CURRICULUM VITAE

Name: Susan Smith Ellenberg

Date and Place of Birth: May 27, 1946, Tucson, Arizona

Citizenship: United States

Education:

1967 A.B.	Radcliffe College
1968 M.A.T.	Harvard University Graduate School of Education (Mathematics)
1980 Ph.D.	The George Washington University (Mathematical Statistics)

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Current Position

Professor, Division of Biostatistics, Department of Biostatistics, Epidemiology and Informatiaacs
Senior Scholar, Center for Clinical Epidemiology and Biostatistics
Professor (secondary appointment), Department of Medical Ethics and Health Policy
Perelman School of Medicine at the University of Pennsylvania

Prior Positions:

1999-2004	Director, Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, Food and Drug Administration
1993-1999	Director, Division of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, Food and Drug Administration
1988-93	Chief, Biostatistics Research Branch, Division of AIDS, National Institute of Allergy and Infectious
1982-88	Statistician, Biometric Research Branch, Division of Cancer Treatment, National Cancer Institute
1979-82	Statistician, The EMMES Corporation. (Cancer Clinical Trials)
1973-79	Statistician, The George Washington University Biostatistics Center
1971-73	Mathematical Programmer, The George Washington University.

Societies and Offices Held:

International Biometric Society
- Council, 2006-2009
- President, Eastern North American Region (ENAR) 1999
- ENAR Regional Committee 1990-92
- ENAR Representative to ASA Board of Directors 1988-89
- ENAR Regional Advisory Board, 1984-6

American Statistical Association

Secretary, Biometrics Section, 1987-89
Society for Clinical Trials
President, 1993
Board of Directors, 1990-94
American Association for the Advancement of Science
Chair, Section on Statistics, 1995-96
Electorate Nominating Committee, Section on Statistics, 1998-2000
National Institute of Statistical Sciences Board of Trustees, 2009-15; Chair, 2011-14
Washington Statistical Society
Representative-at-large, 1985-87
International Society for Clinical Biostatistics
International Statistical Institute
Public Responsibility in Medicine & Research (PRIM&R)

Awards and Honors

Fellow, American Statistical Association, 1991
Fellow, American Association for the Advancement of Science, 1990
Elected Member, International Statistical Institute, 1993
American Statistical Association Founders Award, 1996
Fellow, Society of Clinical Trials (inaugural group), 2006
Appointed to Senior Biomedical Research Service, 1997
Food and Drug Administration Commissioner's Special Citation, 1993, 1996, 1997
Food and Drug Administration Group Recognition Award, 1995, 1996, 2002
Food and Drug Administration Commendable Service Group Award, 1997
American Statistical Association Council of Chapters Award, 1991, 1994
Washington Statistical Society President's Service Award, 1990
National Institutes of Health Quality Award, 1986
College of Medicine Lecture, U Iowa, 1995
DHHS Secretary's Award for Distinguished Service (Group Award), 2001
John Wiley Europe Statistics Book of the Year award, 2003
Drug Information Association Outstanding Service Award, 2004
Challis Lectureship, University of Florida, 2004
Food and Drug Administration Center Director's Distinguished Service Award, 2004
Food and Drug Administration Distinguished Career Award, 2004
Center for Clinical Epidemiology and Biostatistics Teaching Award, 2007
Food and Drug Administration: cited as one of 11 women making major contributions to the FDA throughout its history, 2013
National Institute of Statistical Sciences Distinguished Achievement Award, 2014
John Rock Visiting Scholar, Louisiana State University, 2016
Curtis Meinert Lecturer, Annual Meeting of Society for Clinical Trials, Liverpool, UK, 2017
Johns Hopkins University Center for Clinical Trials Visiting Scholar, 2018
Janet Norwood Award for outstanding achievement by a woman in the statistical sciences, 2018
Committee of Presidents of Statistical Societies F.N. David Award for a female statistician who serves as a role model for other women based on her contributions to research and the statistical profession, 2019

Editorial Boards

Controlled Clinical Trials, 1992-94; 1999-2003
Clinical Trials, 2004-present
Statistics in Medicine, 1990-96
Journal of the National Cancer Institute (JNCI), 1992-present
Public Health Reports, 1994-98

Other Editorial

Advisory Board, Cambridge University Press, 2005 – 2014
Advisory Board, *Trials*, 2005 –
Guest Editorial Board member for special issue of *Statistics in Biopharmaceutical Research* in honor of Robert O'Neill, 2012-13.
Guest editor, proceedings of annual Penn conference on statistical issues in clinical trials, *Clinical Trials*, 2008-present

Task Forces and Committees, U.S. Public Health Service

HHS/PHS

CDC Working Group on HIV/AIDS Projections, 1989
PHS Task Force on PCP Prophylaxis, 1989-1992
PHS Working Group for the National Task Force on AIDS Drug Development, 1993-1995
HHS Gene Transfer Clinical Trials Design Working Group, 2003-2004
HHS H1N1Vaccine Safety Risk Assessment Working Group, 2009-12

NIH

NIH-University of California Expert Panel for Corticosteroids as Adjunctive Therapy for Pneumocystis Pneumonia, 1990
NEI/NIAID Studies of Ocular Complications of AIDS, Executive Committee and Policy and Data Monitoring Board, 1990-1992
NIMH Clinical Trial of Peptide T in AIDS, Steering Committee, 1990-92
NIAID DSMB of intramural trial of zidovudine and interferon in early HIV infection (chair), 1991-1992
NEI DSMB for intramural trial of intraocular ganciclovir for CMV retinitis in AIDS patients, 1992-1995
NCI Advisory Committee on auditing practices in cancer clinical trials, 1994
National Surgical Adjuvant Breast and Bowel Project Data and Safety Monitoring Board, 1994-97
NCI Committee on Phase II Window Designs in Pediatric Cancer, 1997-1998
NCI Implementation Committee to the Clinical Trial Review Report, 1997-1998
NIH Cancer Advisory Panel for Complementary and Alternative Medicine, 1998-2002
NIH State-of-Science Panel for Management of Menopause-Related Symptoms, 2005
NIAID, International DSMB for Africa (Chair), 2005 – 2009
NCI, Cancer and Leukemia Group B DSMB, 2005 – 2011
NIAID Regulatory Working Group ("Sullivan Committee"), 2005-6
NHLBI Working Group on Clinical Trials Methodology, 2006
NIMH Interventions for Anxiety and Mood Disorders in Adults (ITMA) review committee, 2008
NCI Alliance Oncology Group DSMB, 2011 -
NHLBI Protocol Review Committee Cardiovascular Inflammation Reduction Trial, 2011-12
NHLBI Data and Safety Monitoring Board, Cardiovascular Inflammation Reduction Trial (CIRT), 2012 - 2018
NIAID, DSMB for International AIDS Prevention Trials, 2012 - 2017 (Chair)
NIA, DSMB for STrategies to Reduce Injuries and Develop confidence in Elders (STRIDE) trial, 2014 -
NHLBI, Working Group on Small Clinical Trials, Co-Chair, 2016

FDA

FDA Antiviral Drug Advisory Committee, Consultant, 1990, 1991
FDA Biological Response Modifiers Committee, Consultant, 1991
FDA Vaccines and Related Products Advisory Committee, Consultant, 1991
FDA Task Force for developing guidelines for use of surrogate endpoints in AIDS drug development, 1991
FDA Liaison, Vaccine Safety Subcommittee, National Vaccine Advisory Committee, 1995-2003
FDA Topic Leader, International Conference on Harmonization, 1996-1998
CFSAN Food Advisory Committee Working Group on Meta-Analysis, 1997-99
FDA Data Monitoring Committee Guidance Working Group (Chair), 2000-2004
FDA Executive Oversight Committee, Risk Management Guidance development, 2002-2004
FDA Science Board Review Working Group, 2006-7
FDA Antiviral Drug Advisory Committee, 2010-13
FDA Endocrinologic and Metabolic Drugs Advisory Committee, 2018-2022

Institute of Medicine/National Academy of Sciences Activities

Committees
National Academy of Sciences Committee on Applied and Theoretical Statistics, 1998-2002
Institute of Medicine Committee on Assessment of U.S. Drug Safety System, 2005-6
National Research Council Committee on the Development of a Health Risk-Ranking Model for FDA Product Categories 2008-11
Institute of Medicine Committee on Cancer Clinical Trials and NCI Cooperative Group Program 2008-10
Institute of Medicine Committee on Clinical Trials During the 2014-15 Ebola Outbreak, 2016-17
National Academy of Medicine Committee on the Clinical Utility of "Bioidentical Compounded Hormone Replacement Therapy," 2019-20.

Workshop Planning
Institute of Medicine Workshop on Assuring Data Quality and Validity in Clinical Trials for Regulatory Decision-Making, Organizing Committee, 1998
National Academy of Sciences Committee on Applied and Theoretical Statistics Workshop on Statistical Methods for Post-Marketing Surveillance of Medical Products, Organizing Committee (Chair), 2001
Institute of Medicine Planning Committee, Drug Safety Symposium, 2007

Panels
Institute of Medicine Panel on Expanding Access to Investigational Therapies, 1990
Panelist, Institute of Medicine Workshop on Assuring Data Quality and Validity in Clinical Trials for Regulatory Decision-Making, 1998

Report Review
Reviewer, IOM report on Methodological Challenges in Biomedical HIV Prevention Trials, 2008.
Reviewer, IOM letter report on Research Priorities for Assessing Health Effects from the Gulf of Mexico Oil Spill, 2010.
Reviewer, National Academy of Sciences report on Prevention and Treatment of Missing Data in Clinical Trials, 2010
Reviewer, Institute of Medicine report on Ethical and Scientific Issues in Studying the Safety of Approved Drugs, 2012
Reviewer, IOM report on Safe and Effective Medications for Children, 2012
Reviewer, IOM report on Evolution of Translational Omics: Lessons Learned and the Path Forward, 2012.

International Advisory Committees

World Health Organization Data and Safety Monitoring Board for trial of low dose oral alpha interferon in AIDS, 1991-1992
World Health Organization Data and Safety Monitoring Board for HIV/AIDS Studies, 1994-1995
World Health Organization Global Vaccine Safety Advisory Committee, 2000-2004
Council of Canadian Academies, review of report: Assessment of Pediatric Products, 2013
World Health Organization Working Group on Preparation for Vaccine Trials during Infectious Disease Outbreaks, 2016 -

Other Task Forces and Committees

American Foundation for AIDS Research, Scientific Advisory Committee, 1990-1992
Agency for International Development Grant Advisory Committee, 1991
Keystone National Policy Dialogue on Expanded Access to Therapeutic Drugs and Biologics for AIDS and other Life-Threatening Diseases, 1992
American Foundation for AIDS Research Clinical Programs Advisory Committee, 1994-1995
VA Cooperative Studies Evaluation Committee, 1994-1998
American College of Epidemiology Committee on Ethics of Placebos in Clinical Trials, 1998-99
Harvard University Department of Statistics Visiting Committee, 2003-4

Bristol-Myers Squibb Data and Safety Monitoring Boards, 2007- present
University of Colorado CFAR Scientific Advisory Committee, 2008 – 2009
Wyeth/Pfizer Pharmaceuticals Data Monitoring Committee, 2008 – 2010
Clinical Trial Transformation Initiative Steering Committee, 2008 - 2013
National Science Foundation Division of Mathematical Sciences Visiting Committee, 2013
Chair, Foundation for the International Prize in Statistics, 2014 –
External Advisory Committee, Institute for Advanced Clinical Trials for Children, 2017 -

Scientific Conferences (Organizing Committee)

NIH Scientific Symposium in honor of Jerome Cornfield, 1981
New Computer Applications in Cancer Clinical Trials, 1983*
Methodology and Quality Assurance in Cancer Clinical Trials, 1984
Methodology of Overviews of Randomized Clinical Trials, 1986
Methodological Issues in AIDS Clinical Trials, 1989*
FDA workshop on the role of alternative data sources in AIDS drug development, 1991
Practical Aspects of Data Monitoring in Clinical Trials, 1992*
NIH Biostatistical Symposium, 1993
FDA Epidemiology Workshop, 1996
DIA Clinical Trials in Biotechnology Workshops, 1994-1996
DIA Data Integrity Symposium, 1996
Third International Meeting on Statistical Methods in Biopharmacy, 1997
FDA Statistical Association Statistical Conference, 1997
NIH Workshop on Research Needs for the Design and Analysis of Surrogate Endpoints in Clinical Trials, 1998
FDA-NIH Workshop on Evaluating Safety of New Vaccines, 2000*
FDA Workshop on Draft Guidance on Clinical Trial Data Monitoring Committees, 2001*
DIA Workshops on Data Monitoring Committees, 2002*, 2003*
FDA-Johns Hopkins University workshop on Bayesian approaches to drug development, 2004
FDA-Harvard/MIT Health Sciences and Technology workshop on adaptive clinical trial designs, 2004*
University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials: Early, Translational and Proof of Concept Studies, 2008
University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials: Statistical Methods for Targeted Therapies, 2009
Annual Human Research Protections Program Conference (PRIM&R), 2008
4th Seattle Symposium in Biostatistics, 2008-2010
University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials: Statistical Issues in Comparative Effectiveness Studies, 2010
University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials: Emerging Statistical Issues in the Conduct and Monitoring of Clinical Trials, 2011
University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials: Statistical Issues in Biomarker Validation, 2012
University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials: Dynamic Treatment Regimes, 2013
University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials: Current Issues Regarding the Use of Biomarkers and Surrogate Endpoints in Clinical Trials, 2014
University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials: Statistical Issues in Pragmatic Trials, 2015*
University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials: Where Are We with Adaptive Clinical Trial Designs?, 2016*
University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials: Current Issues Regarding Data and Safety Monitoring in Clinical Trials, 2017*
University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials: Estimands, Sensitivity Analyses and Missing Data in Clinical Trials, 2018*

*Chair, Organizing Committee

Professional Society Committees

Local arrangements committee, Fifth Annual Symposium on Coordinating Clinical Trials, 1978
Program Committee, International Biometric Conference, 1988, 1992
Program Chair, Society for Clinical Trials Annual Meeting, 1992
American Statistical Association Committee on AIDS, 1989-1993
Committee for the Joint Directory of Statisticians, 1987-1989
Sesquicentennial Planning Committee, American Statistical Association, 1987-1989
Nominating Committee, Society for Clinical Trials, 1988
Policy Committee, Society for Clinical Trials, 1993-6
Education Committee, Society for Clinical Trials, 1994-7
Snedecor Award Committee, American Statistical Association, 1994-98
Publications Committee, Society for Clinical Trials, 1995-98
Program Chair, International Biometric Conference, 1996
Committee on Professional Ethics, American Statistical Association, 1995-1998
Nominating Committee, American Statistical Association, 1996-1997 (Chair, 1997)
AAAS Committee on Sections, 1996-1998
Committee of Presidents of Statistical Societies, 1998-2000
Task Force, National Institute of Statistical Science, 1999-2000
American Public Health Association Spiegelman Award Committee, 2001-3
International Statistical Institute Committee on Ethics, 2004 – 7
American Statistical Association Task Force on Engaging with Other Organizations, 2006-7
Society for Clinical Trials Publications Committee, 2007 - 9
Society for Clinical Trials Fellows Committee, 2006-8
International Biometric Society General Officer Nominating Committee, 2007-9
American Statistical Association Committee on Establishing an International Prize in Statistics, 2013-present
American Statistical Association Statistical Ambassadors Initiative Working Group, 2015-
Society for Clinical Trials Trial of the Year Award Committee, 2017 -

Academic Committees, University of Pennsylvania

Human Research Advisory Committee, 2005 - 2013
Committee on Appointments and Promotions, School of Medicine, Department of Biostatistics, Epidemiology and Informatics, 2005-10; 2013 -
Faculty Advisory Committee, Office of Human Research, School of Medicine (Chair), 2005-2013
Committee on Admissions, School of Medicine, Department of Biostatistics, Epidemiology and Informatics, Division of Biostatistics, 2005-10
Committee on Awards, School of Medicine, Department of Biostatistics, Epidemiology and Informatics, Division of Biostatistics (Chair), 2006 -
Search Committee, Chair of Department of Dermatology, 2009-2010
Committee on Recruitment, School of Medicine, Department of Biostatistics, Epidemiology & Informatics, Division of Biostatistics, 2010 –
Center for Clinical Epidemiology and Biostatistics Appointments Committee, 2011 – 2013
Graduate Group, Epidemiology and Biostatistics, 2015 -

Ongoing Research Support

P30-AI45008	Penn Center for AIDS Research
NIH/NIAID	Role: Director, Biostatistics and Data Management Core
	07/01/14 - 06/30/19

AbbVie Pharmaceuticals	Testosterone Trial in Aging Men 05/15/2018 - 12/31/2019 Role: Co-investigator, Senior Statistician
UM1-AI126620 : .	Delaney Collaboratory to Cure HIV-1 Infection 07/14/16 – 06/30/21 Role: Co-Investigator, Senior Statistician
R01-HL134904	Anastrozole in Pulmonary Arterial Hypertension 01/01/17 – 12/31/21 Role: Co-investigator, Senior Statistician
PCORI	Pragmatic Randomized Trial of Proton vs Photon Radiotherapy in Stage II and III Breast Cancer 2015-2020 Role: Co-Investigator, Senior Statistician
PCORI	A Practical Intervention to Improve Patient-Centered Outcomes After Surgery to Repair Hip Fracture in Older Adults 2015-2020 Role: Co-Investigator, Senior Statistician

BIBLIOGRAPHY

Peer-Reviewed Articles

1. Moskovitz, P., Ellenberg, S., Feffer, H., Kenmore, P., Neviaser, R., Rubin, B. and Varma, V.: The use of low dose heparin for the prevention of venous thromboembolism in patients undergoing total hip arthroplasty and surgical repair of hip fractures. *Journal of Bone and Joint Surgery*, 604: 65-1069, 1978.

2. Krueger, D. E., Ellenberg, S. S., Bloom, S. S., Calkins, B., Jacyna, R., Nolan, D. C., Phillips, R., Rios, J. C., Sobieski, A. R., Shekelle, R. B., Spector, K., Stadel, B., Stolley, P. D. and Terris, M.: Fatal myocardial infarction and the role of oral contraceptives. *American Journal of Epidemiology*, 111: 55-674, 1980.

3. Krueger, D. E., Ellenberg, S. S., Bloom, S. S., Calkins, B., Jacyna, R., Nolan, D. C., Phillips, R., Rios, J.C., Sobieski, A. R., Shekelle, R. B., Spector, K., Stadel, B., Stolley, P.D. and Terris, M.: Risk factors for fatal heart attack in young women. *American Journal of Epidemiology*, 113: 357-370, 1981.

4. Steele, G., Ellenberg, S., Ramming, K., O'Connell, M., Moertel, C., Holyoke, E. D., Lessner, H., Bruckner, H., Horton, J., Schein, P., Zamcheck, N. and Novak, J.: CEA monitoring among patients in multi-institutional adjuvant G.I. therapy protocols. *Annals of Surgery*, 196: 162-169, 1982.

5. Lokich, J., Ellenberg, S. and Gerson, B.: Criteria for monitoring CEA: variability of sequential assays at elevated levels. *Journal of Clinical Oncology*, 2: 181-186, 1984.

6. Boice, J.D., Greene, M.H., Killen, J.Y., Ellenberg, S.S., et al.: Leukemia and preleukemia after adjuvant treatment of gastrointestinal cancer with semustine (methyl-CCNU). *New England Journal of Medicine*, 309: 1074-1084, 1983.

7. Ellenberg, S.S. and Wittes, J.T.: Analysis of data from clinical trials. (Letter to the Editor). *Annals of Internal Medicine*, 99: 874, 1983.

8. Lessner, H. E., Mayer, R. J., Ellenberg, S. S., et al.: Adjuvant therapy of colon cancer--results of a prospectively randomized trial. *New England Journal of Medicine*, 310: 737-742, 1984.

9. Gerber, L. H., Helfgott, R. K., Gross, Earl G., Hicks, J. E., Ellenberg, S. S. and Peck, G. L.: Vertebral abnormalities associated with synthetic retinoid use. *Journal of American Academy of Dermatology*, 10: 817-823, 1984.

10. Lokich, J., Ellenberg, S., Gerson, B., Knox, W. E. and Zamcheck, N.: Plasma clearance of carcinoembryonic antigen (CEA) following hepatic metastectomy. *Journal of Clinical Oncology*, 2: 462-465, 1984.

11. Smith, F. P., Ellenberg, S. S., Mayer, R. J., Lessner, H. E. and Horton, J. B.: Phase II study of MOF-streptozotocin (methyl-CCNU, vincristine, 5-fluorouracil and streptozotocin) in advanced colorectal cancer: A GITSG study. *Journal of Clinical Oncology*, 2: 770-773, 1984.

12. Ellenberg, S. S.: Randomization designs in comparative clinical trials. *New England Journal of Medicine*, 310: 1404-1408, 1984.

13. Lessner, H. E., Mayer, R. J., Ellenberg, S. S. and Stablein, D. M.: Adjuvant therapy for colon cancer (Letter to the Editor). *New England Journal of Medicine*, 311: 410, 1984.

14. The Gastrointestinal Tumor Study Group: Prolongation of disease free interval in surgically cured rectal carcinoma. *New England Journal of Medicine*, 312: 1465-1472, 1985.

15. Kalser, M. H., Ellenberg, S. S., et al.: Pancreatic cancer: adjuvant combined radiation and chemotherapy following curative resection. *Archives of Surgery* 120: 899-903, 1985.

16. Ellenberg, S. S., Simon, R. and Wittes, R. E. (eds.): Methodology and quality assurance in cancer clinical trials (symposium proceedings). *Cancer Treatment Reports*, 69, 1985.

17. Ellenberg, S. S. and Eisenberger, M. A.: An efficient design for Phase III studies of combination chemotherapies. *Cancer Treatment Reports*, 69: 11471152, 1985.

18. Simon, R., Wittes, R. E. and Ellenberg, S. S.: Randomized phase II clinical trials. *Cancer Treatment Reports*, 69: 1375-1381, 1985.

19. Gardner, L. B., Gannon, J., O'Malley, D. T., Ellenberg, S. S., Besser, P. M., Mitchell, S., Paul, K., Carty, C., Hoffman, F. A. and DeWys, W. D.: Assessing 24-hour dietary intakes with a calorie/protein estimator. *Journal of Nutrition, Growth, and Cancer*, 2: 219-228, 1985.

20. Boice, J. D., Greene, M. H., Killen, J. Y., Ellenberg, S. S., et al.: Leukemia after adjuvant chemotherapy with semustine (methyl-CCNU)--evidence of a dose-response effect (Letter). *New England Journal of Medicine*, 313: 119-120, 1986

21. Evans, W. K., Nixon, D. W., Daly, J. M., Ellenberg, S. S., et al.: A randomized study of oral nutritional support versus ad lib nutritional intake during chemotherapy for advanced colorectal and non-small cell lung cancer. *Journal of Clinical Oncology*, 5: 113-124, 1987.

22. Walton, L., Ellenberg, S. S., Major, Jr., F., Miller, A., Park, R. and Young, R. C.: The results of second-look surgery in patients with early stage ovarian carcinoma. *Obstetrics and Gynecology*, 70: 770-773, 1987.

23. Yusuf, S., Simon, R. and Ellenberg, S. S. (eds.): Methodologic issues in overviews of randomized clinical trials (workshop proceedings). *Statistics in Medicine*, 6, 1987.

24. Thall, P. F., Simon, R., Ellenberg, S. S. and Shrager, R.: Optimal two-stage designs for clinical trials with binary response. *Statistics in Medicine*, 7: 571-579, 1988.

25. Thall, P. F., Simon, R. and Ellenberg, S. S.: Two-stage selection and testing designs for clinical trials. *Biometrika*, 75: 303-310, 1988.

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27. Avis, F. P., Ellenberg, S. S. and Friedman, M. A.: Surgical oncology research: a disappointing status report. *Annals of Surgery*, 207: 262-266, 1988.

28. Ellenberg, S. S., Mayer, R. J. and Lessner, H. E.: Prognostic factors for colon cancer (letter). *Journal of Clinical Oncology*, 6: 1066, 1988.

29. Ellenberg, S. S. and Hamilton, J. M.: Surrogate endpoints in clinical trials: cancer. *Statistics in Medicine*, 8: 405-413, 1989.37.

30. Ellenberg, S. S.: Meta-analysis: the quantitative approach to research review. *Seminars in Oncology*, 15: 472-481, 1988.

31. Grem, J. L., Ellenberg, S. S., King, S. A. and Shoemaker, D. D.: Correlates of severe or life-threatening toxicity from trimetrexate. *Journal of the National Cancer Institute*, 80: 1313-1318, 1988.

32. Thall, P. F., Simon, R. and Ellenberg, S. S.: A two stage design for choosing among several experimental treatments and a control in clinical trials. *Biometrics*, 45: 537-547, 1989.

33. Eisenberger, M., Krasnow, S., Ellenberg, S., et al.: A comparison of carboplatin plus methotrexate versus methotrexate alone in patients with recurrent and metastatic head and neck cancer. *Journal of Clinical Oncology*, 7: 1341-1345, 1989.

34. Ellenberg, S. S.: Discussion of papers on cost and efficiency of data collection in clinical trials. *Statistics in Medicine*, 9:145-148, 1990.

35. Green, S. B., Ellenberg, S. S., Finkelstein, D., et al.: Issues in the design of drug trials for AIDS. *Controlled Clinical Trials*, 11:80-87, 1990.

36. Young, R. C., Walton, L. A., Ellenberg, S. S., Homesley, H. D., Wilbanks, G. D., Decker, D. G., Miller, A., Park, R. and Major, Jr., F.: Adjuvant therapy of epithelial ovarian cancer in stage I and stage II. *New England Journal of Medicine*, 322:1021-1027, 1990.

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39. Ellenberg, S. S. and Kahn, J. O. (eds.): Methodological issues in AIDS clinical trials (symposium proceedings). *Journal of Acquired Immune Deficiency Syndrome*, 3 (Supplement 2), 1990.

40. NIH-UC expert panel for corticosteroids as adjunctive therapy for pneumocystis pneumonia. Consensus Statement. *New England Journal of Medicine*, 323:1444-50, 1990.

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42. Ellenberg, S. S.: Comment on "Ethics and Clinical Trials: Some Neglected Issues" (Zelen M.),

BioPharmaceutical Quarterly, 1:12-13, 1992.

43. Ellenberg, S. S.: Randomized consent designs for clinical trials: an update. (letter). *Statistics in Medicine*, 11:131-132, 1992.

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47. Ellenberg, S.S.: Comment on "Evaluating Therapeutic Interventions: Some Issues and Experiences" (Fleming, T.), *Statistical Science*, 7:445-446, 1992.

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51. Ellenberg, S.S. and Foulkes, M.A.: The utility of large, simple trials in the evaluation of AIDS treatment strategies. *Statistics in Medicine*, 13:405-415, 1994.

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54. Ellenberg, S.S. and Dixon, D.O.: Statistical issues in designing clinical trials of AIDS treatments and vaccines. *Journal of Statistical Planning and Inference*, 42:123-135, 1994.

55. Ellenberg, S.S.: Discussion of "Surrogate End Points: AIDS and Cancer" (Fleming, T.), *Statistics in Medicine*, 13:1437-1440, 1994.

56. Ellenberg, S.S.: Comment on "Bayesian Approaches to Randomized Trials" (Spiegelhalter, D.S., Freedman, L.S., Parmar, M.K.B.), *Journal of the Royal Statistical Society A*, 157:402, 1994

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58. Ellenberg, S.S.: The use of data monitoring committees in clinical trials. *Drug Information Journal*, 30:553-557, 1996.

59. Ellenberg, S.S.: Methodological issues in pivotal trials: discussion. *Drug Information Journal*, 30: 563-565, 1996.

60. Niu, M.T., Davis, D.M., Ellenberg, S.S.: Recombinant hepatitis B vaccination of infants: emerging safety data from the Vaccine Adverse Event Reporting System (VAERS). *The Pediatric Infectious Disease Journal*, 15:771-76, 1996.

61. Ellenberg, S.S. and Chen, R.T.: The complicated task of monitoring vaccine safety. *Public Health Reports*, 112:10-20, 1997.

62. Braun, M.M., Patriarca, P., Ellenberg, S.S.: Syncope after immunization. *Archives of Pediatric and Adolescent Medicine*, 151:255-259, 1997.

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Invited Editorials

1. Ellenberg SS: Studies to compare treatment regimens: The randomized clinical trial and alternative strategies. *Journal of the American Medical Association*, 246: 2481-2482, 1981.
2. Ellenberg SS: Surrogate endpoints in clinical trials. *British Medical Journal*, 302: 63-64, 1991.
3. Ellenberg SS: Surrogate endpoints. *British Journal of Cancer*, 68:457-459, 1993
4. Ellenberg SS Surrogate endpoints: the debate goes on. *Pharmacoepidemiology and Drug Safety*, 10:493-496, 2001.
5. Ellenberg, SS. Are all monitoring boundaries equally ethical? *Controlled Clinical Trials*, 24:585-588, 2003
6. Ellenberg SS. Monitoring data on data monitoring. *Clinical Trials*, 1:6-8, 2004
7. Ellenberg SS. and Sun W. Adjuvant therapy for gastric cancer: how negative results can help patients. *Journal of the National Cancer Institute*, 99:580-82, 2007
8. Ellenberg SS. Accelerated approval of oncology drugs: Can we do better? *JNCI*, 103:616-7, 2011
9. Begg CB and Ellenberg SS. Expedited approval programs at the FDA. *Clin Trials*, 15:217-18, 2018.

Books

1. Ellenberg, S.S., Fleming T.R., DeMets D.L. *Data Monitoring Committees in Clinical Trials: A Practical Perspective*. John Wiley & Sons, London, 2002.
2. Ellenberg, S.S., Fleming T.R., DeMets D.L. *Data Monitoring Committees in Clinical Trials: A Practical Perspective*. Second Edition. John Wiley & Sons, London, 2019.

Book Chapters/Articles in Conference Proceedings/Other Non-Peer-Reviewed Articles

1. Killen, Jr., J. Y., Holyoke, E. D., Mittelman, A., Ellenberg, S. S., et al.: Adjuvant therapy of adenocarcinoma of the colon following clinically curative resection: An interim report from the Gastrointestinal Tumor Study Group. I Salmon, S. E. and Jones, S. E. (eds): *Adjuvant Therapy of Cancer III*, New York, Grune and Stratton, 1981, pp. 527-538.

3. Mittelman, A., Holyoke, E., Thomas, P. R. M., Novak, J. W., Ellenberg, S. S.,et al.: Adjuvant chemotherapy and radiotherapy following rectal surgery: An interim report from the Gastrointestinal Tumor Study Group. In Salmon, S. E. and Jones, S. E. (eds): *Adjuvant Therapy of Cancer III*, New York, Grune and Stratton, 1981, pp. 547-558.

4. Killen, J. Y. and Ellenberg, S. S.: Adjuvant chemotherapy and immunotherapy of gastrointestinal cancer. In *Gastrointestinal Malignancy*, Riddell, R. and Levin, B., eds. Elsevier, North Holland, 1984.

5. Lippman, M. E., Lichter, A. S., Danforth, D., Ellenberg, S., D'Angelo, T. and Gorrell, C.: The influence of primary breast cancer treatment-- mastectomy or excisional biopsy plus radiation--on the ability to deliver adjuvant chemotherapy. In Salmon, S. E. and Jones, S. E. (eds.): *Adjuvant Therapy of Cancer IV*, New York, Grune and Stratton, 1984.

6. Ellenberg, S. S.: Pre-randomization: a preliminary assessment. In Salmon, S. E. and Jones, S. E. (eds.): *Adjuvant Therapy of Cancer IV*, New York, Grune and Stratton, 1984.

7. Ellenberg, S. S.: Determining sample sizes for clinical trials. *Oncology*, 3: 39-46, 1989.

8. Ungerleider, R. S. and Ellenberg, S. S.: Cancer clinical trials: design, conduct, analysis and reporting. In Pizzo, P. A. and Poplack, D. G. (eds.), *Principles and Practice of Pediatric Oncology*, J. B. Lippincott Company, 1988. (Revised Chapters 1992, 1996, 2000, 2005)

9. Ellenberg, S. S.: Large simple trials: do they have a place in evaluation of therapies for AIDS? *Oncology*, 6:55-63, 1992.

10. Ellenberg, S.S.: *Tools for Primary Care Research, Volume 2: Research Methods for Primary Care.* Book Review, *Annals of Internal Medicine*, 119:444, 1993.

11. Ellenberg, S.S.: Monitoring the safety of biological products. In Bankowski, Z. and Dune, J.F. (eds), *Drug Surveillance: International Cooperation Past, Present and Future, Council for International Organizations of Medical Sciences*, 1994.

12. Foulkes, M.A. and Ellenberg, S.S.: Large, simple trials of HIV therapies. In Finkelstein, D. and Schoenfeld, D. (eds), *AIDS Clinical Trials*, Springer-Verlag, 1995.

13. Ellenberg, S.S.: Statistical considerations for early studies in the rheumatic diseases. In *Biotechnology Agents in Autoimmune Disease* (Conference proceedings), Arthritis Foundation, 1996.

14. Ellenberg, S.S.: *Clinical Measurement in Drug Evaluation.* Book Review, *Controlled Clinical Trials*, 17:354-55, 1996

15. Ellenberg, S.S. Noncompliance in clinical trials and the intention-to treat principle. ASCO Education Book: 196-198, Spring 1997.

16. Ellenberg, S.S. and Siegel, J.P.: Survival analysis in the regulatory setting. In Lin, D.Y. and Fleming, T.R. (eds), *Proceedings of the First Seattle Symposium in Biostatistics: Survival Analysis.* Springer-Verlag, 1997

17. Levine, R.J. and Ellenberg, S.S. Stopping rules for randomized clinical trials: ethical considerations. In Murray T.J and Mehlman, M.J. (eds.), *Encyclopedia of Ethics, Legal and Policy Issues in Biotechnology.* John Wiley & Sons, 2000.

18. Lachenbruch, P.A., Horne, A.D., Lynch, C.J., Tiwari, J., Ellenberg, S.S. Biologics. In Chow SC (ed), *Encyclopedia of Biopharmaceutical Statistics*, Marcel Dekker, Inc., 2000, 47-54; 2nd ed., 2002.

19. David, S.R., Ellenberg, S.S. Food and Drug Administration. In Chow SC (ed), *Encyclopedia of Biopharmaceutical Statistics*, Marcel Dekker, Inc., 2000, 224-30.

20. Foulkes, M.A., Ellenberg S.S. Vaccine efficacy and safety evaluation. *Jordan Report*, National Institute of Allergy and Infectious Diseases, 2002.

21. Zhou, W., Pool, V., Iskander, J.K., English-Bullard, R., Ball, R., Wise, R.P., Haber, P., Pless, R.P., Mootry, G., Ellenberg, S.S., Braun, M.M., Chen, R.T. Surveillance for safety after immunization: Vaccine Adverse Event Reporting System (VAERS) -- United States, 1991-2001. In: *Surveillance Summaries*, January 24, 2003. MMWR 2003; 52(No. SS-1): 1-24.

22. Weir A., S.S. Ellenberg. *Drug Safety Evaluation*. Book review, *Controlled Clinical Trials*, 24:201-205, 2003

23. Ellenberg, S.S. Food and Drug Administration. In Armitage P, Colton T (eds.), *Encyclopedia of Biostatistics* (2nd ed), John Wiley, 2004.

24. Ellenberg, S.S. Bridging studies in vaccines research. In Takeuchi M. and Lagakos, S.W. (eds.), *Forefront of New Drug Development Strategies* (conference proceedings), 2004.

25. Ellenberg, S.S. and Siegel, J.P. FDA and clinical trial data monitoring committees. In Friedman L, DeMets D, Furberg C (eds.), *Case Studies in Data Monitoring*, Springer-Verlag, 2005.

26. Ellenberg, S.S. Data monitoring committees. In D'Agostino R, Sullivan L, Massaro J (eds.), *Encyclopedia of*

Clinical Trials, John Wiley, 2008.

27. Ellenberg, S.S. The use of placebo control groups in clinical trials. In Ravitsky, V., Fiester, A. and Caplan, A. (eds.) *The Penn Center Guide to Bioethics*, Springer, 2009.

28. Ellenberg, S.S. and French, J.A. Bias and Random Error. In Ravina (ed) *Clinical Trials in Neurology: From Idea to Implementation.* Cambridge University Press, 2012.

29. French J. and Ellenberg, S.S. Clinical trials in epilepsy. In Ravina (ed) *Clinical Trials in Neurology: From Idea to Implementation.* Cambridge University Press, 2012.

30. Ellenberg J.H, Ellenberg, S.S. Proceedings of the University of Pennsylvania annual conference on statistical issues in clinical trials: statistical issues in developing targeted therapies. Forward. *Clin Trials* 2010 Oct;7(5):513-5.

31. Ellenberg SS. Book Review: *Design and Analysis of Clinical Trials for Predictive Medicine*. *Journal of the American Statistical Association*, 2016.

MAJOR PRESENTATIONS 2014-2019

1. Oversight of pragmatic randomized trials. IOM Workshop on Contemporary Issues in Human Subjects Protections, Washington, DC, February 2014
2. The Role of statistical thinking in the evolution of methods and practice of medical research. Janssen Pharmaceuticals Statistical Seminar, Spring House, PA, March 2014
3. Leadership in biostatistics: some personal reflections. National Institute of Statistical Sciences Annual Affiliates Workshop, Baltimore, MD, March 2014
4. Trials and errors: what have we learned about how not to design, conduct and analyze clinical trials? University at Buffalo, Buffalo, NY, May 2014.
5. Role of data monitoring committees in post-marketing commitment studies. Joint Statistical Meetings, Boston, MA, August 2014.
6. Interim data monitoring for global trials. FDA-Industry Statistics Workshop, Washington, DC, September 2014.
7. Theory and goals of randomization in clinical trials. IOM Workshop on Ethical and Oversight Roles in Research Involving Standard of Care Interventions. Washington, DC, December 2014.
8. Statistics without tears. Public Responsibility in Medicine and Research Annual Meeting, Baltimore, MD, December 2014.
9. Data and safety monitoring in pragmatic trials. NIH Collaboratory webinar, February 2015.
10. When perspectives differ on appropriate criteria for early termination for benefit. Society for Clinical Trials annual meeting, Arlington, VA, May 2015.
11. Data monitoring committees for pragmatic clinical trials. Webinar, NIH Collaboratory series, October 2015.
12. The case for randomized controlled clinical trials. FDA Emerging Infectious Diseases Workshop, Bethesda, MD, November 2015.
13. Basic principles for clinical trials and considerations for outbreaks. Institute of Medicine Committee on Clinical Trials During Ebola Outbreak 2014-15, Washington, DC, February 2016
14. Studying effects of medical treatments: the need for randomized clinical trials. Thomas Pitts Lectureship in Medical Ethics, Charleston, SC, April 2016.
15. Challenges in studying treatments for uncommon diseases: a biostatistical perspective. NHLBI Workshop on designing trials for uncommon diseases and therapeutics, Bethesda, MD, May 2016
16. Statisticians and the early days of AIDS clinical trials. Seminar, Department of Biostatistics, Vanderbilt University School of Medicine, Nashville, TN, May 2016.
17. Studying effects of medical treatments mid-epidemic: randomized clinical trials and the alternatives. New York Pharma Forum, New York City, June 2016.
18. Data and Safety Monitoring Boards: Principles, Practices and Controversies. NIMH, Bethesda, MD, June 2016.
19. The role of hypothesis testing in medical research. CRiSM Workshop on Contemporary Issues in Hypothesis Testing, University of Warwick, UK, September 2016
20. Clinical trials in the twenty-first century: emerging issues and controversies. John Rock Lecture, Louisiana

State University Health Sciences Center, New Orleans, LA, November 2018
21. Statisticians and the early days of AIDS Clinical Trials. Louisiana State University Biostatistics Colloquium, New Orleans, LA, November 2016.
22. Clinical trials in the twenty-first century: emerging issues and controversies. Keynote lecture, Statistical Practice in Cancer Conference 2017, Tampa, FL, March 2017
23. Oversight of accumulating data in clinical trials: current issues. Cystic Fibrosis Foundation Data and Safety Monitoring Board Annual Meeting, Phoenix, AZ, March 2017
24. How Far Should a DMC Stray From the Planned Monitoring Approach? Combined 4th International Clinical Trials Methodology Conference and 38th Annual Meeting of the Society for Clinical Trials, Liverpool, UK, May 2017
25. Statistical methods for monitoring interim data in clinical trials. Combined 4th International Clinical Trials Methodology Conference and 38th Annual Meeting of the Society for Clinical Trials, Liverpool, UK, May 2017
26. Ongoing and upcoming challenges to clinical trials. Keynote address (Curtis Meinert Lecture), combined 4th International Clinical Trials Methodology Conference and 38th Annual Meeting of the Society for Clinical Trials, Liverpool, UK, May 2017
27. Clinical Research during epidemics: challenges for randomized clinical trials. FDA Statistical Association, Silver Spring, MD, August 2017.
28. Data monitoring in clinical trials: current issues. FDA, Division of Biometrics II, Silver Spring, MD, August 2017.
29. Evaluating treatments and vaccines in settings demanding urgency: lessons from the 2014-15 Ebola epidemic. Sanofi Pasteur, Swiftwater PA, October 2017
30. Interim analysis in clinical trials. Conference on the role of data and safety monitoring boards in clinical research. Weill-Cornell Medical College, Doha, Qatar, January 2018..
31. Evaluating treatments in settings demanding urgency: lessons from the 2014-15 Ebola epidemic. Harvard Law Scholl Petrie-FlomCenter, Cambridge, MA, February 2018
32. Evaluating treatments and vaccines in settings demanding urgency: lessons from the 2014-15 Ebola epidemic. Johns Hopkins University Center for Clinical Trials and Evidence Synthesis, March 2018
33. Data monitoring in clinical trials: current issues and controversies. . Johns Hopkins University Center for Clinical Trials and Evidence Synthesis, March 2018
34. The ABCs of DMCs. Food and Drug Administration, White Oak, MD, September 2018
35. Things you don't learn in graduate school: the early days of AIDS clinical trials. Janet Norwood Award Lecture, University of Alabama Birmingham, Birmingham AL, September 2018
36. Avoiding bias and random error in data analysis. FDA Clinical Investigator Training Course, Silver Spring, MD, November 2018
37. DSMB oversight of trials and relationships with IRBs. Research Ethics and Policy Series, University of Pennsylvania, February 2019
38. Clinical Trials Data Monitoring Committees: An introduction. Society for Clinical Trials, New Orleans, LA, May 2019.

OTHER PROFESSIONAL ACTIVITIES

1. Associate editor for special supplement to *Biometrics* devoted to proceedings of Cornfield Memorial Symposium, 1981-82.
2. Coordinator of Washington Statistical Society participation in D.C. area Science Fairs, 1986-1992.
3. Coordinator of American Statistical Association participation in International Science and Engineering Fair, 1987-1993.
4. Invited organizer of session on statistical topics for Educational Program, American Society of Clinical Oncology, May 1987.
5. Organizer of invited paper session on meta-analysis, annual meeting of American Public Health Association, October 1987.
6. Organizer and Chair of Statistical Working Group for issues in AIDS clinical trials, 1989-1992.
7. Organizer of invited paper session on statistical issues in AIDS research, spring meeting of Biometric Society, Eastern North American Region (ENAR), March 1989.
8. Invited organizer of panel discussion on AIDS clinical trials, annual meeting of Society for Clinical Trials, May 1990.
9. Faculty, Conference on Expedited Access to Unproven Pharmaceuticals, Cambridge, MA, November 1990.

10. Faculty, Statistical Seminars for Community Programs for Clinical Research in AIDS, 11/91, 2/92.
11. Organizer of invited paper session on clinical trials in expanded access programs, spring meeting of Biometric Society, Eastern North American Region (ENAR), March 1993.
12. Invited participant and Discussant, workshop on Stopping Rules in Clinical Trials, Cambridge, U.K., April 1993.
13. Organizer of session on data monitoring committees, Harvard-Schering Plough workshop on Biostatistical Perspectives in Clinical and Pharmaceutical Research, Boston, MA, June 1993.
14. Panelist, International Workshop on Combined Vaccines and Simultaneous Administration, Bethesda, MD, July 1993.
15. Organizer of invited paper session on designing trials with community participation, Joint Statistical Meetings, August 1993.
16. Organizer of session on methodological issues in pivotal trials, Drug Information Association Workshop on Clinical Trials in Biotechnology, Newport Beach, CA, January 1994.
17. Invited participant, Conference on Role of Meta-Analysis in Monitoring Clinical Trials, National Institute of Child Health and Human Development, June 1994.
18. Invited discussant, Fourth Annual Merck-Temple Conference on Biostatistics, Philadelphia, PA, October 1994.
19. Faculty, PhRMA Education and Research Institute Course on Post-marketing Safety Monitoring, Washington, DC, October 1994.
20. Faculty, Regulatory Affairs Professionals Society Course on Post-Marketing Surveillance, Washington, DC, October 1994.
21. Organizer and Chair of Session on Risk Assessment, Communication and Public Policy, American Association for the Advance of Science Annual Meeting, Atlanta, GA, February 1995.
22. Session moderator, FDA Conference on Comparing Treatments: Safety, Effectiveness and Cost-Effectiveness, Bethesda, MD, March 1995.
23. Participant, PBS documentary on use of statistics and probability in evaluation of medical treatments, July 1995.
24. Session Moderator, Internal version of FDA Conference on Comparing Treatments: Safety, Effectiveness, and Cost-Effectiveness, Bethesda, MD, October 1995.
25. Panelist, FDA Epidemiology Workshop, Rockville, MD, January 1996.
26. Discussant, session on surrogate endpoints, International Biometric Society (Eastern North American Region), Richmond, VA, March 1996.
27. Panelist, workshop on Flexible Strategies for Clinical Trials, Harvard School of Public Health, May 1996.
28. Discussant, session on statistical issues in vaccine trials, International Biometric Conference, Amsterdam, The Netherlands, July 1996.
29. Coordinator/organizer, CBER clinical trials course. First offering fall 1996.
30. Invited participant, Oberwolfach Conference on Medical Statistics, Oberwolfach, Germany, February 1997.
31. Organizer, workshop on statistical leadership in clinical trials, Society for Clinical Trials Annual Meeting, Boston, MA, July 1997.
32. Member, NIH Office of Alternative Medicines panel on the Practice Outcomes Monitoring and Evaluation System, Rockville, MD, August 1997.
33. Presenter, Continuing Education session on finding employment in biostatistics, Joint Statistical Meetings, Anaheim, CA, August, 1997, 1998.
34. Panelist, American Enterprise Institute Conference on Safety of Pharmaceutical Products, Washington, D.C, March 1998.
35. Panelist, Satellite Broadcast, The Role of Data Safety Monitoring Boards in Drug, Biologic and Medical Device Clinical Trials: An FDA, industry and clinical perspective. January 1999.
36. Discussant, session on Ethical Issues in Clinical Trials, International Biometric Society Eastern North American Region Annual Meeting, Atlanta, GA, March 1999.
37. Invited panelist, congressional hearing of subcommittee on Criminal Justice, Drug Policy and Human Resources, "Hepatitis B vaccine: Helping or Hurting Public Health." May 1999.
38. Invited panelist, congressional hearing of subcommittee on National Security, Veterans Affairs and International Relations, "Anthrax Vaccine Adverse Reactions," July 1999.
39. Discussant, session on homeopathic cancer treatments. Comprehensive Cancer Care 2000, Crystal City, VA, June 2000.
40. Discussant, session on intent-to-treat analysis. Drug Information Association Annual Meeting, San Diego, CA, June 2000.

41. Panelist, workshop on Medical Defense Against Bioterrorism: Efficacy and Safety of New Products. Bethesda, MD, December 2000.
42. Discussant, NIAID workshop on endpoints in AIDs clinical trials, Bethesda, MD, February 2001.
43. Discussant, Harvard-Schering workshop on Datamining, with Applications in Genomics, Clinical Trials and Post-Marketing Drug Risk. Boston, MA, May 2001.
44. Invited participant, Conference on International Differences in Clinical Trial Conduct and Results, London, UK, June 2001.
45. Faculty, NIH course on Ethical and Regulatory Aspects of Human Subject Research, 2001-2004.
46. Discussion leader, roundtable discussion on FDA draft guidance on clinical trial data monitoring committees, Joint Statistical Meetings, NY, NY, August 2002.
47. Faculty, FDA-JHU course on Tools for Pre-Approval Drug Safety Evaluation. Rockville, MD, May 2003
48. Organizer, session on risk management for biological products, DIA Annual Meeting, San Antonio, TX, June 2003.
49. Discussant, session on flexible designs and electronic data capture, DIA Annual Meeting, San Antonio, TX, June 2003.
50. Organizer, mini-symposium on clinical trial data monitoring committees, Society for Clinical Trials/International Society of Clinical Biostatistics joint meeting, London, UK, July 2003.
51. Organizer and presenter, workshop on the relative responsibilities of data monitoring committees and IRBs, Public Responsibility in Medicine and Research (PRIM&R), Washington, D.C., December 2003.
52. Visiting Committee, Harvard University Department of Statistics, 2004.
53. Organizer and co-presenter, short course on clinical trial data monitoring, spring meeting, Eastern North American Region of the International Biometrics Society, Pittsburgh, PA, March 2004. Also presented for FDA reviewers, Rockville, MD, April 2004.
54. Panelist, Workshop on Independence in Data Monitoring of Clinical Trials, Society for Clinical Trials annual meeting, New Orleans, LA, May 2004.
55. Organizer and chair, session on last observation carried forward analysis, Society for Clinical Trials annual meeting, New Orleans, LA, May 2004.
56. Organizer and leader, workshop on data monitoring committees, Public Responsibility in Medicine and Research (PRIM&R) annual meeting, San Diego, CA, October 2004.
57. Organizer and chair, session on safety of COX-2 inhibitors, JSM, Minneapolis, August 2005
58. Member, Vaccine Ethics Roundtable, University of Pennsylvania, 2005-6
59. Organizer and chair, session on use of historical controls in drug development, Society for Clinical Trials annual meeting, Orlando, FL, May 2006.
60. Guest editor, proceedings of joint FDA-HST symposium on adaptive clinical trial designs, *Statistics in Medicine*, October 2006.
61. Organizer and chair, ASCO Educational Session: Evidence of Therapeutic Effectiveness: How Much is Enough to Change Clinical Practice?
62. Invited participant, Brookings Institution Roundtable on Post-Market Evidence, Washington, DC, January 2008
63. Moderator, Roundtable discussion on data monitoring committees, ENAR spring meeting, Crystal City, VA, March 2008.
64. Discussant, session on large simple clinical trials, ENAR spring meeting, Crystal City, VA, March 2008.
65. Moderator, panel discussion on DSMBs and IRBs: communication and decision-making, Public Responsibility in Medical Research annual meeting, Orlando, FL, Nov 2008
66. Faculty, FDA course on small clinical trials, Rockville, MD, Jan 2009
67. Organizer, session on clinical trials in obesity, Society for Clinical Trials annual meeting, Atlanta, GA, May 2009
68. Organizer, session on why investigational drugs fail, Society for Clinical Trials annual meeting, Baltimore, MD, May 2010.
69. Discussant, session on safety signal detection in new drug development., Joint Statistical Meetings, Vancouver, Canada, August 2010.
70. Moderator, session on tailored therapeutics in drug development, Joint Statistical Meetings, Vancouver, Canada, August 2010.
71. Faculty, American Course on Drug Development and Regulatory Sciences, Bethesda, MD, September 2010.
72. Faculty, short course on data monitoring committees, 4th Seattle Symposium in Biostatistics, Seattle, WA, November 2010.
73. Faculty, PRIM&R Webinar, January 2011.

74. Faculty, short courses on Clinical Trial Data Monitoring Committees presented to medical reviewers at the SFDA (Chinese regulatory agency) and cancer researchers, Beijing, China, March 2011.
75. Organizer, panel discussion on current problems in clinical trial data monitoring committees, International Biometrics Society (Eastern North American Region) Annual Meeting, Miami, FL, March 2011.
76. Organizer, session on the CATT Avantis-Lucentis Study, Society for Clinical Trials Annual Meeting, Vancouver, BC, May 2011.
77. Faculty, American Course on Drug Development and Regulatory Sciences, San Francisco, CA, October 2011.
78. Moderator, Great Debate session on equipoise as the ethical basis for randomization, annual Advancing Ethical Research Conference (PRIM&R), December 2011.
79. Organizer and Chair, session on a centennial celebration of the contributions of Jerome Cornfield to clinical trials. Society for Clinical Trials Annual Meeting, Miami, FL, 2012.
80. Panelist, session on multiplicity in clinical trials, Society for Clinical Trials Annual Meeting, Miami, FL, 2012.
81. Organizer and Chair, session on special issues in pediatric clinical trials, Society for Clinical Trials Annual Meeting, Philadelphia, PA, 2014.
82. Organizer and chair, invited session on current issues in assessing performance in health facilities. Joint Statistical Meetings, Seattle, WA, 2015.
83. Discussant, session on crossover designs in clinical trials, Society for Clinical Trials Annual Meeting, Montreal CA, 2016.
84. Organizer and chair, invited session in memory of Daniel Sargent. ENAR Spring Meeting, 2017
85. Panelist, New York Academy of Sciences Workshop: The Need to Accelerate Therapeutic Development — Must Randomized Controlled Trials Give Way?. NY, NY, March 2017.
86. Panel Discussant, session on role of central IRB vs DSMB in decision-making for early termination or suspension of a multicenter trial. Society for Clinical Trials Annual Meeting, Vancouver, CA, May 2018.
87. Organizer, invited session in memory of Douglas Altman. ENAR Spring Meeting, 2019.