

SMG 1258.20

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

Effective: December 14, 2018

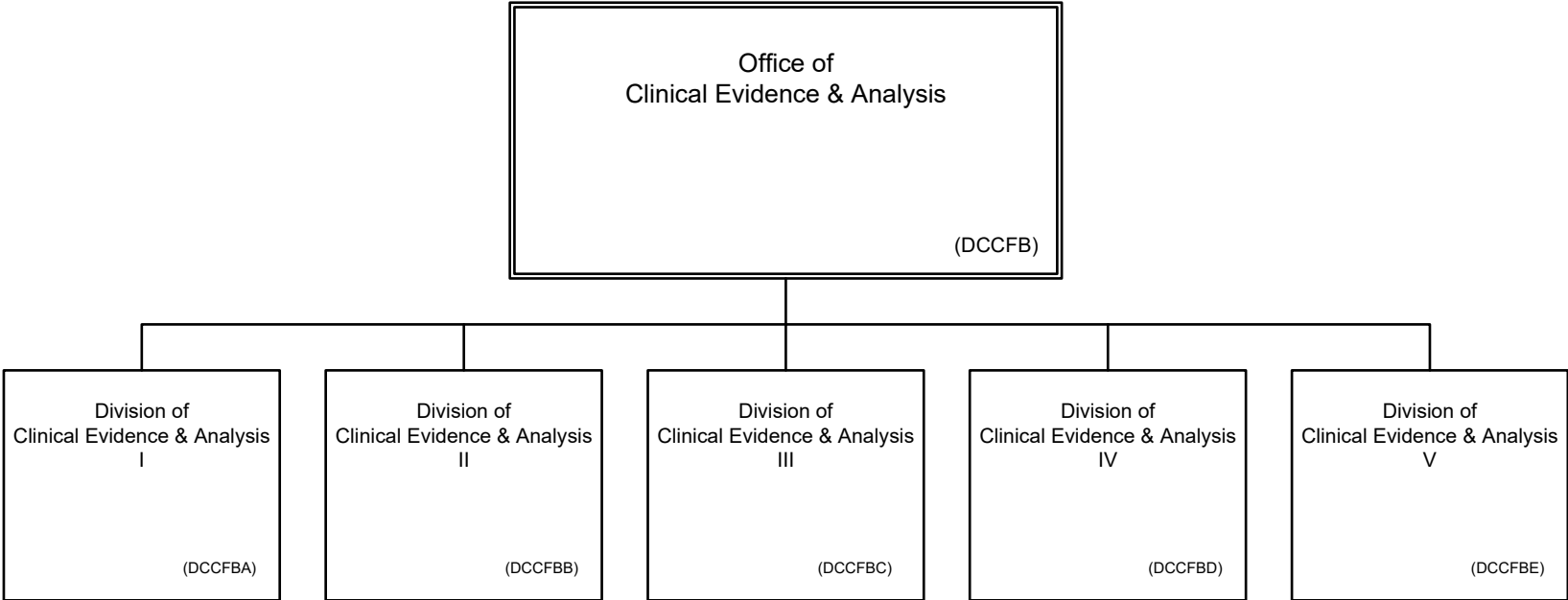
1. Office of Clinical Evidence and Analysis (DCCFB).

- A. Responsible for providing policy and program support regarding clinical evidence and human subject protection and for supporting device reviews that require expert clinical investigation and real-world evidence analysis.
- B. Provides analysis and support on biostatistics and epidemiologic analyses, as well as data infrastructure and expertise on clinical investigations and real-world evidence. Provides high-level programmatic support for Device Specific Offices engaging in total product life cycle review of devices.
- C. Conducts outreach and collaboration with hospitals and other external stakeholders.

2. Authority and Effective Date.

The functional statements for the Office of Clinical Evidence and Analysis were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
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Office of Product Evaluation and Quality
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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 organization structure depicting all the organizational structures reporting to the Director:

Office of Clinical Evidence and Analysis (DCCFB)
Division of Clinical Evidence and Analysis I (DCCFBA)
Division of Clinical Evidence and Analysis II (DCCFBB)
Division of Clinical Evidence and Analysis III (DCCFBC)
Division of Clinical Evidence and Analysis IV (DCCFBD)
Division of Clinical Evidence and Analysis V (DCCFBE)