

Updates from the Office of Biostatistics Analytics and Informatics Staff Initiatives and Projects

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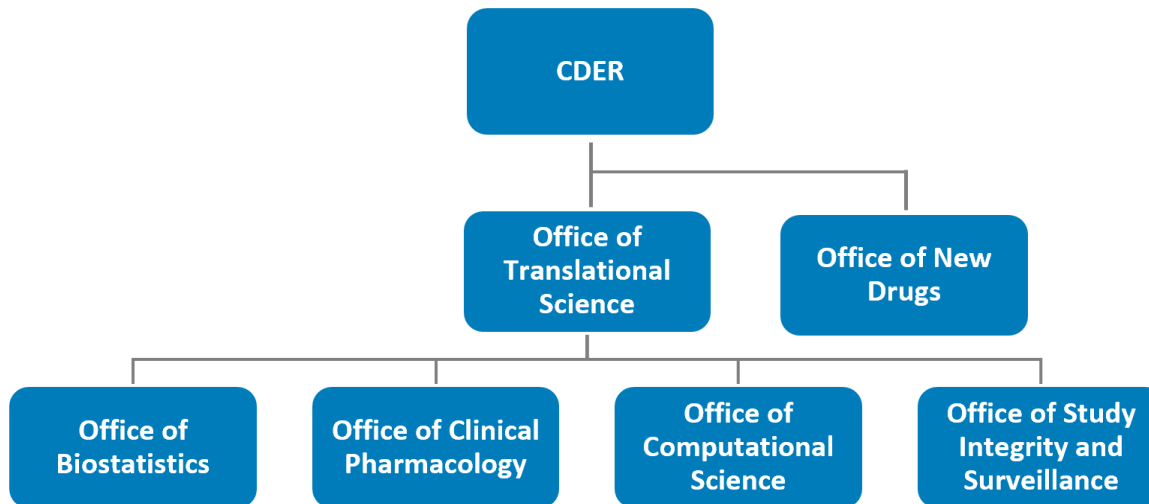
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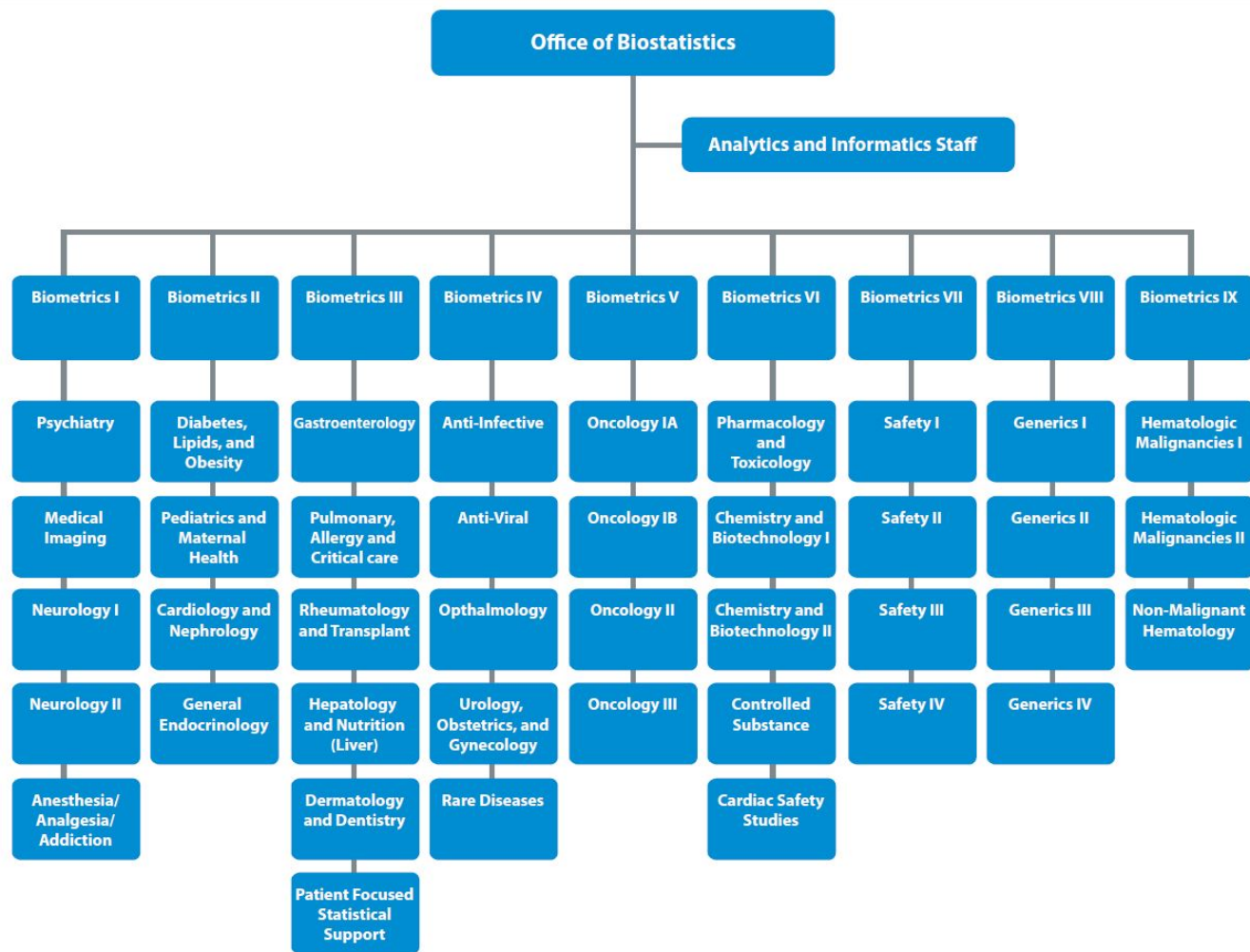
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Outline

- Office of Biostatistics (OB) Overview
- Analytics Informatics Staff (AIS)
 - Initiatives and Projects
 - Enhancing Review Process
 - Role of Statistical Analyst
 - Standardization Initiatives
 - Data Science and Data Tools
 - Scientific Computing

CDER Organizational Chart





OB Analytics and Informatics Staff

- Works jointly with all 9 Divisions of Biometrics (DB)
- Provides leadership in the areas of:
 - Data Standards
 - Data Integrity and Data Quality
 - Data Science and Data Tools
 - Scientific Computing and Statistical Programming
 - Project Management
- Includes Statistical Analysts to enhance statistical IND/NDA/BLA review and special projects

Initiatives/Projects



- Analysis Data Standards (ADS) – PDUFA VI Goal
 - Enhance capacity to support ADS for product development and review
 - Repository of recent review experiences related to standardized datasets and programs
- Roles and responsibilities of Statistical Reviewer and Statistical Analyst
- Standardization and tools development
 - Standard tables and figures for efficacy analyses
 - Library of validated codes/scripts to support standard tables and figures
- Development of standard processes for:
 - Programming best practices
 - Program validation and documentation

Enhancing the review process

The Vision: Who's Doing What?

- Statistical Reviewers
 - Instrumental at planning stage (IND review)
 - NDA/BLA review is multi-faceted
- Statistical Analysts
 - New role to enhance NDA/BLA review

Role of Statistical Analyst?

- Assessed IND/NDA/BLA/ANDA review processes from a Statistical Reviewer's perspective
 - Pain Points for Statistical Reviewers
 - Tasks that can be done by Statistical Analyst
 - Analysis that could be standardized
 - Possible issues/concerns working with Statistical Analyst

The Statistical Analyst (1)

- NDA/BLA Tasks:
 - Traceability/Data Quality/Data Integrity/Site Selection
 - Data management
 - Creation of 'review-ready' datasets from ADaM
 - Analysis and display of common descriptive analyses
 - Baseline characteristics, exposure, disposition, etc.
 - Independent corroboration of sponsor's analyses
 - Implementation of computationally intensive methods (ML, Bayesian)

The Statistical Analyst (2)

- NDA/BLA Tasks (cont.):
 - Safety analyses
 - Support Advisory Committee presentations and special projects
- IND Review Tasks:
 - For complex designs (Bayesian and Adaptive designs), help with simulations to verify operating characteristics

Standardization Initiatives

- Tables and Figures (Efficacy)
 - Develop “core” tables and figures
 - Table aesthetics, formats, and structures (shells, etc.)
- Macros/Scripts
 - Create a repository of standardized and validated code
- Applications
 - R-Shiny
 - SAS

Data Science and Data Tools

- Pilot of a R shiny server to support R Shiny applications developed by OB and other OTS staff in collaboration with the Office of Innovation in OIMT
- Help with data visualization, data management and data preparation
- Explore data science tools to facilitate & enable simulations to evaluate CID, adaptive designs, and Bayesian analyses
- Develop tools/apps to assist with the COVID-19 application reviews
 - Example: Futility analysis for stopping trial

Scientific Computing

- Hardware
 - Manage scientific workstations
 - POC for the CDRH High Performance Computing (HPC) environment
- Programming Expertise:
 - Simulations
 - Macros/Scripts
 - QC/Efficiency
 - Data Visualization

Analytics & Informatics Staff (AIS)

- Enhance review process
- Provides expertise in the following areas:
 - Data Standards
 - Data Integrity and Data Quality
 - Data Science and Data Tools
 - Scientific Computing and Statistical Programming
 - Project Management

