

## Daniel Francis Heitjan, PhD

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### Personal

- Born at Detroit, Michigan; US citizen.
- Pronunciation of my last name: 'hīt-jən.

### Education

- The University of Chicago: 1977–1981.
  - BSc with general honors, Mathematics, June 1981.
- Massachusetts Institute of Technology: 1981–1982.
  - Graduate study in Applied Mathematics, specializing in Statistics.
- The University of Chicago: 1982–1985.
  - MSc, Statistics, March 1984.
  - PhD, Statistics, December 1985.

### Professional Positions

- University of California, Los Angeles: 1985–1988.
  - Department of Biomathematics (School of Medicine):
    - \* Adjunct Assistant Professor of Biomathematics.
  - Jonsson Comprehensive Cancer Center:

- \* Associate Member, 1988.
- The Pennsylvania State University: 1988–1995.
  - Center for Biostatistics & Epidemiology (College of Medicine):
    - \* Assistant Professor of Biostatistics, 1988–1992.
    - \* Associate Professor of Biostatistics (tenured), 1992–1995.
  - Merck & Company, Inc., Blue Bell, PA:
    - \* Stanley S. Schor Visiting Scholar, Clinical Biostatistics & Research Data Systems, 1994–1995.
- Columbia University: 1995–2002.
  - Department of Biostatistics (Mailman School of Public Health):
    - \* Visiting Associate Professor of Public Health (Biostatistics), 1995–1996.
    - \* Associate Professor of Public Health (Biostatistics), 1996–2001; tenured, 1998.
    - \* Professor of Biostatistics, 2001–2002.
  - Herbert Irving Comprehensive Cancer Center:
    - \* Member and Director of Biostatistics Resource, 1995–2002.
  - International Center for Health Outcomes Innovation & Research:
    - \* Director of Biostatistics, 1996–2002.
- University of Pennsylvania: 2002–2014.
  - Department of Biostatistics & Epidemiology (Perelman School of Medicine):
    - \* Professor of Biostatistics, 2002–2014.
    - \* Director, Educational Programs in Biostatistics, 2005–2011.
    - \* Chair, Graduate Group in Epidemiology & Biostatistics, 2008–2013.
  - Department of Statistics (Wharton School):
    - \* Professor of Statistics, 2003–2014.
  - Abramson Cancer Center:
    - \* Member and Director, Biostatistics Unit, 2003–2014.
- Southern Methodist University: 2015–.

- Department of Statistics & Data Science (Dedman College of Humanities & Sciences):
  - \* Professor of Statistics & Data Science.
  - \* Director, SMU/UTSW Collaborative PhD Program in Biostatistics.
  - \* Department Chair, 2019–.
- University of Texas Southwestern Medical Center: 2015–.
  - Peter O’Donnell Jr. School of Public Health:
    - \* Professor.
    - \* Director, SMU/UTSW Collaborative PhD Program in Biostatistics.
  - Simmons Cancer Center.
    - \* Member, 2015–.
    - \* Member, Educational Advisory Committee, 2023–.

## Honors & Awards

- Student awards:
  - National Merit Scholar, University of Chicago, 1977–1981.
  - State of Michigan Legislative Scholar, University of Chicago, 1977–1981.
  - Warner-Lambert Fellow, Statistics Department, University of Chicago, 1984–1985.
  - ENAR Spring Meeting Student Award Paper, 1985.
- Honorary fellowships:
  - Fellow of the American Statistical Association, elected 1997.
  - Fellow of the Institute of Mathematical Statistics, elected 2012.
  - Fellow of the Society for Clinical Trials, elected 2017.
- Invited lectures:
  - Distinguished Speaker, Department of Biostatistics, UT M. D. Anderson Cancer Center, 2015.12.

- Distinguished Lecturer, Department of Statistical Sciences & Operations Research and Department of Biostatistics, Virginia Commonwealth University, 2020.02.
- Robert F. Woolson Lecturer, Department of Biostatistics, University of Iowa, 2023.02.
- Other awards:
  - Stanley S. Schor Visiting Scholar, Merck Research Laboratories, 1994–1995.
  - 1994 CDC & ATSDR Statistics Award, recognizing statistical publication # 12 below.
  - Donald B. Owen Award, San Antonio Chapter of the American Statistical Association, 2017.

## Professional Service Positions

- Program Chair, American Statistical Association (ASA) Biometrics Section, 2002 Joint Statistical Meetings.
- Chair, Program Committee, 2005 Joint Statistical Meetings.
- Chair-Elect (2008), Chair (2009), Past Chair (2010), ASA Biometrics Section.
- Elected member of Regional Committee, Eastern North American Region (ENAR), International Biometric Society (IBS), 2009–2011.
- President-Elect (2012), President (2013), Past President (2014), ENAR.
- Member, Board of Directors, Korean International Statistical Society, 2012–2016.
- Member, Scientific Organizing Committee, International Conference on Health Policy Statistics, 2015.
- Member, Student Scholarship Committee, Society for Clinical Trials, 2020.

## Papers Published or In Press—Statistical

1. **Heitjan DF** (1989). Inference from grouped continuous data: A review (with discussion). *Statistical Science* **4**, 164–183.
2. **Heitjan DF**, Rubin DB (1990). Inference from coarse data *via* multiple imputation with application to age heaping. *Journal of the American Statistical Association* **85**, 304–314.
3. **Heitjan DF** (1991). Generalized Norton-Simon models of tumor growth. *Statistics in Medicine* **10**, 1075–1088.
4. **Heitjan DF** (1991). Nonlinear modeling of serial immunologic data: A case study. *Journal of the American Statistical Association* **86**, 891–898.
5. **Heitjan DF** (1991). Regression with bivariate grouped data. *Biometrics* **47**, 549–562.
6. **Heitjan DF**, Little RJA (1991). Multiple imputation for the Fatal Accident Reporting System. *Applied Statistics* **40**, 13–29.
7. **Heitjan DF**, Rubin DB (1991). Ignorability and coarse data. *Annals of Statistics* **19**, 2244–2253.
8. **Heitjan DF**, Derr JA, Satyaswaroop PG (1992). The multi-site tumor transplantation model for human endometrial carcinoma: A statistical evaluation. *Cell Proliferation* **25**, 193–203.
9. **Heitjan DF**, Houts PS, Harvey HA (1992). A decision-theoretic evaluation of early stopping rules. *Statistics in Medicine* **11**, 673–683.
10. **Heitjan DF** (1993). Ignorability and coarse data: Some biomedical examples. *Biometrics* **49**, 1099–1109.
11. **Heitjan DF**, Manni A, Santen RJ (1993). Statistical analysis of *in vivo* tumor growth experiments. *Cancer Research* **53**, 6042–6050.
12. Smith PJ, **Heitjan DF** (1993). Testing and adjusting for departures from nominal dispersion in generalized linear models. *Applied Statistics* **42**, 31–41.
13. **Heitjan DF** (1994). Estimation with missing data. Letter to the editor. *Biometrics* **50**, 580.

14. **Heitjan DF** (1994). Ignorability in general incomplete-data models. *Biometrika* **81**, 701–708.
15. **Heitjan DF** (1994). The NSABP trials. Letter to the editor. *New England Journal of Medicine* **331**, 809–810.
16. **Heitjan DF**, Landis JR (1994). Assessing secular trends in blood pressure: A multiple-imputation approach. *Journal of the American Statistical Association* **89**, 750–759.
17. **Heitjan DF** (1995). Bayesian analysis of a protocol for sampling preserved tumor specimens. *Journal of the American Statistical Association* **90**, 38–44.
18. **Heitjan DF**, Kunselman S (1995). Time until first significant difference in *in vivo* tumor growth experiments. *In Vivo* **9**, 7–9.
19. **Heitjan DF**, Basu S (1996). Distinguishing “missing at random” and “missing completely at random”. *The American Statistician* **50**, 207–213.
20. **Heitjan DF** (1997). Bayesian interim analysis of phase II cancer clinical trials. *Statistics in Medicine* **16**, 1791–1802.
21. **Heitjan DF** (1997). Ignorability, sufficiency and ancillarity. *Journal of the Royal Statistical Society, Series B* **59**, 375–381.
22. **Heitjan DF**, Sharma D (1997). Modeling repeated-series longitudinal data. *Statistics in Medicine* **16**, 347–355.
23. **Heitjan DF** (1998). Coarse data. Pp. 125–127 in *Encyclopedia of Statistical Sciences Update Volume 2*. New York: John Wiley.
24. **Heitjan DF** (1998). Grouped data. In *Encyclopedia of Biostatistics*. New York: John Wiley.
25. **Heitjan DF** (1998). Sheppard’s corrections. In *Encyclopedia of Biostatistics*. New York: John Wiley.
26. **Heitjan DF**, Ten Have TR (1998). Missing data, types of. Pp. 408–411 in *Encyclopedia of Statistical Sciences Update Volume 2*. New York: John Wiley. Will also appear in *Methods and Applications of Statistics in the Life and Health Sciences*, edited by N. Balakrishnan.

27. **Heitjan DF** (1999). Causal inference in a clinical trial: A comparative example. *Controlled Clinical Trials* **20**, 309–318.
28. **Heitjan DF** (1999). Ignorability. Pp. 347–350 in *Encyclopedia of Statistical Sciences Update Volume 3*. New York: John Wiley.
29. **Heitjan DF** (1999). Ignorability and bias in clinical trials. *Statistics in Medicine* **18**, 2421–2434.
30. **Heitjan DF**, Moskowitz AJ, Whang W (1999). Bayesian estimation of cost-effectiveness ratios from clinical trials. *Health Economics* **8**, 191–201.
31. **Heitjan DF**, Moskowitz AJ, Whang W (1999). Problems with interval estimation of the incremental cost-effectiveness ratio. *Medical Decision Making* **19**, 9–15. (Accompanying editorial: Stinnett AA (1999). Is it really so bad to be unambiguously inefficient? The role of dominance in stochastic cost-effectiveness analysis. *Medical Decision Making* **19**, 102–103.)
32. Bagiella E, Sloan RP, **Heitjan DF** (2000). Mixed effects models in psychophysiology. *Psychophysiology* **37**, 13–20.
33. **Heitjan DF** (2000). Fieller’s method and net health benefits. *Health Economics* **9**, 327–335.
34. Bagiella E, **Heitjan DF** (2001). Predicting analysis times in randomized clinical trials. *Statistics in Medicine* **20**, 2055–2063.
35. Hoh J, **Heitjan DF**, Mérette C, Ott J (2001). Ascertainment and anticipation in family studies. *Human Heredity* **51**, 23–26.
36. Chuang J-H, Hripcsak G, **Heitjan DF** (2002). Design and analysis of controlled trials in naturally clustered environments: Implications for medical informatics. *Journal of the American Medical Informatics Association* **9**, 230–238.
37. Hripcsak G, **Heitjan DF** (2002). Measuring agreement in medical informatics reliability studies. *Journal of Biomedical Informatics* **35**, 99–110.
38. **Heitjan DF**, Li H (2004). Bayesian estimation of cost-effectiveness: An importance-sampling approach. *Health Economics* **13**, 191–198.
39. **Heitjan DF**, Kim CY, Li H (2004). Bayesian estimation of cost-effectiveness from censored data. *Statistics in Medicine* **23**, 1297–1309.

40. Ma G, **Heitjan DF** (2004). Sensitivity to nonignorability in frequentist inference. Chapter 16 in *Applied Bayesian Modeling and Causal Inference from Incomplete-Data Perspectives*, edited by Gelman A and Meng X-L. New York: John Wiley.
41. Troxel A, Ma G, **Heitjan DF** (2004). An index of local sensitivity to nonignorability. *Statistica Sinica* **14**, 1221–1237.
42. Xie H, **Heitjan DF** (2004). Sensitivity analysis of causal inference in a clinical trial subject to crossover. *Clinical Trials* **1**, 21–30.
43. Ying G-S, **Heitjan DF**, Chen T-T (2004). Nonparametric prediction of analysis times in randomized clinical trials. *Clinical Trials* **1**, 352–361.
44. Gelman A, Van Mechelen I, Verbeke G, **Heitjan DF**, Meulders M (2005). Multiple imputation for model checking: Completed-data plots with missing and latent data. *Biometrics* **61**, 74–85.
45. Ma G, Troxel AB, **Heitjan DF** (2005). An index of local sensitivity to nonignorable dropout in longitudinal modeling. *Statistics in Medicine* **24**, 2129–2150.
46. Zhang J, **Heitjan DF** (2005). Nonignorable censoring in randomized clinical trials. *Clinical Trials* **2**, 488–496.
47. Donovan JM, Elliott MR, **Heitjan DF** (2006). Predicting event times in clinical trials when treatment arm is masked. *Journal of Biopharmaceutical Statistics* **16**, 343–356.
48. Li H, **Heitjan DF** (2006). A pattern-mixture model for the analysis of censored quality-of-life data. *Statistics in Medicine* **25**, 1533–1546.
49. Ma G, Troxel AB, **Heitjan DF** (2006). Authors’ reply to comment on “An index of local sensitivity to nonignorable dropout in longitudinal modeling”. *Statistics in Medicine* **25**, 3218–3220.
50. Zhang J, **Heitjan DF** (2006). A simple sensitivity analysis tool for nonignorable coarsening: Application to dependent censoring. *Biometrics* **62**, 1260–1268.
51. Donovan JM, Elliott MR, **Heitjan DF** (2007). Predicting event times in clinical trials when randomization is masked and blocked. *Clinical Trials* **4**, 481–490.



52. Mitra N, **Heitjan DF** (2007). Sensitivity of the hazard ratio to nonignorable treatment assignment in an observational study. *Statistics in Medicine* **26**, 1398–1414.
53. Zhang J, **Heitjan DF** (2007). Impact of nonignorable coarsening on Bayesian inference. *Biostatistics* **8**, 722–743.
54. **Heitjan DF**, Asch DA, Rukstalis M, Patterson F, Lerman C (2008). Cost-effectiveness of pharmacogenetic testing to tailor smoking cessation treatment. *The Pharmacogenomics Journal* **8**, 391–399.
55. **Heitjan DF**, Guo M, Ray R, Wileyto EP, Epstein LH, Lerman C (2008). Identification of pharmacogenetic markers in smoking cessation therapy. *The American Journal of Medical Genetics: Neuropsychiatric Genetics* **147B**, 712–719.
56. Wang H, **Heitjan DF** (2008). Modeling heaping in self-reported cigarette counts. *Statistics in Medicine* **27**, 3789–3804.
57. Ying G-S, **Heitjan DF** (2008). Weibull prediction of event times in randomized clinical trials. *Pharmaceutical Statistics* **7**, 107–120.
58. Griffith SD, Shiffman S, **Heitjan DF** (2009). A method comparison study of timeline followback and ecological momentary assessment of daily cigarette consumption. *Nicotine & Tobacco Research* **11**, 1368–1373. doi:10.1093/ntr/ntp150.
59. Xie H, **Heitjan DF** (2009). Local sensitivity to nonignorability: Dependence on the assumed dropout mechanism. *Statistics in Biopharmaceutical Research* **1**, 243–257.
60. Gastonguay MR, French JL, **Heitjan DF**, Rogers JA, Ahn JE, Ravva P. (2010). Missing data in model-based pharmacometric applications: Points to consider. *The Journal of Clinical Pharmacology* **50**, 63S–74S. doi:10.1177/0091270010378409.
61. Guo M, **Heitjan DF** (2010). Multiplicity-calibrated Bayesian hypothesis tests. *Biostatistics* **11**, 473–483. doi:10.1093/biostatistics/kxq012.
62. Li Y, Wileyto EP, **Heitjan DF** (2010). Modeling smoking cessation data with alternating states and a cure fraction using frailty models. *Statistics in Medicine* **29**, 627–638. doi:10.1002/sim.3825.

63. Li Y, Wileyto EP, **Heitjan DF** (2011). Prediction of individual long-term outcomes in smoking cessation trials. *Biometrics* **67**, 1321–1329; doi:10.1111/j.1541-0420.2011.01578.x.
64. Li Y, Wileyto EP, **Heitjan DF** (2011). Statistical analysis of daily smoking status in smoking cessation clinical trials. *Addiction* **106**, 2039–2046, doi:10.1111/j.1360-0443.2011.03519.x.
65. Li Y, Mick R, **Heitjan DF** (2012). A Bayesian approach for unplanned sample sizes in phase II cancer clinical trials. *Clinical Trials* **9**, 293–302.
66. Liu T, **Heitjan DF** (2012). Sensitivity of the discrete-time Kaplan-Meier estimate to nonignorable censoring: Application in a clinical trial. *Statistics in Medicine* **31**, 2998–3010, doi:10.1002/sim.5454.
67. Wang H, Shiffman S, Griffith S, **Heitjan DF** (2012). Truth and memory: Linking instantaneous and retrospective self-reported cigarette consumption data. *Annals of Applied Statistics* **6**, 1689–1706.
68. Handorf EA, Bekelman JE, **Heitjan DF**, Mitra N (2013). Evaluating costs with unmeasured confounding: A sensitivity analysis for the treatment effect. *Annals of Applied Statistics* **7**, 2062–2080, doi:10.1214/13-AOAS665.
69. Li Y, **Heitjan DF** (2013). A note on the complementary mixture Pareto II distribution. *Communications in Statistics — Theory & Methods* **42**, 201–213, doi:10.1080/03610926.2011.581787.
70. Wileyto EP, Li Y, Chen J, **Heitjan DF** (2013). Assessing the fit of parametric cure models. *Biostatistics* **14**, 340–350, doi:10.1093/biostatistics/kxs043.
71. Ying G-S, **Heitjan DF** (2013). Prediction of event times in the REMATCH Trial. *Clinical Trials* **10**, 197–206, doi:10.1177/1740774512470314.
72. **Heitjan DF**, Ge Z, Ying G-S (2015). Real-time prediction of clinical trial enrollment and event counts: A review. *Contemporary Clinical Trials* **45**, 26–33, doi:10.1016/j.cct.2015.07.010.
73. Li Y, Mick R, **Heitjan DF** (2015). Suspension of accrual in phase II cancer clinical trials. *Clinical Trials* **12**, 128–138, doi:10.1177/1740774514562029.

74. Griffith SD, Shiffman S, Li Y, **Heitjan DF** (2016). Model-based imputation of latent cigarette counts using data from a calibration study. Published online, *International Journal of Methods in Psychiatric Research* **25**, 112–122, doi:10.1002/mpr.1468.
75. Allen C McC, Griffith SD, Shiffman S, **Heitjan DF** (2017). Proximity and gravity: Modeling heaped self-reports. *Statistics in Medicine* **36**, 3200–3215, doi:10.1002/sim.7327.
76. Bender S, **Heitjan DF** (2017). Ignorability conditions for frequentist nonparametric analysis of conditional distributions with incomplete data. *Communications in Statistics — Theory & Methods* **46**, 5252–5264, doi:10.1080/03610926.2015.1099673.
77. **Heitjan DF** (2017). Coarse data. *Wiley StatsRef: Statistics Reference Online*, 1–3. Update based on original article by Daniel Heitjan. John Wiley & Sons, Ltd.
78. Ying G-S, Zhang Q, Lan Y, Li Y, **Heitjan DF** (2017). Cure modeling in real-time prediction: How much does it help? *Contemporary Clinical Trials* **59**, 30–37, doi:10.1016/j.cct.2017.05.012.
79. Lan Y, **Heitjan DF** (2018). Adaptive parametric prediction of event times in clinical trials. *Clinical Trials* **15**, 159–168, doi:10.1177/1740774517750633.
80. Ge Z, **Heitjan DF**, Gerber DE, Xuan L, Pruitt SL (2018). Estimating lead-time bias in lung cancer diagnosis of patients with previous cancers. *Statistics in Medicine* **37**, 2516–2529, doi:10.1002/sim.7691.
81. Mokdad AA, Xie X-J, Zhu H, Gerber DE, **Heitjan DF** (2018). Statistical justification of expansion cohorts in phase I cancer trials. *Cancer* **124**, 3339–3345, doi:10.1002/ncr.31577. (With invited discussion by Dahlberg SE, Gray RJ.)
82. Xie H, Gao W, Xing B, **Heitjan DF**, Hedeker D, Yuan C (2018). Measuring the impact of nonignorable missingness using the R package `isni`. *Computer Methods & Programs in Biomedicine* **164**, 207–220, doi:10.1016/j.cmpb.2018.06.014.
83. Handorf EA, **Heitjan DF**, Bekelman JE, Mitra N (2019). Estimating cost-effectiveness from claims and registry data with measured and unmeasured

- confounders. *Statistical Methods in Medical Research* **28**, 2227–2242, doi:10.1177/0962280218759137.
84. Lan Y, Tang G, **Heitjan DF** (2019). Statistical modeling and prediction of clinical trial recruitment. *Statistics in Medicine* **38**, 945–955.
85. Li S, Xie X-J, **Heitjan DF** (2020). Flexible, rule-based dose escalation: The cohort-sequence design. *Contemporary Clinical Trials Communications*. doi:10.1016/j.conctc.2020.100541.
86. Chen X, **Heitjan DF**, Greil G, Jeon-Slaughter H (2021). Estimating the optimal timing of surgery from observational data. *Biometrics* **77**, 729–739, doi:10.1111/biom.13311.
87. Chen X, **Heitjan DF**, Greil G, Jeon-Slaughter H (2021). Estimating the optimal timing of surgery by imputing potential outcomes. *Statistics in Medicine* **40**, 6900–6917, doi:10.1002/sim.9217.
88. Li S, **Heitjan DF** (2021). Generalizing clinical trial results to a target population. *Statistics in Biopharmaceutical Research* doi:10.1080/19466315.2021.1942975.
89. Chen H, **Heitjan DF** (2022). Analysis of local sensitivity to nonignorability with missing outcomes and predictors. *Biometrics* **78**, 1342–1352, doi:10.1111/biom.13532.
90. Chen H, **Heitjan DF** (2023). Sensitivity of estimands in clinical trials with imperfect compliance. *International Journal of Biostatistics*, <https://doi.org/10.1515/ijb-2022-0105>.
91. Jing B, Qian Y, **Heitjan DF**, Xie H (2023). Tutorial: Assessing the impact of nonignorable missingness on regression analysis using Index of Local Sensitivity to Nonignorability. *Psychological Methods*, <https://doi.org/10.1037/met0000616>.
92. Yun J, Filardo G, Ahuja V, Bowen ME, **Heitjan DF** (2023). Predicting hospital readmission in Medicaid patients with diabetes using administrative and claims data. *American Journal of Managed Care* **29(8)**, <https://doi.org/10.37765/ajmc.2023.89409>.

93. Yun J, Ahuja V, **Heitjan DF** (2023). Predicting hospital readmission in Medicaid patients with heart failure using administrative and claims data. *Perspectives in Health Information Management* **20(3)**, <https://perspectives.ahima.org>.
94. **Heitjan DF**, Wang Y, Yun J (2024). Predicting hospital readmission in Medicaid patients with chronic obstructive pulmonary disease. Accepted for publication, *Respiratory Care*, 2024.01.01.

### Papers Published or In Press—Other

95. Ojo-Amaize E, Nishanian P, Keith DE Jr., Houghton RL, **Heitjan D**, Fahey JL, Giorgi JV (1987). Antibodies to human immunodeficiency virus in human sera induce cell-mediated lysis of human immunodeficiency virus-infected cells. *Journal of Immunology* **139**, 2458–2463.
96. Tobler A, Munker R, **Heitjan D**, Koeffler HP (1987). *In vitro* interaction of recombinant tumor necrosis factor  $\alpha$  and all-*trans*-retinoic acid with normal and leukemic hematopoietic cells. *Blood* **70**, 1940–1946.
97. Koeffler HP, **Heitjan D**, Mertelsmann R, Kolitz JE, Schulman P, Itri L, Gunter P, Besa E (1988). Randomized study of 13-*cis*-retinoic acid *v* placebo in the myelodysplastic disorders. *Blood* **71**, 703–708.
98. Martínez-Maza O, Mitsuyasu RT, Miles SA, Giorgi JV, **Heitjan DF**, Sherwin SA, Fahey JL (1989).  $\gamma$ -interferon-induced monocyte major histocompatibility complex class II antigen expression in individuals with acquired immune deficiency syndrome. *Cellular Immunology* **123**, 316–324.
99. Ojo-Amaize E, Nishanian PG, **Heitjan DF**, Rezai A, Esmail I, Kornis E, Detels R, Fahey J, Giorgi JV (1989). Serum and effector-cell antibody-dependent cellular cytotoxicity (ADCC) activity remains high during human immunodeficiency virus (HIV) disease progression. *Journal of Clinical Immunology* **9**, 454–461.
100. Gascho JA, Copenhaver GL, **Heitjan DF** (1990). Systolic thickening increases from subepicardium to subendocardium. *Cardiovascular Research* **24**, 777–780.
101. Santen RJ, Manni A, English HF, **Heitjan D** (1990). Androgen-primed chemotherapy — experimental confirmation of efficacy. *Journal of Steroid Biochemistry & Molecular Biology* **37**, 1115–1120.

102. Wengrovitz M, Atnip RG, Gifford RRM, Neumyer MM, **Heitjan DF**, Thiele BL (1990). Wound complications of autogenous subcutaneous infrainguinal arterial bypass surgery: Predisposing factors and management (with discussion). *Journal of Vascular Surgery* **11**, 156–163.
103. English HF, **Heitjan DF**, Lancaster S, Santen RJ (1991). Beneficial effects of androgen-primed chemotherapy in the Dunning R3327 G model of prostatic cancer. *Cancer Research* **51**, 1760–1765.
104. Houts PS, Wojtkowiak SL, Simmonds MA, Weinberg GB, **Heitjan DF** (1991). Using a state cancer registry to increase screening behaviors of sisters and daughters of breast cancer patients. *American Journal of Public Health* **81**, 386–388.
105. Williams GD, Palmer C, **Heitjan DF**, Smith MB (1992). Allopurinol preserves cerebral energy metabolism during perinatal hypoxia-ischemia: A  $^{31}\text{P}$  NMR study in unanesthetized immature rats. *Neuroscience Letters* **144**, 103–106.
106. Williams GD, Palmer C, Roberts RL, **Heitjan DF**, Smith MB (1992).  $^{31}\text{P}$  NMR spectroscopy of cerebral hypoxic-ischemic injury: A model to evaluate neuroprotective drugs in neonates. *NMR in Biomedicine* **5**, 145–153.
107. Yager JY, **Heitjan DF**, Towfighi J, Vannucci RC (1992). Effect of insulin-induced and fasting hypoglycemia on perinatal hypoxic-ischemic brain damage. *Pediatric Research* **31**, 138–142.
108. Mawhinney H, Spector SL, **Heitjan D**, Kinsman RA, Dirks JF, Pines I (1993). As-needed medication use in asthma. Usage patterns and patient characteristics. *Journal of Asthma* **30**, 61–71.
109. Palmer C, Towfighi J, Roberts RL, **Heitjan DF** (1993). Allopurinol administered *after* inducing hypoxia-ischemia reduces brain injury in 7 day old rats. *Pediatric Research* **33**, 405–411.
110. Manni A, Badger B, Wei L, Zaenglein A, Grove R, Khin S, **Heitjan DF**, Shimasaki S, Ling N (1994). Hormonal regulation of IGF-II and IGF binding protein expression by breast cancer cells *in vivo*: Evidence for stromal-epithelial interactions. *Cancer Research* **54**, 2934–2942.
111. Mujsce DJ, Towfighi J, **Heitjan DF**, Vannucci RC (1994). Differences in intra-ischemic temperature influence neurologic outcome after hypothermic circulatory arrest in newborn dogs. *Stroke* **25**, 1433–1442.

112. Sautter RL, Jones S, Weber DI, Lebar WD, **Heitjan DF**, Kopreski MMC, Curcio FD (1994). The prevalence of hepatitis C virus antibody in patients with sexually transmitted diseases (STD) attending a Harrisburg, PA STD clinic. *Infectious Disease in Obstetrics & Gynecology* **1**, 269–274.
113. Towfighi J, Housman C, Vannucci RC, **Heitjan DF** (1994). Effect of unilateral perinatal hypoxic-ischemic brain damage on the gross development of the opposite hemisphere. *Biology of the Neonate* **65**, 108–118.
114. Towfighi J, Housman C, **Heitjan DF**, Vannucci RC, Yager JY (1994). The effect of focal cerebral cooling on perinatal hypoxic-ischemic brain damage. *Acta Neuropathologica* **87**, 598–604.
115. Cataltepe O, Barron TF, **Heitjan DF**, Vannucci RC, Towfighi J (1995). Effect of hypoxia/ischemia on bicuculline-induced seizures in immature rats: Behavioral and electrocortical phenomena. *Epilepsia* **36**, 396–403.
116. Cataltepe O, Vannucci RC, **Heitjan DF**, Towfighi J (1995). Effect of status epilepticus on hypoxic-ischemic brain damage in the immature rat. *Pediatric Research* **38**, 251–257.
117. Manni A, Wechter R, Wei L, **Heitjan D**, Demers L (1995). Phenotypic features of breast cancer cells overexpressing ornithine-decarboxylase. *Journal of Cellular Physiology* **163**, 129–136.
118. Masamura S, Santner SJ, **Heitjan DF**, Santen RJ (1995). Estrogen deprivation causes estradiol hypersensitivity in human breast cancer cells. *Journal of Clinical Endocrinology & Metabolism* **80**, 2918–2925.
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204. Hamilton DA, Mahoney MC, Novalen M, Chenoweth MJ, **Heitjan DF**, Lerman C, Tyndale RF, Hawk LW Jr. (2015). Test-retest reliability and stability

- of the nicotine metabolite ratio among treatment-seeking smokers. Published on-line, *Nicotine & Tobacco Research* **17**, 1505–1509, doi:10.1093/ntr/ntv031.
205. Kennedy GT, Okusanya OT, Keating JJ, **Heitjan DF**, Deshpande C, Litzky LA, Albelda SM, Drebin JA, Nie S, Low PS, Singhal S (2015). The optical biopsy: A novel method for rapid intraoperative diagnosis of primary pulmonary adenocarcinomas. *Annals of Surgery* **262**, 602–609.
206. Lerman C, Schnoll RA, Hawk LW, Cinciripini P, George TP, Wileyto EP, Swan GE, Benowitz NL, **Heitjan DF**, Tyndale RF for the PGRN-PNAT Research Group (2015). Use of the nicotine metabolite ratio as a genetically informed biomarker of response to nicotine patch or varenicline for smoking cessation: A randomized, double-blind, placebo-controlled trial. *Lancet Respiratory Medicine* **3**, 131–138, doi:10.1016/S2213-2600(14)70294-2.
207. Luskin MR, Heil DS, Tan KS, Choi S, Stadtmauer EA, Schuster, SJ, Porter DL, Vonderheide RH, Bagg A, **Heitjan DF**, Tsai DE, Reshef R (2015). The impact of EBV status on characteristics and outcomes of post-transplantation lymphoproliferative disorder. *American Journal of Transplantation* **15**, 2665–2673, doi:10.1111/ajt.13324.
208. Nath K, Nelson DS, **Heitjan DF**, Leeper DB, Zhou R, Glickson JD (2015). Lonidamine induces intracellular tumor acidification and ATP depletion in human breast, prostate and ovarian cancer xenografts and potentiates response to doxorubicin. *NMR in Biomedicine* **28**, 281–290, doi:10.1002/nbm.3240.
209. Nath K, Nelson DS, **Heitjan DF**, Zhou R, Leeper DB, Glickson JD (2015). Effects of hyperglycemia on lonidamine-induced acidification and de-energization of human melanoma xenografts and sensitization to melphalan. *NMR in Biomedicine* **28**, 395–403, doi:10.1002/nbm.3260.
210. Okusanya OT, DeJesus EM, Jiang JX, Judy RP, Venegas OG, Deshpande CG, **Heitjan DF**, Nie S, Low PS, Singhal S (2015). Intraoperative molecular imaging can identify lung adenocarcinomas during pulmonary resection. *Journal of Thoracic & Cardiovascular Surgery* **150**, 28–35, doi:10.1016/j.jtcv.2015.05.014.
211. Tyndale RF, Zhu AZX, George TP, Cinciripini P, Hawk LW Jr., Schnoll RA, Swan GE, Benowitz NL, **Heitjan DF**, Lerman C for the PGRN-PNAT Research Group (2015). Lack of associations of *CHRNA5-A3-B4* genetic variants

- with smoking cessation treatment outcomes in Caucasian smokers despite associations with baseline smoking. *PLoS One* **10**, doi:10.1371/journal.pone.0128109.
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213. Keefe SM, Hoffman-Censits J, Cohen RB, Mamtani R, **Heitjan D**, Eliasoff S, Nixon A, Turnbull B, Garmey EG, Gunnarsson O, Walicki M, Ciconte J, Jayaraman L, Senderowicz A, Tellez AB, Hennessy M, Piscitelli A, Vaughn D, Smith A, Haas NB (2016). Efficacy of the nanoparticle-drug conjugate CRLX101 in combination with bevacizumab in metastatic renal cell carcinoma: Results of an investigator-initiated phase I-IIa clinical trial. *Annals of Oncology* **27**, 1579–1585, doi:10.1093/annonc/mdw188.
214. Sterman DH, Alley E, Stevenson JP, Friedberg J, Metzger S, Recio A, Moon EK, Haas AR, Vachani A, Katz SI, Sun J, **Heitjan DF**, Hwang WT, Litzky L, Yearley JH, Tan KS, Papasavvas E, Kennedy P, Montaner LJ, Cengel KA, Simone CB II, Culligan M, Langer CJ, Albelda SM (2016). Pilot and feasibility trial evaluating immuno-gene therapy of malignant mesothelioma using intrapleural delivery of adenovirus-IFN $\alpha$  combined with chemotherapy. *Clinical Cancer Research* **22**, 3791–3800, doi:10.1158/1078-0432.CCR-15-2133.
215. Mokdad AA, Yopp AC, Polanco PM, Mansour JC, Reznik SI, Choti MA, Minter RR, Wang SC, **Heitjan DF**, Porembka MR (2017). Adjuvant chemotherapy v. postoperative observation following preoperative chemoradiotherapy and resection in gastroesophageal cancer: A propensity score-matched analysis. *JAMA Oncology* doi:10.1001/jamaoncol.2017.2805. (Accompanying editorial: Smyth EC, Cunningham D (2017). Adjuvant chemotherapy following neoadjuvant chemotherapy plus surgery for patients with gastroesophageal cancer — Is there room for improvement? *JAMA Oncology* doi:10.1001/jamaoncol.2017.2792.)
216. Nath K, Roman J, Nelson DS, Guo, L, Lee S-C, Muriuki K, Orlovskiy S, Leeper DB, **Heitjan DF**, Blair IA, Putt ME, Glickson JD (2018). Lonidamine selectively acidifies, de-energizes, and sensitizes WM983B human melanoma

- xenografts to doxorubicin chemotherapy. *Scientific Reports* **8**, 14654, doi:10.1038/s41598-018-33019-4.
217. Santen RJ, Jewell CM, Yue W, **Heitjan DF**, Raff H, Katen KS, Cidlowski JA (2018). Glucocorticoid receptor mutations and hypersensitivity to endogenous and exogenous glucocorticoids. *Journal of Clinical Endocrinology & Metabolism* **103**, 3630–3639, doi:10.1210/jc.2018-00352.
218. Santen RJ, **Heitjan DF**, Gompel A, Lumsden MA, Pinkerton JAV, Davis SR, Stuenkel CA (2020). Underlying breast cancer risk and menopausal hormonal therapy. *Journal of Clinical Endocrinology & Metabolism* **105**, e2299–e2307, doi:10.1210/clinem/dgaa073.
219. Santen RJ, **Heitjan DF**, Gompel A, Lumsden MA, Pinkerton JAV, Davis SR, Stuenkel CA (2020). Approach to managing a postmenopausal patient. *Journal of Clinical Endocrinology & Metabolism* **105**, doi:10.1210/clinem/dgaa623.
220. Balagopal A, Morgan H, Dohopolski M, Timmerman R, Shan J, **Heitjan DF**, Liu W, Nguyen D, Hannan R, Garant A, Desai N, Jiang S (2021). PSA-Net: Deep learning–based physician style–aware segmentation network for postoperative prostate cancer clinical target volumes. *Artificial Intelligence in Medicine* **121**, doi.org/10.1016/j.artmed.2021.102195
221. Pruitt SL, Gerber DE, Zhu H, **Heitjan DF**, Maddineni B, Xiong D, Singal AG, Tavvakoli A, Halm EA, Murphy CC (2021). Survival of patients newly diagnosed with colorectal cancer and with a history of previous cancer. *Cancer Medicine* **10**, 4752–4767, doi:10.1002/cam4.4036.
222. Pruitt SL, Zhu H, **Heitjan DF**, Rahimi A, Maddineni B, Tavvakoli A, Halm EA, Gerber DE, Xiong D, Murphy CC (2021). Survival of women diagnosed with breast cancer and who have survived a previous cancer. *Breast Cancer Research & Treatment*, doi:10.1007/s10549-021-06122-w.
223. Tsai S, Nguyen H, Ebrahimi R, Barbosa MR, Ramanan B, **Heitjan DF**, Hastings JL, Modrall JG, Jeon-Slaughter H (2021). COVID-19-associated mortality and cardiovascular disease outcomes among U.S. women veterans. *Scientific Reports* **11**, 8497, doi:10.1038/s41598-021-88111-z.
224. Pruitt SL, Tavakkoli A, Zhu H, **Heitjan DF**, Gerber DE, Singal AG, Halm EA, Beg MS, Maddineni B, Kansagra AJ, Murphy CC (2023). Survival of

cancer survivors with a new pancreatic cancer diagnosis. *Cancer Medicine* **12**, 200–212, doi:10.1002/cam4.4903.

225. Turer CB, Park JJ, Gupta OT, Ramirez C, Basit MA, **Heitjan DF**, Barlow SE (2023). Electronic phenotypes to distinguish clinician attention to high body mass index, hypertension, lipid disorders, fatty liver, and diabetes in pediatric primary care: Diagnostic accuracy of electronic phenotypes compared to masked comprehensive chart review. *Pediatric Obesity*, 2023;e13066, doi:10.1111/ijpo.13066.

## Reviews, Discussions, Editorials, & Committee Reports

1. **Heitjan DF** (1990). Review of *Interpreting Data* by Alan J. B. Anderson. *Statistics in Medicine* **9**, 858.
2. **Heitjan DF** (1996). Review of *Observational Studies* by Paul R. Rosenbaum. *SIAM Review* **38**, 529.
3. **Heitjan DF** (1997). Annotation: What can be done about missing data? Approaches to imputation. *American Journal of Public Health* **87**, 548–550.
4. **Heitjan DF** (1998). Review of *The EM Algorithm and Extensions* by Geoffrey J. McLachlan and Thriyambakam Krishnan. *Statistics in Medicine* **17**, 1187.
5. **Heitjan DF** (1998). Analysis of longitudinal binary data from multiphase sampling — Discussion on the papers by Forster and Smith and Clayton *et al.* *Journal of the Royal Statistical Society, Series B* **60**, 89–102.
6. **Heitjan DF** (2009). Review of *Missing Data in Longitudinal Studies: Strategies for Bayesian Modeling and Sensitivity Analysis* by Michael J. Daniels and Joseph W. Hogan. *Biometrics* **65**, 328.
7. **Heitjan DF** (2011). Biology, models and the analysis of tumor xenograft experiments. *Clinical Cancer Research* **17**, 949–952; doi:10.1158/1078-0432.CCR-10-3279.
8. **Heitjan DF** (2011). Incomplete data: What you don't know might hurt you. *Cancer Epidemiology, Biomarkers & Prevention* **8**, 1567–1570; doi:10.1158/1055-9965.EPI-11-0505.

9. Committee on the Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule, Board on Population Health & Public Health Practice, Institute of Medicine of the National Academies (2013). *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies*. Washington, DC: The National Academies Press.
10. **Heitjan DF** (2016). Review of *Handbook of Missing Data Methodology* by Geert Molenberghs, Garrett Fitzmaurice, Michael G. Kenward, Anastasios Tsiatis, and Geert Verbeke (editors). *Journal of the American Statistical Association* **111**, 443; doi:10.1080/01621459.2016.1154360.
11. **Heitjan DF** (2017). Commentary on Mason *et al.* *Clinical Trials* **14**, 368–369, doi:10.1177/1740774517711443.
12. Begg C, Gönen M, **Heitjan DF** (2020). Editorial: Clinical trial design in the era of COVID-19. *Clinical Trials* **17**, 465–466; doi:10.1177/1740774520940230.
13. **Heitjan DF**(2024). Comment on Fay and Li. *Clinical Trials*, doi:10.1177/17407745241243307.
14. Chen H, **Heitjan DF**(2024). Response to Comments on 'Sensitivity of estimands in clinical trials with imperfect compliance'. In press, *International Journal of Biostatistics*, 2024.03.27.

## Books

1. Ng HK, **Heitjan DF**, editors (2022). *Recent Advances on Sampling Methods and Educational Statistics: In Honor of S. Lynne Stokes*. Springer.

## Special Invited Lectures

1. Projecting survival and lifetime costs from short-term smoking cessation trials. Distinguished Speaker series, Department of Biostatistics, UT M. D. Anderson Cancer Center, Houston, TX, 15.12.
2. Measuring sensitivity to nonignorable incompleteness. Distinguished Lecturer series, Department of Statistical Sciences & Operations Research and Department of Biostatistics, Virginia Commonwealth University, Richmond, VA, 20.02.

3. Real-time prediction in clinical trials: A statistical history of REMATCH. The Woolson Lecture. Department of Statistics and Department of Biostatistics, University of Iowa, Iowa City, IA, 23.02.

## Major Editorial Service

- Statistical Consultant, *Annals of Internal Medicine*, 1994–2009.
- Associate Editor, Applications & Case Studies, *Journal of the American Statistical Association*, 1995–2002.
- Member, Editorial Board, *Statistics in Medicine*, 1996–2005.
- Statistical Editor, *Journal of the National Cancer Institute*, 2001–2017.
- Associate Editor, *Statistics in Biopharmaceutical Research*, 2006–2015.
- Associate Editor, *Clinical Trials*, 2008–2020.
- Associate Editor, *Annals of Applied Statistics*, 2014–2021.
- Senior Statistical Editor, *Circulation*, 2016–2018.
- Deputy Editor, *Clinical Trials*, 2020–.

## Doctoral Students Trained

1. Nandita Mitra, PhD; Columbia, 2001. *Analyzing Data from Non-Randomized Studies using Propensity Score Methodology*. Professor, Department of Biostatistics, Epidemiology & Informatics, University of Pennsylvania.
2. Guoguang Julie Ma; PhD, Columbia, 2001; winner of John Van Ryzin Award for best Columbia Biostatistics PhD dissertation. *Measuring Local Sensitivity to Nonignorability*. Vice President of Biometrics, AlloVir.
3. Hui Xie, PhD; Columbia, 2003. *An Index of Sensitivity to Nonignorability: Extensions and Applications*. Professor, Maureen & Milan Ilich/Merck Chair in Statistics for Arthritis & Musculoskeletal Diseases, Faculty of Health Sciences, Simon Fraser University.



4. Jiameng Zhang, PhD; University of Pennsylvania, 2004; winner of Saul Winegrad Award for Outstanding Dissertation; first PhD awarded in Biostatistics at the University of Pennsylvania. *Sensitivity Analysis of Coarsened Data*. Senior Director and Senior Principal Statistical Scientist, Genentech, Inc.
5. Gui-shuang Ying, PhD; University of Pennsylvania, 2004. *Prediction of Event Times in Randomized Clinical Trials*. Carolyn F. Jones Professor, Department of Ophthalmology, University of Pennsylvania.
6. Huiling Li, DrPH; Columbia, 2004; winner of John Fertig Award for best Columbia Biostatistics DrPH dissertation. *Analysis of Incomplete Health-Related Quality of Life Data in the REMATCH Trial*. VP, Head of Biometrics, Iovance Biotherapeutics.
7. Clara Yuri Kim, PhD; University of Pennsylvania, 2005. *Bayesian Cost-Effectiveness Analysis*. Lead Mathematical Statistician, CDER, FDA.
8. J. Mark Donovan, PhD; University of Pennsylvania, 2006; winner of Saul Winegrad Award for Outstanding Dissertation. *Predicting Event Times in Clinical Trials: Effects of Masking and Blocking*. Senior Director, Bristol-Myers Squibb. (Co-advisor with Michael Elliott.)
9. Tao Liu, PhD; University of Pennsylvania, 2006. *Measuring Sensitivity to Non-ignorable Censoring in Nonparametric and Semiparametric Survival Modeling*. Associate Professor, Department of Biostatistics, Brown University.
10. Carin Joo Kim, PhD; University of Pennsylvania, 2008. *Statistical Design of Tumor Xenograft Studies*. Mathematical Statistician, CDER, FDA.
11. Mengye Guo, PhD; University of Pennsylvania, 2009. *Bayesian Methods for Identifying Genetic Predictors in Smoking Cessation Studies*. Senior Data Scientist, Microsoft.
12. Hao Wang, PhD; University of Pennsylvania, 2009. *Statistical Methods for Heaped Data*. Associate Professor, Division of Oncology Biostatistics, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University.
13. Yimei Li, PhD; University of Pennsylvania, 2010. *Statistical Modeling of Data from Smoking Cessation Trials*. Associate Professor, Departments of Biostatistics, Epidemiology & Informatics and Pediatrics, University of Pennsylvania; Research Biostatistician, Division of Oncology, Children's Hospital of Philadelphia.

14. Elizabeth A. Handorf, PhD; University of Pennsylvania, 2012. *Statistical Methods for Cost-Effectiveness Analysis Using Observational Data*. Associate Professor, Biostatistics & Bioinformatics Facility, Fox Chase Cancer Center. (Co-advisor with Nandita Mitra.)
15. Sandra D. Griffith, PhD; University of Pennsylvania, 2012. *Statistical Methods for Heaped Data with Application to Smoking Cessation Research*. Principal Methodologist, Flatiron Health.
16. Chelsea McCarty Allen, PhD; Southern Methodist University, 2016. *Modeling of Heaped Cigarette Count Data*. Research Associate Biostatistician, Study Design & Biostatistics Center, University of Utah Health.
17. Yu Lan, PhD; Southern Methodist University, 2017. *Real-Time Prediction in Clinical Trials*. Statistical Consultant, Farallon Capital.
18. Zhiyun Ge, PhD; Southern Methodist University, 2018. *Statistical Analysis in Cancer Survivorship*. Data Scientist, Meta.
19. Shuang Nancy Li, PhD; Southern Methodist University, 2019. *Clinical Trial Design and Analysis*. Senior Manager, Gilead.
20. Heng Chen, PhD; Southern Methodist University, 2020. *Sensitivity Analysis for Incomplete Data and Causal Inference*. Manager in Biostatistics, Gilead Biosciences.
21. Xiaofei Chen, PhD; Southern Methodist University, 2020. *Causal Inference and Prediction on Observational Data With Survival Outcomes*. Senior Statistician, AstraZeneca.
22. Jaehyeon Yun, PhD; Southern Methodist University, 2022. *Dynamic Prediction for Alternating Recurrent Events Using a Semiparametric Joint Frailty Model*. Data Scientist, Samsung.
23. Hang Nguyen, PhD; Southern Methodist University, 2023. *Statistical Methods for Evaluating Treatment Effects from Surgical Registry Data*. Biostatistician, Stat4ward.
24. MaryLena Bleile, PhD; Southern Methodist University, 2023. *Optimizing Pre-Clinical Tumor Xenograft Experiments Using Bayesian Linear and Non-Linear Mixed Modelling and Reinforcement Learning*. Post-doctoral fellow, Memorial Sloan Kettering Cancer Center.

25. Jenny Park, PhD; Southern Methodist University, 2023. *Contributions to Causal Inference in Observational Data*. Mathematical statistician, CDRH, FDA.

## Teaching: University Courses

- University of Chicago
  - Statistics 200 (Elementary Statistics), Spring 1985.
- UCLA
  - Biomathematics 170A (Introductory Biomathematics), Fall 1986, 1987.
- Pennsylvania State University
  - Behavioral Science 508 (Experimental Design), Spring 1989, 1991, 1993.
  - Statistics 580 (Statistical Consulting), Fall 1991–Spring 1992. With Janice Derr and James Rosenberger.
- Columbia University
  - Biostatistics P6104 (Introduction to Biostatistical Methods), Spring 1996, Fall 1996, 1999.
  - Biostatistics P8116/Statistics W4327 (Design of Medical Experiments), Spring 1997, 1998, 1999, 2001, 2002.
- University of Pennsylvania
  - Biostatistics 782 (Incomplete Data), Spring 2003, 2005.
  - Biostatistics 621/Statistics 512 (Inference I), Spring 2004.
  - Biostatistics 659 (Design of Biomedical Studies), Spring 2006 (with Kevin Lynch), 2007, 2008, 2009, 2011.
  - Epidemiology 645 (Cancer Epidemiology, Biomarkers, and Prevention), Summer 2008, 2009, 2010, 2012, 2013 (coordinated by Kathryn Schmitz; gave one lecture on statistical design of cancer clinical trials).
  - Biostatistics 657 (Design of Biomedical Studies I), Spring 2012.
  - Biostatistics 799 (Advanced Topics in Biostatistics — Incomplete Data), Spring 2012, Spring 2013.

- Biostatistics 620 (Probability), Fall 2013, Fall 2014.
- SMU/UTSW
  - Statistics 6397 (Clinical Trials): Fall 2015, Fall 2016, Fall 2018, Fall 2020, Fall 2022.
  - Center for Translational Medicine 5301 (Clinical Research Design & Analysis): Fall 2015.
  - Center for Translational Medicine 5116 (Clinical Research Protocol Development): Spring 2016.
  - Statistics 6360 (Epidemiology): Spring 2016, Spring 2017, Spring 2018, Spring 2019, Spring 2020, Spring 2021, Spring 2023.
  - Statistics 7331 (Modeling Longitudinal & Incomplete Data): Fall 2017, Fall 2019, Fall 2021.
  - MB 5108 (Advanced Data Analysis & Statistical Learning): Spring 2019, Spring 2020, Spring 2021.

## Data Monitoring & Project Review Boards

- Trials of Amiloride in cystic fibrosis, Glaxo Inc.: 1993–1994.
- Study and Treatment of Post-Lyme Disease (STOP-LD), NIAID: 1997–2001.
- Trials in GVHD, Protein Design Labs: 2002.
- MicroMed Bridge to Transplantation Study, Columbia University: 2004–2006.
- Trials of Apisol for reducing cholesterol, Wyeth Consumer Healthcare: 2004–2005.
- Carotid Atherosclerosis Progression Trial Investigating Vascular ACAT Inhibition Treatment Effects (CAPTIVATE), Sankyo Pharma Development: 2004–2005.
- Intervention to Improve Memory in Patients with MS (AIMS 2), SUNY-Stony Brook and NIH (NCMR): 2004–2010.
- HeartMate II Pivotal Trial, Thoratec, Inc.: 2005–2009.
- MicroMed Destination Study, Columbia University: 2005.

- Obesity clinical program, Merck & Co., Inc.: 2005–2008.
- A clinical trial of aspirin and simvastatin for the treatment of patients with pulmonary arterial hypertension (ASA-STAT), NHLBI and Columbia University: 2006–2008.
- Cancer clinical program, Centocor: 2006–2009.
- Diabetes and Periodontal Therapy Trial, NIDCR: 2008–2013.
- Advisory Board, “Functional Bowel Disorders in Chinese Medicine”, International Center for Research on Complementary & Alternative Medicine, University of Maryland, Baltimore: 2010.
- External Advisory Board, SPORE in Gastrointestinal Cancer, University of Michigan: 2011–.
- External Scientific Advisory Board, Albert Einstein Cancer Center, Albert Einstein College of Medicine of Yeshiva University: 2012.
- External Scientific Advisory Board, Herbert Irving Comprehensive Cancer Center, Columbia University: 2012.
- Clinical Trials Oversight Committee, Pediatric Research Foundation: 2013–2019.
- DSMB statistician for trials of stem cell transplant in pediatric hematology, New York Medical College: 2013–.
- External Scientific Advisory Board, Moores Cancer Center, University of California San Diego: 2013.
- DSMB Statistician, Heartmate III IDE Study, Thoratec/St. Jude/Abbott: 2014–2019.
- DSMB Statistician and Chair, study of margetuximab plus chemotherapy v. trastuzumab in metastatic breast cancer, MacroGenics, Inc.: 2015–2022.
- DSMB Statistician, MAHOGANY — Study of margetuximab plus INCMGA00012 and chemotherapy or MGD013 and chemotherapy in metastatic or locally advanced, treatment-naïve, HER2-positive gastric or gastroesophageal junction cancer, MacroGenics, Inc.: 2019–2023.

- DSMB Statistician, ARIES HM3 — Antiplatelet removal and hemocompatibility events with the HeartMate 3 pump, Abbott: 2019–2023.
- DMC Statistician, INNOVATE — Investigation of a novel, magnetically levitated VAD for the treatment of refractory left ventricular heart failure, Brio-Health Solutions: 2024–.

## Expert Testimony

- Deposition and expert testimony on behalf of Biogen Idec, arbitration proceeding: 2008.
- *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*: Deposition and expert testimony on behalf of Braintree in US District Court of New Jersey Civil Action No. 3:11-cv-01341 (PGS) (LHG): 2014–2015.
- *Elenza, Inc. v. Alcon Laboratories Holding Corporation, Alcon Research, Ltd., and Novartis AG*: Deposition and expert testimony on behalf of Alcon in Superior Court of Delaware N14C-03-185 MMJ CCLD: 2016–2017.
- *Noven Pharmaceuticals, Inc. v. Actavis Laboratories, UT, Inc.*: Deposition and expert testimony on behalf of Noven in US District Court of Delaware Civil Action: 2018–2019.
- Deposition on behalf of plaintiffs, Women’s Talc Project: 2019–.
- *Guardant Health, Inc. v. Natera, Inc.*: Deposition (twice) on behalf of plaintiff, 2022–.

## Legal Consulting

- *Fallick v. Nationwide Mutual Insurance Co. and Nationwide Life Insurance Co.*: Consultation on statistical methods in summarizing charge data, for the defendant: 1997.
- *Kern v. University of Notre Dame* and *Goltz v. University of Notre Dame*: Analysis of data on alleged sex discrimination in employment practices, for the defendant: 1997.
- Consultant to Next Nutrition in a matter regarding advertising claims: 1999.

- Consultant to attorney for the Consumer Healthcare Products Association in a matter regarding drug safety: 2002.
- *Dr. Reddy's Laboratories v. Eli Lilly & Co.*: Consultation in a patent infringement case, for the plaintiff: 2002.
- Consultant to attorney for McNeil Pharmaceuticals in a matter regarding advertising claims: 2003.
- Consultant to attorney for Discus Dental: 2004.
- Consultant to attorney for Whittier Law School, accreditation proceeding: 2005.
- Expert consultation on behalf of GlaxoSmithKline, product liability litigation: 2010.
- Expert consultation on behalf of Amgen: 2014–2015.
- *Pfizer, Inc. v. Johnson & Johnson and Janssen Biotech, Inc.*: Statistical consultation on behalf of plaintiff: 2020–2022.
- *Actelion Pharmaceuticals Ltd. et al. v. Bristol-Myers Squibb Co. et al.*: Statistical consultation on behalf of defendant, 2022–.
- *United States v. Gilead Sciences, Inc. and Gilead Sciences Ireland UC*: Statistical consultation on behalf of defendant, 2022–.
- Expert consultation on behalf of Steam Punk LLC, tax litigation: 2023–.

## National Scientific Committees

- C-Reactive Protein Pilot Study Planning Committee, NHLBI: 2003.
- Health Care Technology & Decision Science study section, AHRQ: 2003–2007.
- Invited participant, NIH Workshop on the Barriers to Producing Well-Tested, User-Friendly Software for Cutting-Edge Statistical Methodology, NIH: 2008.
- Invited participant, AHRQ Workshop on “Centers for Medicare & Medicaid Services (CMS) Changes in Reimbursement for Hospital-Acquired Infections (HAIs): Setting a Research Agenda”. AHRQ and Columbia University: 2009.

- Institute of Medicine Committee on the Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule: 2012.
- General & Plastic Surgery Devices Panel, Medical Devices Advisory Committee, Center for Devices and Radiological Health, US Food & Drug Administration: 2012–2018.
- Review committee, Division of Intramural Population Health Research, National Institute of Child Health & Human Development: 2016.