**SMG 1270.2**


**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 Strategic Programs**

Effective Date: October 9, 2020

1. **Office of Strategic Programs (DCDK).**

   A. Advises and assists key Food and Drug Administration (FDA) Officials concerning the performance of the Center for Drug Evaluation and Research (CDER) strategic programs, analysis, and business informatics activities.

   B. Directs CDER Office of Program and Strategic Analysis, Office of Business Informatics, Data Standards Staff and Informatics Governance Program Management Staff.

   C. Leads Center-wide strategic and operational programs and analysis.

   D. Leads business process analysis and business process planning to ensure effective design, development and utilization of information systems, electronic data and analytic tools to optimize regulatory business processes.

   E. Develops, installs, and monitors CDER-wide business process and performance tracking systems.

   F. Advises and assists key CDER and FDA Officials concerning the planning and performance, strategic information management, and business process support.

   G. Serves the Office of the Commissioner for strategic and business information needs, a process planning and analysis of business needs, plans and performance results, including briefings for the Commissioner, senior management, and external stakeholders, including Health and Human Services, Office of Management and Budget, Congress, patient and consumer advocates, and regulated industry.

   H. Leads CDER business informatics governance, including Secretariat support and management, Information Technology (IT) strategic planning, investment

portfolio management and program management and oversight, to ensure effective design, development and utilization of information systems, electronic data and analytic tools to optimize regulatory review.

2. **Business Informatics Governance Staff (DCDK1).**

   A. Oversees the development and management of the CDER enterprise-wide IT strategy; develops strategic roadmaps aligned with the IT strategy to modernize and innovate CDER's drug regulatory operations.

   B. Develops and maintains full visibility into the IT portfolio of activities across CDER, ensuring that IT initiatives are aligned with the strategy.

   C. Assesses new and existing IT projects and monitors IT development to reduce duplication and ensure efficient spending of CDER's IT budget.

   D. Assesses return on investment of proposed IT initiatives, makes investment recommendations to the CDER Business Informatics Governance Board based on assessments.

   E. Monitors and reports progress on strategic roadmap implementation.

   F. Provides program management capabilities and practices for CDER enterprise initiatives including resource balancing to manage program across scope schedule and cost; oversees key workstreams to ensure program management practices are implemented.

   G. Makes recommendations to ensure efficient use of IT resources including infrastructure, services and staff allocations.
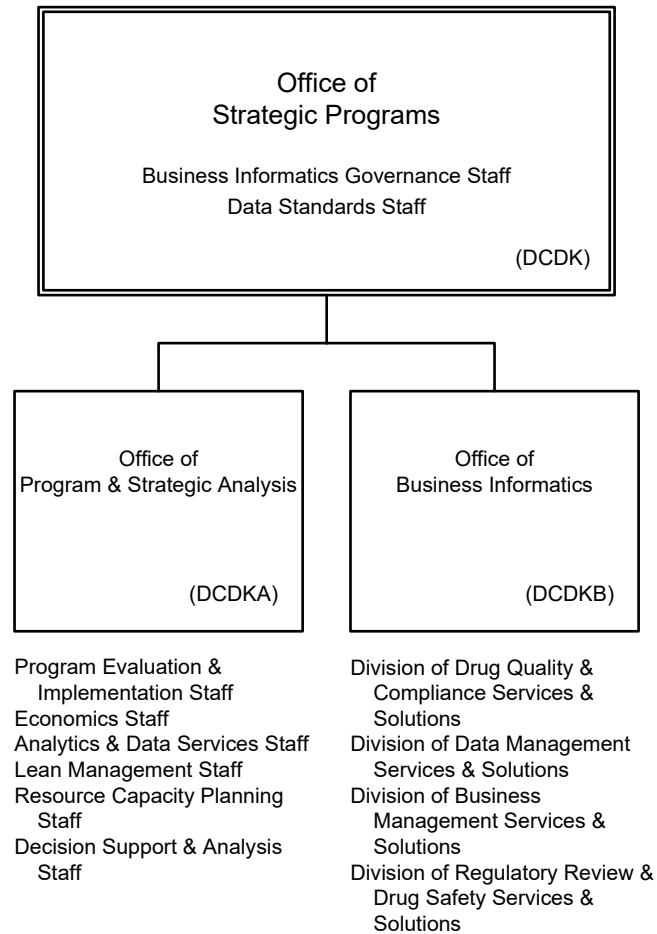
3. **Data Standards Staff (DCDK2).**

   A. Implements CDER's data standards program, promoting development of data standards for the effective and efficient review of regulatory submissions through stakeholder collaboration, policy development and project implementation.

   B. Evaluates business needs and potential solutions to ensure high quality data standards are adopted or adapted to address the need.

   C. Leads standard development activities where development is necessary, establishing and maintaining active working relationships with key standards development organizations to achieve needed results.

   D. Governs use and maintenance of standards; develops, implements and maintains guidance for industry on the use of required standards.

E.  Implements CDER's data governance framework to ensure consistency in the coordination of business decisions and resolution of issues that impact regulatory submission data.

F.  Monitors technological and regulatory change to ensure that standards are updated and/or replaces with improved standards as needed to support regulatory activity.

**4.  Authority and Effective Date.**

The functional statements for the Office of Strategic Programs were approved by the Commissioner of Food and Drugs and effective on October 9, 2020.

**Department of Health and Human Services**
**Food and Drug Administration**
**Center for Drug Evaluation and Research**
**Office of Strategic Programs**

Office of
Strategic Programs

Business Informatics Governance Staff
Data Standards Staff

(DCDK)

Office of
Program & Strategic Analysis

(DCDKA)

Office of
Business Informatics

(DCDKB)

Program Evaluation &
   Implementation Staff
Economics Staff
Analytics & Data Services Staff
Lean Management Staff
Resource Capacity Planning
   Staff
Decision Support & Analysis
   Staff

Division of Drug Quality &
   Compliance Services &
   Solutions
Division of Data Management
   Services & Solutions
Division of Business
   Management Services &
   Solutions
Division of Regulatory Review &
   Drug Safety Services &
   Solutions

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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 Strategic Programs, organization structure depicting all the organizational structures reporting to the Director:

Office of Strategic Programs (DCDK).

These organizations report to the Office of Strategic Programs:

Business Informatics Governance Staff

Data Standards Staff

Office of Program & Strategic Analysis (DCDKA)

Office of Business Informatics (DCDKB)

These organizations report to the Office of Program & Strategic Analysis:

Program Evaluation & Implementation Staff

Economics Staff

Lean Management Staff

Resource Capacity Planning Staff

Decision Support & Analysis Staff

These organizations report to the Office of Business Informatics:

Division of Drug Quality & Compliance Services & Solutions

Division of Data Management Services & Solutions

Division of Business Management Services & Solutions

Division of Regulatory Review & Drug Safety Services & Solutions