Career Opportunities at the FDA

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NISS Virtual Career Fair
March 11, 2020
Agenda

• Brief history of FDA
• Organizational Structure
• The role of the statistician at FDA / CDER
• Job Opportunities at the Office of Biostatistics
• Advice to students
Brief History

• Pure Food and Drugs Act (1906)
  – Prohibited interstate commerce in adulterated and misbranded food and drugs

• Food, Drug, and Cosmetic Act (1938)
  – Drugs must be shown to be safe

• Kefauver-Harris amendment (1962)
  – All new drugs applications must show “substantial evidence” of effectiveness in addition to safety
FDA Legal Foundation

US Constitution

US Law

US Regulation

FDA Guidance
What Does FDA Do?

• Ensures that human and veterinary drugs, vaccines and other biological products and medical devices are safe and effective

• Ensures that foods are safe and properly labeled

• Ensures cosmetics and dietary supplements are safe and properly labeled

• Regulates tobacco products
FDA Organization

Office of the Commissioner

Office of Foods

Office of Regulatory Affairs

Center for Food Safety & Applied Nutrition
Center for Veterinary Medicine
Center for Devices & Radiological Health
Center for Drug Evaluation & Research
Center for Biologics Evaluation & Research
Center for Tobacco Products
National Center for Toxicological Research
Center for Drug Evaluation and Research

CDER

- New Drugs
- Surveillance & Epidemiology
- Translational Sciences
- Generic Drugs
  - Study Integrity & Surveillance
  - Computational Science
  - Clinical Pharmacology
  - Biostatistics
FDA Location: White Oak Campus
Silver Spring, MD
Office of Biostatistics
Mission

• Provide statistical leadership, expertise, and advice to foster the expeditious development of safe and effective drugs for the American people.

• Protect the public health by applying statistical approaches for monitoring the effectiveness and safety of marketed drugs and therapeutic biologic products.
The role of the statistician

- Review regulatory submissions
- Check for data quality and completeness
- Conduct statistical analyses
- Participate in Advisory Committee meetings
- Develop guidance documents for sponsors
- Conduct statistical research
- Present at scientific meetings
- Advise sponsors on study design and analysis
Opportunities for statisticians and data analysts
Opportunities at FDA

• The Office of Biostatistics is actively recruiting
  – Mathematical Statistician (Ph.D. in Statistics)
  – Statistical Analyst (MS in Statistics)

Skills required
• Strong technical skills
• Strong statistical/scientific computing skills
• Experience with SAS and/or R
• Excellent oral and written communication skills
• Interpersonal and teamwork skills
• Strong problem-solving skills
• Creativity and innovation

If you are interested in working for the FDA, send your resume to:

CDEROTSHires@fda.hhs.gov
Opportunities for Students

• ORISE summer internship positions available for advanced PhD graduate students
• Engage in projects on topics relevant to OB scientific needs
• Gain hands-on experience under the guidance of a mentor

Past research project areas have included:
• modeling and simulation
• adaptive designs
• Bayesian design
• meta-analyses
• benefit-risk analyses
• subgroup analyses
• biosimilars
• development of statistical methods and software tools
Opportunities for Students

Information on the summer internship program can be obtained in AMSTAT NEWS at:

https://stattrak.amstat.org/2019/12/01/2020-internship-listings/

• If interested send CV and cover letter to:

CDER-OTS-OB-Recruitment@fda.hhs.gov
Opportunities for Faculty

• Research collaboration

• Special Government Employees
  – Consultant on specific projects
  – Expert opinion on FDA guidance

• Advisory Committee Membership
  – Provide FDA with independent opinions and recommendations on new drug applications
  – Committee membership consists of subject matter experts, including clinicians, pharmacists, patient representatives, and statisticians.
Advice for Students

• The Office of Biostatistics (OB) is a very rewarding place to deploy skills in biostatistics and statistical programming.

• OB offers a great opportunity to apply the most sophisticated techniques in biostatistical analysis.

• Working at OB has many characteristics of academic research.

• Statisticians are not only reviewing state-of-the-art regulatory submissions but also developing fundamentally new statistical approaches.
Thank you
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