FDA Organization
Office of Medical Products and Tobacco
About the Center for Drug Evaluation and Research
CDER Offices and Divisions
Drug Safety Oversight Board
Jobs at the Center for Drug Evaluation and Research (CDER)
Meeting Presentations (Drugs)
Realignment of the Office of Antimicrobial Products within the Office of New Drugs
CDER Exclusivity Board
What We Do (CDER)
FAQs about CDER
Reports & Budgets (CDER)
Manual of Policies & Procedures (CDER)
Contact CDER

CDER Office Of Biostatistics

The Office of Biostatistics is currently recruiting Mathematical Statisticians for available positions within all of its Biometrics divisions.

Introduction

As a member of the Office of Translational Sciences (OTS) within the Center for Drug Evaluation and Research (CDER), the Office of Biostatistics (OB) provides CDER with statistical leadership, expertise, and advice to assure that safe and effective drugs are available to the American people. The Biostatistics Program is recognized as a center of excellence for the development, research, application, and communication of statistical methodology for drug regulation and development.

Office of Biostatistics Organization and Responsibilities

Office of Biostatistics Organization and Responsibilities are defined for 6 Biometrics Divisions.

- 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

Programs and Activities

- Statistical Policy Coordinating Committee
- Statistical Rounds
- Statistical NDA Review Template
- Office of Biostatistics Interactions with CDER Advisory Committees
- Office of Biostatistics Outreach Activities
- Office of Biostatistics Recruitment Program
- FDA Statistical Research
- FDA Statistical Association (FDASA) Membership

Regulations, Guidances and MaPPs

- Regulations, Guidances and MaPPs. This web page provides links to Federal regulations regarding clinical efficacy evaluations, pharmacology/toxicology carcinogenicity analyses, electronic submissions, and final guidance documents.

Publications

- Publications from Office of Biostatistics Staff

Office of Biostatistics Organization

- Lisa LaVange, PhD, Director
- S. Edward Nevius, PhD, Deputy Director
- Sue-Jane Wang, PhD, Associate Director (Pharmacogenomics)
- Ram Tiwari, PhD, Associate Director

Division of Biometrics I

- James Hung, PhD, Director
- Kooros Mahjoob, PhD, Deputy Director

Supports Office of Drug Evaluation I (ODE I)

- Division of Cardiovascular and Renal Products
- Division of Neurology Products
- Division of Psychiatric Products

Division of Biometrics II

- Thomas Permutt, PhD, Director
- Todd Sahlroot, PhD., Deputy Director

Supports Office of Drug Evaluation II (ODE II)

- Division of Anesthesia, Analgesia, and Addiction Products
- Division of Metabolism and Endocrinology Products
- Division of Pulmonary, Allergy, and Rheumatology Products

Division of Biometrics III

- Stephen E. Wilson, Dr.PH., Director
- Michael Welch, Ph.D., Deputy Director

Supports Office of Drug Evaluation III (ODE III)

- Division of Gastroenterology and Inborn Errors Products
- Division of Dermatology and Dental Products
- Division of Reproductive and Urologic Products

Division of Biometrics IV

- Mohammad Huque, Ph.D., Director
- Daphne Lin, Ph.D., Deputy Director

Supports Office of Antimicrobial Products and Office of Drug Evaluation IV (Nonprescription)

- Division of Anti-infective Products
- Division of Antiviral Products
- Division of Transplant and Ophthalmology Products

Division of Biometrics V

- Rajeshwari Sridhara, Ph.D., Director
- Thomas Gwise, Ph.D., Deputy Director

Supports Office of Hematology and Oncology Products and Division of Medical Imaging Products within Office of Drug Evaluation IV

- Division of Oncology Products (DOP1)
- Division of Oncology Products (DOP2)
- Division of Hematology Products
- Division of Medical Imaging Products

Division of Biometrics VI

- Stella Machado, Ph.D., Director
- Yi Tsong, Ph.D., Deputy Director

Supports Pharmacology/Toxicology review, new drug bioequivalence review, and the Interdisciplinary Review Team for thorough QT studies within the Office of New Drugs, the Controlled Substance Staff, and the Office of Generic Drugs, Office of Testing and Research, and Office of Biotechnology Products within the Office of Pharmaceutical Science.

Division of Biometrics VII

- Aloka Chakravarty, Ph.D., Director
- Mark Levenson, Ph.D., Deputy Director

Provides quantitative safety evaluations and expertise to support CDER regulatory decisions throughout the lifecycle of regulated drug and biological products. In particular, this division has unique expertise in statistical and epidemiological methods relevant to safety evaluation, including design and analysis of safety clinical trials, design and analysis of observational studies, meta-analysis, signal detection, survey methodology, time series analysis, and graphical and computational tools.

Office of Biostatistics Role and Responsibilities

The Office of Biostatistics (OB) provides leadership, direction, policy development, and coordination to the Center for Drug Evaluation and Research (CDER) on statistical, mathematical, and computational aspects of review, evaluation, and research. OB provides independent and collaborative evaluations and reviews to all programs and disciplines of CDER in support of CDER's scientific and regulatory review process. It develops statistical and mathematical methods to enhance the drug review and development processes through research and application on clinical trial methodology and on modeling in pharmacokinetics; pharmacodynamics; bioequivalence and bioavailability testing; drug safety monitoring; analysis and risk assessment; chemical testing and evaluation; and product quality assessment and control. OB statisticians evaluate and utilize analytic statistical and mathematical simulation software to enhance the drug development process.

The statistical staff of CDER are assigned to one of 7 Divisions of Biometrics within the Office of Biostatistics. Statistical staff in Divisions 1-5 work with the 15 new drug and biologic review divisions as well as nonprescription product divisions in the Office of New Drugs (OND). There they serve as team leaders and review members of multi-disciplinary clinical review teams. Statistical reviewers evaluate the results of studies conducted to investigate the efficacy and safety of therapeutic and diagnostic products as submitted in New Drug Applications, Biological Licensing Applications, Investigational New Drugs, ANDA's, protocols, and related work. Reviewers use mathematical and statistical methods to draw inferences from data submitted by drug applicants. Through specialized data extraction and data analysis software, they evaluate evidence in clinical trials. Statisticians also contribute to the body of statistical understanding and research as it applies to clinical trials and the drug evaluation process.

OB statisticians provide leadership and guidance to industry on statistical, computational and mathematical aspects of CDER's programs. They also provide training and mentoring to CDER staff in biostatistics and related areas. Their responsibilities extend to statistical and regulatory issues by interacting with FDA Advisory Committees, academia, and fellow statistician members in the FDA Statistical Association (FDASA) of all FDA Centers. Furthermore, they provide support to CDER on information technology issues related to the statistical review process, including the processing and analysis of data in electronic submission.

Statistical Policy Coordinating Committee

MAPP 6610.1: Statistical Policy Coordinating Committee

The Statistical Policy Coordinating Committee (SPCC) provides statisticians working within CDER with a mechanism for identifying and resolving important statistical policy issues and establishing consistent statistical policy and procedures across the various biostatistical components within CDER. The SPCC also serves as a venue for dealing with statistical reviewer issues.

During the review of INDs, NDAs, and ANDAs, statistical policy questions arise for which there may be no clear policy or precedent. Such statistical issues can relate to study design, statistical aspects of data handling, and the analyses of data. Occasionally, CDER may be challenged on its perceived statistical standard or on the manner with which statistical decisions are reached. Statistical policy issues have been addressed by establishing *ad hoc* working groups that are charged with the responsibility of sorting out the policy issues in question. Examples of such working groups are the Covariate Adjustment Working Group, the Interim Analysis Working Group, and the Research Synthesis Working Group. Other *ad hoc* working groups have been established under various authorities within CDER to produce documents with a statistical policy component.

Statistical Rounds

On a monthly basis, Statistical Reviewers from Biometrics Divisions present particularly challenging or noteworthy cases that are discussed with the Office of Biostatistics senior statistical counsel. Reviewers identify key information, issues, and questions in preparation for response to sponsor meetings, presentation before Advisory Committee, or final decision on analysis and evaluation of NDA submissions.

Statistical NDA Review Template

The Office of Biostatistics implemented a Statistical NDA Review Template that is being used as a review

development tool to document statistical findings in a structured, organized format.

Review standards define workable guidelines, which assure that all key review areas are addressed. The Template promotes consistency in review practices so that all relevant information is adequately reflected and essential results of evaluations are relayed in an organized order of presentation. Template use allows flexibility in intellectual execution of the review while requiring minimal adherence to prescriptive methods of documenting findings and conclusions.

This tool serves as a guide in review development and fosters effective communication among a range of audience disciplines. Reviewers are encouraged to summarize overall findings from detailed discussion of individual study reports by distilling this information into the concise, clear summation of an Executive Summary.

Office of Biostatistics Interactions with CDER Advisory Committees

There are currently 16 CDER Advisory Committees primarily defined by drug product. These CDER Advisory Committees are to provide independent advice and recommendation to the Commissioner of Food and Drugs as part of the regulatory responsibility of ensuring that drugs are safe and effective for human consumption. Their function is to evaluate data concerning marketed and investigational human drug products according to use in particular medical areas and drug applications.

New members to Advisory Committees and new Special Government Employees attend orientation and training sessions to become acquainted with Committee procedure and expectations. This consists of a program of discussion with CDER leadership, study of videotaped, past Committee meetings, and briefing sessions with the Medical and Biometrics Divisions whose Committees they are joining.

The Office of Biostatistics in CDER works with statisticians from the Center for Biologic Evaluation and Research (CBER) and the Center for Devices and Radiologic Health (CDRH) in presenting an orientation program specifically for statistician members to FDA Advisory Committees. This provides an introduction to the FDA Advisory Committee process, procedures, and expectations.

Additionally, there is a Statistical Advisors and Consultants Working Group (SACWG) that is under the direction of the Statistical Policy Coordinating Committee within the Office of Biostatistics. This group addresses ongoing issues involving recruitment, communications, orientation, and tracking of statistical consultants and advisors to CDER Advisory Committees.

Statisticians interested in learning more about the role of statistician members and consultants to CDER Advisory Committees should contact the Office of Biostatistics Deputy Director, Dr. S. Edward Nevius [SEdward.Nevius@fda.hhs.gov].

Office of Biostatistics Outreach Activities

The Office of Biostatistics interacts with the Pharmaceutical Manufacturers' Association (PhRMA) through collaborative efforts that address regulatory statistical issues of concern. CDER statisticians coordinate annual visitation programs and workshops for discussion on such topics as non-inferiority trials, multi-national studies, and pharmacogenomics. Past topics included data safety monitoring boards and interim analyses; exploratory versus confirmatory analyses; role of statistics in safety evaluations; role of statistics in labeling and promotion; and electronic data capture. Members from both the FDA and industry also jointly engage in annual workshops to address regulatory topics of importance. A panel of speakers leads discussion on a designated topic before the program is channeled into breakout working sessions. All participants then reconvene so that results from these subgroups can be presented.

Furthermore, FDA statisticians participate in many of the programs sponsored by professional societies that support research and interest in pharmaceutical and statistical topics. Through the Drug Information Association (DIA), the Office of Biostatistics works with industry colleagues to further education and training by engaging in panel discussions, delivering presentations, and serving in workshops. In these forums, statistical regulatory issues and research topics are disseminated to a vast membership from the pharmaceutical industry, consultant organizations, academia, research, and professional societies. Other collaboration is shared with the Society for Clinical Trials (SCT), American Statistical Association (ASA), International Biometric Society (IBS) and its subdivision, the Eastern North American Region (ENAR).

As part of the FDA Statistical Association activities, statisticians from the Office of Biostatistics participate in annual workshops between FDA and members of the Biopharmaceutical Section of the American Statistical Association. One of the more recent programs on statistically sound decision making addressed topics on multiple data imputation, computer intensive methods, rational drug development, and alternative study designs.

In addition to presenting at these professional seminars, statisticians from the Office of Biostatistics also engage in many formal educational programs. Several teach in the Pharmaceutical Education and Research Institute (PERI). They share current thoughts regarding ongoing research in regulatory statistics and explain progress realized in guidance development. Still others teach in academic environments at local universities. Some key members promote collaboration with an international community of other regulatory bodies through the International Conference of Harmonization.

Office of Biostatistics Recruitment Program

The Office of Biostatistics recruits statisticians through a continuous search for qualified masters and doctoral degree candidates who are interested in the areas of statistical methods in clinical trial conduct and evaluation; risk assessment; pharmacovigilance; and operations research.

Working as a statistician reviewer in the Office of Biostatistics offers an exceptional way of developing experience in regulatory statistical issues, diverse methodologies, clinical trial designs, and drug indications. Reviewers collaborate with highly trained statisticians and other regulatory scientists. They can also engage in scientific and regulatory research and participate in programs of professional societies and associations. Their interest and efforts are supported through research grants and publishing opportunities. Most importantly, Office of Biostatistics regulatory statisticians serve to protect the American public in assuring that safe and effective drugs are made available.

Information on employment with the Food and Drug Administration is available on both the FDA and CDER web sites:

- Food and Drug Administration
- FDA Center for Drug Evaluation and Research

Questions of interest can be sent directly to the Office of Biostatistics Deputy Director, Dr. S. Edward Nevius, SEdward.Nevius@fda.hhs.gov.

FDA Statistical Research

Regulatory Science and Review Enhancement: CDER statisticians develop research interests through extended work offered under a Regulatory Science and Review Enhancement (RSR) program. Grants have been issued for research in the areas of adverse experiences; QT prolongation; *in vivo / in vitro* HIV therapies; flexible designs; mixed models and repeated measures; stability analyses; non-inferiority trials; event times;

and correlation between risk and efficacy.

FDA Statistical Association (FDASA) Membership

The statistical staff in the Office of Biostatistics at CDER form an integral component to the FDA Statistical Association (FDASA). This association of statistical scientists from 6 FDA centers was formed to serve as a collective voice in promoting the advancement of statistical sciences within the regulatory environment of the FDA. The Association addresses issues specific to the concerns of all FDA statisticians and fosters FDA-wide consistency and harmonization on crucial regulatory statistical issues.

The Association follows this mission by conducting inter-center seminars on common regulatory statistical issues and conducting workshops and conferences on both common and special issues. FDASA also promotes continuing education activities and programs for FDA Regulatory Statistical Scientists and encourages increased communications among FDA statistical scientists. Additionally, the Association supports statistically focused educational programs for other FDA scientists.

Statistical Guidances and Manual of Policies and Procedures (MaPPs)

Guidances

- Guideline for the Format and Content of the Clinical and Statistical Sections of an Application
- Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products
- E9 Statistical Principles for Clinical Trials
- E10 Choice of Control Group and Related Issues in Clinical Trials
- Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products
- Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals
- Providing Regulatory Submissions in Electronic Format - General Considerations

MaPPs

- Statistical Policy Coordinating Committee
- Office of New Drugs and Office of Pharmacoepidemiology and Statistical Science / Office of Biostatistics - Responsibilities and Procedures for Statistical Review and Evaluation of Animal Carcinogenicity Studies

How to Contact Us

We ask you to take time to communicate with CDER about this web site. Please use our comments form.

Page Last Updated: 12/28/2011
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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