BIOGRAPHICAL SKETCH

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NAME: Dianne Finkelstein

eRA COMMONS USER NAME (credential, e.g., agency login): DMFINKELSTEIN

POSITION TITLE: Professor of Medicine (Biostatistics)

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of California, Berkeley	BS	06/1970	Mathematics
Wayne State University	MS	06/1973	Mathematics
University of Michigan	PhD	09/1981	Biostatistics

A. Personal Statement

I have 35 years experience in the design and analysis of clinical trials and epidemiology studies in chronic diseases, with a strong focus in cancer, including 20 years experience in cooperative cancer and AIDS clinical trials groups (ECOG, CALGB, ACTG). I have long-term collaborative relationships with many investigators at the Mass General Hospital where I have worked as a statistician since 1986. I have been the Director of the MGH Cancer Center Biostatistics since 1995, and as Director of the MGH Biostatistics Center since 2007. I have served as Director of a Biostatistics Core of several cancer projects and have been the PI of NIH funded cancer genetics network coordinating centers and I have an established and funded research program for statistical methods required for observational studies and clinical trials in cancer.

B. Positions and Honors

Positions and Employment

1981–1982 Assistant Professor, Department of Statistics, Rutgers University, New Brunswick, NJ
1982–1989 Assistant Professor in the Department of Biostatistics, Harvard School of Public Health, and Division of Biostatistics, Dana–Farber Cancer Institute, Boston, Massachusetts
1986–1989 Assistant Professor in the Department of Medicine, Harvard Medical School, and Associate Biostatistician, Massachusetts General Hospital, Boston, Massachusetts
1990–2004 Associate Professor in the Department of Medicine, Harvard Medical School, and Associate Biostatistician, Massachusetts General Hospital, Boston, Massachusetts
1990–2005 Associate Professor, Department of Biostatistics, Harvard School of Public Health
1995– Director of Biostatistics, Massachusetts General Hospital Cancer Center, Boston
2004– Professor in the Department of Medicine, Harvard Medical School
2005– Professor in the Department of Biostatistics, Harvard School of Public Health
2007– Director of Biostatistics, Massachusetts General Hospital Biostatistics Center, Boston

Honors

1970 Phi Beta Kappa, University of California, Berkeley
1987–1990 Principal Investigator, NIH R01 Grant CA47048, “Analysis of Carcinogenicity Experiments for Environmental Health”
1990–1994 Principal Investigator, NIH R01 Grant AI30885, “Statistical Methods for Failure Time Data in AIDS”

1992–2010 Associate Editor, Biometrics
1994 Fellow of American Statistical Association
1996– Associate Editor, Statistics in Medicine
1997–2010 Principal Investigator, NIH R01 CA74302 Statistical Methods for Research in Cancer and AIDS
1998–2007 Principal Investigator, NIH U01 CA78284 Coordinating Center for Cancer Genetics Network
1999– Associate Editor, Controlled Clinical Trials
2007–2010 Principal Investigator, NIH R03 Grant HD055201, Analysis of Longitudinal High Dimensional Data for Burn/Trauma Studies"
2007–2010 Principal Investigator, NIH R03 Grant CA 125766, Methods for Statistical Analysis of Cancer Genetics Network Studies
2007–2012 Principal Investigator for NIH Contract HHSN261200744000C , Cancer Genetics Network
2009–2012 Principal Investigator for NIH (ARRA) Grant RC1 CA144706, Rare Cancer Genetics Registry
2012–2014 Principal Investigator for NIH Grant R03CA167570–01 Analysis of Risks and Outcomes in Rare Cancers
2012–2017 Principal Investigator for NIH Grant 1R01CA160233–01, Rare Cancer Genetics Registry

C. Contributions to Science

1. My statistical methodology research has focused on methods for survival analysis for clinical trials and observational studies. My earliest focus was on interval censored data is regarded as the seminal work in this area. Recognizing that survival analysis can be improved with inclusion of longitudinal information, I worked on methods that analyzed these combined outcomes. These methods have been most recently applied to microarray data.
   a. Finkelstein DM. A proportional hazards model for interval-censored failure time data. Biometrics 1986;42:845-854. PMID: 3814726
   b. Finkelstein, DM and Schoenfeld, DA. Combining mortality and longitudinal measures in clinical trials. Statistics in Medicine 1999;18:1341-1354. PMID: 10399200
   c. Rajicic, N, Finkelstein, DM, and Schoenfeld, DA, Survival analysis of longitudinal microarrays, Bioinformatics, 2006. 22: 2643-2649. PMID: 17032680
   d. Ramchandani R, Schoenfeld DA, Finkelstein DM. Global rank tests for multiple, possibly censored, outcomes. Biometrics. 2016 Sep; 72(3):926-35. PMID: 26812695; PMCID: PMC4960007.

2. Methods of survival analysis rely on independence of the censoring and event processes. This may fail for many reasons, and I focused research on obtaining unbiased and efficient estimators and tests in the context of clinical trials in lethal diseases that obtain auxiliary information on the event and censoring process. Methods such as the IPCW test allow one to remove bias in the treatment comparison on survival in the case where patients selectively crossover or become non-compliant to protocol medication.
   a. Finkelstein DM and Schoenfeld DA. Analyzing survival in the presence of an auxiliary variable. Statistics in Medicine 1994;13:1747-54.PMID: 7997708
   b. Robins J, and Finkelstein DM. Correcting for non-compliance and dependent censoring in an AIDS clinical trial with inverse probability of censoring weighted (IPCW) logrank Tests. Biometrics 2000; 56(3):779-788. PMID: 10985216
   c. Finkelstein, DM. Goggins, WB, Schoenfeld, DA, Analysis of failure time data with dependent interval censoring. Biometrics, 2002; 58(2). 298-304. PMID: 12071402
   d. Ramchandani R, Finkelstein DM, Schoenfeld DA. A model-informed rank test for right-censored data with intermediate states. Stat Med. 2015 Apr 30; 34 (9):1454-66. PMID:25582933 PMCID: PMC4390437

3. I have worked for 35 years in the area of clinical trials in cancer and HIV/AIDS. In the context of this work, I have developed many methods required for the design and analysis of data from such trials, including general issues as well as methods that are needed for specific study designs (such as single population studies or studies of rare populations such as pediatric patients).
   a. Finkelstein DM and Schoenfeld DA AIDS Clinical Trials Wiley: 1995
   b. Byar DP, Schoenfeld DA, Amato D, Anderson J, Collins R, Davis R, DeGruttola V, Ellenberg S, Finkelstein DM, Freedman L, Gail M, Gatsonis C, Gelber R, Green SB, Lagakos S, Lefkopoulou M,

Peto J, Peto R, Simon R, Tsiatis AA, Zelen M. Design considerations for AIDS trials. New England Journal of Medicine 1990;323:1343-1348..

c. Finkelstein, DM, Muzikansky, A, Schoenfeld, DA., Comparing Survival of a Sample to that of a Standard Population, JNCI. 2003; 95(19) 1434-1439 PMID: 14519749
d. Schoenfeld, DA, Zheng, H, Finkelstein, DM. Bayesian design using adult data to augment pediatric trials. (2009) Clinical Trials Aug; 6(4):297-304. PMID: 19667026 PMCID: PMC3374646

4. In 1998, I was awarded a contract by NCI to establish a Statistical and Coordinating Center for the multi-institutional Cancer Genetics Network which conducted interventional and observational studies on the genetic susceptibility of cancer. In 2009, I was awarded an ARRA (later an R01) grant to develop the Rare Cancer Genetics Registry. These large registries made discoveries that were beyond previous observational or clinical studies, including discovery of genetic aggregation of cancers, models for prediction of genetic mutations, design of genetic linkage studies and screening for family history of cancer.
   a. Matthews AG, Betensky RA, Anton-Culver H, Bowen D, Griffin C, Isaacs C, Kasten C, Mineau G, Nayfield S, Schildkraut J, Strong L, Weber B, Finkelstein DM, Analysis of co-aggregation of cancer based on registry data, Community Genet. 2006;9(2):87-92. PMID: 16612058
   b. Parmigiani G, Chen S, Iversen ES, Friebel T, Finkelstein D, Anton-Culver H, Ziogas A, Weber BL, Eisen A, Malone KE, Daling JR, Hsu L, Ostrander EA, Peterson LE, Schildkraut JM, Isaacs C, Peshkin BN, Corio C, Leondaridis L, Tomlinson G, Amos CI, Strong LC, Berry DA, Weitzel JN, Sand S, Dutson D, Kerber R, Euhus DM. Validity of models for prediction of BRCA1 and BRCA2 mutations. (2007) Annals of Internal Medicine. 147(7):441-50. PMID: 17909205 PMCID: PMC2423214
   c. Kerber, RA, Amos, CI, Yeap, BY, Finkelstein, DM, Thomas, DC, Design Considerations in a Sib-pair Study of Linkage for Susceptibility Loci in Cancer (2008) 2008 Jul 10;9(1):64. BMC Medical Genetics. PMID: 18616822 PMICD: PMC2488325
   d. Ziogas A, Horick N, Kinney AY, Lowery JT, Domchek SM, Isaacs C, Griffin CA, Moorman PG, Edwards KL, Hill DA, Berg JS, Tomlinson GE, Anton-Culver H, Strong LC, Kasten CH, Finkelstein DM, Plon SE. Clinically relevant changes in family history of cancer over time. JAMA. 2011 Jul 13;306(2):172-8. PMID: 21750294 PMCID: PMC3367662

5. My work in cancer and HIV/AIDS has resulted in many papers that were important to the understanding of the disease etiology and treatment. These include using sophisticated statistical methods to discover the natural history of HIV/AIDS, discovery of germ-line mutations in cancer, and discovery of co-primary malignancies. Most recently, I have worked on global issues in cancer control.
   a. Finkelstein DM, Williams PL, Molenberghs G, Feinberg J, Powderly WG, Kahn J Dolin R, Cotton D. Patterns of opportunistic infections in patients with HIV infection. Journal of Acquired Immune Deficiency Syndromes and Human retrovirology1996;12:38-45. PMID: 8624759
   b. Fitzgerald MG, Harkin DP, Silva-Arrieta S, MacDonald DJ, Lucchina LC, Unsal H, O'Neill E, Koh, Finkelstein DM, Isselbacher KJ, Sober A, Haber DA. Prevalence of germ-line mutations in p16, p19ARF, and CDK4 in familial melanoma: analysis of a clinic-based population. Proc. Natl. Acad. Sci. 1996;93:8541-8545. PMID: 8710906 PMCID:PMC38708
   c. Aisenberg, AC and Finkelstein, DM , Second malignancies in Hodgkin's disease. J Clin Oncol. 2000; (10):2186-7.
   d. Liedke PE, Finkelstein DM, Szymonifka J, Barrios CH, Chavarri-Guerra Y, Bines J, Vasconcelos C, Simon SD, Goss PE. Outcomes of breast cancer in Brazil related to health care coverage: a retrospective cohort study. Cancer Epidemiol Biomarkers Prev. 2014 Jan;23(1):126-33. doi: 10.1158/1055-9965.EPI-13-0693. Epub 2013 Oct 28. PMID: 24165578

Complete List of Published Work
http://www.ncbi.nlm.nih.gov/pubmed?term=((Finkelstein%20DM%5BAuthor%5D)%20OR%20Finkelstein%2C%20Dianne%20M%5BAuthor%5D)%20OR%20Finkelstein%2C%20Dianne%5BAuthor%5D

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

5R01CA160233-05 (Finkelstein) 09/05/2012-06/30/2017

NIH, Rare Cancer Genetics Registry
The major goals are to develop a registry capable of rapidly recruiting individuals with rare cancers, and collecting rare-cancer-specific information, tumor tissue, and genetic results from registrants.
Role: Principal Investigator

5P30CA06516-48 (Benz) 05/15/2012-02/28/2021

NIH-NCI
Cancer Center Support Grant (Biostatistics CORE)
The major goals of this project are to support CORE activities that represent shared resources used by a variety of investigators in different labs throughout the DF/HCC. This is a subcontract through the Dana-Farber Cancer Institute.
Role: Director Biostatistics Core

1 UL1 R001102-02 (Orf) 10/01/2013-09/30/2018

NIH/NCRR
Harvard Clinical and Translational Science Center
Provide enriched resources to educate and develop the next generation of researchers trained in the complexities of translating research discoveries into clinical trials and ultimately into practice. Design new and improved clinical research informatics tools for analyzing research data and managing clinical trials. Support outreach to underserved populations, local community and advocacy organizations, and health care providers. Assemble interdisciplinary teams and forge new partnerships with private and public health care organizations.
Role: Director Biostatistics Core

(Autism Speaks) 11/01/13-08/31/2017

Autism Speaks
Data Coordinating Center Autism Treatment Network Registry
The mission of the ATN is to promote a sustainable bi-national system of community-accessible programs offering state-of-the-art comprehensive and coordinated medical care for children and adolescents with ASD, and to develop evidence to support the improvement of medical care for these children and their families.
Role: Senior Advisor

1P50CA165962-04 (Batchelor) 07/01/2013-06/30/2018

NIH-NCI
SPORE: Targeted Therapies for Glioma (Core B)
The Core provides shared resources of statistical and related expertise for long-term collaboration and short-term consultation with SPORE investigators in the research and developmental projects.
Role: Director Biostatistics Core

2P50CA127003-07 (Fuchs) 07/01/2013-6/30/2018

NIH-NCI (subcontract)
DF/HCC SPORE in Gastrointestinal Cancer (Core 3)
The main goal of the DF/HCC SPORE in GI Cancer is the translation of biological and technological advances into improvements in prevention, diagnostics, predictors of outcome, and advances in the treatment of gastrointestinal malignancies
Role: Director Biostatistics Core

Completed Research Support

HHSN261200744000C (Finkelstein) 5/1/2007-4/30/2012

NIH-NCI
Cancer Genetics Network
The major goals for this project are to serve as the Data Coordinating Center of the Cancer Genetics Network to provide statistical and logistical support and a secure database that will encourage investigations utilizing the resources of the CGN.
Role: Principal Investigator

1RC1 CA144706-02 (Finkelstein) 09/30/2009-08/31/2012

NIH
Rare Cancer Genetics Registry
The major goals are to develop a registry capable of rapidly recruiting individuals with rare cancers, and collecting rare-cancer-specific information and genetic results from registrants.
Role: Principal Investigator

5P01CA021239-33 (Delaney) 09/25/2008-07/31/2014

NIH-NCI
Optimizing Proton Radiation Therapy (Statistics, Data Exchange, Management and Support Core)
The Core provides shared resources of statistical and database expertise for collaboration with the Program Project investigators on study design and data analysis of clinical protocols applying advanced techniques of proton radiation planning and delivery to improve clinical outcome for cancer patients.
Role: Statistician

5R03CA167570-02 (Finkelstein) 04/04/2012-03/31/2016

NIH
Analysis of Risks and Outcomes for Rare Cancers
The major goals are to undertake analyses of the characteristics associated with elevated risk of rare cancers, as well as long-term outcomes of these diseases.
Role: Principal Investigator

5 UA3MC11054-07-01 (Finkelstein) 09/01/2015-8/31/2020

Health Resources and Services Administration
MGH Biostatistics in the Autism Intervention Research Network on Physical Health
The major goals of this project are the coordination, design, and statistical analysis of clinical trials in Autism
Role: Director Biostatistics

02-2010-083 (Goss) 01/01/2011-06/30/2018

The Avon Foundation
International Breast Cancer Tumor Bank
Major goal to provide statistical support for the international tumor bank and design of trials Role: Statistician