



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



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, Medtronic, 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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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
 - <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>
- 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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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, Kendzierski, 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

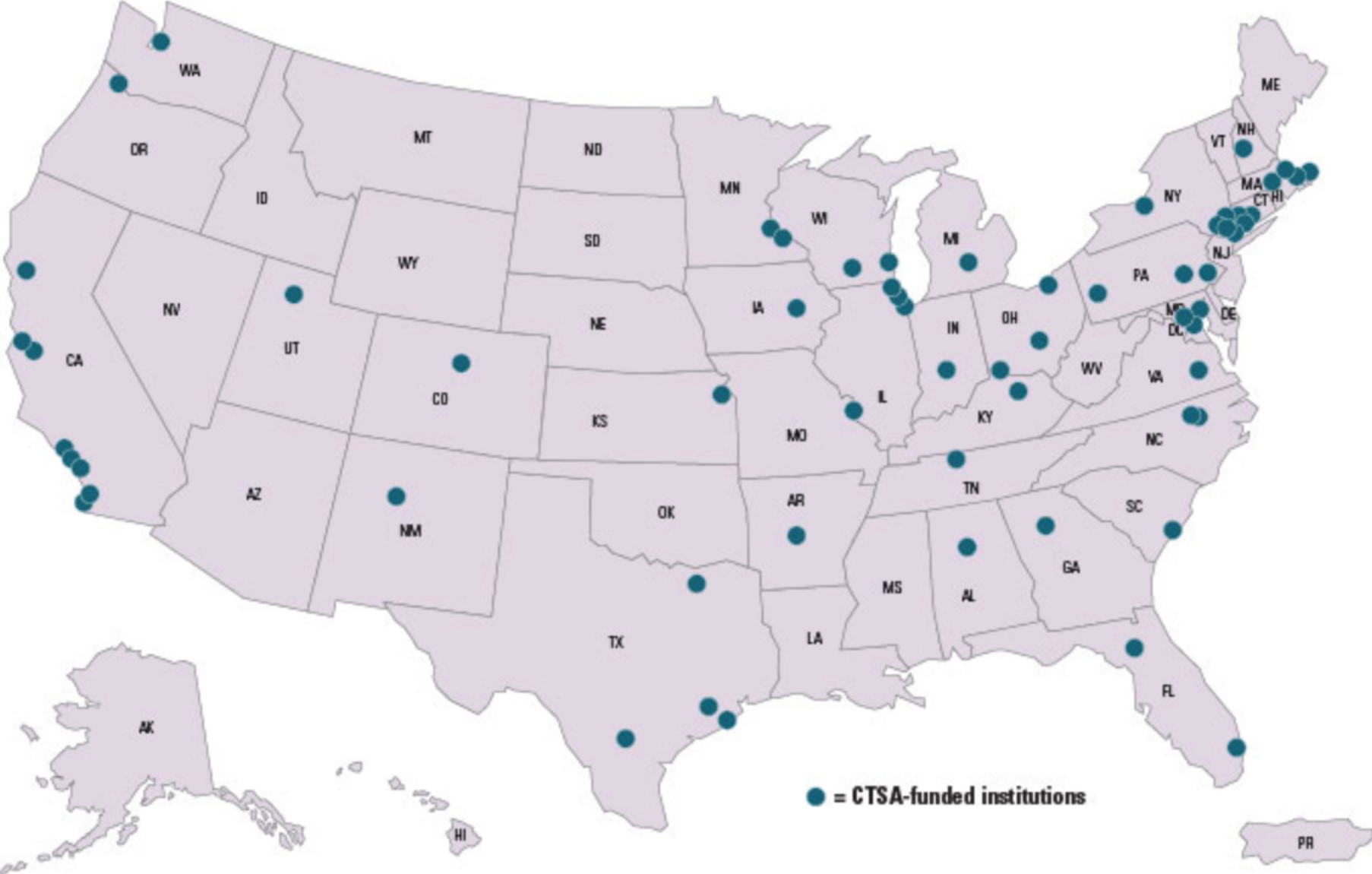
- Joint modeling of panel count data and longitudinal biomarkers
 - Marginal analyses scientifically unsatisfactory
 - Yulin Zhang at San Jose State University
- Bivariate panel count data for basal cell carcinoma and squamous cell carcinoma
 - Correlation between BCC and SCC
 - Li-yin Lee at St. Jude 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)
 - 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)
 - <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

- Expert witness
 - Van Matre and Clark. *Amer Statist* 30:2-5, 1976
 - Newell. *J. R. Statist. Soc. A* 145:403-9, 1982
- Clinical Trials Training
 - *Biometrics* 36:677-706, 1980
- Collaboration
 - Goldstein. *Public Health Rep* 76:43-50, 1961
 - Zelen. *Amer Statist* 23:14-5, 1969
 - Bliss. *Amer Statist* 23:15-20, 1969
 - Ederer. *Amer Statist* 33:116-9, 1979
 - Williford et al. *Amer Statist* 49:221-5, 1995
 - Billard. *Amer Statist* 52:319-24, 1998
 - Sowe. *Amer Statist* 57:8993, 2003