
POLICY AND PROCEDURES

OFFICE OF STRATEGIC PROGRAMS

CDER Master Data Management

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PURPOSE

This Manual of Policies and Procedures (MAPP) establishes the operating model to 7600.10, program in the Center for Drug Evaluation and Research (CDER). This MAPP also defines decision making authorities, roles and responsibilities, and assigns accountability for the ongoing governance, daily operations, and project processes of CDER’s MDM program.

BACKGROUND

The U.S. Food and Drug Administration (FDA) receives a vast amount of data for regulatory submissions, from multiple sources, in a variety of formats. The data hold great potential to advance CDER’s regulatory and scientific work. However, lack of standardized data creates challenges to conducting thorough and well-organized reviews.

CDER is committed to the development, implementation, and maintenance of the CDER MDM program called “Integrity.” CDER’s MDM Integrity program promotes the implementation of data standards for the effective and efficient review of regulatory submissions through stakeholder collaboration, standards, and project implementation.

POLICY

1. CDER's MDM program employs open, consensus-based data standards in support of CDER's regulatory review process.
 2. CDER MDM projects are prioritized by projected impacts towards improving CDER's regulatory review process.
 3. CDER MDM activities are performed in support of, and in compliance with, the principles identified in the 2021 FDA Data Modernization Plan and the 2018 Center for Biologics Evaluation and Research (CBER) / CDER Data Standards Program Action Plan.
 4. The CDER MDM program is reviewed quarterly. The review measures progress toward the FDA Data Modernization Plan.
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RESPONSIBILITIES

Business Informatics Governance (BIG) Board

- Establishes effective governance of data, technology, and business informatics activities to support CDER's IT strategic advancement and modernization.
- Provides Center-level support and leadership to the Data Standards and Data Governance Board (DSDG), as needed (refer to MAPP 7610.7).
- Receives periodic updates on the CDER MDM Program from the DSDG.
- Decides the organizational commitment of resources for potential CDER projects.
- Provides oversight and decision-making authority over CDER IT investment decisions and proposed changes to overall business processes and priorities.
- Drives the work of subsidiary bodies, including CDER project, process, and data control boards, toward implementation of informatics capabilities and high-quality data for decision support.
- Responsible for the approval of projects and budget for the master data management program related activities.

Data Standard and Data Governance Board (DSDG)

- Provides leadership and strategic oversight to CDER data standard and data governance programs.
- Provides guidance to resolve issues, analyzes potential change request impacts, and evaluates master data quality challenges.
- Ensures relevant rules, regulations and guidances, and other position statements are aligned with CDER's mission and strategic plan.
- Establishes and adopts clear roles, responsibilities, and governance processes for CDER offices.
- Provides recommendation the implementation of MDM in accordance with national and international standards in areas impacting CDER.

- Supports the implementation of MDM related business processes to define, adopt, and facilitate compliance to the supported standards.
- Reviews and maintains oversight of data standards initiatives, projects, and governance activities being implemented by the MDM Program.
- Promotes communication on data standards development and implementation needs within and across CDER Offices and other agency stakeholders.
- Establishes subcommittees when appropriate.
- Provides CDER metadata oversight, including consistent definitions, data standards, controlled terminologies, data flow, and quality control processes.
- Presents recommendations, updates, and unresolved issues to the BIG Board, as needed.

Data Management Capability (Integrity Capability) Team

- Maintains a portfolio (including timeline, budget and resource allocation) of MDM projects. Manages the roadmap of MDM projects approved by the BIG Board.
- Executes MDM projects, as outlined in roadmap, with oversight provided by DSDG Board and the BIG Board. Presents MDM project information to the DSDG and the BIG Board, upon request.
- Updates the MDM program portfolio periodically. Ensures projects with policy or broader CDER impacts are reviewed by team members of the MDM program.
- Delivers timely internal and external program communications regarding MDM activities and plans, as appropriate.
- Coordinates and develops guidance, standards, policy, and process for MDM.
- Recommends the use of an existing master data, changes to master data or the acquisition of new master data to support recently identified business needs.
- Provides oversight to the development of all data profiling activities, and testing activities, and ensures business requirements related to master data are captured correctly.
- Performs metadata and technical oversight, including implementation of consistent definitions, data standards, controlled terminologies, data flow, and quality control processes.
- Implements resolutions for policy, standards and process gaps identified by DSDG and OSP Project teams.
- Identifies and assesses alternatives against defined assessment criteria by submitting one or more recommendations to the requestor.
- Executes and monitors MDM development and implementation projects in alignment with the Data Modernization Plan.
- Analyzes the business impact of each MDM change request, to prioritize change.
- Establishes clear roles and responsibilities for implementing the MDM processes.
- Ensures procedures for creating, accessing, using, modifying, and disposition of data are compliant with defined CDER Data Standards Program policies.
- Quantifies stakeholder data support requirements by capturing the requirements in the business rules and plans for stakeholder's long-term data management needs.

- Coordinates regular meetings with the Data Management Operations Team to assess the progress of data management activities, and projected business impact from change requests, and potential data conflicts.
- Establishes internal working groups, when appropriate.
- Collaborates with the Data Management Operations Team to data profile and test each new MDM solution.
- Collaborates with the OSP Project Team to ensure the completeness of the MDM implementation. Implementation is considered complete when the data can be assessed, processed, and curated utilizing the new business process, policy, standards, and guidance.
- Establishes new methods to incorporate test automation to support the MDM process.

Data Management Operations (Integrity Services) Team

- Ensures the MDM program staff follow data standards program guidelines described in MAPP 7610.7, CDER Data Standards Program.
- Supports MDM program in the identification, tracking, coordination, and resolution of master data-related questions, issues and activities.
- Leads the initial review of requests. Escalates critical issues or service requests to the Data Management Capability Team as required.
- Ensures the data entered meets data quality guidelines and service level agreements (SLAs) defined for the data domain.
- Collaborates with DSDG, to establish the operating procedure for data standards adoption.
- Reviews and makes recommendations to Data Management capability team on new master data standards or updates to currently supported data standards.
- Coordinates and provides oversight on data entry, data management operations, issue coordination, resolution, monitoring, and quality control for multiple master data domains, as needed.
- Coordinates the development and implementation of MDM standard operating procedures and service level agreements, when appropriate.
- Collaborates with the Data Management Capability Team to data profile and test each new MDM solution.

OSP Project Managers

- Ensures each project has sufficient resources, including Data Management Capability team, Data Management Operations team, end users, data analysts, process analysts, and subject matter experts (SMEs).
- Establishes project timelines.
- Reports project progress and changes, to the Data Management Capability team, Data Management Operations team and OSP Project Teams.
- Provides scheduled updates to the BIG Board.

OSP Project Team

- Functions for a specified OSP project.
- Triage the CDER staff request, routes to the Data Management Operations team and/or the Data Management Capability Team.
- Ensures business requirements are captured.
- Develops projecting testing plans.
- Develops and executes a plan to implement the master data.
- Maintains open communication with the CDER staff requestor.
- Fulfills project objectives within the agreed timeframe.
- Collaborates with the Data Management Capability Team to ensure the completeness of each of the MDM components related implementation. Implementation is considered complete when the data can be assessed, processed, and curated utilizing the new business process, policy, standards, and guidance.

CDER Staff Requestors

- Identifies a need. Initiates a request ticket to FDA ERIC.
 - Communicates with assigned OSP project team.
 - If the request is approved by the BIG Board or the DSDG then the requesting staff is required to participate in all stages of the project, including problem identification, gathering requirements, solution implementation, and quality testing.
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PROCEDURES

Note: The procedures are not in sequential order and are listed by activities performed by the team.

1) Request Intake Process

a) There are two intake process methods

i) Method I:

- The CDER requestor submits the identified data needs and request for data operations support to the Data Management Operations team via FDA ERIC.
- The Data Management Operations Team transfers the request to the data management capability team if it meets any one of the following criteria:
 - (a) Impacts multiple business processes
 - (b) CDER wide master data need
 - (c) Development master data solutions
 - (d) Input and approval from DSDG or Big Board as required
 - (e) Adoption of Master data solutions

ii) Method II

- The CDER requestor submits the identified business problem with a need for data management to the Data Management Capabilities team via FDA ERIC.
 - (a) Data Management Capability team will review the request and submits the request to DSDG and Big Board for approval.

2) Define scope and requirements

- a) The Data Management Capability Team reviews the change request for relevance, clarity, problem and scope and works with the CDER Requestor or OSP Project team to further define the high level requirement for the proposed MDM changes.
- b) The Data Management Capability Team submits the request for review, proposed budget and timeline for prioritization, and approval to both the DSDG and the BIG Board.
- c) The DSDG and the BIG Board meets on a monthly basis to review and assess the project documentation to determine if the proposed project should move forward, and if project constraints are appropriate.

3) Analyze Alternatives:

- a) The Data Management Capability Team is the responsible for performing in-depth alternatives analysis, assessing, and evaluating the solution based on the scope of the requirements from the CDER Requestor.
- b) The Data management capability team informs the DSDG board on the proposed recommended changes to MDM solutions.

4) Solution Implementation of Change to the MDM

- a) The Data Management Capability Team recommends the use of an existing master data, changes to master data, or the acquisition of new master data to support the CDER Requestor or OSP Project team's identified business need.
 - i) If the Data Management Capability Team recommends the use of existing master data to resolve the business problem, the OSP project team proceeds directly to the testing and validation phase.
 - ii) If the Data Management Capability Team recommends either a change to an existing master data, or a new data, the Data Management Capability Team communicates with the OSP Project team. The OSP Project team collaborates with FDA SMEs to implement subsequent changes to MDM solution.

5) Data Profiling and Testing the MDM Solution

- a) The Data Management Capability Team and the Data Management Operations Team are responsible for the data profiling and testing of the MDM solutions.
- b) The Data Management Capability Team collaborates with Data Management operations team and the OSP Project Team document the scope of data profiling and testing required.

- c) The Data Management Capability Team provides oversight to the development of all data profiling activities, testing activities and ensures business requirements related to master data are captured correctly.
- d) The Data Management Capability Team and the OSP Project team review the documentation, the data profiling results and the testing recommendations. Comments are shared with DSDG, as needed.
- e) If required by the testing method, the Data Management Operations Team and the OSP Project team perform actual tests, generation, receipt, and processing of electronic submissions utilizing the MDM solution.
- f) Data Management Capability Team works with the OSP Project Team to decide if the MDM solution is ready for adoption by CDER business users.

6) Determine master data solution adoption

- a) The Data Management Capability Team collaborates with the OSP Project Team to determine the scope and timeline for master data solution adoption.
- b) The OSP Project Team delivers input criteria to the Data Management Capability Team and the Data Management Operations Team for review. Input examples include, but are not limited to:
 - Project Plan.
 - Requirements.
 - Alternative analysis results.
 - Estimated cost, if applicable.
 - Impact on people, process, or systems.
 - Any testing reports.
- c) The data management capability team assesses the results to decide to recommend adoption of the standard. If the standard has broad center impact, it may be referred to the DSDG for final approval.

7) The Data Management Capability Team Implements the MDM solution.

- a) The Data Management Capability Team collaborates with the OSP Project Team to develop and execute a plan to implement the MDM solution.
- b) Implementation activities may include, but are not limited to:
 - Communication with all stakeholders.
 - Initiation of IT tools or software changes.
 - Initiation of necessary process changes.
 - Identification of the needed process, and policy changes.
- c) Development and delivery of standard operating procedures (SOPs) and training.
- d) The Data Management Capability Team conducts periodic health checks on the MDM processes, data flow and data quality.
- e) The Data Management Capability Team and the OSP Project Team are responsible for ensuring the completeness of the MDM implementation. Implementation is considered complete when the data can be assessed, processed, and curated utilizing the new business process, policy, standards, and guidance.

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DEFINITIONS

Data Standards and Data Governance Board (DSDG): A team of data subject matter experts. Members of the DSDG represent each CDER office.

Data Profiling: Data profiling is the process of analyzing the data available from the source systems. The analysis of data for use helps to understand anomalies and assess data quality, but also to discover, register, and assess enterprise metadata. The result of the analysis is used to determine the suitability of the candidate source systems, usually giving the basis for an early go/no-go decision.

ERIC: Employee Research & Information Center serves as a help desk, providing administrative and information technology services.

Integrity: An initiative within CDER to build capabilities necessary to enable a single authoritative source of master data.

Integrity Services Operations: A centralized data management operations team within CDER's OBI, responsible for actively managing and maintaining CDER's master data.

Master Data: A centralized, shared source of business data used across multiple systems, applications, and processes. CDER’s master data may include highly curated data about products, sponsors, applications, studies, drug supply chains, ingredients, facility, or reference data and their relationships.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
07/18/2013	Initial	n/a
4/13/2022	1	Update includes new governance structures and expands roles, and responsibilities.

ATTACHMENT 1 -CDER Master Data Management Organization

