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FDA Staff Manual Guides, Volume I – Organizations and Functions

Food and Drug Administration

Office of the Commissioner

Office of Digital Transformation

Office of Data, Analytics, and Research

Effective: August 24, 2021

1. Office of Data, Analytics, and Research (DCADC).

A. Manages and improves FDA's ability to leverage data as a strategic asset by establishing enterprise data strategy and priorities.

B. Develops and manages a centralized comprehensive data inventory accounting for all data assets across the FDA.

C. Provides enterprise data services to FDA customers.

D. Develops and maintains a technological and analytical infrastructure that is responsive to FDA's strategic data needs, leveraging traditional and emerging analytical methods to improve decision making, optimize outcomes, and create efficiencies.

E. Provides enterprise data governance and advisory services related to data lifecycle management processes.

F. Develops data policy to set guidelines for data sharing and ensuring that FDA's data assets are effectively managed and secured.

G. Coordinates and sponsors driver and foundation projects to advance the use of data and Real-World Data at FDA and the broader stakeholder ecosystem.

H. Fosters, coordinate and sponsor use and applicability of Real-World Data (RWD) and Real-World Evidence (RWE) in evaluation and research of medical products.

I. Develop FDA-wide talent capabilities of data scientists and a data workforce in collaboration with other Government agencies).

2. Data Staff (DCADC1)

A. Provides data analytics to enable customers to have their data collected, processed and presented to them in the form of actionable insights.

B. Provides data visualizations to enable customers to understand and identify trends, patterns, and outliers within large data sets to support data-driven decisions.

C. Provides data lakes to support big data processing in the cloud for faster and efficient business outcomes in a cost-effective way.

D. Develop regulatory standards for use of Real-World Data (RWD) through consistent use of data elements, metadata assets mapping in RWD catalogs; disseminate for FDA-wide implementation through driver projects

E. Assist in Real-World Evidence (RWE) generation for regulatory use through development of innovative methodologies and analytics in partnership with internal and external partnerships

F. Supports the Data Laboratory to conduct research studies with internal and external collaborators that advance the use and understanding of data, RWD, and RWE.

3. Health Informatics Staff (DCADC2)

A. Coordinates and sponsors standards-based electronic data submission, brokering, storage, retrieval, analysis, and knowledge dissemination.

B. Assists in the development of the Knowledge Architecture through standards-based Master Data capability.

C. Defines, advocates and implements data exchange standards consistent with health information technology and the industry.

D. Implements harmonized controlled vocabularies; implements Master Data Management for key elements; and utilizes enterprise information flow processes.

4. Knowledge Management Staff (DCADC3)

A. Plans, directs and coordinates FDA Library programs and knowledge services to determine policy and provide oversight for the provision of library, information, and data services to better serve the FDA and the public.

B. Provides knowledge, information, and data services for ODAR to carry out its public health mission.

C. Collaborates on research and product development projects to provide FDA with information and data to meet its public health mission.

D. Collects, organizes, maintains and preserves information resources and data in all areas of FDA's research and regulated products.

E. Increases awareness of Library and ODAR services, staff expertise, and its research through customer engagement. Provides services and resources to FDA, Health and Human Services (HHS), other Federal employees and the public on a limited basis.

F. Curates data to facilitate data discovery, retrieval, re-use, and preservation. Transforms legacy data to standardized formats.

5. **Authority and Effective Date**

The functional statements for the Office were approved by the Acting Commissioner of Food and Drugs on July 22, 2021 and effective on August 24, 2021.

Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner
Office of Digital Transformation
Office of Data, Analytics, & Research

Office of
Data, Analytics, & Research

Data Staff
Health Informatics Staff
Knowledge Management Staff

(DCADC)

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of Digital Transformation, Office of Data, Analytics, and Research organization structure depicting all the organizational structures reporting to the Director:

Office of Data, Analytics, and Research (DCADC)

Data Staff

Health Informatics Staff

Knowledge Management Staff