adoption and implementation of regulatory submission data standards. The DSP collaborates closely with Subject Matter Experts and review offices across CBER and CDER to accurately capture their data requirements and recommendations. This collaborative approach helps ensure that the Agency’s data standards policies remain aligned with regulatory decision-making needs, enhance data quality, promote interoperability across systems, and support harmonization with other regulators.

Guidance Documents

No guidance documents issued in 2025.

FDA Data Standards Catalog

The FDA Data Standards Catalog lists the study data models, associated technical documents, terminologies, and exchange formats FDA supports and requires for use in regulatory submissions for eCTD modules 4 and 5. In 2025, the Agency published one update to the FDA Data Standards Catalog.

IDMP

FDA released the IDMP Implementation Guidance and the associated Federal Register Notice.

Real-World Data

No guidance documents issued in 2025.

Study Data Technical Conformance Guide

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 2025. The sdTCG provides specifications, recommendations, and general considerations on how to submit standardized study data using the FDA Data Standards Catalog. In 2025, the Agency published two versions of the sdTCG.

5.3 Goal 3: Efficient Information Management

The CDER Enterprise Data Governance (DG) program aims to improve data trust, discoverability, and clarify context to enable efficient data-driven decision-making and the use of Artificial Intelligence (AI) at the center.

In 2025, the DG program coordinated with the FDA Office of Digital Transformation (ODT) data governance leads to align CDER's data governance mission and vision with agency-wide data governance strategic objectives, ensuring program coherence across organizational levels. The DG program drafted and presented a new Metadata Management policy to the Data Standards and Data Governance (DSDG) board with the goal of establishing clear procedures for metadata management across CDER and outlining the purposes of metadata creation and how it can be shared. The policy covers all mission critical datasets and establishes roles and responsibilities for maintaining technical and business datasets.

The DG program compiled a CDER Data Asset Inventory, improving data completeness for approximately 80% of inventoried systems. This encompassed metadata on datasets stored outside of CDER systems, shared datasets from other centers, agencies, and organizations, and vendor-purchased datasets. The program engaged over 70 unique points of contact across CDER to identify and confirm business, data, and system ownership for over 120 CDER IT systems, compiling detailed information on system owners, identification and description, data types, FDA data domain classifications, business capability mappings, ownership roles, data sensitivity and classification, sharing permissions, provenance, and system lifecycle.

The DG program continued to implement an Enterprise Data Catalog (EDC) tool to catalog data within CBER/CDER systems and act as a centralized metadata repository where trusted data knowledge can be built collaboratively to reduce redundancies, improving the accuracy and efficiency of data analysis through increased data discoverability and context. The program connected the tool to core CDER systems and onboarded users (giving them access to metadata and lineage across these systems) to enable efficient discovery of needed data and its context. The program created data lineage in the EDC tool that shows upstream and downstream impacts of architectural changes which can be used to efficiently implement AI and retire legacy systems. The program has trained over 70 Subject Matter Experts on 30+ systems connected to the Informatica Enterprise Data Catalog tool, enabling them to be more efficient at data management and lay a data management foundation to prepare the center for wider use of AI. The program prioritized and scanned additional CDER systems using EDC and Informatica Data Quality (IDQ) to expand metadata coverage and data quality monitoring capabilities. In addition, the program coordinated with other offices to migrate EDC from CDER-specific instances and licenses to

Agency-wide licenses, which supports the broader goal of scaling data governance tools across the agency while reducing operational costs. The program also trained data stewards, captured business glossary entries, and drafted and configured data quality rules in the center's enterprise data quality tool.

The program represented CDER interests on an ongoing multi-year effort known as Harmonized AI and Lifecycle Operations for Data (HALO), which modernizes FDAs data infrastructure by expanding the CDEROne Data Platform into a centralized, AI-ready system that unifies regulatory data from all Centers. As part of the HALO effort, the program coordinated, communicated, and provided Center level input, to ensure discussion of data governance aspects impacting CDER and the Agency. The program submitted a GenAI use case, as part of the Orange Book modernization, intended to automatically structure and extract data from approval letters and approved labeling documents, which currently require manual extraction. The Orange Book identifies drug products approved by the FDA under the Federal Food, Drug, and Cosmetics (FD&C) Act and the GenAI solution is intended to reduce the manual effort of reading and entering data for approximately 2,000 yearly new product listings and around 46,000 existing listings that require updates.

5.4 Goal 4: Enhance Transparency and Stakeholder Engagement

The FDA led and/or participated in the initiatives listed in Table 1 in support of this goal.

Table 1 - Stakeholder Engagement Initiatives

Program Operations	Updates
Outreach Opportunities, Public Meetings & Educational Activities	• CDISC interchange meetings • FDA-UTMB Course on Achieving Data Quality and Integrity in Maximum Containment Laboratories • eHealth Exchange 2025 Annual Meeting • HL7 Weekly Calls, Work Group Meetings and Connectathon • ICH E2B Expert Working Group Meetings • ICH M2 Expert Working Group Meetings • ICH M8 Implementation Work Group Meetings • ICH M11 Expert Working Group Meetings • ISPE 41st Annual Meeting • MITRE Real World Data Technical Exchange Meeting • Monthly FDA/CDISC Technical Meetings • Vulcan FHIR Accelerator, co-leads and/or participants in multiple track

FDA actively engaged with 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 ensured alignment with CDISC standards through collaborative discussions, and participation in workshops, public meetings, and other ongoing communications.

FDA maintained a collaborative relationship with the ISO, particularly regarding the global implementation of ISO IDMP and ICSR standards. For example, based on FDA guidance, ISO IDMP implemented an FDA substance registration system (SRS), eVAERS and AEMS systems. Through this collaboration, the Agency enhanced global alignment of regulatory data management and medicinal product identification processes across international borders, improving global pharmacovigilance and facilitating efforts to address drug shortages.

FDA participated in the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, 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 the goal to reduce duplication of efforts.

6 Moving Forward - 2026 CBER-CDER Data Standards Program Direction

With required electronic study data standards and electronic submissions in effect or coming into effect, CBER and CDER continued to focus on ensuring that the review environment is capable of supporting receipt, processing and review of all electronic data. A key focus of the Data Standards Program will be 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.

To support communication of new technical specifications, conformance guides, and relevant standards information, the sdTCG will be updated in March and October of 2026 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 2026. These updates will ensure a consistent external web presence, revised materials, and interactive tools for both internal and external stakeholders. For updates on a comprehensive list of ongoing projects in 2026, see the DSP Action Plan published quarterly on the CDER Data Standards Program webpage.

Appendix A: Glossary of Acronyms

ADAM	Analysis Data Model
AE	Adverse Event
AEMS	Adverse Event Monitoring System
ANVISA	Brazilian Health Regulatory Agency
BEST - IM	Biologics Effectiveness and Safety - Innovative Methods
BR	Business Rules
BR&R	HL7 Biomedical Research and Regulation 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
DDF	Digital Data Flow
DSP	Data Standards Program
DSDG	Data Standards and Data Governance Board
E2B	Electronic-to-Business
eCRF	Electronic Case Report Form
eCTD	Electronic Common Technical Document
EDC	Electronic Data Collection
her	Electronic Health Record
EMA	European Medicines Agency
ESG NextGen	Electronic Submissions Gateway Next Generation
EUA	Emergency Use Authorization
FD&C Act	Federal Food, Drug, and Cosmetic Act
FHIR	Fast Healthcare Interoperability Resources
FRN	Federal Register Notice
FY	Fiscal Year
GIDWG	Global IDMP Working Group
GSRS	Global Substance Registration System
HL7	Health Level Seven
ICH	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
IDMP	Identification of Medicinal Product
ICSR	Individual Case Safety Reports
IG	Implementation Guide
IND	Investigational New Drug
ISO	International Organization for Standardization
JHU	Johns Hopkins University
JSON	JavaScript Object Notation
NDA	New Drug Application
NIH	National Institutes of Health
PDUFA	Prescription Drug User Fee Act
PhUSE	Pharmaceutical Users Software Exchange
PhPID	Pharmaceutical Product Identification
PQ/CMC	Pharmaceutical Quality/ Chemistry, Manufacturing, and Controls
QRS	Questionnaires, Ratings and Scales (QRS) Assessment

RECIST	Response Evaluation Criteria in Solid Tumors
RWD	Real World Data
SBIA	Small Business & Industry Assistance
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
UMC	Uppsala Monitoring Centre
XML	Extensible Markup Language