Career Opportunities in Biostatistics and Consulting/Collaboration

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Outline

• Career opportunities in biostatistics
• Professional service
  – Federal government
  – Professional organizations
• Consulting/collaboration
  – NCI-designated cancer centers
  – Industry
• Discussion
Career Opportunities in Biostatistics

- Academia
- Government
- Industry
- Skill sets outside statistics to succeed
  - Communication
  - Leadership
  - Interpersonal
Academia

- Schools of Public Health
- Medical Schools and Centers
- Dental Schools
- Cancer Centers
- Clinical and Translation Science Awards
- Academic Research Organization
  - Duke, Harvard, etc
Academia

• Broad-based interest and knowledge
  – Basic
  – Clinical
  – Population
  – Translational

• Publish or Perish

• Research funding tighter
Government: The Federal Health Tree

- Department of Health and Human Services
  - National Institutes of Health (NIH)
  - Food and Drug Administration (FDA)
  - Centers for Disease Control and Prevention (CDC)
  - …
- Environmental Protection Agency (EPA)
- Department of Defense
- …
- http://www.first.gov/
National Institutes of Health (NIH)

- 27 Institutes and Centers
  - Biomedical and behavioral research
  - Laboratory of Hygiene at the Marine Hospital Service in Staten Island, NY in 1887
- National Cancer Institute (1937)
- National Heart Lung and Blood Institute (1948)
- National Institute of Allergy and Infectious Diseases (1948)
- ...
- $30.3 billion with > 80% for extramural support
  - 18,000 employees
  - 10% for intramural research support of 6,000 scientists
  - 50,000 competitive grants and 300,000 researchers
  - 2,500 institutes in the US and throughout the world
A Typical NIH Institute

- Office of the Director
- National Advisory Council
- Board of Scientific Advisors/Counselors
- Initial Review Groups
  - Special Emphasis Panels
- Extramural research support
  - Grants (R01, P01)
  - Cooperative agreements (U01)
  - Contracts (N01)
- Intramural research
  - Laboratory, clinical and population-based
Food and Drug Administration (FDA)

- 1906 Pure Food and Drugs Act
  - The Jungle by Upton Sinclair (1907)
- The 1938 Food, Drug, and Cosmetic Act
- 7 Offices, 6 Centers and 1 National Center
  - Center for Drug Evaluation and Research
  - Center for Biologics Evaluation and Research
  - Center for Devices and Radiological Health
  - Center for Tobacco Products
  - Center for Veterinary Medicine
  - Center for Food Safety and Applied Nutrition
  - National Center for Toxicological Research

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Centers for Disease Control and Prevention (CDC)

- Environmental Health and Injury Prevention
- Health Information and Services
  - National Center for Health Statistics
  - National Center for Public Health Informatics
- Health Promotion
- Infectious Diseases
- Global Health
- Terrorism Preparedness & Emergency Response
- National Institute for Occupational Safety and Health
Industry

• Biopharmaceutical Companies
  – Drugs
    • AbbVie, Bayer, BMS, GSK, J&J, Merck, Novartis, Pfizer, Roche, sanofi-aventis, Roche, …
  – Biologicals
    • Amgen, Genetech, Amgen, …

• Medical Device Companies
  – Boston Scientific, Medtronics, St. Jude Medical, …

• Contract Research Organizations (CROs)
  – Covance, Parexel, PRA, Quintiles, …
Contract Research Organizations

- Clinical trials management
- Regulatory support
- Data management
- Biostatistics
- Medical writing
- Manufacturing
- Laboratory
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  – Data monitoring committees
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Professional Service: Why?

- Good Citizenship Professionally
- Biostatistics expertise highly sought after
- Evangelism
  - Good Statistical Practice
- Impact
- Concerned citizen and taxpayer
National Cancer Institute

- Lung Cancer Concept Evaluation Panel
  - Review of proposals from the cooperative groups
- Initial Review Group
  - Clinical trials
  - Epidemiological studies
- Study Sections and Site Visits for Program Project Grants
National Advisory Dental and Craniofacial Research Council

- Clinical Trials Review Committee
- Advise DHHS Secretary, Assistant Secretary of Defense for Health Affairs, NIH Director and NIDCR Director
  - On matters relating to the conduct and support of research, training, health information dissemination and other programs carried out, by and through the Institute
- Make recommendations
  - On applications for grants and cooperative agreements for research and training regarding dental, oral and craniofacial diseases
National Heart, Lung, and Blood Institute

- Clinical Trials Review Committee
  - Peer review of multicenter clinical trial proposals
- Data and Safety Monitoring Boards
  - BRIDGE: Anticoagulation in elective invasive surgery
  - Cardiothoracic Surgical Trials Network (CTSN)
Environmental Protection Agency (EPA)

- Food Quality Protection Act (FQPA) 1996
  - Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
  - Federal Food Drug, and Cosmetic Act (FFDCA)
- National Academy of Science 2004
  - Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues
- Human Studies Review Board (HSRB) 2006
Human Studies Review Board

• Federal Advisory Committee
• Provides advice, information, and recommendations on issues related to scientific and ethical aspects of human subjects research
  – Research proposals and protocols;
  – Reports of completed research with human subjects; and
  – How to strengthen EPA’s programs for protection of human subjects of research
• Reviews ethics and scientific merit of all intentional human dosing studies of pesticides and insect repellents for regulatory purpose
Human Toxicity Studies

- Similar to phase I clinical trials
- Healthy volunteers
- Test toxic substances such as pesticides
- Usually very small in sample size
- Ethically very delicate
- Risk/benefit ratios very complex
- Used to inform EPA in deriving regulatory policy supplemented by animal toxicity studies
Data Monitoring Committees

• NIH policy on data and safety monitoring

• Responsibilities
  – Safety of participants
  – Integrity of clinical trial and data
  – Validity of data (statistical inference)

• Broad background/experience in large-scale randomized, controlled trials (RCTs)
DMC Opportunities

- NIH-sponsored Clinical Trials
- NIH Intramural Clinical Trial Program
- VA Cooperative Studies Program
- U.S. Army Medical Research and Materiel Command
National Institute of Allergy and Infectious Diseases

• HIV/AIDS
  – Large phase III randomized, controlled trials
  – Therapeutic DSMB
  – IL-2 DSMB
  – PENPACT DSMB
  – Multinational DSMB

• Autoimmune diseases
  – Mainly early phase clinical trials
  – ACE/ITN DSMB
Professional Organizations

• Become a member
  – American Statistical Association
  – Institute of Mathematical Statistics
  – Eastern North American Region of the International Biometrics Society
  – Society for Clinical Trials
  – International Society of Clinical Biostatistics

• Volunteer
  – Serve on committees
  – Organize/chair sessions
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  – NIH Clinical and Translational Science Award
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NCI Cancer Centers Program

- National Cancer Act of 1971
- Cancer Center Support Grant (P30)
  - aka Core Grant
  - Shared Resources and Services
- Cancer centers (27)
  - Basic or clinical sciences
- Comprehensive cancer centers (41)
  - Basic + Clinical + Population Sciences + Outreach
UW Carbone Cancer Center

- Continuously funded since 1972
- McArdle Laboratory for Cancer Research in 1940
- Matrix (as against standalone such as MDACC/MSKCC/FHCRC/RPCI)
  - 10 Colleges/Schools and 38 Departments
  - 250+ Members
- 8 Programs
- 16 Shared Resources and Services
  - Biostatistics
  - Cancer Informatics
  - Clinical Research Offices
UWCCC Programs

- Cancer Control
- Cancer Genetics
- Cell Signaling
- Chemoprevention
- Experimental Therapeutics
- Human Cancer Virology
- Imaging and Radiation Sciences
- Tumor Microenvironment
UWCCC Consulting/Collaboration

- Basic, genomics
  - Keles, Kendziorski, Newton
- Translational
  - Chappell, Eickhoff, Kim, Newton, Yu
- Clinical
  - Chappell, Eickhoff, Kim, Yu
- Population-based
  - Gangnon, Rathouz
Clinical and Translational

• Phase I: Determine maximum tolerated dose
• Phase II: Is it worth large-scale trials?
  – Efficacy screening of Rx
  – Small sample size ($n = 30 - 50$)
  – Comparison with historical controls
• Phase III: Is new better than standard?
• Biomarker studies
• Correlative studies
CA77158: DFMO in Skin Cancer

- 0.5g/m²/day PO of DFMO vs placebo for 3-5 years
- Prior history of basal or squamous skin cancer
- Simple randomization
- Follow-up every 6 months: Repeated counts
- Endpoints
  - New non-melanoma skin cancers
  - Toxicities
  - Biomarkers: Ornithine decarboxylase and polyamines
- Biomarkers measured 2, 3 and 4 years in a random subset
Leading to Research Topics

• Joint modeling of panel count data and longitudinal biomarkers
  – Marginal analyses scientifically unsatisfactory
  – Yulin Zhang at San Jose State University

• Bivariate panel count data for basal cell carcinoma and squamous cell carcinoma
  – Correlation between BCC and SCC
  – Li-yin Lee at St. Jude Medical
NIH Clinical and Translational Science Award (CTSA) Program

- National Center for Advancing Translational Sciences (NCATS)
- 62 Medical research institutions in 31 states and the DC
- Mission
  - Transform the Clinical Research Process
    - Translate New Treatments and Prevention Strategies More Efficiently
  - Accelerate Research Nationwide
  - Maximize Research Impact
Map of CTSA-Funded Institutions
CTSA at UW-Madison since 2007

- Institute for Clinical and Translational Research (ICTR)
- UW-Madison
  - Schools of Medicine & Public Health, Nursing, Pharmacy, and Veterinary Medicine
  - College of Engineering
- Marshfield Clinic
UW ICTR Key Resources

• Education and Training
  – MS/PhD Program in Clinical Investigation
  – Career Development Program

• Biostatistics & Informatics

• Community Research
  – Wisconsin Network for Health Research (WiNHR)
  – Community-Academic Partnership Core

• Investigator Resources
  – Shared Services and Resources
Industry: Data Monitoring Committees

- FDA Guidelines (EMA, WHO)
  - Establishment and Operation of Clinical Trial DMCs
- Many opportunities
  - Shortage of experienced statisticians
- Legal liability
Industry: Clinical Trials Consulting

• Consulting on specific clinical trials
  – Protocol design
  – Interim monitoring plans

• Scientific Advisory Committees
  – Allergy immunotherapy tablet for house dust mite
  – TTX, a sodium channel blocker, for cancer pain
  – Contraceptive vaginal rings for dysmenorrhea

• Mock FDA Advisory Committees for s/NDA
  – Taxotere® for prostate cancer
  – Tarceva® for NSCLC
  – orBec® for GI GvHD
Industry: Law Firms

• Expert witness
  – Provide statistical opinion on legal cases
  – Challenging and very tricky
  – Very smart lawyers

• Vioxx®
  – Review of publications
  – Statistical opinion on design and analysis

• Merit of legal cases
  – Review of a Clinical Study Report (CSR) for Yaz®
  – Review of an advertisement for RxGuardian®
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Requirements for Successful Career

• Solid statistical training
• Interest and commitment in biomedical and public health research
  – Academia: Theory/methods research
  – Industry: Data analysis and statistical computing
  – Government: Either
• Non-technical skills, Chuang-Stein (2005)
  – [Link to article](http://www.amstat.org/sections/sbiop/biopharmreport/2005_Spring_BR.pdf)
  – Communications skills: Very critical for success
  – Leadership skills in order to have impact
  – Interpersonal skills: You deal with people
• Influence: Essential for success, Berg (2013)
  – [Link to blog post](http://magazine.amstat.org/blog/2013/09/01/influence/)
Discussion

- Consulting vs Collaboration
- Evolving challenges
- Impact on biomedical research
- Teaching and education
- Service to science and community
- Great career opportunities
References

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  – Ederer. Amer Statist 33:116-9, 1979