SMG 1268.1

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 Translational Science

Effective: September 25, 2019

1. Office of Translational Science (DCDJ).

A. Promotes efficient and informative study designs and data analysis methods to quantitatively evaluate the efficacy, safety, and dosing of drugs through collaboration among the Office of Biostatistics, Office of Clinical Pharmacology, and other offices in the Center for Drug Evaluation and Research (CDER) and centers in the Food and Drug Administration (FDA). Fosters novel drug development strategies through research and application of statistical and mathematical modeling and simulation techniques in the review and analysis of data in the areas of exposure-response, pharmacokinetics, pharmacodynamics, pharmacogenomics, bioequivalence assessment, clinical trials, quantitative risk assessment, toxicology, and product quality assessment.

B. Collaborates with, and implements through, the Office of Biostatistics, provides leadership, direction, policy development, and coordination to CDER on statistical, mathematical, and computational aspects of regulatory and scientific review. Provides independent and collaborative statistical evaluations and reviews to all programs and disciplines of CDER in support of the scientific and regulatory review process related to drugs and therapeutic biologics with special attention to the safety and efficacy of these products.

C. Collaborates with, and implements through, the Office of Clinical Pharmacology evaluates, recommends, and sets policy for data and information in clinical pharmacology necessary for an evaluation of benefit/risk, including optimal dosing in patients and special programs. Provides advice and recommendations at critical industry meetings, such as End of Phase 2A meetings, and regarding inclusion of clinical pharmacology information in the label of drug products.

D. Collaborates with the Office of Clinical Pharmacology, Office of Biostatistics and other offices in CDER to develop existing staff and train new scientists and medical officers in novel drug development methodologies.

E. Plans, manages, and evaluates human resource and financial management activities and analysis for Office user fee programs, including Prescription Drug User Fee Amendments (PDUFA), Biosimilar User Fee Act (BsUFA), and Generic Drug User Fee Amendments (GDUFA) programs.

F. Provides leadership, advocacy, direction, scientific skill, coordination, and tracking for all Critical Path Institute (CP) activities across CDER in partnership with individual CDER offices. Informs CDER Center Director's Office of CP activities and progress. Serves as the initial point of contact and coordination for CP projects originating inside and outside of CDER and FDA.

G. Conducts study-directed and comprehensive surveillance inspections of firms that conduct pharmacokinetic, bioavailability/bioequivalence (BA/BE), Good Laboratory Practice (GLP), and Animal Rule (AR) studies in support of human drug applications.

H. Develops and refines strategies to improve inspections planning, execution, evaluation, and to provide recommendations to CDER review divisions, while focusing on human subject safety and data integrity.

I. Engages stakeholders in developing and delivering effective tools, technologies, services, and training to enhance their ability to meet CDER's mission.

J. Collaborates with CDER offices to write and issue concept papers/guidance to address methodologies to foster innovative approaches to drug development.

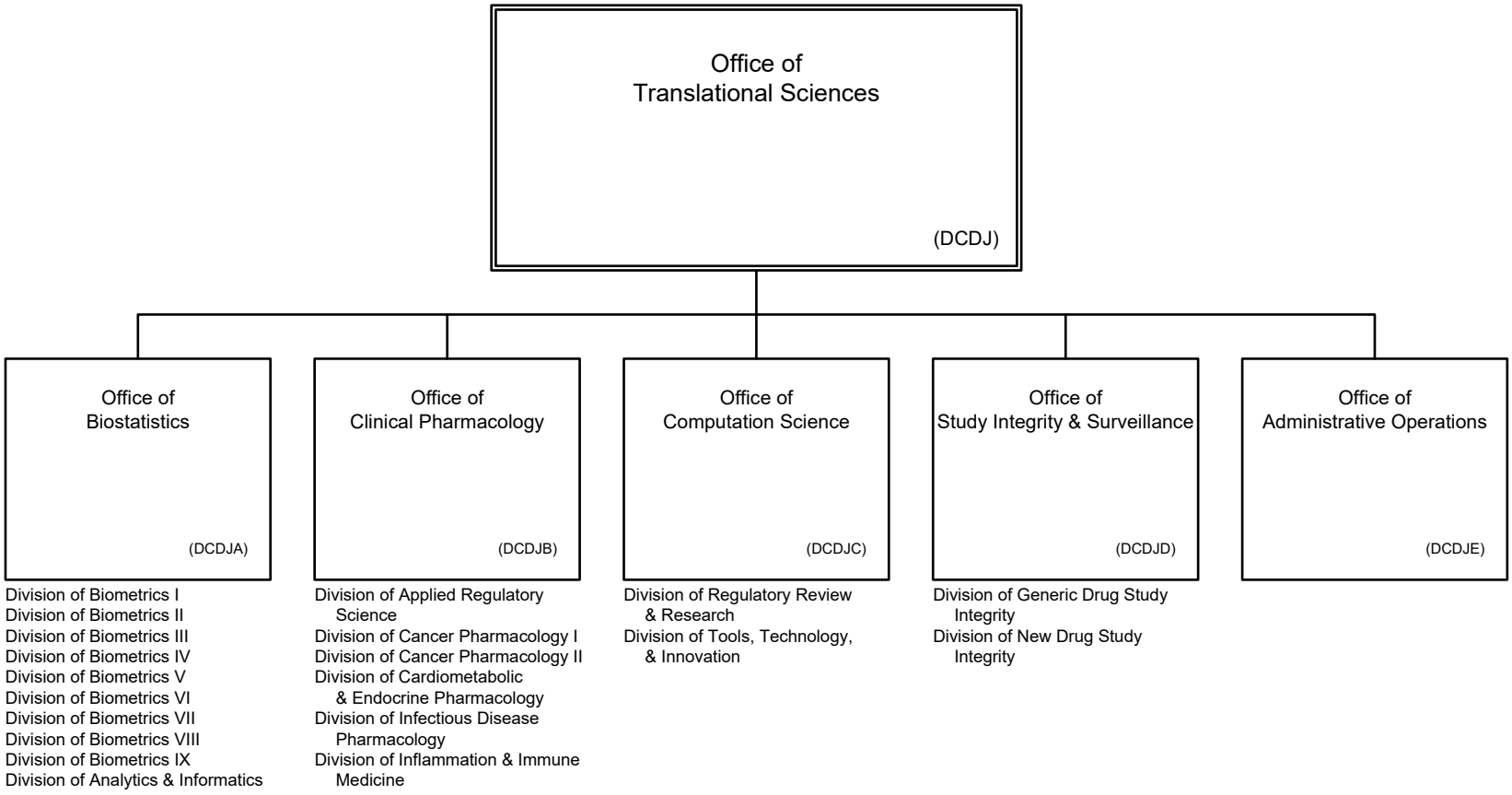
K. Evaluates and aligns research to support the mission and functions of CDER. Coordinates and facilitates CDER research activities by providing oversight and governance for CDER research activities involving human subjects; and guides and administrates the CDER regulatory science research priorities, grants, and strategic partnerships.

L. Supports data mining, data visualization, and health informatics to enhance pre- and post-market reviews. Collaborates with CDER offices to develop data repositories that support a knowledge management system to enhance the design and efficient conduct of future clinical studies.

2. Authority and Effective Date.

The functional statements for the Office of Translational Science were approved by the Secretary of Health and Human Services on August 26, 2019, and effective on September 25, 2019.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translation Science



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Organizations and Functions
Effective Date: February 9, 2022

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

Office of Translational Science (DCDJ)

Office of Biostatistics (DCDJA)

Office of Clinical Pharmacology (DCDJB)

Office of Computational Science (DCDJC)

Office of Study Integrity and Surveillance (DCDJD)

Office of Administrative Operations (DCDJE)

These organizations report to the Office of Biostatistics (DCDJA)
Division of Biometrics I
Division of Biometrics II
Division of Biometrics III
Division of Biometrics IV
Division of Biometrics V
Division of Biometrics VI
Division of Biometrics VII
Division of Biometrics VII
Division of Biometrics IX
Division of Analytics and Informatics

These organizations report to the Office of Clinical Pharmacology (DCDJB)
Division of Applied Regulatory Science
Division of Cancer Pharmacology I
Division of Cancer Pharmacology II
Division of Cardiometabolic and Endocrine Pharmacology
Division of Infectious Disease Pharmacology
Division of Inflammation and Immune Medicine

These organizations report to the Office of Computational Science (DCDJC)

Division of Regulatory Review and Research

Division of Tools, Technology, and Innovation

These organizations report the Office of Study Integrity and Surveillance (DCDJD)

Division of Generic Drug Study Integrity

Division of New Drug Study Integrity