SMG 1213.1

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

Effective Date: September 30, 2022

1. Office of Biostatistics and Pharmacovigilance (DCBD).

A. Provides comprehensive statistical, pharmacovigilance, and epidemiological evaluation of data submitted to the Center in support of regulatory requirements.

B. Collaborates with other Center components to provide reviews and assessments of regulated biological products.

C. Represents the Center within the Food and Drug Administration (FDA), the Public Health Service, the Department, and elsewhere regarding initiatives relating to the statistical and/or epidemiological evaluation of medical products, including the evaluation of product safety.

D. Contributes to the development of regulatory policy in areas relevant to the disciplines of biostatistics, pharmacovigilance, and epidemiology, such as post-marketing surveillance and the design, conduction, and analysis of studies to evaluate medical products.

E. Conducts independent research relating to statistical, pharmacovigilance, and epidemiological methods for assessing the efficacy and safety of biological products, and for assuring the quality and consistency of their manufacture.

2. CBER Surveillance Program Staff (DCBD1).

A. Works collaboratively with the Office of Biostatistics and Pharmacovigilance (OBPV) and Center for Biologics Evaluation and Research (CBER) staff to identify key post-market safety and effectiveness questions for biologics to be addressed by Sentinel studies.

B. Coordinates and formulates the design of appropriate studies and analytic plans.

C. Builds the infrastructure for an active surveillance system of biologics using large-scale administrative claims and electronic health record data from a variety of sources.

3. Business Management Staff (DCBD3).

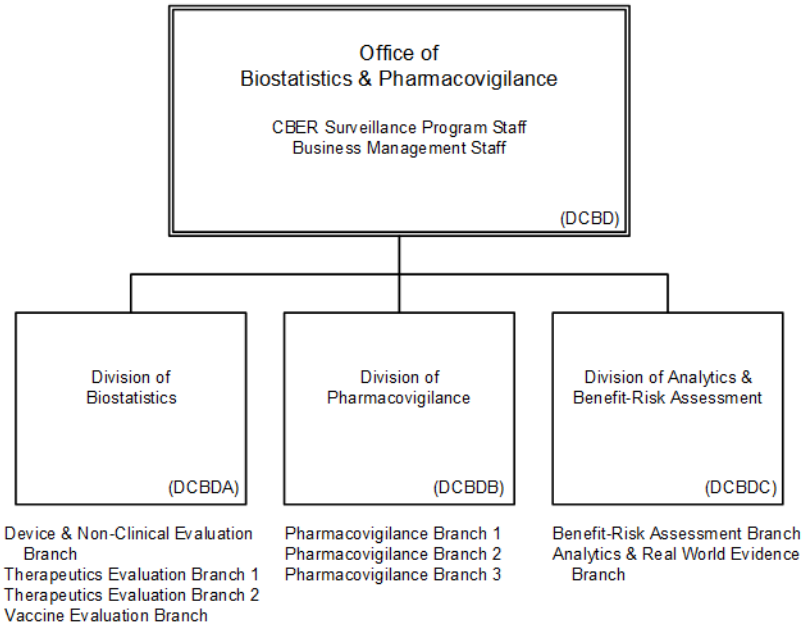
A. Provides administrative management and oversight for the Office of Biostatistics and Pharmacovigilance activities and resource allocations. Advises the office director on administrative services and develops policies and procedures for these services.

B. Plans and directs office operations for financial and personnel management.

4. Authority and Effective Date.

The functional statements for the Office of Biostatistics and Pharmacovigilance 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
Center for Biologics Evaluations and Research
Office of Biostatistics and Pharmacovigilance



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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 organization structure depicting all the organizational structures reporting to the Director:

Office of Biostatistics and Pharmacovigilance (DCBD)

These organizations report to the Office of Biostatistics and Pharmacovigilance:

CBER Surveillance Program Staff (DCBD1)

Business Management Staff (DCBD3)

Division of Biostatistics (DCBDA)

Division of Pharmacovigilance (DCBDB)

Division of Analytics & Benefit Risk-Assessment (DCBDC)

These organizations report to the Division of Biostatistics:

Device & Non-Clinical Evaluation Branch (DCBDA3)

Therapeutics Evaluation Branch 1 (DCBDA2)

Therapeutics Evaluation Branch 2 (DCBDA4)

Vaccine Evaluation Branch (DCBDA1)

These organizations report to the Division of Pharmacovigilance:

Pharmacovigilance Branch 1 (DCBDB1)

Pharmacovigilance Branch 2 (DCBDB2)

Pharmacovigilance Branch 3 (DCBDB3)

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

Benefit-Risk Assessment Branch (DCBDC1)

Analytics & Real World Evidence Branch (DCBDC2)