

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Center for Devices and Radiological Health**

**Office of Product Evaluation and Quality**

**Office of Clinical Evidence and Analysis**

**Division of Clinical Evidence and Analysis III**

Effective: January 22, 2024

**1. Division of Clinical Evidence and Analysis III (DCCFBC).**

- A. Responsible for providing expert biostatistics analysis and input to the review of therapeutic and diagnostic devices.
- B. Responsible for providing statistical leadership and conducting statistical analyses in support of FDA programs, such as:
  - i. Development and analysis of complex innovative study designs.
  - ii. Real world data (RWD) / real world evidence (RWE).
  - iii. Development and dissemination of original research advancing statistical methodology.

**2. Authority and Effective Date.**

The functional statements for the Division of Clinical Evidence and Analysis III were approved by the Secretary of Health and Human Services on December 21, 2023, and effective on January 22, 2024.

**Department of Health and Human Services  
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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Product Evaluation and Quality, Office of Clinical Evidence and Analysis, Division of Clinical Evidence and Analysis III organization structure depicting all the organizational structures reporting to the Director:

Division of Clinical Evidence and Analysis III (DCCFBC)