

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

Effective: September 30, 2022

1. Office of Biostatistics (DCDJA).

- A. Provides leadership, direction, policy development and coordination to the Center for Drug Evaluation and Research (CDER) on statistical, mathematical, and computational aspects of review, evaluation and research, clinical trials, and pre-clinical toxicological studies.
- B. Provides independent and collaborative evaluations and reviews to all programs and disciplines of CDER in support of CDER's scientific and regulatory review process related to new and generic drugs and new and biosimilar therapeutic biologics with special attention to the safety and efficacy of these products.
- C. Develops statistical and mathematical methods to enhance the drug review and development processes through research and applications of modeling and data analyses methods to pharmacokinetics, pharmacodynamics, pharmacoepidemiology, pharmacogenomics studies and product quality assessment.
- D. Evaluates and utilizes analytic statistical and mathematical simulation software to enhance the drug development process.
- E. Provides leadership and guidance to industry on statistical, computational and mathematical aspect of CDER's programs.
- F. Provides training and mentoring to CDER staff in biostatistics and related areas.
- G. Interacts with, Food and Drug Administration staff, Advisory Committees and interacts nationally and internationally with academia and the regulatory industry on statistical and regulatory aspects of CDER's missions.
- H. Provides support to CDER in information technology issues related to statistical review process, including the processing and analysis of data in electronic submissions.
- I. Provides independent and collaborative evaluation of pre-marketing and post-marketing safety evaluations including quantification of risks and benefits.

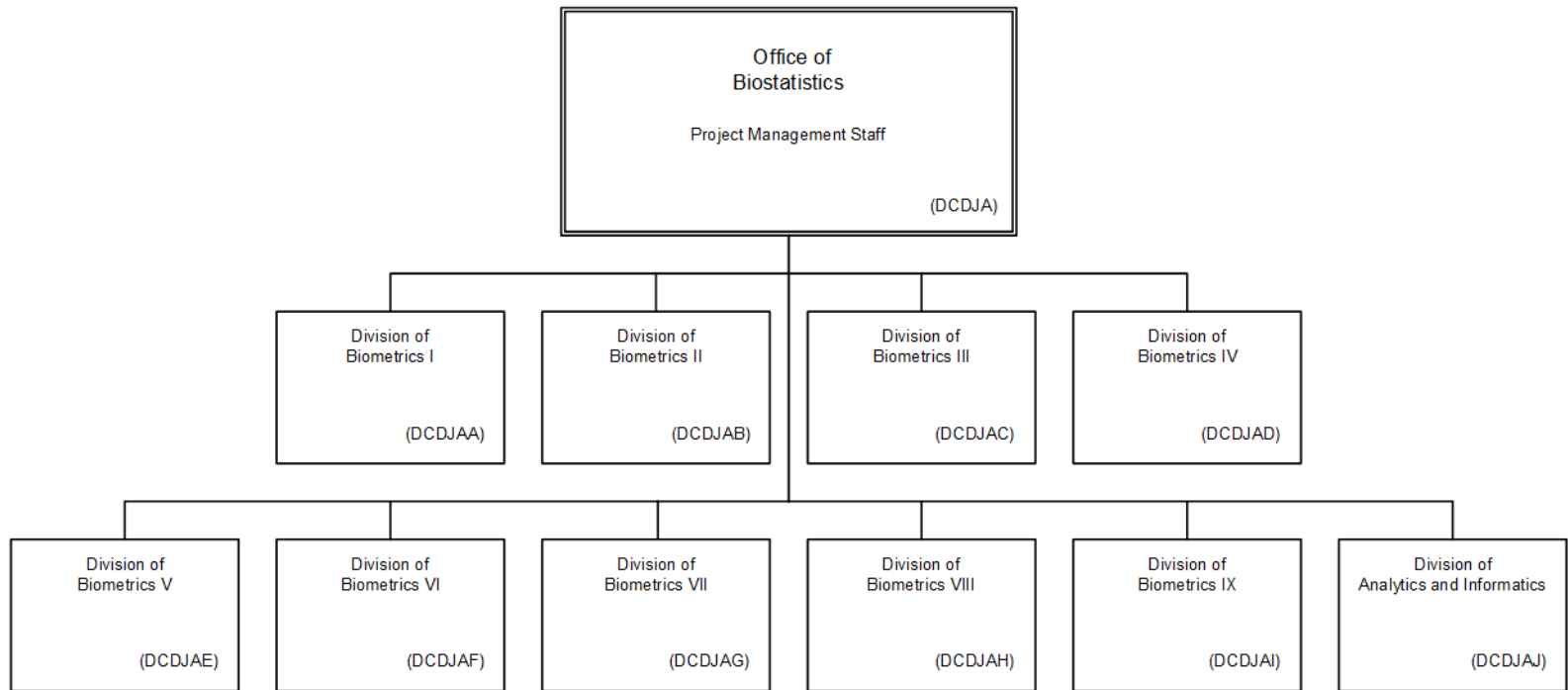
2. Project Management Staff (DCDJA2)

- A. Assists in the development of policies, processes and procedures for the Office of Biostatistics and for assigned project teams.
- B. Serves as the manager of OB projects throughout the full project lifecycle, including developing, planning, budgeting, and implementing project activities.
- C. Builds tools and knowledge management systems to enable scientific and policy analysis.
- D. Coordinates cross-cutting initiatives to address unmet needs in drug development.
- E. Liaises with internal and external stakeholders in support of regulatory review, research, and workload management.

3. Authority and Effective Date

The functional statements for the Office of Biostatistics were approved by the Commissioner of Food and Drugs on August 11, 2022, and effective on September 30, 2022.

**Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Science
Office of Biostatistics**



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

Office of Biostatistics (DCDJA)

These organizations report to the Office of Biostatistics:

Project Management Staff (DCDJA2)

Division of Biometrics I (DCDJAA)

Division of Biometrics II (DCDJAB)

Division of Biometrics III (DCDJAC)

Division of Biometrics IV (DCDJAD)

Division of Biometrics V (DCDJAE)

Division of Biometrics VI (DCDJAF)

Division of Biometrics VII (DCDJAG)

Division of Biometrics VIII (DCDJAH)

Division of Biometrics IX (DCDJAI)