# Peter F. Thall

# **Curriculum Vitae**

# **Contact Information**

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# Education

1971	BS, Mathematics	Michigan State University
1973	MS, Statistics	Florida State University
1975	PhD, Statistics and Probability	Florida State University

# **Professional Experience**

Biometry Intern, 1973 Department of Statistics, Biology Division Oak Ridge National Laboratory

Assistant Professor, 1975-1980 Program in Mathematical Sciences University of Texas at Dallas

Assistant Professor, 1980-1984 Associate Professor, 1984 -1990 Department of Statistics George Washington University

Statistician The Biostatistics Center, Department of Statistics George Washington University Diabetes Control and Complications Trial, 1982

Statistician The Biostatistics Center, Department of Statistics George Washington University National Cooperative Gallstone Study, 1983

Special Assistant to the Chief, 1986-1987 Biometric Research Branch, Cancer Therapy Evaluation Program Division of Cancer Treatment, National Cancer Institute Visiting Lecturer, 1997 Medical and Pharmaceutical Statistics Research Unit Department of Applied Statistics University of Reading, England

Associate Professor, 1991-1998, Professor, 1998 – 2000 Department of Biomathematics University of Texas M.D. Anderson Cancer Center

Professor, 2000 – present Department of Biostatistics University of Texas M.D. Anderson Cancer Center

Visiting Research Scientist, 2016 INSERM Unit 1138, Data Science and Personalized Medicine French National Institute for Health and Medical Research Paris, France

# **Honors and Awards**

All University Competitive Fellow, Florida State University, 1971

Anise J. Sorrell Professor, Endowed Chair, M.D. Anderson Cancer Center, 2004-Present

Fellow, Society for Clinical Trials, 2014

Owen Award, American Statistical Association, 2014

Fellow, American Statistical Association, 2015

Editors' award for the best paper published in *Biometrics* in 2019: 'A hybrid phase I-II/III clinical trial design allowing dose re-optimization in phase III'

Paper chosen for the Wall of Science at MD Anderson: *J Clinical Oncology*, 2021. 'Third-party BK virus specific cytotoxic T lymphocyte therapy for hemorrhagic cystitis following allotransplantation'

Paper chosen for the Wall of Science at MD Anderson: *Nature Medicine*. 2024. 'Safety, efficacy and determinants of response of Allogeneic CD19-specific CAR-NK cells in CD19+ B cell tumors: a phase 1/2 trial'

One of the 10 most cited papers published in *Pharmacetical Statistics* during 2022-2023, 'Generalized phase I-II designs to increase long term therapeutic success rate'

Invited Papers: 11 in statistical journals, 5 in medical journals

#### **Papers with Discussions**

J American Statistical Association, 2012

J American Statistical Association, 2016

Biometrics, 2019

#### Invited Keynote Lectures

- 1. 'Assessment of Stratum-Covariate Interactions in Cox's Proportional Hazards Regression Model'. Soc for Clinical Trials Annual Meeting, St. Louis, Missouri, 1983
- 2. 'Bayesian Clinical Trial Design: 23 Years of Theory and Practice' presented at the Council of Texas Statisticians Annual Meeting, University of Texas at Dallas, 2014.
- 3. 'SMART Design, Conduct, and Analysis in Oncology' presented at the Innovative Methods Program for Advancing Clinical Trials (IMPACT), Cary, NC, 2014
- 'Bayesian Clinical Trial Designs to Evaluate Precision Medicine in Oncology', 4th International Conference on Big Data and Information Analytics, SAMSI Session on Precision Medicine, Houston, TX, 2018
- 5. 'Applications of Bayesian Precision Medicine', International Society for Clinical Biostatistics, Annual Meeting, Leuven, Belgium, 2019
- 'Bayesian Personalized Treatment Selection for Advanced Breast Cancer', Bayesian Biostatistics Conference, Bayes 2024, Sponsored by The Adolphe Quetelet Society, Rockville, Maryland 23-25 October 2024

#### **Editorial Boards**

Associate Editor, Stat in Medicine, 1994-2005

Associate Editor, J National Cancer Institute, 1995-1997

Associate Editor, Statistics in Biosciences, 2008-2018

Associate Editor, Biometrics, 2003-2008 and 2017 - 2021

Editorial Board, Special Issue of *Clinical Trials* on modern dose finding methods, 2022-2024

Associate Editor, Clinical Trials, 2003 - present

# **M.D. Anderson Institutional Activities**

Search Committee for Chief, Section of Biostatistics and Clinical Biostatistics Center, 1993-1994 Institutional Research Support Committee, 1994-1997 Chair, Mid-Tenure Review Committee for J. Jack Lee, PhD 1995 Achievement Award Subcommittee, Clinical Research Category, 1998 Chair, Biostatistics Department Faculty Recruitment Committee, 1999-2000. Study Section Review Committee for Clinical, Translational and Population-based Projects, Institutional Research Grants Program, 2002-2008 Multidisciplinary Research Advisory Committee, 2004-2007 Chair, Mid-Tenure Review Committee for Guosheng Yin, PhD, 2006. Institutional Research Grants Program, 2002-2008 Statistical Computing Committee, Biostatistics Department, 2012 – 2014 Reviewer, Startup Funds Proposal, MDACC Research Administration, January 2013 Mid-Tenure Review Committee for M. Guindani, PhD, 2013 Chair, Mid-Tenure Review Committee for B. Hobbs, PhD, 2014 Multidisciplinary Research Advisory Committee, 2014 – 2017 Mid-Tenure Review Committee for D. Fuentes, PhD, 2016 Biostatistician, Nanobiotix Strategic Alliance, Dept of Radiation Oncology, 2019 - present Biostatistician, Protocol PA-13-0786, Zhongxing Liao, PI, Dept of Radiation Oncology, 2019 – present Biostatistician, Translational Molecular Pathology Clinical Research Group, Division of Pathology and Laboratory Medicine 2020 - present Biostatistical Reviewer, Multidisciplinary Research Project Grant Application, 2021 Small Group Session Biostatistics Expert: Leading Clinical Research Faculty Learning Series, 2021 **External Committees and Review Activities** 

External Grant Proposal Reviewer, National Cancer Institute, NIH, 1993

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External Advisory Committee, "Growth Control in Multiple Myeloma" (B. Barlogie, P.I.) Myeloma Institute for Research and Therapy, Arkansas Cancer Research Center, 2000-2006.

Data Safety Monitoring Board, "ReoPro Retavase Reperfusion of Stroke Safety Study – Imaging Evaluation" NINDS (S. Warach, P.I.) 2002-2007.

Data Safety Monitoring Board, "An Adaptively Randomized Trial of Gemcitabine 1200 mg/m<sup>2</sup> versus Gemcitabine 900 mg/m<sup>2</sup> + Docetaxel for Unresectable Soft Tissue Sarcoma." Connective Tissue Oncology Soc, (R. Maki, P.I.), 2002-2005.

Liposomal Topotecan Advisory Board, GlaxoSmithKline, 2003.

Co-Chair, "Better Clinical Studies", Science–Centric Session, National Cancer Institute, Sarcoma Progress Review Group, Philadelphia, PA, 2003.

External Advisory Board, Head and Neck Cancer SPORE, Winship Cancer Institute, Emory University (D. Shin, PI; F. Khuri, Co-PI), 2006.

External Advisory Board, Epithelial Ovarian Cancer Program Project Grant, Memorial Sloan Kettering Cancer Center (D. Spriggs, PI), 2005 – 2010.

Special Emphasis Panel/Scientific Review Group, NINDS, NIH, Washington, D.C., 2007

Data Safety Monitoring Board, "A Phase II Trial of IT-101 for Advanced Ovarian Cancer," Calando Pharmaceuticals, 2008 – 2009.

Special Emphasis Panel/Scientific Review Group 2010/01 ZHL1 CSR-D (F1), NHLBI, RFA-HL-10-007: Prematurity and Respiratory Outcomes Program. Bethesda, MD, November 23, 2009.

Data Safety Monitoring Board, "Multi-institutional Trial of Allogeneic Bone Marrow Transplantation for Hematologic Malignancies using HLA-matched Related or Unrelated Donors with Fludarabine and IV Busulfan as Pre-transplant Conditioning followed by Post-transplant Immunosuppression with High Dose Cyclophosphamide," 2010 – 2011.

AML Working Group, Lymphoma Steering Committee, NCI, NIH, Bethesda, MD, October 4, 2010

Androgen Receptor Signaling in Prostate Cancer: Translating Biology into Clinical Practice. Invited speaker and participant. Prostate Cancer Task Force, Genitourinary Steering Committee, National Cancer Institute, NIH, Dec 6-7, 2010.

Program Chair for Section on Bayesian Statistical Science, 2013 Joint Statistical Meetings, American Statistical Association, 2012 – 2013

Member, ENAR Regional Advisory Board, International Biometric Soc, 2013 – 2015.

Member, NINDS Preclinical Assessment Network (SPAN) Special Emphasis Panel/Scientific Review Group 2019/05 ZNS1 SRB-D (03), March 18-19, 2019

Biostatistical Reviewer, NINDS NHLBI, SIREN Emergency Clinical Trial Network, grant proposal for a phase II multicenter double-blind placebo-controlled trial to establish ketogenic formula dose specifications to safely induce ketosis in established refractory status epilepticus, Dec 20, 2019.

Biostatistical Reviewer, NIH NINDS Special Emphasis Panel ZNS1 SRB-A(47), Early Phase Clinical Trial Network EPPIC-NET, stage 3 protocols focused on the use of drugs for treatment of painful diabetic neuropathy, August 2, 2021.

Scientific Advisory Board, Cellenkos RESOLVE Trial of Cryopreserved Cord Blood Derived T-Regulatory Cells in the Treatment of COVID-19 Induced Acute Respiratory Distress Syndrome, 2022

Member, Review Panel, FDA Center for Drug Evaluation and Research, Workshop on Efficient Evaluation of Biosimilar Products, September 19, 2022

Member, Stakeholder Advisory Board, "Pragmatic Comparative Effectiveness using SMARTs" sponsored by Patient Centered Outcomes Research Institute (PCORI), A. Wahed, PI. 2023-25

External Grant Proposal Reviewer, Molecular and Cellular Sciences and Technologies Review Branch, Center for Scientific Review, NIH, June 17, 2024

Data and Safety Monitoring Board, SMART-JIA trial, PI Laura Schanberg PI, Dual PI Huiman Barnhart, International PI Fabrizio De Benedett. Funded by PCORI. 2024 – 2025.

# **Current Research Funding**

#### **Grants and Contracts**

1R01CA261978 (Thall, Lin) NIH/NCI 7/1/2021-6/30/2025 \$1,620,300

Bayesian Methods for Complex Precision Biotherapy Trials in Oncology Major goals: To provide novel Bayesian models and clinical trial designs for developing and evaluating biological treatments, including cell therapies, immunotherapies, and targeted agents, accounting for complex clinical and biological outcomes and multidimensional treatment effects that may vary with disease subtypes and patient subgroups. FP00012214 Role: Co-PI

5 P30 CA016672 47 (Draetta) 8/28/1996-6/30/2026 NIH/NCI \$77,483,432 Cancer Center Support Grant (CCSG) - Biostatistics Resource Group (BRG) Major goals: The Biostatistics Resource Group provides biostatistical expertise and quantitative research resources in support of all CCSG programs at MDACC. PID858033 Role: Biostatistician

5R01CA061508-25(Lin)7/1/2023-6/30/2026Conquer Cancer Foundation\$199,997

CD70 Chimeric Antigen Receptor Natural Killer Cells in the Treatment of Relapsed/Refractory Multiple Myeloma

Major goals: To determine the safety, day 30 response rate, day 180 treatment failure rate (defined as disease progression or death) and optimal cell dose of CAR.70/IL15-transduced CB-NK cells in patients with relapsed/refractory hematological malignances. PID15285 Role: Co-Investigator

RP230160(Dondossola)3/1/2023-2/28/2026NIH/NCI\$1,025,622Cancer Prevention & Research Institute of Texas CPRITMajpr Goals: Overcoming therapy resistance by integrated computational modeling of the bonemetastatic niche in prostate and renal cancers.Role: Biostatistician

 1R01CA280827 (Daher)
 4/1/2023-3/31/2028,

 NIH/NCI
 \$2,025,000

 Next Generation Engineered NK Cells for Lymphoma Patients after CD19 CAR-T Cell Failure.

 Major goals: Develop novel cell based therapies to harness the antileukemic potential of NK cells against AML.

 Role: Biostatistician

# Selected Consulting

Georgetown University School of Nursing, Washington, DC, 1984.

Logistics Management Institute, Bethesda, MD, 1989.

Novartis Pharmaceuticals, Basel, Switzerland and Morristown, NJ, USA 1996-2004.

Orphan Medical, Minnetonka, MN, 2002-2003.

ESP Pharmaceuticals, Edison, NJ, 2004.

Applied Molecular Evolution, San Diego, CA, 2004

Chiron Corporation, Emeryville, CA, 2005.

Scian Services, Toronto, Canada, 2006.

Hoffman-LaRoche, Nutley, NJ 2008-2009

Fertility Center of Las Vegas, Las Vegas, NV, 2009

Takeda Oncology, Millenium Pharmaceuticals, Boston, MA, 2010

AstraZeneca, Waltham, MA, 2016

# Publications

# Books

1. **Thall PF,** editor. *Recent Advances in Clinical Trial Design and Analysis.* Boston: Kluwer Academic Publishers, 1995.

2. Yuan Y, Nguyen HQ, **Thall PF**. *Bayesian Designs for Phase I-II Clinical Trials*. Chapman & Hall/CRC Press, Biostatistics Series, 2016.

- 3. Thall PF. Statistical Remedies for Medical Researchers. Springer Nature, 2020.
- 4. Thall PF. Bayesian Precision Medicine. Chapman & Hall / CRC Press, 2024.

# Papers Pubished in Statistical Journals

- 1. Kullback S, **Thall PF.** An information-theoretic proof of the integral representation theorem. *J. Combinatorics, Information and System Sciences* 2: 97-103, 1977.
- 2. Ammann LP, **Thall PF.** On the structure of regular infinitely divisible point processes. *Stochastic Processes and Their Applications* 6: 87-94, 1977.
- 3. Ammann LP, **Thall PF.** Random measures with aftereffects. *Ann Probability* 6: 216-230, 1978.
- 4. Ammann LP, **Thall PF.** Count distributions, orderliness and invariance of Poisson cluster processes. *J Applied Probability* 16: 261-273, 1979.
- 5. **Thall PF.** Huber-sense robust M-estimation of a scale parameter with application to the exponential distribution. *J American Statistical Assoc* 74: 147-152, 1979.
- 6. **Thall PF.** Cluster shock models. *J Applied Probability* 18: 104-111, 1981.
- 7. Kimeldorf G, **Thall PF.** A joint characterization of the multinomial distribution and the Poisson process. *J Applied Probability* 20: 202-208, 1981.
- 8. **Thall PF.** A theorem on regular infinitely divisible Cox processes. *Stochastic Processes and Their Applications* 16: 205-210, 1983.
- 9. **Thall PF**, Lachin JM. Assessment of stratum-covariate interactions in Cox's proportional hazards regression model. *Stat in Medicine* 5:73-83, 1986.
- 10. **Thall PF.** Mixed Poisson likelihood regression models for longitudinal interval count data. *Biometrics* 44: 197-209, 1988.
- 11. **Thall PF**, Simon R, Ellenberg SS, Shrager R. Optimal two-stage designs for clinical trials with binary response. *Stat in Medicine* 71: 571-579, 1988.

- 12. **Thall PF**, Simon R, Ellenberg SS. Two-stage selection and testing designs for comparative clinical trials. *Biometrika* 75: 303-310, 1988.
- 13. **Thall PF,** Lachin JM. Analysis of recurrent events: nonparametric methods for random interval count data. *J American Statistical Assoc* 83: 339-347, 1988.
- 14. **Thall PF**, Simon R, Ellenberg SS. A two-stage design for choosing among several experimental treatments and a control in clinical trials. *Biometrics* 45: 537-547, 1989.
- 15. Halperin M, Hamdy M, **Thall PF.** Distribution-free confidence intervals for a parameter of Wilcoxon-Mann-Whitney type for ordered categories and progressive censoring. *Biometrics* 45: 509-521, 1989.
- 16. **Thall PF**, Simon R. Incorporating historical control data in planning Phase II clinical trials. *Stat in Medicine* 9: 215-228, 1990.
- 17. **Thall PF,** Vail SC. Some covariance models for longitudinal count data with overdispersion. *Biometrics* 46: 657-671, 1990.
- 18. **Thall PF**, Simon R, Grier, DA. Test-based variable selection via cross-validation. *J Computational and Graphical Stat* 1: 41-61, 1992.
- 19. **Thall PF.** Score tests in the two-way layout of counts. *Communications in Statistics: Theory and Methods* 21: 3017-3036, 1992.
- 20. **Thall PF**, Estey EH. A Bayesian strategy for screening cancer treatments prior to Phase II clinical evaluation. *Stat in Medicine* 12: 1197-1211, 1993.
- 21. Simon R, **Thall PF**, Ellenberg SS. New designs for the selection of treatments to be tested in randomized clinical trials. *Stat in Medicine* 13: 417-429, 1994.
- 22. **Thall PF**, Simon R. Practical Bayesian guidelines for phase IIB clinical trials. *Biometrics* 50: 337-349, 1994.
- 23. Ensign LG, Gehan EA, Kamen DS, **Thall PF.** An optimal three-stage design for phase II clinical trials. *Stat in Medicine* 13:1727-1736, 1994.
- 24. **Thall PF,** Simon R. A Bayesian approach to establishing sample size and monitoring criteria for phase II clinical trials. *Controlled Clinical Trials* 15:463-481, 1994.
- 25. **Thall PF**, Simon R, Estey EH. Bayesian sequential monitoring designs for single-arm clinical trials with multiple outcomes. *Stat in Medicine* 14:357-379, 1995.
- 26. **Thall PF**, Jacoby D, Zimmerman SO. Estimating genomic category probabilities from fluorescent *in situ* hybridization counts with misclassification. *J Royal Statistical Soc, C* 45:431-446, 1996.
- 27. Staniswalis JG, **Thall PF**, Salch J. Semiparametric regression analysis for recurrent event interval counts. *Biometrics* 53:1334-1353, 1997.

- 28. **Thall PF**, Russell KT, Simon RM. Variable selection in regression via repeated data splitting. *J Computational and Graphical Stat,* 6:416-434, 1997.
- 29. **Thall PF,** Russell KT. A strategy for dose finding and safety monitoring based on efficacy and adverse outcomes in phase I/II clinical trials. *Biometrics* 54:251-264, 1998.
- 30. Shen Y, **Thall PF.** Parametric likelihoods for multiple non-fatal competing risks and death. *Stat in Medicine*, 17:999-1016, 1998.
- 31. **Thall PF,** Sung H-G. Some extensions and applications of a Bayesian strategy for monitoring multiple outcomes in clinical trials. *Stat in Medicine*, 17:1563-1580, 1998.
- 32. **Thall PF,** Lee JJ, Tseng C-H, Estey EH. Accrual strategies for phase I trials with delayed patient outcome. *Stat in Medicine*, 18:1155-1169, 1999.
- 33. Stallard N, **Thall PF**, Whitehead J. Decision theoretic designs for phase II clinical trials with multiple outcomes. *Biometrics*, 55:971-977, 1999.
- 34. **Thall PF,** Cheng S-C. Treatment comparisons based on two-dimensional safety and efficacy alternatives in oncology trials. *Biometrics*, 55:746-753, 1999.
- 35. **Thall PF,** Simon RM, Shen Y. Approximate Bayesian evaluation of multiple treatment effects. *Biometrics*, 56:213-219, 2000.
- 36. **Thall PF,** Millikan R, Sung, H-G. Evaluating multiple treatment courses in clinical trials. *Stat in Medicine*, 19: 1011-1028, 2000.
- 37. **Thall PF,** Cheng S-C. Optimal two-stage designs for clinical trials based on safety and efficacy. *Stat in Medicine,* 20:1023-1032, 2001.
- 38. **Thall PF,** Sung H-G, Choudhury A. Dose-finding based on feasibility and toxicity in T- cell infusion trials. *Biometrics*, 57:914-921, 2001.
- 39. Staniswalis JG, **Thall PF.** An explanation of generalized profile likelihoods. *Statistics and Computing*, 11:293-298, 2001.
- 40. Stallard N, **Thall PF.** Decision-theoretic designs for pre-phase II screening trials in oncology. *Biometrics*, 57:1089-1095, 2001.
- 41. Thall PF. Bayesian clinical trial design in a cancer center. Chance. 14:23-28, 2001 Invited
- 42. **Thall PF**, Sung H-G, Estey EH. Selecting therapeutic strategies based on efficacy and death in multi-course clinical trials. *J American Statistical Assoc*, 97:29-39, 2002.
- 43. Cheung YK, **Thall PF.** Monitoring the rates of composite events with censored data in phase II clinical trials. *Biometrics*, 58:89-97, 2002.

- 44. **Thall PF.** Ethical issues in oncology biostatistics. *Statistical Methods in Medical Res.* 11:429-448, 2002.(Invited
- 45. **Thall PF,** Inoue LYT, Martin T. Adaptive decision making in a lymphocyte infusion trial. *Biometrics,* 58:560-568, 2002.
- 46. Inoue LYT, **Thall PF**, Berry, DA. Seamlessly expanding a randomized phase II trial to phase III. *Biometrics*, 58:823-831, 2002.
- 47. **Thall PF,** Wathen JK, Bekele BN, et al. Hierarchical Bayesian approaches to phase II trials in diseases with multiple subtypes. *Stat in Medicine*, 22: 763-780, 2003.
- 48. **Thall PF**, Millikan RE, Mueller P, Lee S-J. Dose-finding with two agents in phase I oncology trials. *Biometrics*, 59:487-496, 2003.
- 49. Bekele BN, **Thall PF.** Dose-finding based on multiple toxicities in a soft tissue sarcoma trial. *J American Statistical Assoc*, 99:26-35, 2004.
- 50. **Thall PF**, Cook JD. Dose-finding based on efficacy-toxicity trade-offs. *Biometrics*, 60:684-693, 2004.
- 51. Braun TM, Yuan Z, **Thall PF**. Determining a maximum tolerated schedule of a cytotoxic agent. *Biometrics*, 61:335-343, 2005.
- 52. **Thall PF**, Wathen JK. Covariate-adjusted adaptive randomization in a sarcoma trial with multistage treatments. *Stat in Medicine*, 24:1947-1964, 2005.
- 53. **Thall PF**, Wooten LH, Tannir N. Monitoring event times in early phase clinical trials: some practical issues. *Clinical Trials*. 2:467-478, 2005.
- 54. Cheung YK, Inoue LYT, Wathen JK and **Thall PF.** Continuous Bayesian adaptive randomization based on event times with covariates. *Stat in Medicine*, 25:55-70, 2006.
- 55. **Thall PF**, Cook JD, Estey EH. Adaptive dose selection using efficacy-toxicity trade-offs: illustrations and practical considerations. *J Biopharmaceutical Stat.* 16:623-638, 2006. Invited
- 56. **Thall PF**, Wooten LH, Shpall EJ. A geometric approach to comparing treatments for rapidly fatal diseases. *Biometrics*, 62:193-201, 2006.
- 57. Braun TM, **Thall PF**, Nguyen H, de Lima M. Simultaneously optimizing dose and schedule of a new cytotoxic agent. *Clinical Trials*, 4:113-124, 2007.
- 58. **Thall PF**. Some geometric methods for constructing decision criteria based on two-dimensional parameters. *J Statistical Planning and Inference*. 138:516-527, 2007. Invited.
- 59. **Thall PF**, Wooten LH, Logothetis CJ, Millikan R, Tannir NM. Bayesian and frequentist two-stage treatment strategies based on sequential failure times subject to interval censoring. *Stat in Medicine*. 26:4687-4702, 2007.

- 60. **Thall PF**. A review of phase 2-3 clinical trial designs. *Lifetime Data Analysis*. 14:37-53, 2008. Invited.
- 61. Morita S, **Thall PF**, Mueller P. Determining the effective sample size of a parametric prior. *Biometrics*. 64:595-602, 2008.
- 62. Wathen JK, **Thall PF**, Cook, JD, Estey EH. Accounting for patient heterogeneity in phase II clinical trials. *Stat in Medicine.* 27:2802-2815, 2008.
- 63. Bekele BN, Ji Y, Shen Y, **Thall PF**. Monitoring late onset toxicities in phase I trials using predicted risks. *Biostatistics*. 9:442-457, 2008.
- 64. **Thall PF**, Nguyen H, Estey EH. Patient-specific dose-finding based on bivariate outcomes and covariates. *Biometrics*. 64:1126-1136, 2008.
- 65. Wathen JK, **Thall PF.** Bayesian adaptive model selection for optimizing group sequential clinical trials. *Stat in Medicine*. 27:5586-5604, 2008.
- 66. Morita S, **Thall PF**, Bekele BN, Mathew P. A Bayesian hierarchical mixture model for platelet derived growth factor receptor phosphorylation to improve estimation of progression-free survival in prostate cancer. *J Royal Statistical Soc, C.* 59:19-34, 2010.
- 67. Houede N, **Thall PF**, Nguyen H, Paoletti X, Kramar A. Utility-based optimization of combination therapy using ordinal toxicity and efficacy in phase I/II trials. *Biometrics.* 66:532-540, 2010.
- 68. Morita S, **Thall PF**, Mueller P. Evaluating the impact of prior assumptions in Bayesian biostatistics. *Statistics in Biosciences*. 2:1-17, 2010.
- 69. **Thall PF.** Bayesian models and decision algorithms for complex early phase clinical trials. *Statistical Science.* 25:227-244, 2010. Invited.
- 70. **Thall PF**, Liu D, Berrak SG, Wolff JE. Defining and ranking effects of individual agents based on survival times of cancer patients treated with combination chemotherapies. *Stat in Medicine*. 30:1777-1794, 2011.
- 71. **Thall PF**, Szabo A, Nguyen HQ, Amlie-Lefond CM, Zaidat OO. Optimizing the concentration and bolus of a drug delivered by continuous infusion. *Biometrics.* 67:1638-1646, 2011.
- 72. **Thall PF**, Nguyen HQ, Wang X, Wolff JE. A hybrid geometric phase II-III clinical trial design based on treatment failure time and toxicity. *J Statistical Planning and Inference*. 142:944-955, 2012.
- 73. Yuan Y, **Thall PF**, Wolff J. Estimating progression-free survival in pediatric brain tumor patients when some progression statuses are unknown. *J Royal Statistical Soc, C.* 61:135-149, 2012.
- 74. **Thall PF**, Nguyen HQ. Adaptive randomization to improve utility-based dose-finding with bivariate ordinal outcomes. *J Biopharmaceutical Stat* 22:785-801, 2012.

- 75. Wang L, Rotnitzky A, Lin X, Millikan R, **Thall PF**. Evaluation of viable dynamic treatment regimes in a sequentially randomized trial of advanced prostate cancer. *J American Statistical Assoc.* 107:493-508, 2012. With discussion.
- 76. Wang L, Rotnitzky A, Lin X, Millikan R, **Thall PF**. Rejoinder to comments on "Evaluation of viable dynamic treatment regimes in a sequentially randomized trial of advanced prostate cancer." *J American Statistical Assoc.* 107:518-520, 2012.
- 77. Morita S, **Thall PF**, Mueller P. Prior effective sample size in conditionally independent hierarchical models. *Bayesian Analysis*. 7:591-614, 2012.
- 78. **Thall PF**. Bayesian adaptive dose-finding based on efficacy and toxicity. *J Statistical Research.* 14:187-202, 2012. Invited.
- 79. Wahed AS, **Thall PF**. Evaluating joint effects of induction-salvage treatment regimes on overall survival in acute leukemia. *J Royal Statistical Soc, C.* 62:67-83, 2013.
- 80. **Thall PF**, Nguyen HQ, Braun TM, Qazilbash M. Using joint utilities of the times to response and toxicity to adaptively optimize schedule-dose regimes. *Biometrics*. 69:673-682, 2013.
- 81. Jin I-H, Liu S, **Thall PF**, Yuan Y. Using data augmentation to facilitate conduct of phase I/II clinical trials with delayed outcomes. *J American Statistical Assoc.* 109:525-536, 2014.
- 82. **Thall PF**, Nguyen HQ, Zohar S, Maton P. Optimizing sedative dose in preterm infants undergoing treatment for respiratory distress syndrome. *J American Statistical Assoc.* 109:931-943, 2014.
- 83. Wang L, Shen J, **Thall PF**. An adaptive Lasso for identifying interactions in the Cox model with the heredity constraint. *Statistics and Probability Letters*. 93:126-133, 2014.
- 84. **Thall PF**, Herrick RC, Nguyen HQ, Venier JJ, Norris JC. Using effective sample size for prior calibration in Bayesian phase I-II dose-finding. *Clinical Trials.* 11:657-666, 2014.
- 85. Graziani R, Guindani M, **Thall PF**. Bayesian nonparametric estimation of targeted agent effects on biomarker change to predict clinical outcome. *Biometrics* 71:188-197, 2015.
- 86. Lee J, **Thall PF**, Ji Y, Muller P. Bayesian dose-finding in two treatment cycles based on the joint utility of efficacy and toxicity. *J American Statistical Assoc.* 110:711-722, 2015.
- 87. Huang X, Choi S, Wang L, **Thall PF**. Optimization of multi-stage dynamic treatment regimes utilizing accumulated data. *Stat in Medicine*. 34:3424-3443, 2015.
- 88. Hobbs B, **Thall PF**, Lin S. Bayesian group sequential clinical trial design using total toxicity burden and progression-free survival. *J Royal Statistical Soc, C.* 65:273-297, 2016.
- 89. Lee J, **Thall PF**, Ji Y, Mueller P. A practical decision-theoretic phase I-II design for ordinal outcomes in two cycles. *Biostatistics*. 17:304-319, 2016.

- 90. Xu Y, Mueller P, Wahed A, **Thall PF**. Bayesian nonparametric estimation for dynamic treatment regimes with sequential transition times. *J American Statistical Assoc* 111:921-935, 2016. *With discussion.*
- 91. Xu Y, Mueller P, Wahed A, **Thall PF**. Rejoinder to comments on "Bayesian nonparametric estimation for dynamic treatment regimes with sequential transition times" *J American Statistical Assoc* 111:948-950, 2016.
- 92. Murray TA, **Thall PF**, Yuan Y. Utility-based designs for randomized comparative trials with discrete outcomes. *Stat in Medicine.* 35:4285-4305, 2016.
- 93. **Thall PF**, Nguyen HQ, Zinner RG. Parametric dose standardization for two-agent combinations in a phase I-II trial with ordinal outcomes. *J Royal Statistical Soc, Series C.* 66:201-224, 2017.
- 94. Morita S, **Thall, PF**, Takeda K. A simulation study of methods for selecting subgroup-specific doses in phase I trials. *Pharmaceutical Stat.* 16:143-156, 2017.
- 95. Chapple AG, Vannucci M, **Thall PF**, Lin SH. Bayesian variable selection for a semi-competing risks model with three hazard functions. *Computational Stat and Data Analysis.* 112:170-185, 2017.
- 96. Murray TA, **Thall PF**, Yuan Y, McAvoy S, Gomez, DR. Robust treatment comparison based on utilities of semi-competing risks in non-small-cell lung cancer. *J American Statistical Assoc.* 112:11-23, 2017.
- 97. Xu Y, **Thall PF**, Mueller P, Mehran RJ. A decision-theoretic comparison of treatments to resolve air leaks after lung surgery based on nonparametric modeling. *Bayesian Analysis.* 12(3):639-652, 2017.
- 98. Mueller P, Xu Y, **Thall PF**. Clinical trial design as a decision problem. *Applied Stochastic Models in Business and Industry*. Special issue in honor of Kathryn Chaloner. 33:296-301, 2017. Invited.
- 99. Wathen JK, **Thall PF**. A simulation study of outcome adaptive randomization in multi-arm clinical trials. *Clinical Trials*. 14:432-440, 2017.
- 100. **Thall PF**, Mueller P, Xu Y, Guindani M. Bayesian nonparametric statistics: A new toolkit for discovery in cancer research. *Pharmaceutical Stat.* 16:414-423, 2017.
- 101. Murray TA, Yuan Y, **Thall PF**, Elizondo JA, Hofstetter WL. A utility-based design for randomized comparative trials with ordinal outcomes and prognostic subgroups. *Biometrics*. 74:1095-1103, 2018.
- 102. Murray TA, Yuan Y, **Thall PF**. A Bayesian machine learning method for optimizing dynamic treatment regimes. *J American Statistical Assoc.* 113:523, 1255-1267, 2018.
- 103. Chapple AG, **Thall PF**. Subgroup-specific dose finding in phase I clinical trials based on time to toxicity allowing adaptive subgroup combination. *Pharmaceutical Stat.* 17:734-749, 2018.

- 104. **Thall PF**, Ursino M, Baudouin V, Alberti C, Zohar S. Bayesian treatment comparison using parametric mixture priors computed from elicited histograms. *Statistical Methods in Medical Res.* 28:404-418, 2019.
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#### Letters to the Editor

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# **Manuscripts Submitted for Publication**

- 1. Lee J, **Thall PF**. U-Bayes: A unified Bayesian monitoring rule using the joint utility of bivariate ordinal response and toxicity. Revised per favorable reviews from *Statistics in Medicine*
- 2. Yang C-H, **Thall PF**; Lin R. DEMO: Dose exploration, monitoring, and optimization using a biological mediator for toxicity, response, and survival.
- 3. Nieto Y, Ramdial J, Valdez B, **Thall PF**, Andersson BJ, et al. Prospective clinical trial of the combination of the PARP inhibitor Olaparib with high dose chemotherapy and autologous stem cell transplant for refractory lymphomas.
- 4. Berg SA, La Rosa S, **Thall PF**, Masouel P, et al. Impact of post-progression therapies on overall survival: Recommendations from the 2023 Kidney Cancer Association think tank meeting.
- 5. Zhao S, Thall PF, Yuan Y, Lee J, Msaouel P, Yang Y. Precision generalized phase I-II designs.

# Manuscripts in Preparation

- 1. Xu Y, Thall PF, Msaouel P, Tannir, N. A SMART trial of targeted agents for advanced kidney cancer.
- 2. Zang Y, Yuan Y, **Thall PF**. A review of outcome-adaptive randomization methods with probability domain restriction and context dependent bias correction
- 3. Lee J, Msaouel P, and **Thall PF**. Bayesian randomized precision phase II treatment screening based on response, toxicity, and long term therapeutic success.
- 4. Yang Y, Cheng Y, **Thall PF**, Wahed A. U-SMART: A utility based generalized outcome-adaptive sequential multiple assignment randomized trial design evaluating response and toxicity.
- 5. Qazilbash M, **Thall PF**, Milton D, Bashr Q, et al. Comparison of busulfan plus melphalan versus melphalan alone in multiple myeloma patients receiving autologous stem cell transplantation: Results after long term follow up

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- 6. Thall PF, Msaouel P. Bayesian randomized pilot studies: Recommendations and practical guidelines.
- 7. Wang S, Yuan Y, **Thall PF**. A Bayesian phase I-II design with adaptive rules for staggering patient entry.
- 8. Olson A, **Thall PF**, Marin D, et al. A phase II study to assess the effect of BK specific CTL lines generated by *ex vivo* expansion in patients with BK or JC virus infection
- 9. Lee J, **Thall PF**, Bronk J, Lin S. A phase III clinical trial design to compare fractionation schedules for radiation therapy of inoperable advanced non-small cell lung cancer based on the trade-off between total toxicity burden and progression free survival time.

# Journal Referee

The American Statistician Annals of Applied Statistics Annals of Clinical Gastroenterology and Hepatology **Bayesian Analysis Biological Psychiatry** Biometrics **Biometrika Biopharmaceutical Statistics Biostatistics** Blood **BMC** Cancer BMC Medical Research Methodology British J Hematology **Canadian J Statistics** Cancer **Cancer Medicine Clinical Cancer Research** Clinical Epidemiology **Clinical Trials** Communications in Statistics **Computational Statistics** Computer Methods and Programs in Biomedicine **Controlled Clinical Trials Contemporary Clinical Trials Critical Care Medicine** Dose-Response Expert Systems With Applications European J Cancer European J Haematology Expert Review of Clinical Pharmacology Helivon Investigational New Drugs J Applied Probability

J American Medical Association J American Medical Association. Open J American Medical Association, Oncology J American Statistical Association **J** Biopharmaceutical Statistics J Clinical Medicine J Clinical Oncology **J** National Cancer Institute J Royal Statistical Soc, Series A J Royal Statistical Soc, Series B J Royal Statistical Soc, Series C J Statistical Planning and Inference Leukemia Leukemia and Lymphoma Mathematical Population Dynamics Medical Decision Making Nature Nature Cancer Nature Communications Nature Medicine Naval Research Logistics Quarterly New Zealand and Australian J Statistics **Pharmaceutical Statistics** Scientific Reports Sequential Analysis Stat Stat in Medicine Stat in Biopharmaceutical Research Stat in Biosciences Stat Methods in Medical Research **Statistical Science Technometrics** Urology

# PhD Committee Member and Dissertation Reader, George Washington University, 1980-1994:

Belcher G, Blodgett R, Cowan C, El-Dessouky S, Fan M, Johnson A, Lindblad A, Mohadjer L, Palesch Y, Rundek B, Wright E, Younes, N

# PhD Committee Member, Other Outside Institutions

University of Waterloo, Department of Statistics and Actuarial Science, Canada, 1999: Min Zhan, "Analysis of Incomplete Event History Data."

Universite Montpellier, U.F.R. de Medicine, France, 2008: Nadine Houede, "Recherche de strategie biostatistique dans les essais cliniques de phase I/II d'association comprenant un agent non cytotoxique"

University of California at Santa Cruz, 2021 : Arthur Lui, Jack Baskin School of Engineering, Department of Applied Mathematics and Statistics, "Bayesian Modeling for Heterogeneous Multivariate Data"

#### **PhD Thesis Supervisor**

J. Kyle Wathen, "Bayesian Doubly Optimal Group Sequential Designs for Randomized Clinical Trials," Graduate School of Biomedical Sciences, U. T. M.D. Anderson Cancer Center, 2005.

Andrew G. Chapple, "Bayesian Models for Clinical Trials and Survival Analysis," Department of Statistics, Rice University, 2018.

#### PhD Committee Member, MD Anderson

PhD exam committee member, GSBS, Yujie Zhao, 2020-21.

#### PhD Student Supervisor, Graduate School of Biologial Sciences, MD Anderson

Wen Zhang 2022

#### **Postdoctoral Research Fellow Supervisor**

Brian Hobbs Juhee Lee Ick-Hoon Jin Yanxun Xu Thomas Murray Ruitao Lin	2010-2011 2012 2012-2013 2014-2015 2014-2017 2017-2019	( jointly with Yuan Ji) ( jointly with Ying Yuan) ( jointly with Peter Mueller and Yuan Ji) ( jointly with Ying Yuan) ( jointly with Ying Yuan)
Ruitao Lin	2017-2019	(jointly with Ying Yuan)
Shuqi Wang	2023-2024	( jointly with Ying Yuan)

#### **Rice University Summer Intern Supervisor**

Andrew Chapple, 2015, 2016 Shengbin Ye, 2020

#### Undergraduate Courses Taught - Univ Texas at Dallas and George Washington Univ

1975 - 1990 Introductory statistics Regression analysis Design of experiments Probability Mathematical statistics Gambling and games of chance Complex variables Linear algebra Calculus

# Graduate Courses Taught - Univ Texas at Dallas and George Washington Univ

1975 – 1990 Probability theory Mathematical statistics Stochastic processes Large-sample theory Distribution theory Linear models Design of experiments Generalized linear models Applied statistics

# Graduate Course taught jointly for Rice University, MDACC Graduate School of Biological Sciences, and UT School of Public Health

Topics in Clinical Trials: 2002, 2004, 2006, 2008, 2010, 2012, 2014, 2016, 2020, 2022

# Organization of National and International Conferences and Symposia

- 1. "New Designs for Dose-Response Studies" (Discussant), Biometric Soc ENAR Meeting, Birmingham, AL, March 1995.
- 2. Scientific Program Committee, (Planning and organization of the conference scientific program, Invitation of speakers), International Soc for Clinical Biostatistics, Annual Meeting, Barcelona, Spain, July 31-August 4, 1995.
- 3. Scientific Program Committee, (Session Organizer) Soc for Clinical Trials, Annual Meeting, Anaheim, CA, May 2-5, 1999.
- 4. "Dose-Finding Methods for Early Phase Clinical Trials" (Session Organizer), Soc for Clinical Trials, Annual Meeting, Anaheim, CA, 1999.
- 5. "Design and Analysis of Clinical Trials with Multiple Endpoints" (Session Organizer), ENAR Annual Meeting, International Biometric Soc, Chicago, IL 2000.
- 6. "Outcome Adaptive Methods in Early Phase Clinical Trials" (Session Organizer), ENAR 2002 Spring Meeting, International Biometric Soc, Alexandria, VA, 2002.
- 7. "Recent Advances in Clinical Trial Design" (Session Organizer), WNAR Meeting of the International Biometric Soc, UCLA, June 23-26, 2002.
- 8. "New Statistical Methods for Dose-Finding", (Chairman and Conference Organizer), Henry Stewart Conferences, Washington, D.C., September 18-19, 2002.

- 9. "Bayesian Biostatistics: Introduction and Recent Advances", (Conference Organizer), M.D. Anderson Cancer Center, Houston, TX, January 28-31, 2003.
- 10. Scientific Program Committee, Soc for Clinical Trials Annual Meeting, (Planning and organization of the conference scientific program, Invitation of speakers), Portland, OR, May 22-25, 2005.
- 11. "Joint Modeling of Longitudinal and Time-to-Event Outcomes: Implications for Biomarkers and Surrogacy" (Session Organizer and Chair) Soc for Clinical Trials, Annual Meeting, Portland, OR, May 22-25, 2005.
- 12. "Ethical Issues in Early Phase Clinical Trials: The Physician's Perspective." Plenary Session, (Session Organizer and Chair) Soc for Clinical Trials, Annual Meeting, Portland, OR, May 22-25, 2005.
- 13. "Recent Innovations in Clinical Trial Design", (Session Organizer and Chair), Joint Statistical Meetings, Minneapolis, MN, August 7-11, 2005.
- 14. "Bayesian Approaches to Clinical Trials" (Session Chair). Joint Statistical Meetings, Salt Lake City, UT, August 1, 2007.
- 15. "Dynamic Treatment Regimes: Practice and Theory" (Session Organizer). ENAR Meeting of the International Biometric Soc, Crystal City, VA, March 16-19, 2008.
- 16. "Bayesian Methods in Clinical Trials" (Session Organizer). Drug Information Association, Statistical European Meeting, Ljubljana, Slovenia, October 22-24, 2008.
- 17. "Practical Applications of Dynamic Treatment Regimes in Medicine" (Session Organizer and Chair). ENAR Meeting of the International Biometric Soc, Miami, FL, March 20-23, 2011.
- 18. Scientific Program Committee, International Indian Statistical Association Bi-Annual Conference, Chennai, India, January 2-5, 2013
- 19. "Recent Advances in Bayesian Methods for Clinical Trials" (Session Organizer). International Indian Statistical Association Bi-Annual Conference, Chennai, India, January 2-5, 2013.
- 20. "Section on Bayesian Statistical Science Student Paper Travel Award Winners I", Topic Contributed, (Session Organizer), Joint Statistical Meetings, Montreal, Canada, 2013
- 21. "Section on Bayesian Statistical Science Student Paper Travel Award Winners II", Topic Contributed, (Session Organizer), Joint Statistical Meetings, Montreal, Canada, 2013
- 22. Section on Bayesian Statistical Science Student Travel Award Winners, Session 3, Topic Contributed Papers (Session Chair), Joint Statistical Meetings, Boston, MA, 2014
- 23. "Response-Adaptive Randomization: Recent Developments and Controversies" Topic Contributed, (Session Chair), Joint Statistical Meetings, Seattle, WA, 2015.

- 24. "Bayes and Nonparametric Bayes Methods in Medical Studies" Invited Papers (Session Organizer) sponsored by Section on Bayesian Statistical Science, Joint Statistical Meetings, Seattle, WA, 2015.
- 25. "Practical Utility-Based Bayesian Clinical Trial Design" Topic Contributed Papers (Session Organizer and Chair) co-sponsored by Section on Bayesian Statistical Science, Biopharmaceutical Section, and International Soc for Bayesian Analysis, Joint Statistical Meetings, Chicago, IL, 2016.
- 26. "Recent Advances in Practical Clinical Trial Design" (Session Organizer). Invited Paper Session, ENAR Meeting of the International Biometric Soc, Atlanta, GA, March 25-28, 2018.
- 27. "Applied Bayesian Precision Medicine" (Session Organizer). Invited Paper Session, Workshop on Bayesian Causal Inference, Ohio State University, Columbus, OH, June 2-4, 2019.
- "Practical Bayesian Precision Medicine: Design and Analysis" (Session Organizer). Invited Paper Session, iBRIGHT 2019 conference, Department of Biostatistics, M.D. Anderson Cancer Center, Houston, TX, November 11-13, 2019.

## Short Courses Presented

- 1. Two-day short course "Phase I / Phase II Designs for Oncology Trials", CIBA-Geigy Pharma, Basel, Switzerland, September 9-10, 1996.
- 2. Two-day short course, "Statistical Methods for Design and Monitoring of Early Phase Clinical Trials", Novartis Pharma, Basel, Switzerland, October 20-21, 1997.
- 3. Half-day short course, "Design of Early Phase Oncology Clinical Trials", Pediatric Blood and Marrow Transplant Consortium, St. Louis, MO, April 4, 1998.
- 4. Two day tutorial workshop on clinical trial design and conduct. Novartis Pharma, Morristown, NJ, March 6-7, 2003.
- 5. Tutorial workshop on adaptive Bayesian methods for clinical trials. Novartis Pharma, Basel, Switzerland, November 10-11, 2003.
- 6. Two day tutorial workshop on adaptive Bayesian methods for clinical trials. Serono International, Geneva, Switzerland, November 12, 2003.
- Three-day short course, "Modern Bayesian Methods for Clinical Trials", Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Rockville, MD. Taught jointly with B. Carlin, December 10-12, 2003.
- 8. One-day short course, "Designing Clinical Trials: Practical Bayesian Methods", Joint Statistical Meetings, Toronto, Canada, August 8, 2004.
- 9. Half-day short course, "Recent Advances in Bayesian Adaptive Dose-Finding", Annual Meeting of the Soc for Clinical Trials, Portland, OR, May 22, 2005.

- Three-day short course, "Modern Methods for Clinical Trials", Departamento de Bioestadística Epidemiología, Escuela de Salud Pública, RCM, UPR, San Juan, Puerto Rico. Taught jointly with M. Munsell and G. Yin, February 22-24, 2006.
- 11. Three-lecture tutorial: (i) Introduction to Bayesian Statistical Concepts. (ii) Bayesian Dose-Finding in Early Phase Clinical Trials. (iii) Covariate-Adjusted Adaptive Randomization in a Clinical Trial with Multi-Stage Therapy. Presented at "Innovative Proof-of-Concept Designs for Phase I/II and IIIb Studies." Scian Services, Toronto, Canada, May 3-4, 2006.
- 12. Three-day short course, "Bayesian Clinical Trial Designs", Institut Bergonie, Bordeaux, France. Taught jointly with J. Cook, June 12-14, 2006.
- 13. Half-day short course, "Practical Bayesian Dose-Finding Methods", Thirtieth Annual Midwest Biopharmaceutical Statistics Workshop, Ball State University, Muncie, IN, May 21, 2007.
- 14. One-day short course, "Practical Bayesian Clinical Trial Design", Joint Statistical Meetings, Salt Lake City, UT, July 30, 2007.
- 15. Half-day short course, "Bayesian Methods for Phase II Clinical Trials", City of Hope Cancer Center, Duarte, CA, October 18, 2007.
- 16. Three-day short course, "Practical Bayesian Clinical Trial Design", Northern Illinois Pharmaceutical Group, Abbott Laboratories, Lake Bluff, IL. Taught jointly with J. Wathen, December 5-7, 2007.
- 17. One-day short course, "Modern Practical Bayesian Clinical Trial Design", Joint Statistical Meetings, Denver, CO. Taught jointly with J. Wathen, August 3, 2008.
- 18. Half-day short course "Some Practical Bayesian Phase I and Phase I/II Designs", Hoffman-LaRoche, Inc., Nutley, NJ. October 10, 2008.
- 19. One-day short course, "Recent Developments in Practical Bayesian Methods for Clinical Trials", International Chinese Statistical Association, Applied Statistics Symposium, San Francisco, June 21, 2009.
- 20. Half-day short course, "Recent Advances in Bayesian Adaptive Methods for Clinical Trials", FDA/Industry Statistics Workshop, Washington DC, Sept. 23, 2009.
- Three-day short course, "Recent Developments in Practical Bayesian Methods for Clinical Trials", Savannah, GA, Sixteenth Annual Biopharmaceutical Applied Statistics Symposium, November 11-13, 2009.
- 22. One-day short course, "Recent Developments in Practical Bayesian Methods for Clinical Trials", Indianapolis, IN, International Chinese Statistical Association, Applied Statistics Symposium, June 20, 2010.
- 23. One-day short course, "Bayesian Methods in Early Phase Clinical Trials." Millennium Pharmaceuticals, Inc. The Takeda Oncology Company, Boston, MA, August 30, 2010.

- 24. Webinar, "Dysfunctional Paradigms in Clinical Trials: Some Bayesian Alternatives," sponsored by the Section on Bayesian Statistical Science, American Statistical Association, June 7, 2012.
- 25. One-day short course, "Hybrid Bayesian Adaptive Clinical Trial Designs," International Chinese Statistical Association, 2012 Applied Statistics Symposium, Boston, MA, June 23, 2012.
- 26. Half-day short course, "Utility-Based Clinical Trial Design and Analysis", FDA/Industry Statistics Workshop, Washington DC, Sept. 12, 2012.
- 27. One-day short course, "Recent Advances in Bayesian Clinical Trial Design", taught jointly with B. Hobbs, Joint Statistical Meetings, Montreal, Canada, August 4, 2013.
- 28. One-day short course, "Recent Advances in Bayesian Clinical Trial Design", taught jointly with B. Hobbs, International Chinese Statistical Association and Korean International Statistical Soc Joint Applied Statistics Symposium, Portland, Oregon, June 15, 2014.
- 29. Half-day short course. "Practical Solutions for Simple Problems with Bad Consequences in Clinical Trials" ENAR Meeting of the International Biometric Soc, Austin, TX, March 6, 2016.
- 30. One-day short course, "Bayesian Designs for Phase I-II Clinical Trials", taught jointly with Y. Yuan, Joint Statistical Meetings, Baltimore, MD, July 29, 2017.
- 31. Half-day short course, "Statistical Remedies for Flawed Conventions in Medical Research" Stat4Onc Annual Meeting, Hartford, CT, April 25, 2019.
- 32. Half-day short course, "Bayesian Designs for Phase I-II Clinical Trials", taught jointly with Y. Yuan, ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop, September 22, 2020.
- 33. Half-day short course, "Statistical Remedies for Flawed Conventions in Medical Research" International Chinese Statistical Association, Applied Statistics Symposium, December 13, 2020.
- 34. Half-day short course, "Statistical Remedies for Flawed Conventions in Medical Research" Harvard Catalyst Biostatistics Program, October 15, 2021.

### **Invited Talks at Professional Meetings**

- 1. Cluster Shock Models. American Statistical Association Meeting, Washington, D.C., 1979
- 2. Gambling and Games of Chance. Washington Statistical Soc, Washington, D.C., 1983
- 3. Assessment of Stratum-Covariate Interactions in Cox's Proportional Hazards Regression Model. Soc for Clinical Trials Annual Meeting, St. Louis, Missouri, 1983.
- 4. Nonparametric Two-Sample Tests for Recurrence Rates Based on Censored Count Data. Soc for Clinical Trials Meeting, Montreal, Canada, 1986.

- 5. Mixed Poisson Likelihood Regression Models for Longitudinal Interval Count Data. American Statistical Association Meeting, Chicago, IL, 1986.
- 6. A Two-stage Design for Choosing Among Several Experimental Treatments and a Control in Phase III Clinical Trials. Soc for Clinical Trials Meeting, Atlanta, GA, 1987.
- 7. Optimal Two-Stage Designs for Clinical Trials with Binary Response. Soc for Clinical Trials Meeting, San Diego, CA, 1988.
- 8. Some Covariance Models for Longitudinal Count Data with Overdispersion. Biometric Soc ENAR Meeting, Baltimore, Maryland, 1990.
- 9. Some Covariance Models for Longitudinal Count Data with Overdispersion. Biometric Soc WNAR Meeting, Santa Barbara, CA, July 2, 1991.
- 10. Test-based Variable Selection via Cross-Validation. Presented at the 1992 Conference of Texas Statisticians, Baylor University, Waco, TX, February 28-29, 1992.
- 11. Practical Bayesian Guidelines for Phase IIB Clinical trials. 1992 annual meetings for the Soc for Clinical Trials, Philadelphia, PA, May 10-13, 1992.
- 12. A Bayesian Strategy for Screening Cancer Treatments Prior to Phase II Clinical Evaluation. 13th annual meeting of the International Soc of Clinical Biostatistics, Copenhagen, Denmark, August 17-21, 1992.
- 13. Bayesian Design and Monitoring of Phase II Clinical Trials. Presented at the International Biometrics Conference, Hamilton, New Zealand, December 7-11, 1992.
- 14. Sample Size and Monitoring Criteria for Bayesian Phase II Clinical Trials. 14th Annual Meeting of the Soc for Clinical Trials, Orlando, FL, May 25, 1993.
- 15. Bayesian Designs for Phase II Clinical Trials With Single or Multiple Endpoints. 14th Meeting, International Soc. Clinical Biostat, Cambridge, UK, September 20-24, 1993
- 16. Bayesian Sequential Monitoring Designs For Single-Arm Clinical Trials with Multiple Outcomes. ENAR Meeting of Biometric Soc, Cleveland, OH, April 10-14, 1994
- 17. Bayesian Sequential Monitoring Designs For Single-Arm Clinical Trials with Multiple Outcomes. 1994 Meeting of the Soc. for Clinical Trials, Houston, TX, May 8-11, 1994
- 18. Estimating Genomic Category Probabilities from Fluorescent *in situ* Hybridization Counts with Misclassification. Presented at the 1996 Eastern North American Region of the International Biometric Soc Meeting, Basic Science Session, Richmond, VA, March 20, 1996.
- 19. A Strategy for Monitoring Multiple Outcomes in Early Phase Trials, or How to Conduct Single-Arm Trials if You Must. Presented at the Symposium on Bayesian Approaches to Clinical Trials, Harvard School of Public Health, Brookline, MA, March 28, 1996.

- 20. Semiparametric Regression Analysis for Recurrent Event Interval Counts. 1996 ENAR Spring Meeting, Richmond, VA, March 19, 1996.
- 21. Parametric Likelihoods for Multiple Nonfatal Competing Risks and Death. Presented in the session "*Topics in Lifetime Data Analysis in Medical Research*," at the Silver Jubilee Annual Meeting of the Statistical Soc of Canada, University of New Brunswick, Fredericton, Canada, June 1-4, 1997.
- 22. A Strategy for Dose-Finding and Safety Monitoring Based on Efficacy and Adverse Outcomes in Phase I/II Clinical Trials, Symposium on Treatment Selection in Early Phase Clinical Research, MPS Research Unit, The University of Reading, U.K., October 15, 1997.
- 23. Variable Selection in Regression Via Repeated Data Splitting. ENAR Spring Meeting, Memphis, TN, March 23, 1997.
- 24. Variable Selection in Regression Via Repeated Data Splitting. 29th Symposium on the Interface Between Computing Science and Statistics, Houston, TX, May 15, 1997.
- 25. A Strategy for Dose-Finding and Safety Monitoring Based on Efficacy and Adverse Outcomes in Phase I/II Clinical Trials. 3rd International Congress on Statistical Methods in Biopharmacy: Optimising in Drug Development, Paris, France, September 15-16, 1997.
- 26. A Strategy for Dose-Finding and Safety Monitoring Based on Efficacy and Adverse Outcomes in Phase I/II Clinical Trials. ENAR Spring Meeting, Pittsburgh, PA, March 28-April 1, 1998.
- A Strategy for Dose-Finding and Safety Monitoring Based on Efficacy and Adverse Outcomes in Phase I/II Clinical Trials, Drug Information Association's Annual Symposium "Global Challenges and Strategies in the Pharmaceutical Industry, Recent Developments in Design and Analysis of Oncology Trials", Hilton Head, SC, March 15-17, 1998.
- 28. Some Experiences Applying the Continual Reassessment Method at M.D. Anderson Cancer Center, Drug Information Association's 34th Annual Meeting, Boston, MA, June 7-11, 1998.
- 29. Treatment Comparisons based on Two-Dimensional Safety and Efficacy Alternatives in Oncology Trials. ENAR Spring Meeting, Atlanta, GA, March 28-31, 1999.
- A Strategy for Dose-Finding and Safety Monitoring Based on Safety and Efficacy Outcomes in Phase I/II Clinical Trials, 1998 WNAR Annual Meeting/IMS Western Regional Meeting, San Diego, CA, June 28-30, 1998.
- Treatment Comparisons Based on Two-Dimensional Safety and Efficacy Alternatives in Oncology Trials. International Biometric Soc, Region Oesterreich-Schweiz, Advances in Biometry, Basel, Switzerland, September 27-30, 1999.
- 32. Approximate Bayesian Evaluation of Multiple Treatment Effects: An Alternative to Hypothesis Testing. Mathematisches Forschungsinstitut Oberwolfach, Medical Statistics:

Current Developments in Statistical Methodology for Clinical Trials, Oberwolfach, Germany, February 6-12, 2000.

- 33. Evaluating Multiple Treatment Courses in Clinical Trials. ENAR Meeting of the International Biometric Soc, Session on "*Design and Analysis of Clinical trials With Multiple Endpoints*", Chicago, IL, March 19-22, 2000.
- 34. Treatment Comparisons Based on Two-Dimensional Safety and Efficacy Alternative in Clinical Trials. International Chinese Statistical Association, Applied Statistics Symposium, Piscataway, NJ, June 1-3, 2000.
- 35. Bayesian Methods in Early Phase Clinical Trial Design. American Statistical Association, Section on Bayesian Statistics, Joint Statistical Meetings, Indianapolis, IN, August 13-17, 2000.
- Bayesian Strategies for Small *n* Clinical Trials. Conference on Future Directions for Small *n* Clinical Research Trials, National Academy of Sciences, Washington, D.C., September 28, 2000.
- 37. Bayesian Methods for Early Phase Clinical Trials: Dose-Finding and Safety Monitoring, First Annual Short Course in Bayesian Biostatistics: Applications to Clinical and Pharmaceutical Research, M.D. Anderson Cancer Center, Houston, TX, January 16-19, 2001.
- Adaptive Designs: A Non-Small Cell Lung Cancer Trial. First Annual Short Course in Bayesian Biostatistics: Applications to Clinical and Pharmaceutical Research, M.D. Anderson Cancer Center, Houston, TX, January 16-19, 2001.
- 39. Practical Adaptive Sequential Dose-Finding in Phase I/II Clinical Trials. Statistics of Optimal Dosing, Henry Stewart Conferences, Washington, DC, July 26, 2001.
- 40. Seamlessly Expanding a Randomized Phase II Trial to Phase III. Joint Statistical Meetings, American Statistical Assoc., Section on Bayesian Statistics, Atlanta, GA, August 5-9, 2001.
- 41. Multi-course Treatment Strategies for Clinical Trials of Rapidly Fatal Diseases. Bayesian Workshop VI, Carnegie Mellon University, Pittsburgh, PA, September 28-29, 2001.
- 42. A Hierarchical Bayesian Model for an Activity Trial of Gleevec in Sarcoma: Borrowing Strength Across Disease Subtypes. Connective Tissue Oncology Soc Consortium Meeting, West Palm Beach, FL, November 1-3, 2001.
- 43. Recent Advances in Outcome-Adaptive Clinical Trial Design. 9<sup>th</sup> Genitourinary Oncology Conference, Melvin Samuels Lectureship, Houston, TX, February 7-8, 2002.
- 44. Seamlessly Expanding a Randomized Phase II Trial to a Phase III Trial. Statistics of Multi-Center Trials, Henry Stewart Conferences, Washington, D.C. March 5, 2002.

- 45. Adaptive Decision Making in a Lymphoctye Infusion Trial. ENAR Meeting of the International Biometric Soc, Session on "*Outcome Adaptive Methods in Early Phase Clinical Trials*," Alexandria, VA, March 17-20, 2002.
- 46. Adaptive Design Strategies for Gene Therapy Trials. Workshop "*Cancer-How to Design Cancer Gene Therapy Clinical Trials*," American Soc of Gene Therapy, 5<sup>th</sup> Annual Meeting, Boston, MA, June 5-9, 2002.
- 47. Seamlessly Expanding a Randomized Phase II Trial to a Phase III Trial, Session "*Recent Advances in Clinical Trial Design*." WNAR Meeting of the International Biometric Soc, UCLA, CA, June 23-26, 2002.
- 48. Dose-Finding with Two Agents in Phase I Oncology Trials. *New Statistical Methods for Dose-Finding*, Henry Stewart Conferences, Washington, D.C., September 18-19, 2002.
- 49. Some Bayesian Approaches to Sarcoma Trials. Annual Meeting of the Connective Tissue Oncology Soc, San Francisco, CA, October 31-November 2, 2002.
- 29. Practical Adaptive Decision-Making in Oncology Clinical Trials. Bayesian Biostatistics: Introduction and Recent Advances Short Course & Symposium, M.D. Anderson Cancer Center, Houston, TX, January 28-31, 2003.
- 30. Evaluating Therapeutic Strategies in Multi-Course Clinical Trials. ENAR 2003 Spring Meeting of the International Biometric Soc, Tampa, Florida, March 30-April 2, 2003.
- 31. Adaptive Decision-Making in a Lymphocyte Infusion Trial. Conference on New Directions in Experimental Design, Chicago, IL, May 14-17, 2003.
- 32. Covariate-Adjusted Adaptive Randomization in a Multi-Stage Sarcoma Trial. Dept. of Biostatistics, Harvard Schering-Plough Workshop on Development and Approval of Oncology Drug Products: Impact of Statistics, Boston, MA, May 28-30, 2003.
- Biostatistical Consulting: The Doctor-Statistician relationship. Roundtable Luncheon, Section on Bayesian Statistical Sciences, American Statistical Association, Joint Meetings, San Francisco, CA, August 2–7, 2003.
- 34. Adaptive Randomization in a Multi-Stage Trial: Gemcitabine +/- Docetaxel for Soft Tissue Sarcoma. In the session "Clinical Trials: 2003 and Beyond," annual meeting of the Connective Tissue Oncology Soc, Barcelona, Spain, November 6-8, 2003.
- 35. Dose-Finding With Two Agents in Phase I Oncology Trials. In the session "*Recent Developments in Phase I Trials Design*," ENAR 2004 Meeting of the International Biometric Soc, Pittsburgh, PA, March 27-31, 2004.
- Dose-Finding Based On Efficacy-Toxicity Trade-Offs. Design and Analysis of Phase II Clinical Trials, 25<sup>th</sup> Annual Meeting of the Soc for Clinical Trials, New Orleans, LA, May 23-26, 2004.

- 37. A Donor Lymphocyte Infusion Trial: Adaptively Optimizing Infusion Times. In the Jiann-Ping Hsu Invited Paper Session on Pharmaceutical/Regulatory Sciences: *Adaptive Designs for Clinical Trials.* International Chinese Statistical Association 2004 Applied Statistics Symposium, San Diego, CA, June 6-9, 2004.
- Bayesian Sensitivity Analyses of Confounded Treatment Effects in Survival Analysis. 25<sup>th</sup> Spring Symposium, New Jersey Chapter, American Statistical Assoc. "Advances in Survival Analysis Methods for Clinical Trials." Piscataway, NJ, June 29, 2004.
- 39. Hybrid Adaptive Designs for Clinical Trials. Session on "Flexible Adaptive Design," Joint Statistical Meetings, Toronto, Canada, August 8-12, 2004.
- 40. Practical Hybrid Clinical Trial Designs. Session on "Clinical trial designs to combine different stages of drug development," 25<sup>th</sup> Annual Conference of the International Soc for Clinical Biostatistics, Leiden, The Netherlands, August 15-19, 2004.
- 41. Bayesian Adaptive Methods for Clinical Trial Design and Conduct. Future Clinical Trials Issues in Multiple Sclerosis, Annual Meeting of the Multiple Sclerosis Soc, Washington, D.C., December 2-4, 2004.
- 42. Some Phase 23 Clinical Trial Designs. Biostatistical Issues and the Design of Type 1 Diabetes TrialNet Protocols, NIDDK, Bethesda, Maryland, March 7, 2005.
- 43. Dose-Finding Based On Efficacy and Toxicity in Phase I/II Clinical Trials. In the session *"Recent Developments in Sequential Clinical Trials Methodology"* ENAR Meeting of the International Biometric Soc, Austin, Texas, March 20-23, 2005.
- 44. On the Hazards of Survival Time Comparisons in the Presence of Recurrent Disease. Sarcoma Alliance for Research through Collaboration Biannual Meeting, Orlando, Florida, May 13, 2005.
- 45. Adaptive Multi-Course Treatment Strategies in Two Oncology Trials. Session on "Dynamic Treatment Regimes," Joint Statistical Meetings, Minneapolis, Minnesota, August 7-11, 2005.
- 46. Multi-Stage Treatment Trials in Oncology. Dynamic Treatment Regimes Network Meeting, Institute for Social Research, University of Michigan, Ann Arbor, Michigan, September 14-15, 2005.
- 47. Dose Finding Based On Efficacy and Toxicity in Phase I/II Clinical Trials. 5<sup>th</sup> International Meeting on Statistical Methods in Biopharmacy. "*Statistical Innovations in Clinical Trials*." Paris, France, September 26-27, 2005.
- 48. Some Bayesian Methods for Clinical Trial Design and Analysis. 12<sup>th</sup> Annual Biopharmaceutical Applied Statistics Symposium, Savannah, GA, November 7-11, 2005.
- 49. Adaptive Randomization in Sarcoma Trials: Past and Future. Sarcoma Alliance for Research through Collaboration, Biannual Meeting, Atlanta, GA, June 2, 2006.

- 50. Practical Adaptive Randomization in Clinical Trials. Journee des Statisticiens des Centres de Lutte contre le Cancer, Annual Meeting, Institut Bergonie, Bordeaux, France, June 15, 2006
- 51. A Geometric Approach to Comparing Treatments for Rapidly Fatal Diseases. Joint Statistical Meetings, Seattle, WA, August 6, 2006.
- 52. Innovative Bayesian Designs for Early Phase Clinical Trials. Third Strategic Directions in Cancer Therapy, Vancouver, British Columbia, Canada, March 2-3, 2007.
- 53. Patient-Specific Dose-Finding Based On Bivariate Outcomes With Covariates. ENAR Meeting of the International Biometric Soc, Atlanta, GA, March 11-14, 2007.
- 54. Accounting for Heterogeneity in Phase II Clinical Trials Using Bayesian Methods, in the session "*Clinical Trials, Part I: Recent Innovations in Oncology Clinical Trials.*" American Association for Cancer Research, Annual Meeting, Los Angeles, CA April 14-18, 2007.
- 55. Practical Bayesian Adaptive Randomization in Clinical Trials, in the session "*Alternatives to Phase III Trial Design*," Education Session, American Soc of Clinical Oncology Annual Meeting, Chicago, IL, June 5, 2007.
- 56. Designing Clinical Trials to Evaluate Dynamic Treatment Regimes. Introductory Overview Lecture: "Adaptive Designs and Other Emerging Issues in Clinical Trials," Joint Statistical Meetings, Salt Lake City, UT, July 29, 2007.
- 57. Comparing Two-Stage Treatment Strategies Based On Sequential Failure Times Subject to Interval Censoring. Joint Statistical Meetings, Salt Lake City, UT, July 31, 2007.
- 58. Assessing Two-Stage Treatment Strategies for Metastatic Renal Cell Cancer. Sixth Annual Kidney Cancer Association Meeting. Chicago, IL, October 12, 2007
- 59. Accounting for Patient Heterogeneity and Multivariate Outcomes in Early Phase Clinical Trials. In the session "*Bayesian Treatment of Multiplicities in Clinical Trials*", Bayesian Biostatistics Conference, M.D. Anderson Cancer Center, January 31, 2008.
- 60. Comparing Two-Stage Treatment Strategies Based On Sequential Failure Times. In the session "*Dynamic Treatment Regimes: Practice and Theory*," ENAR Meeting of the International Biometric Soc, Arlington, VA, March 19, 2008.
- Select-and-Test Designs for Phase II-III Clinical Trials. Forum on "Decisions at the Phase II / Phase III Interface", American Association for Cancer Research, Annual Meeting, San Diego, CA, April 13, 2008
- 62. Bayesian Methods for Multidimensional Treatment Effects. University of Pennsylvania, Annual Conference on Statistical Issues in Clinical Trials: From Bench to Bedside to Community, Philadelphia, PA, April 18, 2008

- 63. Patient-Specific Dose-Finding Based On Bivariate Outcomes and Covariates. Session on *"Bayesian Analysis of Pharmaceutical Data,"* International Soc For Biopharmaceutical Statistics, First Symposium, Shanghai, China, June 28-July 2, 2008
- 64. Comparing Two-Stage Treatment Strategies Based On Sequential Failure Times. Session on "Survival Analysis," International Soc For Biopharmaceutical Statistics, First Symposium, Shanghai, China, June 28-July 2, 2008.
- 65. Two-Stage Treatment Strategies Based On Sequential Failure Times. Designed Experiments: Recent Advances in Methods and Applications (DEMA2008), Isaac Newton Institute for Mathematical Sciences, Cambridge, UK, August 11-15, 2008.
- 66. Patient-Specific Dose-Finding Based On Bivariate Outcomes and Covariates. FDA/Industry Workshop, "Special Topics in Oncology Drug Development," Arlington, VA, September 16-17, 2008.
- 67. Utility-Based Optimization of Combination Therapy Using Ordinal Toxicity and Efficacy in Phase I/II Trials. Bayesian Biostatistics Conference, Houston, TX, January 26-28, 2009.
- 68. A Geometric Phase II-III Select-and-Test Design Based on Treatment Failure Time and Toxicity. Innovation in Choroid Plexus Tumor Research, Houston, TX, February 14-15, 2009.
- 69. A Prostate Cancer Trial with Re-Randomization: How We Spent a Decade Studying Twelve Dynamic Treatment Regimes. In the session "Application of Dynamic Treatment Regimes" ENAR Meeting of the International Biometric Soc, San Antonio, TX, March 15-18, 2009.
- 70. Optimizing a Two Agent Combination Based On Utilities of Ordinal Toxicity and Efficacy Outcomes. A One-Day Symposium to Honor Ed Gehan. Department of Biostatistics, Bioinformatics and Biomathematics, Georgetown University, Washington, DC, April 27, 2009.
- 71. Bayesian Designs for Clinical Trials with Dynamic Re-Randomization. Biostatistics Workshop in Cancer Research, University of Toronto, Dalla Lana School of Public Health, July 24-26, 2009.
- 72. Utility-Based Optimization of Combination Therapy Using Ordinal Toxicity and Efficacy in Phase I/II Clinical Trials. Workshop in Phase I Designs with a Focus on the Continual Reassessment Method, Memorial Sloan-Kettering Cancer Center, October 2, 2009.
- 73. Navigating the Rocky Shoals of Adaptive Trial Design and Execution. Scientific Advances in Adaptive Clinical Trial Designs Workshop, Bethesda, MD, November 16-17, 2009.
- Application of a Bayesian Doubly Optimal Group Sequential Design for Clinical Trials: Localized Surgery versus Chemotherapy for Non-Small-Cell Lung Cancer. Frontiers of Statistical Decision Making and Bayesian Analysis: A Conference in Honor of James O. Berger. UTSA, San Antonio, Texas, March 17 - 20, 2010

- 75. Using Prior Information and Elicited Utilities for Adaptive Decision Making in Phase I/II Trials. In the session "Recent Developments of Bayesian Methods for Combining Data from Multiple Sources." ENAR Meeting of the International Biometric Soc, New Orleans, LA, March 21-24, 2010.
- A Bayesian Geometric Phase II-III Select-and-Test Design Based On Treatment Failure Time and Toxicity. International Chinese Statistical Association. 19<sup>th</sup> Annual Applied Statistics Symposium, Indianapolis, IN, June 19 - 23, 2010.
- 77. Prior Elicitation in Bayesian Clinical Trial Design. SAMSI Intensive Summer Research Program on Semiparametric Bayesian Inference: Applications in Pharmacokinetics and Pharmacodynamics. Research Triangle Park, NC, July 12 - 23, 2010
- 78. A Hybrid Geometric Select-and-Test Design Based on Treatment Failure Time and Toxicity. Joint Statistical Meetings, Vancouver, British Columbia, Canada, August 3, 2010
- 79. A Phase II-III Select-and-Test Design Based on Treatment Failure Time and Toxicity: Evaluating Chemotherapies for Choroid Plexus Carcinomas in Children. Soc of Paediatric Oncology, Choroid Plexus Tumor Committee, Boston, MA, October 23, 2010
- 80. Bayesian Designs for Prostate Cancer Trials Involving Androgen Receptor Signaling. Androgen Receptor Signaling in Prostate Cancer: Translating Biology into Clinical Practice. Prostate Cancer Task Force, Genitourinary Steering Committee, NCI, Dec 6-7, 2010.
- 81. Optimizing the Bolus and Concentration of a Drug Administered by Continuous Infusion. In the session "Innovative Adaptive Designs in Early-Phase Oncology Clinical Trials," ENAR Meeting of the International Biometric Soc, Miami, FL, March 20-23, 2011.
- 82. Optimizing the Concentration and Bolus of a Drug Delivered by Continuous Infusion. In the session "Adaptive Designs for Clinical Trials," International Conference on Design of Experiments, Memphis, TN, May 10-13, 2011.
- 83. Optimizing the Concentration and Bolus of a Drug Delivered by Continuous Infusion. In the session "Phase I/II clinical studies: safety versus efficacy," International Chinese Statistical Association. 20<sup>th</sup> Annual Applied Statistics Symposium, New York, NY, June 26 29, 2011.
- 84. Practical Issues in Bayesian Adaptive Designs for Early Phase Clinical Trials. Leader, Roundtable discussion, sponsored by the Section on Bayesian Statistical Science, Joint Statistical Meetings, Miami, FL, August 2, 2011.
- 85. Optimizing the Bolus and Concentration of a Drug Administered by Continuous Infusion. Workshop on Design of Experiments in Healthcare, Isaac Newton Institute for Mathematical Sciences, Cambridge, England, August 15-19, 2011.
- 86. Establishing Priors from Elicited Values for Bayesian Dose-Finding Designs. Second Workshop, Continual Reassessment Method and Related Issues in Dose-Finding, Paris, September 15-16, 2011.

- 87. Practical Issues in the Design, Conduct, and Analysis of Randomized Oncology Trials Comparing Dynamic Treatment Regimes. In the session "Recent Advances in Dynamic Treatment Regimes Research" ENAR Meeting of the International Biometric Soc, Washington, DC, April 1-4, 2012.
- 88. Dysfunctional Paradigms in Clinical Trials: Our Conventions Are Killing Us. In the session "Decision Making in the Process of Drug Development," Midwest Biopharmaceutical Statistics Workshop, Ball State University, Muncie, IN, May 21-23, 2012.
- 89. Practical Challenges in the Design, Conduct, and Analysis of Randomized Trials of Dynamic Treatment Regimes in Oncology, International Chinese Statistical Association. 21<sup>st</sup> Annual Applied Statistics Symposium, Boston, MA, June 23 26, 2012.
- 90. Utility-Based Dose-Finding with Ordinal Toxicity and Efficacy. In the session "Dose Selection in Clinical Trials," Joint Statistical Meetings, San Diego, CA, July 29 August 2, 2012
- 91. Evaluating Joint Effects of Induction-Salvage Treatment Regimes on Overall Survival in Acute Leukemia, UAI Workshop on Causal Structure Learning, Catalina Island, CA, August 18, 2012.
- 92. Bayesian Dose-Finding in Two Treatment Cycles based on the Joint Utility of Efficacy and Toxicity. In the session "Multi-Stage Randomized Clinical Trials for the Development of Dynamic Treatment Regimes," Soc for Clinical Trials, Annual Meeting, Boston, MA, May 19-22, 2013.
- 93. Practical Adaptive Bayesian Methods for Early Phase Clinical Trials. In the pre-ASCO two-day workshop "Designs for Contemporary Early-Phase Clinical Trials," Chicago, IL, May 30-31, 2013.
- 94. Discussant, for the session "Dynamic Treatment Regimes and Adaptive Designs Toward Personalized Health Care," Joint Statistical Meetings, Montreal, Canada, August 4-8, 2013.
- 95. Utility-Based Dose-Finding with Ordinal Toxicity and Efficacy, in the session "Adaptive Designs for Clinical Trials," Annual Conference of the International Soc for Clinical Biostatistics, Munich, Germany, August 25-29, 2013.
- 96. Dose-Finding Based On Elicited Joint Utilities of Ordinal Toxicity and Efficacy. Third Biennial Workshop on Adaptive Early-Phase Clinical Trial Design, University of Michigan School of Public Health, September 26-27, 2013.
- 97. Bayesian Designs for Early Phase Clinical Trials. In the session "Shared Challenges of Small Group Trials" 17th ECCO 38th ESMO 32nd ESTRO European Cancer Congress, Amsterdam, The Netherlands, September 30, 2013
- 98. Bayesian Dose-Finding in Two Treatment Cycles based on the Joint Utility of Efficacy and Toxicity. In the session "Personalized Medicine and Dynamic Treatment Regimes" International Conference on Health Policy Statistics, Chicago, IL, October 9-11, 2013.

- 99. Bayesian Dose-finding Methods for Targeted Agents in Early Phase Clinical Trials. In the session "Recent Developments in Personalized Medicine" ENAR Meeting of the International Biometric Soc, Baltimore, MD, March 16-19, 2014.
- 100. Bayesian Clinical Trial Design: 23 Years of Theory and Practice. Council of Texas Statisticians, Annual Meeting, University of Texas at Dallas, March 21-22, 2014.
- 101. Discussant, "Clinical Trials for Adaptive Intervention Designs: Design and Conduct of Sequential Multiple Assignment Randomized Trials," Half day workshop, Soc for Clinical Trials, Annual Meeting, Philadelphia, PA, May 18, 2014.
- 102. Utility-Based Optimization of Schedule-Dose Regimes based on the Times to Response and Toxicity. International Chinese Statistical Association & Korean International Statistical Soc Joint Applied Statistics Symposium, Portland, Oregon, June 15, 2014.
- 103. Adaptively Optimizing Schedule-Dose Regimes based on Utilities of Competing Event Times. In the session 'Design of Clinical Trials' International Indian Statistical Association Conference, Riverside, CA, July 11-13, 2014
- 104. Evaluating Joint Effects of Induction-Salvage Treatment Regimes on Overall Survival in Acute Leukemia. Presented jointly with Yanxun Xu. AML Hackathon, DREAM 9, Rice University, Houston, TX, July 26, 2014.
- 105. Utility-Based Optimization of Schedule-Dose Regimes based on the Times to Response and Toxicity. In the session "Designs and Analyses of Studies with Small Sample Sizes" Joint Statistical Meetings, Boston, MA, August 5, 2014
- 106. Utility-Based Optimization of Schedule-Dose Regimes based on the Times to Response and Toxicity. Fourth Adaptive Early Phase Clinical Trials Workshop, Hollings Cancer Center, Medical University of South Carolina, Charleston, South Carolina, October 16 – 17, 2014
- 107. SMART Design, Conduct, and Analysis in Oncology. Keynote Address, Innovative Methods Program for Advancing Clinical Trials (IMPACT), Cary, North Carolina, November 20-21, 2014.
- Bayesian Utility-Based Sequentially Adaptive Designs for Early Phase Clinical Trials. Symposium on Early Phase Dose Finding Methodology, Pierre and Marie Curie University, Paris, April 15–17, 2015
- 109. Bayesian Adaptive Optimization of Sedative Dose in Preterm Infants Being Treated for Respiratory Distress Syndrome. In the invited paper session, *Bayesian Adaptive Designs for Better Clinical Decision Making*, sponsored by WNAR, Joint Statistical Meetings, Seattle, Washington, August 11, 2015.
- Utility-Based Bayesian Adaptive Designs for Early Phase Clinical Trials. 2015 ASA Biopharmaceutical Section, FDA-Industry Statistics Workshop, Washington D.C., September 16-18, 2015.

- 111. Bayesian Designs for Early Phase Clinical Trials. Kidney Cancer Association Annual Meeting, Miami, FL, November 6-7, 2015.
- 112. Adaptive Treatment Assignment: Getting Personal in Oncology. ENAR Meeting of the International Biometric Soc, Austin, TX, March 6-9, 2016.
- 113. Caveats for Outcome Adaptive Randomization in Comparative Clinical Trials. 9th Annual Conference on Statistical Issues in Clinical Trials, University of Pennsylvania Center for Clinical Epidemiology and Biostatistics, Philadelphia, PA, April 13, 2016.
- 114. Bayesian Nonparametric Estimation for Dynamic Treatment Regimes with Sequential Transition Times. Invited Paper Session, JASA Applications and Case Studies, Joint Statistical Meetings, Chicago, IL, July 30 – August 4, 2016.
- 115. Discussant, Showcase of the Power of Statistics on Evaluating Dynamic Treatment Regimes Leading Toward Personalized Health Care, Invited Paper Session, Sponsored by ENAR and ICSA, Joint Statistical Meetings, Chicago, IL, July 30 – August 4, 2016.
- 116. Parametric Dose Standardization for Two-Agent Phase I-II Trials with Ordinal Efficacy and Toxicity. In the session, "Bringing Adaptive Trials into the Real World," ENAR Meeting of the International Biometric Soc, Washington, DC, March 12-15, 2017.
- 117. Parametric Dose Standardization for Two-Agent Phase I-II Trials with Ordinal Efficacy and Toxicity. In the session, "Recent Developments in Early Phase Dose-Finding," International Chinese Statistical Association, Applied Statistics Symposium, Chicago, IL, June 25-29, 2017.
- 118. Some Caveats for Outcome Adaptive Randomization in Two Arm Clinical Trials, in the session "Adaptive randomization: a balance between innovation, bias reduction, regulatory and ethical considerations," ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop, Washington, DC, September 25–27, 2017.
- 119. Robust Treatment Comparison Based on Utilities of Semi-Competing Risks in Non-Small-Cell Lung Cancer, in the session "Recent Advances in Practical Clinical Trial Design" Invited Paper Session, ENAR Meeting of the International Biometric Soc, Atlanta, GA, March 25-28, 2018.
- 120. Roundtable discussion leader, 'Practical Issues in Clinical Trial Design and Analysis,' ENAR Meeting of the International Biometric Soc, Atlanta, GA, March 25-28, 2018.
- 121. Discussant, Drug Information Association, Virtual Journal Club Meeting, 'Novel Designs in Dose Finding' April 26, 2018.
- 122. Bayesian Clinical Trial Designs to Evaluate Precision Medicine in Oncology, The Statistics and Applied Mathematics Institute Workshop on Precision Medicine, North Carolina State University, Raleigh, NC, August 13-17, 2018
- 123. Bayesian Clinical Trial Designs to Evaluate Precision Medicine in Oncology, 4th International Conference on Big Data and Information Analytics, SAMSI Session on Precision Medicine, Houston, Texas, December 17-19, 2018

- 124. Two Bayesian Clinical Trial Designs for Precision Medicine in Oncology. 2019 TCT Meetings of the ASBMT and CIBMTR, Houston, TX, February 20-24, 2019.
- 125. Roundtable discussion leader, 'Practical Issues in Clinical Trial Design and Analysis for Precision Medicine,' ENAR Meeting of the International Biometric Soc, Philadelphia, PA, March 24-27, 2019.
- 126. Bayesian Oncology Clinical Trial Designs with Subgroup-Specific Decisions. Stat4Onc Annual Meeting, Hartford, CT, April 27-28, 2019.
- 127. Subgroup-Specific Dose Finding in Phase I Clinical Trials Based on Time to Toxicity Allowing Adaptive Subgroup Combination. In the session 'Using adaptive treatment strategies to give the right patient the right dose at the right time' ICSA Applied Statistics Symposium, Raleigh, NC, June 9-12, 2019.
- 128. Applications of Bayesian Precision Medicine. Keynote Address, International Soc for Clinical Biostatistics, Annual Meeting, Leuven, Belgium, July 14-18, 2019.
- 129. Bayesian Clinical Trial Designs to Evaluate Subgroup-Specific Treatment Effects. In the session 'Recent Developments in Novel Clinical Trial Design and Analysis for Precision Medicine' Invited ENAR, Biometrics Section, Biopharmaceutical Section. Joint Statistical Meetings, July 27 August 1, 2019, Denver, CO.
- 130. Two Bayesian Clinical Trial Designs for Precision Medicine in Oncology, in the session 'The Importance of Clinical Trial Design: Registry Trials, Novel Designs and Common Mistakes To Avoid', Cord Blood Connect Annual Meeting, September 14, 2019, Miami Beach, FL
- 131. A New Hybrid Phase I-II-III Clinical Trial Paradigm. co-presented with Andrew Chapple in the Biometrics Showcase Session for the best paper published in Biometrics in 2019, at the Annual International Biometric Soc meeting, July 8, 2020.
- 132. Bayesian Nonparametric Survival Regression for Optimizing Precision Dosing of Intravenous Busulfan in Allogeneic Stem Cell Transplantation. In the session "Recent Developments in Statistical Methods for Precision Medicine." Joint Statistical Meetings, August 3, 2020.
- 133. Bayesian Nonparametric Survival Regression for Optimizing Precision Dosing of Intravenous Busulfan in Allogeneic Stem Cell Transplantation. International Chinese Statistical Association, Applied Statistics Symposium, Dec 13-16, 2020.
- 134. Bayesian Clinical Trial Design and Data Analysis in Oncology. Radiation Oncology Education Collaborative Study Group Spring Symposium, February 24, 2021.
- 135. A New Hybrid Phase I-II-III Clinical Trial Paradigm. Cytel Webinar on Bayesian Methods, May 4, 2021
- 136. A New Hybrid Phase I-II-III Clinical Trial Paradigm. Stat4Onc Annual Conference, May 7, 2021.

- 137. A Basket Trial Design to Optimize Dose and Schedule Based on Delayed Response and Toxicity. In the session "Statistical Considerations for Master Protocols in I-O and Cell Therapy." International Chinese Statistical Association meeting, Sept 13, 2021
- 138. Evolution of Bayesian Clinical Trial Methodologies: Cooking Up Designs for 30 Years. In the session, "Three Decades of Bayesian Clinical Trial Designs: From Stopping Rules to Hierarchical Models for Precision Medicine". Organizer: Ruitao Lin, ENAR Annual Meeting, March 30, 2022.
- 139. Discussant for the session "Trailblazing SMART Design and Statistical Learning for Precision Health", Organizer: Kelley Kidwell, ENAR Annual Meeting, March 29, 2022.
- 140. A Bayesian group sequential enrichment design with adaptive regression of response and survival time on baseline biomarkers. In the session "Adaptive Enrichment Designs in Clinical Trials", Joint Statistical Meetings, Washington, D.C., August 9, 2022.
- 141. Bayesian precision treatment screening and selection using elicited utilities of response and toxicity. In the session "New Methods for Improved Decision-Making in Precision Medicine", Joint Statistical Meetings, Toronto, Ontario, Canada., August 6, 2023.
- 142. A robust Bayesian phase II design for monitoring a time-to-event endpoint. Pharmaceutical Statistics Journal Club Webinar, November 9, 2023.
- 143. Discussant for the talk "Flexible modeling of adaptive treatment strategies for censored outcomes" presented by E. Moodie in the Stanford Online Causal Inference Seminar, December 5, 2023.
- 144. Generalized phase 1-2 designs to maximize long term therapeutic success rate. In the session, "Innovative Designs for Dose Optimization in Oncology". International Symposium on Biopharmaceutical Statistics, Baltimore, MD, March 7, 2024.
- 145. Optimizing NK cell doses for heterogeneous cancer patients based on multiple event times. In the session *Dose-finding Trials Using Biomarker Information*, at the conference "Advanced Statistical Designs to Empower Biomarker-driven Clinical Trials", Bath, United Kingdom, April 29 May 1, 2024.
- 146. Bayesian Precision Treatment Screening and Selection Using Elicited Utilities of Response and Toxicity. In the session *Subgroup and Small Sample Analysis Issues,* at the Graybill Conference, Colorado State University, Fort Collins, Colorado, June 9-12, 2024
- 147. Bayesian Personalized Treatment Selection for Advanced Breast Cancer. Bayesian Biostatistics Conference, Bayes 2024, Rockville, Maryland, 23-25 October 2024

# Invited Talks at Universities, Medical Centers, Pharmaceutical Companies, Federal Agencies

1. Assessment of Stratum-Covariate Interactions in Cox's Proportional Hazards Regression Model. National Center for Health Statistics, Rockville, MD, 1983.

- 2. Two-Stage Designs. Cancer Therapy Evaluation Program, Division of Cancer Treatment, National Cancer Institute, Bethesda, MD, 1987.
- 3. Mixed Poisson Likelihood Regression Models for Longitudinal Interval Count Data. Department of Biostatistics, Medical College of Virginia, Virginia Commonwealth University, Richmond, VA, 1988.
- 4. Optimal Two-Stage Designs for Clinical Trials with Binary Response. Washington Statistical Soc, Washington, D.C., 1988.
- 5. Some Covariance Models for Longitudinal Count Data with Overdispersion. Department of Statistics, Rice University, Houston, TX, February, 1991.
- 6. Test-Based Variable Selection via Cross-Validation. Biostatistics Center, George Washington University, Rockville, MD, May 15, 1992.
- 7. Practical Bayesian Stopping Rules for Clinical Oncologists. Institut Curie, Paris, France, September 17, 1993.
- 8. Practical Bayesian Stopping Rules for Clinical Oncologists. Institut Gustave-Roussy, Paris, France, September 20, 1993.
- 9. Bayesian Sequential Monitoring Designs for Single-Arm Clinical Trials with Multiple Outcomes. Institut fur Medizinische Biometrie und Medizinische Informatik, Freiburg University, Germany, July 22, 1994.
- 10. Bayesian Sequential Monitoring Designs for Single-Arm Clinical Trials with Multiple Outcomes. Programs in Mathematical Sciences, University of Texas at Dallas, October 11, 1994.
- 11. Statistical Methods for Design and Conduct of Clinical Trials. University of Texas Southwestern Medical Center, Dept. of Academic Computing, Dallas, TX, January 20, 1995.
- 12. A Semiparametric Gamma-Poisson Regression Model for Repeated Interval Counts with Covariates. Dept. of Statistics and Actuarial Science, University of Waterloo, Waterloo, Canada, April 7, 1995.
- 13. Bayesian Sequential Monitoring Designs for Single-Arm Clinical Trials with Multiple Outcomes. Dept. of Health Sciences Research, Mayo Clinic, Rochester, Minnesota, September 18, 1995.
- 14. Bayesian Sequential Monitoring Designs for Single-Arm Clinical Trials with Multiple Outcomes. Houston Chapter, American Statistical Assoc., December 13, 1995.
- 15. Randomized Selection and Testing Designs for Phase II/III Clinical Trials. Swiss Group for Clinical Cancer Research, Bern, Switzerland, September 11, 1996.
- 16. Bayesian Design and Monitoring Strategies for Single-Arm Clinical Trials. Dept. of Statistics, University of Uppsala, Uppsala, Sweden, September 16, 1996.

- 17. Estimating Genomic Category Probabilities from FISH Counts with Misclassification. Dept. of Chemical Engineering, Rice University, October 2, 1996.
- 18. Variable Selection in Regression Via Repeated Data Splitting. Dept. of Statistics, University of Texas at Dallas, December 9-10, 1996.
- 19. A Strategy for Dose-Finding and Safety Monitoring Based on Efficacy and Adverse Outcomes in Phase I/II Clinical Trials. Dept. of Statistics, Carnegie Mellon University, Pittsburgh, Pennsylvania, April 25, 1997.
- 20. A Strategy for Dose-Finding and Safety Monitoring Based on Efficacy and Adverse Outcomes in Phase I/II Clinical Trials. University of Minnesota, Institute for Mathematics and Its Applications, Summer Program "Statistics in the Health Sciences", July 31-August 5, 1997.
- 21. Extensions and Applications of a Bayesian Strategy for Monitoring Multiple Outcomes in Clinical Trials. University of Southampton, U.K., October 28, 1997.
- 22. A Strategy for Dose-Finding and Safety Monitoring Based on Efficacy and Adverse Outcomes in Phase I/II Clinical Trials. Department of Biostatistics, Memorial Sloan Kettering Cancer Institute, New York, March 18, 1998.
- 23. Parametric Likelihoods for Multiple Non-Fatal Competing Risks and Death. Division of Biostatistics, Columbia University, New York, New York, March 19, 1998.
- 24. Approximate Bayesian Evaluation of Multiple Treatment Effects. Medical and Pharmaceutical Statistics Research Unit, Dept. of Applied Statistics, Reading University, England, August 20, 1998.
- 25. Decision-Theoretic Designs for Phase II Clinical Trials with Multiple Outcomes. Dept. of Statistics, Texas A & M University, September 24, 1998.
- 26. Practical Guidelines for Dose-Finding with the Continual Reassessment Method in Phase I Clinical Trials. H. Lee Moffitt Cancer Center, Tampa, FL, October 2, 1998.
- 27. New Dose-Finding Methods for Early Phase Clinical Trials. Department of Hematology, University of Illinois at Chicago, Chicago, IL, February 11, 1999.
- Treatment Comparisons Based on Two-Dimensional Safety and Efficacy Alternatives in Oncology Trials. Dept. of Statistics and Actuarial Science, University of Waterloo, Canada, February 25, 1999.
- 29. Approximate Bayesian Evaluation of Multiple Treatment Effects: An Alternative to Hypothesis Testing. Novartis Pharmaceuticals, Basel, Switzerland, September 27, 1999.
- 30. Science and Safety Monitoring in Clinical Trials. Ares-Serono Group, Geneva, Switzerland, October 1, 1999.

- 31. Evaluating Multiple Treatment Courses in Clinical Trials. Dept. of Biostatistics, University of Missouri at Columbia, Columbia, Missouri, January 25, 2000.
- 32. Evaluating Multiple Treatment Courses in Clinical Trials. Department of Biostatistics & Medical Informatics, Abbott Laboratories Distinguished Lectureship in Pharmaceutical Applications, University of Wisconsin at Madison, Madison, WI, January 26, 2000.
- 33. Approximate Bayesian Evaluation of Multiple Treatment Effects: An Alternative to Hypothesis Testing. Dept. of Biostatistics, Harvard University, April 13, 2000.
- Dose-Finding Based on Response and Toxicity: The Phase I/II Design. Biostatistics Branch, Div. of Intramural Research, National Institute of Neurological Disorders and Stroke, NIH, May 21, 2001.
- 35. Multi-course Treatment Strategies for Clinical Trials of Rapidly Fatal Diseases. Dept. of Statistics, Texas A & M University, October 18, 2001.
- 36. Treatment Comparisons Based on Two-Dimensional Safety and Efficacy Alternatives in Oncology Trials. Dept of Biostatistics, Medical College of Virginia, Virginia Commonwealth University, March 23, 2002.
- 37. Bayesian Methods in Clinical Trials: Recent Practical Innovations in Phase I and II Studies. Grand Rounds, Lombardi Cancer Center, Georgetown University, August 28, 2002.
- 38. Dose-Finding with Two Agents in Phase I Oncology Trials. Dept. of Biostatistics, Columbia University, November 25, 2002.
- 39. Adaptive Decision-Making in a Lymphocyte Infusion Trial. Dept. of Health Studies, University of Chicago, April 30, 2003.
- 40. Covariate-Adjusted Adaptive Randomization in a Sarcoma Trial With Multi-Stage Treatments. Population Science Division, Fox Chase Cancer Center, Philadelphia, PA, July 30, 2003.
- 41. Covariate-Adjusted Adaptive Randomization in a Sarcoma Trial with Multi-Stage Treatments Department of Biostatistics, School of Public Health, University of Michigan, Ann Arbor, MI, September 4, 2003.
- 42. New Methods for Dose-Finding in Early Phase Clinical Trials. Department of Biostatistics, School of Public Health, University of Michigan, Ann Arbor, MI, September 5, 2003.
- 43. Covariate-Adjusted Adaptive Randomization in a Sarcoma Trial with Multi-Stage Treatments. Department of Biostatistics, St. Jude's Children's Research Hospital, Memphis, TN, October 16, 2003.
- 44. Practical Adaptive Decision-Making in Oncology Clinical Trials. Department of Biostatistics, St. Jude's Children's Research Hospital, Memphis, TN, October 16, 2003.

- 45. Adaptive Bayesian Designs for Clinical Trials. Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Rockville, MD, December 15, 2003.
- 46. Some Bayesian Adaptive Methods for Clinical Trial Design and Conduct. Pharsight, Drug Development Consulting Services, Cary, NC, October 12-13, 2004.
- 47. Dose-Finding Based On Efficacy-Toxicity Trade-Offs. Office of Biostatistics Research, National Heart, Lung and Blood Institute, NIH, Bethesda, MD, November 30, 2004.
- 48. Recent Advances in Bayesian Adaptive Dose-Finding. Chiron Corporation, Emeryville, CA, July 12, 2005.
- 49. Dose Finding Based On Efficacy and Toxicity in Phase I/II Clinical Trials. Unité de Biostatistique, CRLC Val d'Aurelle, Montpellier, France, September 28, 2005.
- 50. Some Designs for Combining Phase II and Phase III Clinical Trials. Unité de Biostatistique, CRLC Val d'Aurelle, Montpellier, France, September 29, 2005.
- 51. Patient-Specific Dose-Finding: A New Method Based On Efficacy, Toxicity and Prognostic Covariates. Neurology Grand Rounds, National Institutes of Neurological Diseases and Stroke, Bethesda, MD, November 22, 2005.
- 52. Two New Bayesian Designs for Dose-Finding Trials. Solid Tumor Oncology and Hematologic Oncology Grand Rounds, Memorial Sloan-Kettering Cancer Center, New York, NY, May 9, 2006.
- 53. Covariate-Adjusted Adaptive Randomization in a Clinical Trial with Multi-Stage Therapy. Biometric Research Branch, Division of Cancer Treatment & Diagnosis, National Cancer Institute, Rockville, Maryland, October 16, 2006.
- 54. Improving the Reliability and Precision of Phase 2 Clinical Trials. Clinical Trials Task Force of the Investigational Drug Steering Committee, Division of Cancer Treatment and Diagnosis, Cancer Therapy Evaluation Program, National Cancer Institute, Rockville, Maryland, January 30, 2007.
- 55. A Geometric Approach to Comparing Treatments for Rapidly Fatal Diseases. Department of Biostatistics, Bioinformatics and Biomathematics, Georgetown University, September 20, 2007.
- 56. Some New Bayesian Designs for Early Phase Clinical Trials. City of Hope Cancer Center, Duarte, CA, October 17, 2007.
- 57. Comparing Two-Stage Treatment Strategies Based On Sequential Failure Times. Stanford Cancer Center, Palo Alto, CA, October 19, 2007.
- 58. Patient-Specific Dose-Finding Based On Bivariate Outcomes and Covariates. University of Pittsburgh, Department of Biostatistics, March 6, 2008.
- 59. Comparing Two-Stage Treatment Strategies Based On Sequential Failure Times. University of Pittsburgh, Department of Statistics, March 7, 2008.

- 60. Comparing Two-Stage Treatment Strategies Based On Sequential Failure Times. Department of Biostatistics, Bioinformatics & Epidemiology, Medical University of South Carolina, April 4, 2008
- 61. Comparing Two-Stage Treatment Strategies Based On Sequential Failure Times. Institut Bergonie, Bordeaux, France, May 21, 2008.
- 62. Patient-Specific Dose-Finding Based On Bivariate Outcomes and Covariates. Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, January 30, 2009.
- 63. Patient-Specific Dose-Finding Based On Bivariate Efficacy-Toxicity Outcomes and Prognostic Covariates. Department of Biostatistics, University of North Carolina, January 27, 2010.
- 64. Select-and-Test Designs for Phase II-III Clinical Trials. Kanagawa Cancer Center Clinical Trial Design Workshop, Yokohama, Japan, April 12, 2010
- Patient-Specific Dose-Finding Based On Bivariate (Efficacy, Toxicity) Outcomes and Covariates. Workshop on Contributions of Bayesian Statistics to Clinical Trials. University of Tokyo, April 13, 2010
- 66. Select-and-Test Designs for Phase II-III Clinical Trials. Kyoto University, Clinical Trial Design and Biostatistics Workshop, Kyoto, Japan, April 15, 2010.
- 67. Bayesian Adaptive Dose Finding Designs for Early Phase Clinical Trials. University of Texas, Public Health School, Houston, Texas, September 28, 2010
- 68. New Bayesian Adaptive Designs for Early Phase Clinical Trials. Tufts University School of Medicine, Cancer Center Grand Rounds, Boston, MA, October 22, 2010.
- 69. Establishing Priors for Bayesian Clinical Trials. Department of Biostatistics, Columbia University Medical Center, New York, NY, June 30, 2011.
- 70. Navigating the Rocky Shoals of Adaptive Clinical Trial Design and Conduct. Biosatistiques et Epidémiologie Clinique, Hôpital Saint-Louis, Paris, France, September 14, 2011.
- 71. Patient-Specific Dose-Finding Based on Bivariate Efficacy-Toxicity Outcomes and Prognostic Covariates. Department of Biostatistics, Vanderbilt University School of Medicine, Nashville, TN, November 2, 2011.
- 72. Utility-Based Dose-Finding with Ordinal Toxicity and Efficacy. Department of Biostatistics and Medical Informatics, University of Wisconsin-Madison, May 4, 2012.
- 73. A Bayesian Adaptive Design to Optimize Sedative Dose for Neonates Prior to Intubation. Hôpital Universitaire des Enfants Reine Fabiola, Brussels, Belgium, October 2, 2012.
- 74. Utility-Based Dose-Finding with Ordinal Toxicity and Efficacy. Department of Epidemiology, Biostatistics, and Occupational Health, McGill University, Montreal, Canada, February 12, 2013.

- 75. Bayesian Hybrid Adaptive Designs for Clinical Trials. Cancer Outcomes Research Program and Sheps Center for Health Services Research, University of North Carolina, September 13, 2013.
- 76. Bayesian Sequentially Adaptive Clinical Trial Design: General Concepts and Applications. University of Texas Public Health School, Center for Clinical and Translational Sciences, Houston, TX, October 18, 2013.
- 77. Bayesian Dose-Finding in Two Treatment Cycles Using Joint Efficacy-Toxicity Utilities. Biostatistics Department, University of Michigan, April 17, 2014
- 78. Utility-Based Bayesian Adaptive Designs for Early Phase Clinical Trials. Radiation Oncology Department, University of Michigan, April 18, 2014
- 79. Optimizing Schedule-Dose Regimes in Early Phase Clinical Trials, Department of Biostatistics, Mailman School of Public Health, Columbia University, May 1, 2014
- 80. Bayesian Methods for Targeted Agents in Early Phase Clinical Trials. INSERM UMRS 1138, Information Sciences to support Personalized Medicine, Centre de Recherche des Cordeliers, Paris, France, May, 26, 2014
- 81. Utility-Based Bayesian Adaptive Designs for Early Phase Clinical Trials. INSERM UMRS 1138, Clinical Epidemiology and Economic Evaluation Applied to Vulnerable Populations, UEC - Hopital Robert Debre, Paris, France, May 28, 2014
- 82. Utility-Based Bayesian Adaptive Designs for Early Phase Clinical Trials. Greehey Children's Cancer Research Institute, University of Texas Health Science Center, San Antonio, Texas, February 13, 2015.
- 83. SMART Design, Conduct, and Analysis in Oncology. Systèmes d'Information et Médecine Personnalisée, Centre de Recherche des Cordeliers, INSERM, Paris, France, April 13, 2015.
- 84. Utility-Based Bayesian Adaptive Designs for Early Phase Clinical Trials. University of Texas Southwestern Medical Center, Dallas, Texas, October 2, 2015.
- 85. Dysfunctional Conventions in Clinical Trials: Some Practical Alternatives. Early Phase Biometrics, AstraZeneca Phamaceuticals, Boston, MA, March 18, 2016.
- 86. Utility-Based Bayesian Adaptive Designs for Early Phase Clinical Trials. Early Phase Biometrics, AstraZeneca Phamaceuticals, Boston, MA, March 18, 2016.
- 87. Caveats for Outcome Adaptive Randomization in Comparative Clinical Trials. Systèmes d'Information et Médecine Personnalisée, Centre de Recherche des Cordeliers, INSERM, Paris, France, June 13, 2016.
- 88. Statistical Remedies for Flawed Conventions in Medical Research. School of Public Health, Louisiana State University, New Orleans, LA, February 11, 2019.

- 89. Statistical Remedies for Flawed Conventions in Medical Research. University of Arizona Cancer Center, Mel and Enid Zuckerman College of Public Health Scholar Seminar, Tucson, Arizona, February 12, 2020.
- 90. A New Hybrid Phase I-II-III Clinical Trial Paradigm. Department of Data Sciences, Frontiers in Biostatistics Seminar, Dana-Farber Cancer Institute, September 15, 2020.
- 91. A New Hybrid Phase I-II-III Clinical Trial Paradigm. Department of Biostatistics, Columbia University, New York, NY, October 13, 2020.
- 92. Invited 'Fireside Chat' with graduate students in the Department of Biostatistics, Harvard University, October 26, 2020.
- 93. Bayesian Precision Medicine Designs for Cancer Clinical Trials. Department of Biostatistics and Bioinformatics, Duke University School of Medicine, December 17, 2021.
- 94. Discussion, in the session "Bayesian Integration of Data Sources to Inform the Stepwise Approach and Comparative Clinical Study", Center for Drug Evaluation and Research, US FDA Public Workshop, "Increasing the Efficiency of Biosimilar Development Programs", September 19, 2022
- 95. Fatal Statistical Conventions in Medical Research. Department of Biostatistics, University of Michigan, December 9, 2022.
- 96. Bayesian Personalized Treatment Selection for Advanced Breast Cancer. Cancer Biostatistics Seminar, Department of Biostatistics, University of Michigan, December 10, 2022.
- 97. Bayesian Personalized Treatment Selection for Advanced Breast Cancer. Landscape Seminar, Department of Mathematical Sciences, Bath University, United Kingdom, May 3, 2024.
- 98. Generalized Phase 1-2 Designs to Maximize Long Term Therapeutic Success Rate. Biostatistics and Bioinformatics seminar, Division of Epidemiology and Biostatistics, University of Illinois at Chicago Cancer Center, December 10, 2024.

### Other Presentations

- 1. A Comparative Analysis of Complete Remission and Survival in AML Patients Treated with High Dose ARA-C Alone or +GM-CSF. Department of Hematology, MDACC, June 5, 1991.
- 2. A Bayesian Treatment Selection Design for Evaluating New Therapies in Leukemia. Dept. of Hematology, MDACC, September 26, 1991.
- 3. A Bayesian Strategy for Screening Cancer Treatments Prior to Phase II Evaluation. Division of Medicine, MDACC, April 7, 1992.
- 4. Basic Concepts in Statistics. Melanoma/Sarcoma Research Conference, MDACC, April 13, 1992.
- 5. How to Survive Statistics. Melanoma/Sarcoma Research Conference, MDACC, April 20, 1992.

- 6. Your Friend, the Sample Statistic. Melanoma/Sarcoma Research Conference, MDACC, April 27, 1992.
- 7. The Mythology of P-values: Hypothesis Testing in the Clinic. Melanoma/Sarcoma Research Conf, MDACC, May 4 and June 8, 1992.
- 8. Confidence Intervals and Multiple Testing. Melanoma/Sarcoma Research Conference, MDACC, June 15, 1992.
- 9. Regression: Fitting Equations to Data. Melanoma/Sarcoma Research Conference, MDACC, June 22, 1992.
- 10. Statistical Designs for Phase II Clinical Trials. Melanoma/Sarcoma Research Conference, MDACC, July 6, 1992.
- 11. Phase II Trials With Continuous Monitoring: a Bayesian Design. Melanoma/Sarcoma Research Conference, MDACC, July 20, 1992.
- 12. A Bayesian Design for a Phase IIB Study of Transretinoic Acid + Idarubicin in APL Patients. Dept. of Hematology, MDACC, September 30, 1992.
- 13. Bayesian Death in the Clinic. Department of Hematology, MDACC, April 14, 1993.
- 14. Design of Phase II Bone Marrow Transplant Studies. Section of Bone Marrow Transplant, Dept. of Hematology, MDACC, April 27, 1993.
- 15. Results of Accelerated Radiotherapy with Carboplatin in Glioblastomas. Department of Neuro-Oncology, MDACC, May 6, 1993.
- 16. Q-Twist: A Quality-of-Life Oriented Statistic for Cancer Clinical Trials. Quality of Life Multidisciplinary Study Group, MDACC, July 8, 1993.
- 17. New Designs for Clinical Trials With Multiple Endpoints. Department of Hematology, MDACC, August 25, 1993.
- 18. Practical Bayesian Stopping Rules for Clinical Oncologists. Research Council, MDACC, September 13, 1993.
- 19. Prevalence of a Transient Condition: A Quantitative Method for Evaluating Quality of Life in Clinical Trials. Quality of Life Multidisciplinary Study Group, MDACC, February 22, 1994.
- 20. A Quantitative Method for Evaluating Quality of Life in Clinical Trials. Dept of Hematology, MDACC, March 9, 1994.
- A Statistical Design for the CD34 Allogeneic Bone Marrow Transplant Trial: Application of the Thall-Simon-Estey Monitoring Strategy. Section of Bone Marrow Transplant, Dept. of Hematology, MDACC, April 19, 1994.

- 22. Statistical Designs for Monitoring Single-Arm Clinical Trials with Multiple Outcomes. Pediatrics Research Conference, Division of Pediatrics, MDACC, June 13, 1994.
- 23. Phase II Trials. Hematology/Oncology Fellows, MDACC, September 19, 1994.
- 24. Analysis of Prognostic Factors. Hematology/Oncology Fellows, MDACC, September 23, 1994.
- 25. A Strategy for Selecting Treatments for Phase II Study: The Phase I 1/2 Design. Program in Experimental Therapeutics, MDACC, January 17, 1995.
- 26. Bayesian Sequential Monitoring Designs for Single-Arm Clinical Trials with Multiple Outcomes. Department of Statistics, Rice University, Houston, TX, January 30, 1995.
- 27. Statistical Data Analysis: Fitting Equations to Data. Medical Oncology Fellows, MDACC, May 8, 1995.
- 28. Balancing Prognostic Factors in Randomized Clinical Trials: The Pocock-Simon Design. Leukemia Section, Hematology Dept., MDACC, September 6, 1995.
- 29. Statistical Designs for Phase II and Phase III Cancer Clinical Trials. Rhône-Poulenc Rorer Preceptorship Program, MDACC, October 24, 1995.
- 30. Statistical Designs for Phase II and Phase III Cancer Clinical Trials Rhône-Poulenc Rorer Preceptorship Program, MDACC, February 21, 1996.
- 31. A Strategy for Monitoring Multiple Outcomes in Developmental Clinical Trials. Dept. of Nuclear Medicine, MDACC, April 30, 1996.
- 32. A New Statistical Strategy for Monitoring Multiple Adverse and Efficacy Outcomes in Phase I/II Clinical Trials. Division of Medicine Grand Rounds, MDACC, July 9, 1996.
- 33. Statistical Design of Phase II and Phase III Clinical Trials. ICC/Janssen Preceptorship Program, MDACC, July 30, 1996.
- 34. New Graphical Methods for Evaluating and Improving Goodness-of-Fit in Survival Analysis With the Cox Model. MDACC "Advances in Oncology" Grand Rounds, August 15, 1997.
- 35. Practical Guidelines for Dose-Finding with the Continual Reassessment Method in Phase I Clinical Trials. Pediatric Research Conf., MDACC, September 14, 1998.
- 36. A Strategy for Dose-Finding and Safety Monitoring Based on Efficacy and Toxicity in Phase I/II Clinical Trials. Pediatric Research Conference, MDACC, October 5, 1998.
- 37. Safety Monitoring and Science in Clinical Trials. Rhone-Poulenc-Rohrer Preceptorship, MDACC, November 11, 1999.

- 38. A New Statistical Strategy for Evaluating AML/MDS Treatment Strategies. Department of Leukemia, MDACC, March 7, 2001.
- 39. A Survival Analysis of Data from 90 Chronic Lymphocytic Leukemia patients treated at MDACC. Department of Leukemia, MDACC, June 29, 2001.
- 40. Adaptive Designs for Early Phase Oncology Trials. Department of GI Medical Oncology, MDACC, February 27, 2002.
- 41. A General Approach to a Two-Component Phase I Trial. Grand Rounds, MDACC, June 21, 2002 (presented jointly with R. Millikan).
- 42. Dose-Finding in Early Phase Clinical Trials I: Methods Based on Toxicity. Department of Pediatrics, MDACC, March 19, 2003.
- 43. Dose-Finding in Early Phase Clinical Trial. Pediatric Grand Rounds, MDACC, April 21, 2003.
- 44. Adaptive Designs for Multi-Course Therapies. Foundation for Integrative Biology Toward Individualized Therapeutic Strategies, MDACC, Houston, TX, February 6, 2003.
- 45. Effects of Tacrolimus Level on Survival Time in Allogeneic Transplant Patients. Department of Blood and Marrow Transplantation, MDACC, April 22, 2003.
- 46. Adaptive Decision-Making in Cancer Clinical Trials. Core Curriculum Lecture, MDACC, May 5, 2003.
- 47. New Methods for Dose-Finding in Early Phase Clinical Trials. Medical Grand Rounds, MDACC, July 8, 2003.
- 48. Adaptive Randomization in Clinical Trials. Human Protocol Research, GS21 0132, Graduate School of Biomedical Sciences, MDACC, October 11, 2006.
- 49. Adaptive Randomization in Clinical Trials. Human Protocol Research, GS21 0132, Graduate School of Biomedical Sciences, MDACC, October 10, 2007.
- Simultaneously Optimizing Dose and Schedule of a New Cytotoxic Agent : A New Paradigm for Phase I Clinical Trials. Presented to the Department of Stem Cell Transplantation and Cellular Therapy, MDACC, February 26, 2008.
- 51. Adaptive Randomization in Clinical Trials. Human Protocol Research, GS21 0132, Graduate School of Biomedical Sciences, MDACC, October 1, 2008
- 52. Two Adaptive Bayesian Designs for Early Phase Clinical Trials. Presented to External Review Panel for the Division of Quantitative Sciences at MDACC, June 2, 2009.
- 53. Innovative Bayesian Methods for Early Phase Clinical Trials. Human Protocol Research, GS21 0132, Graduate School of Biomedical Sciences, MDACC, September 30, 2009.

- 54. Innovative Bayesian Adaptive Clinical Trial Designs. Clinical Trials Faculty Meeting, Department of Investigational Cancer Therapeutics, MDACC, October 14, 2009.
- 55. Monitoring Multiple Events in Early Phase Clinical Trials. Clinical Trial Design Discussion Forum, Department of Biostatistics, MDACC, October 21, 2009.
- 56. A Bayesian-Frequentist Geometric Phase II-III Select-and-Test Design: Evaluating Chemotherapies for Choroid Plexus Carcinomas in Children. Department of Biostatistics, MDACC, February 8, 2010.
- 57. Innovative Bayesian Methods for Early Phase Clinical Trials. Human Protocol Research, GS21 0132, Graduate School of Biomedical Sciences, MDACC, November 3, 2010.
- 58. Innovative Bayesian Methods for Early Phase Clinical Trials. Human Protocol Research, GS21 0132, Graduate School of Biomedical Sciences, MDACC, March 21, 2012.
- 59. Evaluating Induction-Salvage Treatment Regimes in Therapy of AML/MDS. Hematology Grand Rounds, MDACC, May 9, 2012.
- 60. 22 Years Working as a Biostatistician in a Cancer Center: A Few Snapshots. Presentation to the Rice University Summer Institute of Statistics students, July 9, 2012.
- 61. Utility-Based Methods for Early Phase Clinical Trials. Department of Investigational Cancer Therapeutics, Pre-Clinical Meeting, MDACC, October 24, 2012.
- 62. Dysfunctional Conventions in Clinical Trials: Some Practical Alternatives. Grand Rounds, Department of Biostatistics, MDACC, January 17, 2013
- 63. Innovative Bayesian Methods for Early Phase Clinical Trials. Human Protocol Research, GS21 1132, Graduate School of Biomedical Sciences, MDACC, March 27, 2013.
- 23 Years Working as a Biostatistician at M.D. Anderson Cancer Center: Some Very Brief Examples. Presentation to the Rice University Summer Institute of Statistics students, June 7, 2013.
- 65. Dysfunctional Conventions in Clinical Trials: Some Practical Alternatives. Grand Rounds, Department of Anesthesiology, MDACC, July 3, 2013.
- 66. Dysfunctional Conventions in Clinical Trials. Department of Investigational Cancer Therapeutics, MDACC, October 24, 2013.
- 67. Counterintuitive Properties of Clinical Trials: Bayesian Methods to Avoid Getting it Wrong Department of Investigational Cancer Therapeutics, MDACC, February 6, 2014.
- 68. Bayesian Utility-Based Designs, Dynamic Treatment Regimes, and Personalized Medicine. Human Protocol Research, MDACC, March 26, 2014
- 69. Recent Practical Improvements in the EffTox Dose-Finding Design (jointly with R. Herrick). Biostatistics Lunch Discussion, Department of Biostatistics, MDACC, April 14, 2014

- 70. Finding an Optimal Dose Pair of MLN0128 and Paclitaxel with a fixed dose of Carboplatin in Patients with Advanced Tumors: A Phase I-II Design. Department of Investigational Cancer Therapeutics, Clinical Studies Meeting, MDACC, November 6, 2014.
- 71. Dysfunctional Conventions in Cancer Clinical Trials, and Some Practical Alternatives. Human Protocol Research, MDACC, March 25, 2015
- 72. Utility-Based Bayesian Adaptive Designs for Early Phase Clinical Trials. Department of Biostatistics, MDACC, October 12, 2015
- 73. Interim Analyses of Data from the START Trial, Protocol 2010-0085 (N. Tannir, PI). GU Oncology Department, MDACC, October 21, 2015
- 74. Dysfunctional Conventions in Cancer Clinical Trials: Some Practical Alternatives. Human Protocol Research, MDACC, March 23, 2016
- 75. Randomization and Bias in Clinical Research: Basic Concepts and Two Recent Applications. Surgical Oncology and Breast Medical Oncology Departments, MDACC, August 26, 2016
- Dysfunctional Conventions in Clinical Trials: Some Practical Alternatives. Lecture #1, Clinical Trials Workshop for Surgical Oncology and Breast Medical Oncology Fellows, MDACC, January 19, 2018.
- 77. Randomization and Bias in Clinical Research: Basic Concepts and Some Recent Trial Designs. Lecture #2, Clinical Trials Workshop for Surgical Oncology and Breast Medical Oncology Fellows, MDACC, January 19, 2018.
- Robust Treatment Comparison Based on Utilities of Semi-Competing Risks in Non-Small-Cell Lung Cancer. Biostatistics Lunch Discussion Series, Department of Biostatistics, MDACC, April 9, 2018.
- 79. Two Utility-Based Bayesian Designs with Adaptive Subgroup-Specific Decisions for Precision Medicine. Biostatistics Lunch Discussion Series, Department of Biostatistics, MDACC, August 12, 2019.
- 80. Randomization and Bias in Clinical Research: Basic Concepts and Some Recent Trial Designs. Department of Endocrine Neoplasia and Hormonal Disorders, October 28, 2019.
- 81. Survival Analysis and Some Statistical Graphics. Department of Endocrine Neoplasia and Hormonal Disorders, November 4, 2019.
- 82. Bayesian Nonparametric Survival Regression for Optimizing Precision Dosing of Intravenous Busulfan in Allogeneic Stem Cell Transplantation. Biostatistics Lunch Discussion Series, Department of Biostatistics, MDACC, December 9, 2019.
- 83. How to Avoid Crippling Potential New Cancer Treatments. Biostatistics Lunch Discussion Series, Department of Biostatistics, MDACC, May 11, 2020.

- 84. Fatal Statistical Practices in Medical Research. Informal Biostatistics Lunch Discussion Series, Department of Biostatistics, MDACC, October 11, 2021.
- 85. A Randomized Multicenter Pilot Study of T-Cell Therapy for Acute Respiratory Distress Syndrome in COVID-19 ICU Patients. Biostatistics Lunch Discussion Series, Department of Biostatistics, MDACC, March 14, 2022.
- 86. Bayesian Personalized Treatment Selection for Advanced Breast Cancer. Biostatistics Lunch Discussion Series, Department of Biostatistics, MDACC, November 7, 2022.
- 87. New paradigms for dose finding: A response to FDA Project Optimus. Biostatistics Lunch Discussion Series, Department of Biostatistics, MDACC, November 6, 2023.
- 88. Quantifying Statistical Strength of Evidence: P-values, S-values, and Bayesian Methods. Presented to the Bioinformatics Café at MDACC, February 22, 2024.
- 89. Transporting Clinical Trial Results to the Clinic: Randomization and External Validity. Biostatistics Lunch Discussion Series, Dept of Biostatistics, MDACC, April 8, 2024.
- 90. Basic Bayes: A Brief Introduction to Methods for Quantifying Uncertainty. Department of Stem Cell Transplantatoin and Cellular Therapy, MDACC, July 23, 2024.

### Professional Societies

International Biometric Society International Society for Bayesian Analysis