

**SMG 1268.5**

**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**

**Office of Computational Science**

Effective Date: September 25, 2019

**1. Office of Computational Science (DCDJC).**

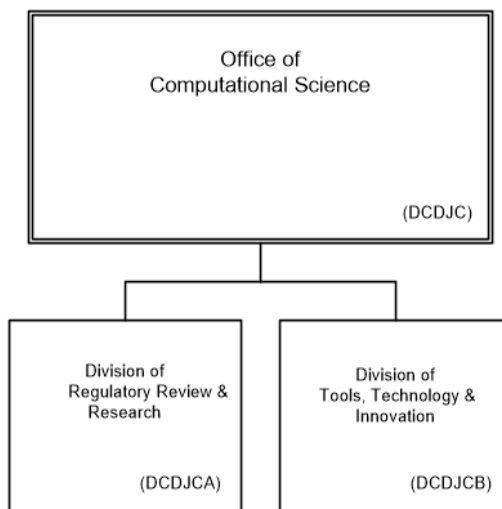
- A. Provides oversight of the development of Center for Drug Evaluation and Research's (CDER) scientific and review computing capabilities, including both infrastructure and operations.
- B. Provides leadership, direction, policy development, and coordination to CDER on strategic computational science plans and implementation.
- C. Promotes efficient and informative data analysis methods to support the quantitative analysis of the efficacy and safety through collaboration with various offices in CDER and Centers in the Food and Drug Administration.
- D. Plans for the development and adoption of study data standards to support CDER's regulatory and research missions, in coordination with the other offices in CDER.
- E. Develops communication plans to ensure timely information sharing and listening to both internal and external stakeholders.
- F. Ensures the effective implementation and operations including the availability of an up-to-date hardware and software infrastructure and systems support that enable needed data access and data analysis.
- G. Provides statistical/technical competencies and services to facilitate data access, analysis and study conduct.

- H. Provides leadership, advocacy, direction, scientific skill, coordination, and tracking for all projects associated with the improvement of CDER regulatory informatics supports.
- I. Catalyzes an interdisciplinary approach to organizational change through collaboration with other disciplines in CDER to enhance integration of computational science in regulatory review.

## **2. Authority and Effective Date.**

The functional statements for the Office of Computational 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 Translational Sciences  
Office of Computational Science**



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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, Office of Computational Science organizational structures depicting all the organizational structures reporting to the Director.

Office of Computational Science (DCDJC).

These organizations report to the Office of Computational Science:  
Division of Regulatory Review & Research (DCDJCA)  
Division of Tools, Technology & Innovation (DCDJCB)