

POLICY AND PROCEDURES

OFFICE OF STRATEGIC PROGRAMS

CDER Master Data Management

Table of Contents

PURPOSE.....1

BACKGROUND1

POLICIES2

RESPONSIBILITIES2

PROCEDURES4

REFERENCES.....5

DEFINITIONS5

EFFECTIVE DATE.....6

 ATTACHMENT 1: Index of Acronyms.....7

 ATTACHMENT 2: MDM Services Organizational Model 8

PURPOSE

This MAPP describes CDER’s Master Data Management Services (MDM Services) policies and procedures. It establishes an operating model to support the master data needs for CDER’s Offices, defines decision making authorities, defines roles and responsibilities, and assigns accountability. This MAPP also establishes centralized master data management for all key data domains, including product, facility, sponsor, and submissions.

BACKGROUND

In order to address CDER’s current IT challenges, a single source for master data called “Integrity” has been established. Master data is a centralized, single source of business data used across multiple systems, applications, and processes. Master data may include data about product, sponsor, application, or facility.

Business processes rely on accurate, good quality regulatory data to satisfy operational requirements and to support the agency’s mission. Effective methods for receiving, storing, disseminating, reporting, analyzing, and retaining regulatory data are required.

CDER’s Office of Business Informatics (OBI) established MDM Services to:

- Define and operationalize centralized data management services
- Support master data needs for key data domains.

- Actively manage the centralized master data through its life cycle
 - Preserve the single authoritative source of CDER's data.
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POLICIES

1. Master Data Management (MDM) Services is a centralized data management team, serving as the single point of contact for all data related needs across CDER business lines.
 2. OBI is accountable for providing MDM Services.
 3. CDER's Center Director is the executive sponsor for MDM Services.
 4. The single source for CDER master data is Integrity.
 5. Integrity will be maintained by CDER's MDM Services.
 6. A Business Group is established to provide subject matter expertise. Each of CDER's offices are responsible for appointing members.
 7. All operational procedures are documented and published in the MDM Services Standard Operating Procedures (SOP). This SOP is available on a centralized portal maintained by MDM Services.
 8. Requests for new master data domains and changes to existing master data domains will be addressed by the CDER Informatics Governance process, as per MAPP 7600.8 Rev. 1.
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RESPONSIBILITIES

MDM Executive Sponsor

- Makes key decisions for MDM Services. Provides overall direction and guidance.
- Serves as an escalation point for master data conflicts across CDER's Offices.

CDER's Office Directors

- Appoints one or more employees to the Business Group.

MDM Services Team

- Meets bi-weekly to discuss issues and change requests.
 - Provides subject matter expertise to assess business impact, and to prioritize change requests.
 - Coordinates with MDM Services Manager to ensure potential changes are incorporated, and documented, in the MDM Services SOP.
 - Monitors overall data quality.
 - Recommends process and master data changes.
 - Informs the Business Group of requests and changes
 - Publishes a monthly consolidated report for the Business Group.
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MDM Services Manager

- Serves as point of contact for the MDM Services Team.
- Manages day-to-day operations. Provides timely resolutions to issues.
- Facilitates weekly status meeting with the MDM Services Team to assess the progress of data management activities.
- Leads the initial review of requests. Escalates critical issues or service requests to the MDM Services Team.
- Ensures all changes and issues are incorporated into MDM Services SOPs, by the Data Steward.
- Meets bi-weekly with the Business Group.

Data Steward

- Evaluates, prioritizes and resolves issues and service requests.
- Maintains single version of truth for each master data domain.
- Performs data management activities, to ensure the master data is accurate.
- Coordinates with the MDM Services Team to assess business impact related to change requests, data conflicts and issues.
- Maintains and updates the issue log and SOP.
- Escalates critical issues to the MDM Services Team.
- Performs routine maintenance tasks such as data entry, verification, modification and reconciliation of master data.
- Ensures procedures for creating, accessing, using, modifying, and disposition of data are not violated in according to defined policies and standards.

Business Group

- Assists Business Process Owners with master data initiatives.
- Represents key business processes and offices for their respective master data needs.
- Participates in MDM Services Team planning meetings, as needed.
- Provides requirements for data standards, quality metrics and service levels to support their Office's business process.
- Provides subject matter expertise for each specific business process.
- Provides guidance to resolve issues, analyzes potential change request impacts, and evaluates master data quality challenges.

Technical Support

- Provides operations and maintenance support for the Master Data Management technology platform.
 - Oversees and ensures effective implementation of technology changes supporting master data related initiatives.
 - Provides IT related impact and cost analysis of master data initiatives, issues and change requests.
 - Ensures the allocation of sufficient resources and expertise to support master data initiatives and change requests
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PROCEDURES

1. The MDM Services Team defines, maintains and publishes the MDM Services SOPs to enable centralized data management activities, including service request management, issue resolution and data maintenance.
2. All MDM Services SOPs will be updated by the MDM Services Team's Data Steward, as required. The MDM Services SOPs are published at the centralized portal, and communicated to the Business Group.
3. Subject matter experts from the Business Group are leveraged for escalation of unresolved issues and other critical master data related decisions. The MDM Services team keeps the Business Group informed of requests and changes and publishes a monthly consolidated report.
4. CDER users should request access to Integrity, the single authoritative source for master data, for their master data needs via MDM Services. MDM Services provides a centralized portal for submitting service requests.
5. The Data Steward reviews and prioritizes service requests and coordinates issue resolution.
6. Service Level Agreements (SLAs) are established and published on the centralized portal.
7. Centralized Data Management will be executed by the MDM Services Team, including:
 - SOPs will be established by MDM Services to support MDM Services in ensuring timely, complete and quality.
 - Data entry users will be responsible for manually entering master data through the implemented technology.
 - Data Stewards will perform routine maintenance tasks such as data entry, verification, quality assurance, modification and reconciliation of master data. In addition, Data Stewards ensure procedures for creating, accessing, using, modifying, and distribution of data are not violated in according to defined policies and standards.
 - Data Entry resources will make sure that the data being entered meets the data quality guidelines and SLAs defined for the data domain.
 - Data entry, data management, issue coordination, resolution and ad hoc support of multiple master data domains will be handled by the MDM Services Team, thus improving the operational efficiencies.

Quality Assurance

A comprehensive quality assurance procedure has been developed to perform ongoing data quality activities.

Issue Resolution

An issue resolution procedure has been developed for escalation of unresolved issues, involving key stakeholders. The principles of CDER MAPP 4151.8, *Equal Voice*, and MAPP 4151.2, *Resolution of Differing Professional Opinions: Review by Ad Hoc Panel and Center Director* will be employed to resolve issues, as appropriate.

REFERENCES

1. OMB, Circular A-130, Revised. Management of Federal Information Resources.
 2. Clinger – Cohen Act, 40 USC 1401 et seq., 1996.
 3. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.8 Equal Voice: Discipline and Organizational Component.
 4. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.2, Rev. 1, Resolution of Differing Professional Opinions: Review by Ad Hoc Panel and Center Director.
 5. FDA, 2013. Staff Manual Guide 1270.2, Office of Strategic Programs.
 6. FDA, 2004. Staff Manual Guide 2010.3. FDA Data Standards Council.
 7. FDA, 2004. Staff Manual Guide 3210.2. IT Investment Management.
 8. FDA, 2004. Staff Manual Guide 3210.3. IT Project Management Policy.
 9. FDA, 2004. Staff Manual Guide 3230.2. Enterprise Architecture Policy.
 10. FDA, 2007. Staff Manual Guide 3251.1. Information Resource Management – Information Technology Security.
 11. FDA, 2013, Center for Drug Evaluation and Research, MAPP 7600.8, Rev. 1, CDER Informatics Governance Process.
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DEFINITIONS

Business Group: is a group of business process subject matter experts representing each office within CDER.

Business Process Owners: The business owners of CDER business processes.

Data Entry Users: Employees of the MDM Services Team and the users that maintain the master data within technology platform.

Data Stewards: OBI staff who perform routine maintenance tasks such as data entry, verification, modification and reconciliation of master data. In addition, Data Stewards ensure procedures for creating, accessing, using, modifying, and disposition of data are not violated in according to defined policies and standards.

Data Quality Monitoring: The continuous process of monitoring and resolving data quality issues geared towards maintaining accurate data for specific business use.

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

Issue Management: is the process of identifying, analyzing, escalating, remediating and monitoring issues related to the activities performed in maintenance of master data.

MDM Executive Sponsor: The overall sponsor for the Integrity initiative.

Master Data: The data that brings meaning to transactional data, normally managed within a technology storing a single source of truth of basic business data used across multiple systems, applications, and processes. Master data may include data about product, sponsor, application, facility, or similar data domains. While it is often non-transactional in nature, it is not limited to non-transactional data, and often supports transactional processes and operations.

Master Data Management (MDM) Services: A centralized data management service within OBI, responsible for actively managing and maintaining CDER's master data.

Pharmaceutical Quality Program: A multi-year effort to improve FDA's ability to better ensure the availability of accurate information on products and facilities, support the use of modern risk-based techniques to ensure an active and efficient inspection regime, and modernize the Agency's work processes along with the development of quality indicators and metrics to further enhance the Agency's ability to ensure the public is confident in the quality, integrity, and security of human drugs.

Service Level Agreement (SLA): A document that outlining the different service levels and performance criteria that MDM Services will commits to. SLAs quantify expected response times for fulfilling change requests and resolving issues.

Single Source of Truth: refers to the practice of storing one version of master data one common place for a specific data domain.

Technology Platform: is the technology implemented to support business processes.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

ATTACHMENT 1: Index of Acronyms

Term	Description
CDER	Center for Drug Evaluation and Research
ESC	Executive Sponsorship Committee
FDA	Food and Drug Administration
HHS	Health and Human Services
IT	Information Technology
MAPP	Manual of Policies and Procedures
MDM	Master Data Management
O&M	Operations and Maintenance
OBI	Office of Business Informatics
OIM	Office of Information Management
OSP	Office of Strategic Programs
SLA	Service Level Agreement
SOP	Standard Operating Procedures

ATTACHMENT 2: MDM Services Organizational Model

For the successful execution of business processes in Product approval lifecycle, an organizational structure will be established. Clearly defined roles and responsibilities will be assigned to stakeholders to perform certain business activity. Outlining the organizational structure also provides clear path for escalation of issues and new development needs towards maintaining quality of data. Figure below is a depiction of the organizational structure for MDM Services which will be applied for each master data domain within the scope.

