SMG 1218A.52

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Therapeutic Products

Office of Clinical Evaluation

Division of Clinical Evaluation Oncology

Effective Date: September 16, 2022

1. Division of Clinical Evaluation Oncology (DCBGIB).

A. Develops and maintains the Office's Clinical Evaluation Oncology Review Programs.

B. Provides clinical, clinical pharmacology, and non-clinical review and recommends appropriate action on Investigational New Drug Applications (INDs), Biologics License Applications (BLAs), New Drug Applications (NDAs), Investigational Device Exemptions (IDEs), Pre-Market Approval Applications (PMAs), and 510(k) submissions pertinent to products within the Office's purview.

C. Provides recommendations on oncology clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

D. Contributes to the interpretation of oncology clinical data submitted in support of INDs, BLAs, and amendments, NDAs and supplements, including data submitted for post-marketing surveillance.

E. Develops regulatory policies and documents concerning oncology clinical aspects of products regulated in the Office.

F. Provides oncology clinical consultation and serves as a source of oncology clinical information within the Center on products regulated in the Office.

G. Cooperates with other Food and Drug Administration (FDA) components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others on oncology clinical issues related to products regulated in the Office.

H. Performs consultative reviews of oncology clinical, clinical pharmacology, and non-clinical data in response to request from other FDA components.

I. Evaluates oncology clinical experience and adverse reaction reports relating to products regulated in the Office.

J. Develops and pursues research programs in clinical trial design and analysis.

2. Oncology Branch 1 (DCBGIB1).

A. Provides oncology clinical review and recommends appropriate action on INDs, BLAs, NDAs, IDEs, PMAs, and 510(k) submissions pertinent to products within the Office's purview.

B. Provides recommendations on oncology clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

C. Provides oncology clinical consultation and serves as a source of clinical information within the Center on products regulated in the Office.

D. Cooperates with other FDA components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others on oncology clinical issues related to products regulated in the Office.

E. Performs consultative reviews of oncology clinical data in response to request from other FDA components.

F. Evaluates clinical experience and adverse reaction reports relating to oncology products regulated in the Office.

G. Develops and pursues research programs in clinical trial design and analysis.

3. Oncology Branch 2 (DCBGIB2).

A. Provides oncology clinical review and recommends appropriate action on INDs, BLAs, NDAs, IDEs, PMAs, and 510(k) submissions pertinent to products within the Office's purview.

B. Provides recommendations on oncology clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

C. Provides oncology clinical consultation and serves as a source of clinical information within the Center on products regulated in the Office.

D. Cooperates with other FDA components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others on oncology clinical issues related to products regulated in the Office.

E. Performs consultative reviews of oncology clinical data in response to request from other FDA components.

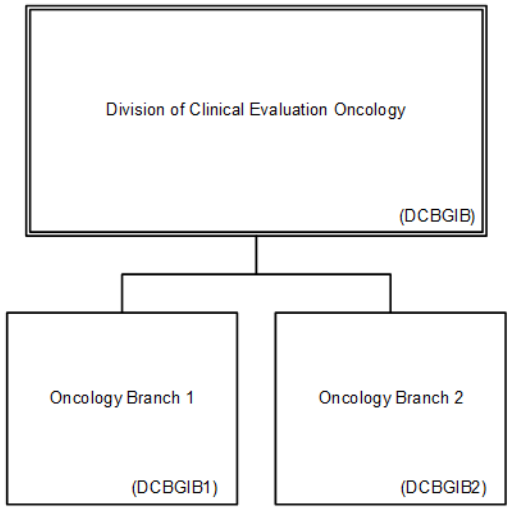
F. Evaluates clinical experience and adverse reaction reports relating to oncology products regulated in the Office.

G. Develops and pursues research programs in clinical trial design and analysis.

4. Authority and Effective Date.

The functional statements for the Division of Clinical Evaluation Oncology were approved by the Secretary of Health and Human Services on August 8, 2022, and effective on September 16, 2022.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Therapeutic Products
Office of Plasma Protein Therapeutics CMC
Division of Clinical Evaluation Oncology



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Therapeutic Products, Office of Clinical Evaluation, Division of Clinical Evaluation Oncology organization structure depicting all the organizational structures reporting to the Director.

Division of Clinical Evaluation Oncology (DCBGIB)