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 Sciences

Effective Date: September 25, 2019

1. Office of Translational Sciences (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 implemented 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 implemented 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/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 stakeholder 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.

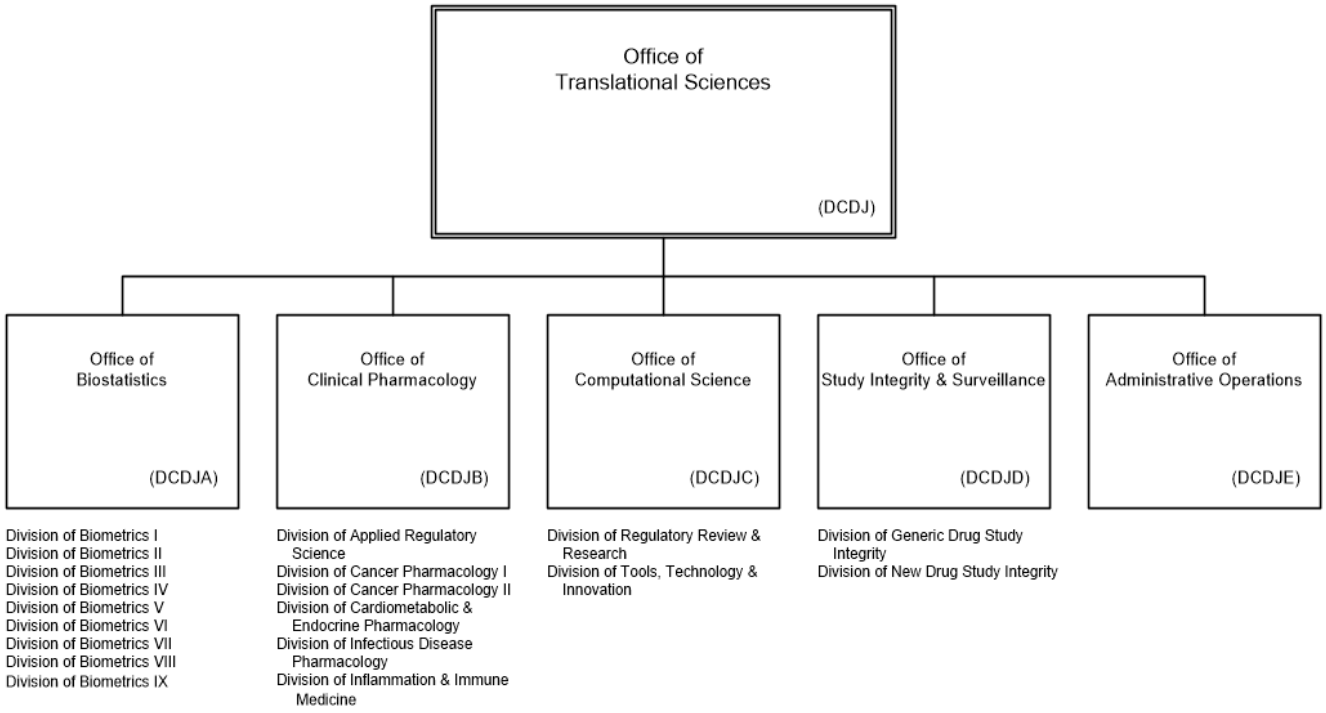
K. Evaluates and aligns research to support the mission and functions of CDER. Coordinates and facilitates CDER research activities by providing oversight and governance for CDER research activities involving human subjects; and guides and administrates the CDER regulatory science research priorities,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



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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 Translational Science organizational structures depicting all the organizational structures reporting to the Director.

Office of Translational Science (DCDJ).

These organizations report to the Office of Translational Science:

Program Management & Analysis Staff

Office of Biostatistics (DCDJA)

Office of Clinical Pharmacology (DCDJB)

Office of Computational Science (DCDJC)

Office of Study Integrity & Surveillance (DCDJD)

These organizations report to the Office of Biostatistics:

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 VIII

These organizations report to the Office of Clinical Pharmacology:

Division of Clinical Pharmacology I

Division of Clinical Pharmacology II

Division of Clinical Pharmacology III

Division of Clinical Pharmacology IV

Division of Clinical Pharmacology V

Division of Pharmacometrics

Division of Applied Regulatory Science

These organizations report to the Office of Study Integrity & Surveillance:

Division of New Drug Study Integrity

Division of Generic Drug Study Integrity

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