

SMG 1258.25

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 V

Effective: January 22, 2024

1. Division of Clinical Evidence and Analysis V (DCCFBE).

- 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 V were approved by the Secretary of Health and Human Services on December 21, 2023, and effective on January 22, 2024.

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

Division of Clinical Evidence and Analysis V (DCCFBE)