

## **SMG 1111.5A**

### **FDA Staff Manual Guides, Volume I – Organizations and Functions**

#### **Food and Drug Administration**

#### **Office of the Commissioner**

#### **Office of Digital Transformation**

Effective: August 24, 2021

#### **1. Office of Digital Transformation (DCAD).**

- A. Works in full partnership with the agency's business areas to develop and communicate the overall vision, mission, values, and roadmap for Information Technology (IT), data, and cybersecurity at FDA.
- B. Works in full partnership with the CIO, Office of Digital Transformation (ODT) Senior Leadership, and operating unit leaders to develop and communicate the overall ODT enterprise vision, mission, values, and roadmap.
- C. Directs and coordinates agency-wide information resource planning to ensure that Agency IT, data, and cybersecurity resources are selected and managed to provide maximum value to FDA.
- D. Provides consultation to the Commissioner, Chief Information Officer (CIO), Executive Committee, and other key FDA officials on IT, data, and cybersecurity resources and programs. This includes activities that affect FDA-wide information technology programs, projects, and initiatives.
- E. Supports initiatives identified by the Commissioner, CIO, and ODT Senior Leadership and ensures strategic business goals, policies, and objectives are fully implemented to achieve measurable results for ODT.
- F. Coordinates the development and updating of agency-wide IT, data, and cybersecurity policies under the direction of the Chief Information Officer (CIO), Chief Technology Officer (CTO), Chief Data Officer (CDO), and Chief Information Security Officer (CISO).
- G. Oversees implementation of the FDA's IT policy and governance, procedures and processes to bring the FDA in conformance with relevant laws, policies, and delegations.
- H. Serves as an advisor to various ODT programs by providing guidance on operational and organizational excellence, including planning, process improvement, change management, performance, evaluation, etc. for services, practices, systems, etc. to align with ODT- and FDA-wide management operations objectives.

- I. Represents the FDA IT, data, and cybersecurity programs on internal and external meetings and workgroups on FDA information technology programs and issues (e.g., Health and Human Services (HHS) Chief Information Officer (CIO) Council, HHS CDO Council, HHS CISO Council, FDA Leadership Council, FDA Level Review Boards, etc.).

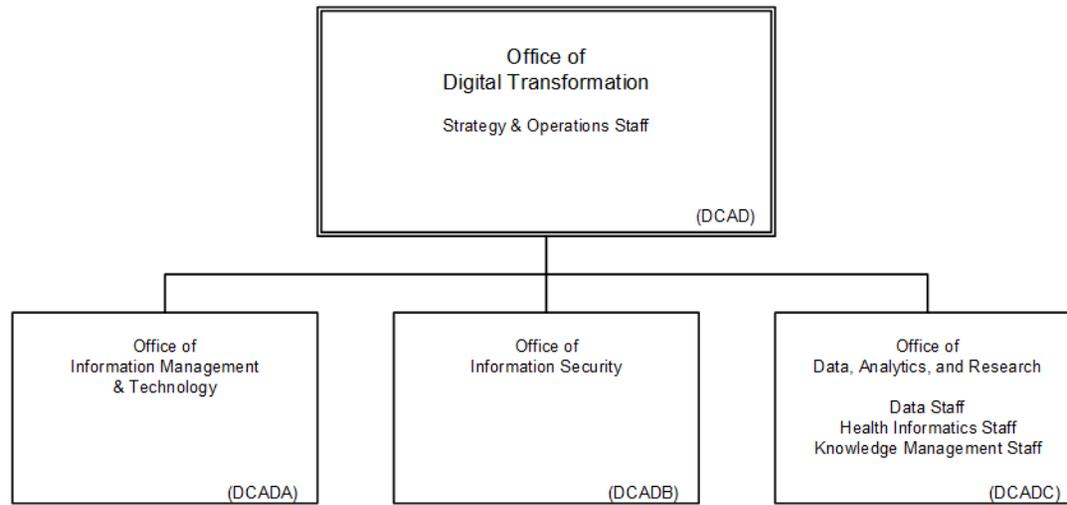
## **2. Strategy and Operations Staff (DCAD1)**

- A. Responsible for the strategic leadership, policy development, and operational management oversight of enterprise services and executive operations, and comprises budget strategy, human capital strategy, planning, performance management, program evaluation, governance, strategic communications, etc. functions.
- B. Develops and manages action plans to ensure the implementation of strategic goals by coordinating with internal and external office components, and facilitating communication with external stakeholders, partners, and customers.
- C. Develops, manages, and executes strategic initiatives and special projects in alignment with the CIO's and FDA's information technology, data, and cybersecurity, and product goals, priorities, strategies, and activities.
- D. Helps to design, spearhead, and transition new programs of strategic significance to the CIO related to critical leadership and operational areas.
- E. Develops and implements operational and organization innovations and efficiencies to deliver improved services across ODT components. This includes the coordination and management of enterprise business process transformation and change across ODT.
- F. Provides organizational planning and design services to ODT executives to translate business strategy into an optimal enterprise structures; helps design optimal functions, components, and teams; and leads organizational change initiatives.
- G. Develops and maintains management information and data necessary for monitoring and reporting the CIO's and FDA's IT, data, cybersecurity, and product goals, priorities, strategies, and enterprise risk management. This includes recommendations, roadmaps, dashboards, and strategic communication products.

## **3. 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 Technology & Delivery  
Office of Business & Customer Assurance  
Office of Enterprise Portfolio Management

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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 organization structure depicting all the organizational structures reporting to the Chief Information Officer:

The organizations below report to the Office Digital Transformation (DCAD):

Strategy and Operations Staff

Office of Information Management and Technology (DCADA)

Office of Information Security (DCADB)

Office of Data, Analytics, and Research (DCADC)

The organizations below report to the Office of Information Management and Technology (DCADA):

Office of Technology and Delivery

Office of Business and Customer Assurance

Office of Enterprise Portfolio Management

The organizations below report to the Office of Data, Analytics, and Research (DCADC):

Data Staff

Health Informatics Staff

Knowledge Management Staff