

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

Division of Clinical Outcome Assessment

Effective Date: September 25, 2019

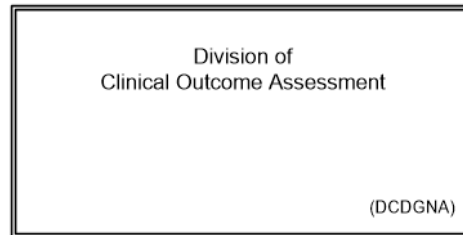
1. Division of Clinical Outcome Assessment (DCDGNA).

- A. Promotes the development and implementation of Clinical Outcome Assessments (COAs) as drug development tools to foster drug development.
- B. Provides oversight of the Food and Drug Administration COA Qualification Program.
- C. Contributes subject matter expertise to Office of New Drugs review divisions on the use of COAs in drug-specific development programs.
- D. Contributes subject matter expertise for Patient Focused Drug Development activities.
- E. Engages with internal and external stakeholders to advance the development of scientific standards and policy for COAs.

2. Authority and Effective Date.

The functional statements for the Division of Clinical Outcome Assessment were approved by the Secretary of Health and Human Services on September 25, 2019.

**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 Drug Evaluation and Research, Office of New Drugs, Office of Drug Evaluation Science, Division of Clinical Outcome Assessment organization structure depicting all the organizational structures reporting to the Director.

Division of Clinical Outcome Assessment (DCDGNA).