

**FDA Staff Manual Guides, Volume I - Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Center for Drug Evaluation and Research**

**Office of New Drugs**

**Office of Drug Evaluation Science**

**Division of Biomedical Informatics, Research & Biomarkers Development**

Effective Date: September 25, 2019

**1. Division of Biomedical Informatics, Research & Biomarkers Development (DCDGNB).**

- A. Promotes the implementation and development of biomarkers as drug development tools, supports Office of New Drugs' (OND) research needs, and evaluates new drug development technologies to foster drug development.
- B. Provides oversight of the Food and Drug Administration (FDA)'s Biomarker Qualification Program.
- C. Contributes subject matter expertise to OND review divisions for use of biomarkers in drug-specific development programs.
- D. Engages with internal and external stakeholders to advance the development of scientific standards and policy for biomarkers.
- E. Provides oversight of OND's research portfolio including budget formulation, execution and tracking.
- F. Coordinates activities of Associate Director for Regulatory Science within the clinical offices.
- G. Bridges clinical and informatics expertise to develop tools and best practices for analyses and interpretation of diverse data sources, thereby empowering clinical reviewers to make data-driven decisions that impact public health.
- H. Provides oversight of OND's knowledge management and data standards

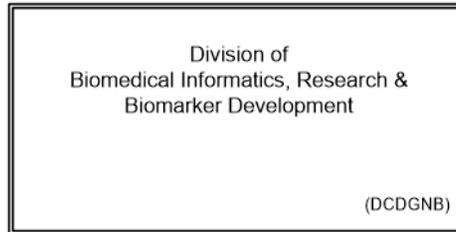
activities.

- I. Coordinates activities of Associate Director for Biomedical Informatics within the clinical divisions.
- J. Engages with internal and external stakeholders to advance improvements to knowledge management, data standards, and safety analytics processes.

## **2. Authority and Effective Date.**

The functional statements for the Division of Biomedical Informatics, Research & Biomarkers Development were approved by the Secretary of Health and Human Services on September 25, 2019.

**Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of New Drugs  
Office of Drug Evaluation Science  
Division of Biomedical Informatics, Research & Biomarker Development**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs, Office of Drug Evaluation Science, Division of Biomedical Informatics, Research & Biomarker Development organization structure depicting all the organizational structures reporting to the Director.

Division of Biomedical Informatics, Research & Biomarker Development (DCDGNB).