SMG 1220.2

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Regulatory Operations

Division of Informatics and Information Technology

Effective Date: January 6, 2022

1. Division of Informatics and Information Technology (DCBIA).

A. Collects, classifies, stores, retrieves, and disseminates of recorded knowledge used by Center for Biologics Evaluation and Research in the review and regulatory process.

B. Oversees receiving, tracking, storing and managing CBER's regulatory submissions and records.

C. Develops and manages CBER's Information Technology (IT) Investments in review, scientific, and administrative areas.

D. Promotes and coordinates the development and management of regulatory data standards for review of regulatory submissions, provides support for CBER review staff and administers compliance of submission with electronic standards.

2. Data Standards Branch (DCBIA1).

A. Promotes the development of data standards for the effective and efficient review of regulatory submissions through stakeholder collaboration, policy development, and project implementation.

B. Develops, implements, and maintains regulatory data standards internal processes and guidance documents.

C. Analyzes and evaluates current regulatory data standards requirements and makes authoritative recommendations to CBER management to revise or modify existing policies and procedures. Identifies areas for improvement and promotes data standard innovation.

D. Strengthens CBER's advocacy for regulatory data standards that facilitate efficient and effective data review, integration, and training.

E. Represents CBER on working groups and committees with stakeholders within and outside of the federal government.

F. Manages electronic validation criteria to ensure sponsor submissions conform to published data standards.

3. Information Technology Branch (DCBIA2).

A. Administers and directs Food and Drug Administration's (FDA) Enterprise IT Initiatives, Policies, and Standards within CBER.

B. Plans and oversees CBER's Information Technology Investments in accordance with the Office of Management and Budget, the Health and Human Services, and Office of Information Management Technology (OIMT) initiatives to ensure CBER's business needs are met. Oversight includes budget formulation and execution and investment reporting.

C. Provides operations and maintenance oversight and support to CBER's IT solutions.

D. Provides IT support to CBER staff in review, scientific, and administrative areas.

E. Represents CBER on OIMT and FDA IT Committees to advocate for the Center's IT needs.

4. Records Management Branch (DCBIA3).

A. Receives, tracks, stores and manages CBER's regulatory submissions and assigned documents.

B. Serves as CBER's Assistant Records Liaison Officer (ARLO) and provides life-cycle, media neutral, records management support services for the Center's digital and physical records, both onsite and at various commercial and government storage facilities.

C. Manages the Scientific Data Abstraction Task Order and oversees the regulatory data abstraction process associated database.

D. Manages the CBER Document Control Center, the CBER Onsite Records and Document Management Task Order and the FDA offsite records storage contract.

E. Manages databases and tools for CBER's regulatory submissions and assigned documents and the CBER Electronic Records Repository.

5. Regulatory Information Branch (DCBIA4).

A. Serves as data stewards and managers for regulatory and review data and manages data governance.

B. Provides reports and analytical assessments to support internal and external requests and CBER operations.

C. Support capacity planning assessments within CBER and FDA.

D. Manages overall data quality in concert with review quality in CBER.

E. Performs initial submission assessment and data entry into CBER regulatory databases for select regulatory submissions.

F. Develops and delivers training on databases.

6. Authority and Effective Date.

The functional statements for the Office of Regulatory Operations, Division of Informatics and Information Technology, were approved by the Deputy Secretary of Health and Human Services and effective on January 6, 2022.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluations and Research
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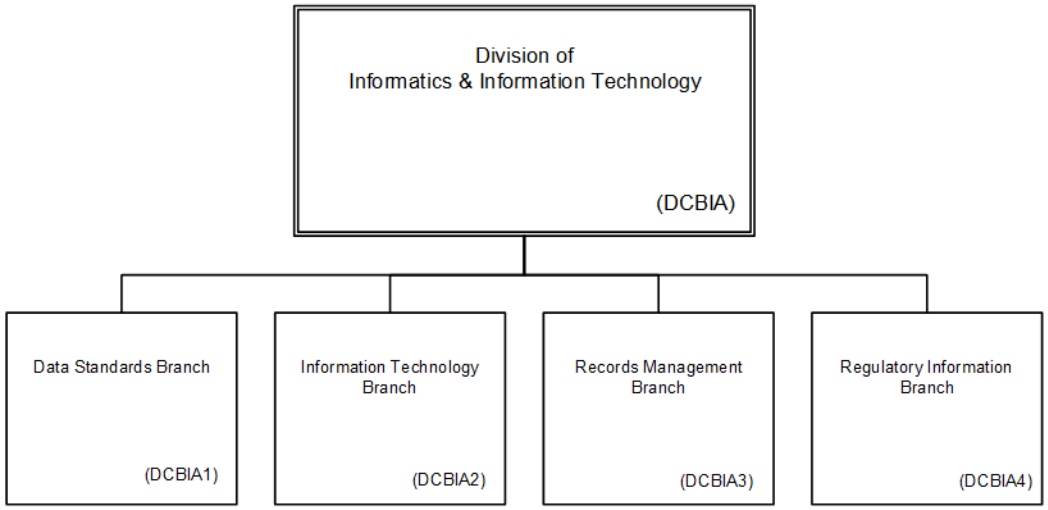

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Regulatory Operations, Division of Informatics and Information Technology organization structure depicting all the organizational structures reporting to the Director:

Division of Informatics and Information Technology (DCBIA)

These organizations report to the Division of Informatics and Information Technology:

Data Standards Branch (DCBIA1)

Information Technology Branch (DCBIA2)

Records Management Branch (DCBIA3)

Regulatory Information Branch (DCBIA4)