

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 New Drugs

Office of Drug Evaluation Science

Effective Date: September 25, 2019

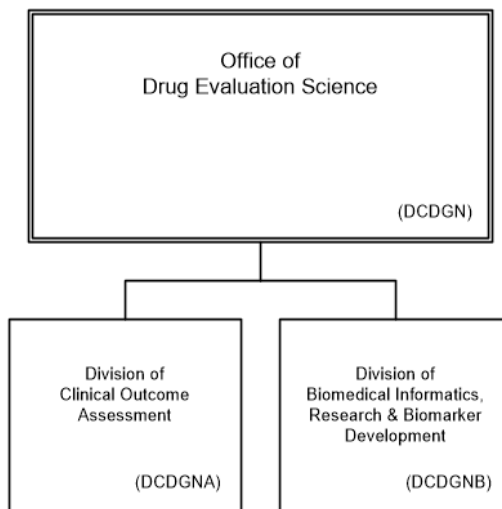
1. Office of Drug Evaluation Science (DCDGN).

- A. Supports Office of New Drug's (OND) mission to foster advances in drug development by providing focused scientific expertise on the development and implementation of novel drug development tools, including clinical outcome assessments, and biomarkers.
- B. Supports OND's patient focused drug development activities to incorporate the patient's voice in drug development.
- C. Facilitates the development of tools and practices for the robust analysis and interpretation of data to support clinical assessment and decision-making.
- D. Supports OND's research portfolio management to promote advancements in regulatory science and foster drug development.

2. Authority and Effective Date.

The functional statements for the Office of Drug Evaluation Science were approved by the Secretary of Health and Human Services on September 25, 2019.

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



Staff Manual Guide 1263.17a
Organizations and Functions
Effective Date: September 25, 2019

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs, Office of Drug Evaluation Science organization structure depicting all the organizational structures reporting to the Director.

Office of Drug Evaluation Science (DCDGN).

These organizations report to the Office of Drug Evaluation Science:

Division of Clinical Outcome Assessment (DCDGNA)

Division of Biomedical Informatics, Research & Biomarker Development (DCDGNB)