

SMG 1213.4

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 Biostatistics and Pharmacovigilance

Division of Analytics and Benefit-Risk Assessment

Effective Date: September 30, 2022

1. Division of Analytics and Benefit-Risk Assessment (DCBDC).

- A. Improve the efficiency, consistency, and rigor of the methods used by the office to evaluate the safety and effectiveness of CBER regulated products.
- B. Develop and apply new methods and tools for improving observational epidemiological studies, data mining, comparative effectiveness studies, and other quantitative aspects of the evaluation of the risks, benefits, and use of biologic products.
- C. Lead the office's programs on quantitative benefit-risk assessment, Real-World Evidence (RWE), analytics, and informatics projects, supporting the office's review, regulatory, and public health missions.
- D. Represent the office, participate, and contribute to discussions, meetings, and conferences related to benefit-risk assessment, RWE, and analytics and informatics projects.
- E. Operate the High-performance Integrated Virtual Environment (HIVE), which consists of a high-performance computing cluster (HPC) with petabyte scale high-availability storage; a sophisticated web-based genomics analysis platform; support for machine learning in Python and R; and a team of expert bioinformaticians, computer scientists, and software developers.

2. Benefit-Risk Assessment Branch (DCBDC1)

- A. Improve the efficiency, consistency, and rigor of the methods used by the office to evaluate the safety and effectiveness of CBER regulated products.

- B. Develop and apply new methods and tools for improving observational epidemiological studies, data mining, comparative effectiveness studies, and other quantitative aspects of the evaluation of the risks, benefits, and use of biologic products.
- C. Lead the office's programs on quantitative benefit-risk assessment work that supports the office's review, regulatory, and public health missions.
- D. Represent the office, participate, and contribute to discussions, meetings, and conferences related to benefit-risk assessment.
- E. Conducts quantitative benefit-risk assessment to support regulatory decisions. Reviews benefit-risk assessments submitted with biologics license applications or other submissions.

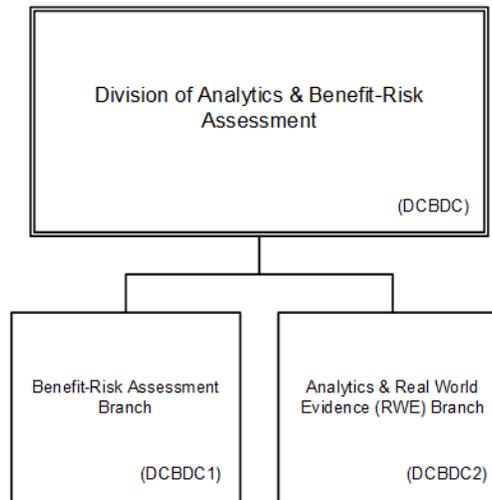
3. Analytics and Real-World Evidence (RWE) Branch (DCBDC2)

- A. Improve the efficiency, consistency, and rigor of the methods used by the office to evaluate the safety and effectiveness of CBER regulated products.
- B. Lead the office's programs on Real-World Evidence, analytics, and informatics projects, supporting the office's review, regulatory, and public health missions.
- C. Develops capability and policy for the use of real-world evidence in regulatory decisions.
- D. Represent the office and participate in and contribute to discussions, meetings, and conferences related to RWE, analytics, and informatics projects.
- E. Performs complex data analysis on next-gen sequencing experiments, adds custom analytics and pipelines to the HIVE platform, trains and support users, and assists with big data transfer and storage.

4. Authority and Effective Date.

The functional statements for the Office of Biostatistics and Pharmacovigilance, Division of Analytics and Benefit-Risk Assessment were approved by the Commissioner of Food and Drugs and effective on September 30, 2022.

**Department of Health and Human Services
Food and Drug Administration
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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 Biostatistics and Pharmacovigilance, Division of Analytics & Benefit-Risk Assessment, organization structure depicting all the organizational structures reporting to the Director:

Division of Analytics & Benefit-Risk Assessment (DCBDC)

These organizations report to the Division of Analytics & Benefit-Risk Assessment:

Benefit-Risk Assessment Branch (DCBDC1)

Analytics & Real World Evidence (RWE) Branch (DCBDC2)