

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 Translational Science

Office of Biostatistics

Division of Analytics and Informatics

Effective: February 9, 2022

1. Division of Analytics and Informatics (DCDJAJ).

- A. Provides leadership, direction, and coordination on emerging needs pertaining to analytics and informatics including the development and application of data standards, statistical programming, documentation and tools to the Office of Biostatistics (OB) and Center for Drug Evaluation and Research (CDER).
- B. Provides policy development and coordination to the CDER on statistical mathematical and computational aspects of review, evaluation and research, clinical trials and pre-clinical toxicological studies.
- C. Develops, maintains, and utilizes analytics and informatics to streamline drug application review including automation of review activities by building standardized tools.
- D. Provides comprehensive oversight of the processes established for the development of analysis data standards for the therapeutic areas and standard operating procedures for the review of data from regulatory submissions.
- E. Provides guidance on use of big data and analytics including strategic preparedness of future trends.
- F. Provides guidance on analytics and informatics as they relate to drug development and regulatory review in CDER and actively collaborates with other offices across the FDA.
- G. Conducts research and development in statistical, biomathematical, computational and other scientific decision-making methodologies.

2. Authority and Effective Date.

The functional statements for the Division of Analytics and Informatics were approved by the Commissioner of Food and Drugs on December 7, 2021, and effective on February 9, 2022.

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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 Translational Science, Office of Biostatistics, Division of Analytics and Informatics organization structure depicting all the organizational structures reporting to the Director:

Division of Analytics and Informatics (DCDJAJ)