SMG 1213.2

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 Biostatistics and Pharmacovigilance

Division of Biostatistics

Effective Date: September 30, 2022

1. Division of Biostatistics (DCBDA).

A. Develops and evaluates statistical methodologies for analyzing preclinical, clinical, laboratory, real world, and epidemiological data and collaborates with other Center components on such methodologies.

B. Collaborates with scientists in the Center and across Food and Drug Administration (FDA) on original research projects of common interest, providing comprehensive statistical input to Center and FDA programs.

C. Participates and provides statistical expertise to scientists in other Center components or/and Centers in the development of standards and guidance.

D. Provides statistical expertise and insight to the design of studies and the analysis and interpretation of the results.

E. Performs statistical review of Investigational New Drug (IND), Investigational Device Exemption (IDE), and 510K submissions. Participates in meetings with regulated industry to ensure optimal design and conducts an analysis of prelicensure studies.

F. Performs a comprehensive statistical review and recommends an appropriate action of licensing applications (biologics license application (BLA), pre-market approval (PMA), new drug application (NDA)) and supplements for safety and efficacy, in coordination with other Center components. Performs original statistical analyses and reviews data analyses submitted by regulated industry.

G. Trains the Center for Biological Evaluation and Research (CBER) reviewers in

the design and analysis of clinical trials and in basic biostatistics. Participates in New Reviewer Training programs.

H. Represents the Center on national and international working groups focusing on statistical methods for evaluating pharmaceutical and device products.

I. Participates in activities of professional societies to improve statistical methodology, the quality of statistical design, and analysis of studies of biological products and related medical devices.

2. Therapeutics Evaluation Branch 1 (DCBDA2).

A. Provides a comprehensive statistical review of clinical studies and/or data included in applications submitted to the Office of Tissues and Advanced Therapies (OTAT).

B. Performs statistical review and makes recommendations regarding investigational applications (IND, IDE) and licensing applications (BLA, PMA, NDA, 510(k)), including supplements for safety and efficacy.

C. Performs original statistical analyses and reviews data analyses submitted by applicants.

3. Therapeutics Evaluation Branch 2 (DCBDA4).

A. Provides a comprehensive statistical review of clinical studies and/or data included in biologics license applications for transfusion products submitted to the Office of Blood Research and Review (OBRR).

B. Provides a comprehensive statistical review of clinical studies and/or data included in applications for therapeutics such as allergenic and probiotic products submitted to the Office of Vaccines Research and Review (OVRR).

C. Provides a comprehensive statistical review of clinical studies and/or data included in applications submitted to the Office of Tissues and Advanced Therapies (OTAT).

D. Performs a statistical review and makes recommendations regarding investigational applications (IND, IDE) and licensing applications (BLA, PMA, NDA, 510(k)), including supplements for safety and efficacy.

E. Performs original statistical analyses and reviews data analyses submitted by applicants.

4. Vaccine Evaluation Branch (DCBDA1).

A. Provides a comprehensive statistical review of clinical studies included in vaccine applications to OVRR.

B. Provides a comprehensive statistical review of clinical assay studies and data included in vaccine applications to OVRR.

C. Performs a statistical review and makes recommendations regarding investigational applications (IND, IDE) and licensing applications (BLA, PMA, NDA, 510(k)), including supplements for safety and efficacy.

D. Performs original statistical analyses and reviews data analyses submitted by applicants.

5. Device and Non-Clinical Evaluation Branch (DCBDA3).

A. Provides a comprehensive statistical review of Chemistry, Manufacturing, and Controls applications submitted to all Center components.

B. Provides a comprehensive statistical review of non-clinical studies and/or data, including non-clinical assay studies, submitted to all Center components.

C. Provides a comprehensive statistical review of medical device applications, including in vitro diagnostic applications, submitted to OBRR.

D. Consults with the Vaccine Clinical Evaluation Branch on the review of clinical assays as needed.

E. Consults with other Branches in the Division of Biostatistics on the review of observational clinical studies as needed.

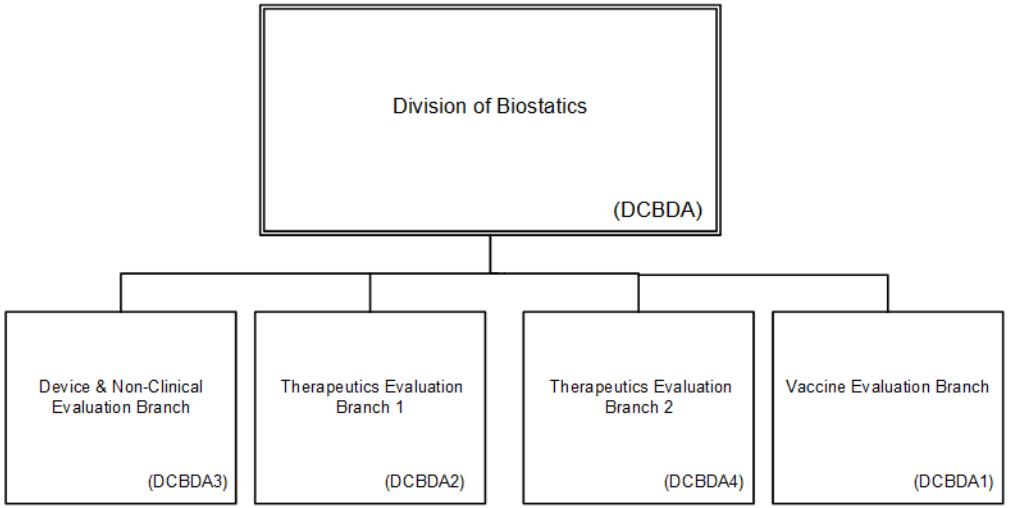
F. Consults with other Branches in the Division of Biostatistics on the review of clinical trials as needed.

G. Performs original statistical analyses and reviews data analyses submitted by applicants.

6. Authority and Effective Date.

The functional statements for the Office of Biostatistics and Pharmacovigilance, Division of Biostatistics, 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
Division of Biostatistics



Staff Manual 1213.2
Organizations and Functions
Effective Date: September 30, 2022

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

Division of Biostatistics (DCBIA)

These organizations report to the Division of Biostatistics:

Data Standards Branch (DCBIA1)

Information Technology Branch (DCBIA2)

Records Management Branch (DCBIA3)

Regulatory Information Branch (DCBIA4)