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CURRICULUM VITAE

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Education:

1998	Ph.D., Statistics George Washington University, Washington, DC
1992	M.S., Applied Statistics George Washington University, Washington, DC
1988	B.S., Mathematics University of Maryland, College Park, MD

Professional Experience:

2019-present	<i>Branch Chief</i> , Biostatistics Branch, Biometric Research Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, Bethesda, MD
1998-2019	<i>Mathematical Statistician</i> , Biometric Research Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, Bethesda, MD
1993-1998	<i>Statistician</i> , The EMMES Corporation, Potomac, MD
1992-1993	<i>Statistician</i> , Synectics, Arlington, VA
1989-1992	<i>Research Assistant</i> , GWU Biostatistics Center, Rockville, MD

Selected Professional Activities:

Associate editor: *Clinical Trials*

Editorial Board: *Journal of Clinical Oncology*

Referee for *American Journal of Epidemiology*, *Annals of Oncology*, *Biometrical Journal*, *Biometrics*, *Biometrika*, *Clinical Cancer Research*, *Clinical Trials*, *Journal of Clinical Oncology*, *Journal of the National Cancer Institute*, *Nature Reviews Clinical Oncology*, *Pharmaceutical Statistics* and *Statistics in Medicine*.

FDA Oncologic Drugs Advisory Committee (ODAC): Temporary voting member, September 2022

Awards:

American Statistical Association Outstanding Statistical Application Award (2002).

Publications:

1. Trimble E, Carter C, Cain D, **Freidlin B**, Ungerleider R, Friedman M. Representation of older patients in cancer treatment trials. *Cancer Supplement* 74:2208-2214, 1994
2. Pompetti F, Rizzo P, Simon R, **Freidlin B**, Mew D, Pass H, Picci P, Levine A, Carbone M. Oncogene alterations in primary, recurrent and metastatic human bone tumors. *Journal of Cellular Biochemistry* 63:37-50, 1996
3. Simon R, **Freidlin B**, Rubinstein L, Arbuck S, Collins J, Christian M. Accelerated titration designs for phase I clinical trials in oncology. *Journal of the National Cancer Institute* 89:1138-1147, 1997
4. Becker KG, Simon RM, Bailey-Wilson J, **Freidlin B**, Biddison W, McFarland H, Trent J. Clustering of non-MHC susceptibility candidate loci in human autoimmune diseases. *Proceedings of National Academy of Science* 17:9979-9984, 1998
5. Smith M, **Freidlin B**, Gloeckler Reis LA, Simon R. Trends in the reported incidence of primary malignant brain tumors in children in the United States. *Journal of the National Cancer Institute* 90:1269-1277, 1998
6. **Freidlin B**, Gastwirth JL. Unconditional versions of several tests commonly used in the analysis of contingency tables. *Biometrics* 55:84-89, 1999

7. Smith M, Rubinstein L, Anderson J, Arthur D, Catalano PP, **Freidlin B**, Heyn, R, Khayat A, Krailo M, Land V, Miser J, Shuster J, Vena D. Secondary leukemia or myelodysplastic syndrome following treatment with epipodophyllotoxins. *Journal of Clinical Oncology* 17:569-577, 1999
8. **Freidlin B**, Podgor MJ, and Gastwirth, JL. Efficiency robust tests for survival and ordered categorical data. *Biometrics* 55:883-886, 1999
9. **Freidlin B**, Korn EL, George SL. Data monitoring committees and interim monitoring guidelines. *Controlled Clinical Trials* 20:395-407, 1999
10. Cheson BD, Vena DA, Barrett J, **Freidlin B**. Second malignancies as a consequence of nucleoside analog therapy for chronic lymphoid leukemias. *Journal of Clinical Oncology* 17:2454-2460, 1999
11. Bubley GJ, Carducci M, Dahut W, Dawson N, Daliani D, Eisenberger M, Figg WD, **Freidlin B**, et al. Eligibility and response guidelines for phase II clinical trials in androgen-independent prostate cancer: recommendations from the Prostate-Specific Antigen Working Group. *Journal of Clinical Oncology* 17: 3461-3467, 1999
12. **Freidlin B**, Gastwirth JL. Should the median test be retired from the general use? *American Statistician* 54:161-164, 2000
13. Gastwirth, JL, **Freidlin B**. On power and efficiency robust linkage tests for affected sibs. *Annals of Human Genetics*, 64:443-453, 2000
14. **Freidlin B**, Gastwirth JL Change point tests designed for the analysis of hiring data arising in employment discrimination cases. *Journal of Business and Economic Statistics* 18:315-322, 2000
15. Breathnach OS, **Freidlin B**, Conley B, Green MR, Johnson DH, Gandara DR, O'Connell M, Shepherd FA, Johnson BE. Twenty-two years of phase III trials for patients with advanced non-small-cell lung cancer: sobering results. *Journal of Clinical Oncology* 19(6):1734-1742, 2001
16. **Freidlin B**, Korn EL A testing procedure for survival data with few responders. *Statistics in Medicine* 21:65-78, 2002
17. **Freidlin B**, Dancey J, Korn EL, Zee B, and Eisenhauer E. Multinomial phase II trial designs (letter). *Journal of Clinical Oncology* 20:599, 2002
18. Zheng G, **Freidlin B**, Gastwirth JL. Robust TDT-type candidate gene association tests. *Annals of Human Genetics* 66:145-155, 2002
19. **Freidlin B** and Korn EL. A comment on futility monitoring. *Controlled Clinical Trials* 23:355-356, 2002

20. **Freidlin B**, Zheng G, Li Z, Gastwirth JL. Trend tests for case-control studies of genetic markers: power, sample size and robustness. *Human Heredity*, 53:146-152, 2002
21. Jane PA, **Freidlin B**, Saxman S, et al. Twenty-five years of clinical research for patients with limited-stage small cell lung carcinoma in North America - Meaningful improvements in survival. *Cancer* 95, 1528-1538, 2002
22. McShane LM, Radmacher MD, **Freidlin B**, et al. Methods for assessing reproducibility of clustering patterns observed in analyses of microarray data. *Bioinformatics* 18:1462-1469, 2002
23. **Freidlin B**, Breathnach OS, Johnson BE. A model to select regimens for phase III trials for patients with advanced-stage non-small cell lung cancer. *Clinical Cancer Research* 9:917-922, 2003
24. Zheng G, **Freidlin B**, Li ZH, Gastwirth JL. Choice of scores in trend tests for case-control studies of candidate-gene associations. *Biometrical Journal* 45:335-348, 2003
25. Dancey JE, **Freidlin B**. Targeting epidermal growth factor receptor - are we missing the mark? *Lancet* 362:62-64, 2003
26. **Freidlin B**, Zheng G, Li ZH, Gastwirth JL. Efficiency robust tests for mapping quantitative trait loci using extremely discordant sib pairs. *Human Heredity* 55:117-124, 2003
27. **Freidlin B**, Miao W, Gastwirth JL. On the use of the Shapiro-Wilk test in two-stage adaptive inference for paired data from moderate to very heavy tailed distributions. *Biometrical Journal* 45:887-900, 2003
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29. Korn EL, **Freidlin B**, Gorge SL. Data monitoring and large apparent treatment effects (letter). *Controlled Clinical Trials* 25:67-69, 2004
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34. Zheng G, **Freidlin B**, Li ZH, Gastwirth JL. Genomic control for association studies under various genetic models. *Biometrics* 61:187-193, 2005
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39. **Freidlin B**, Simon R. Adaptive signature design: An adaptive clinical trial design for generating and prospectively testing a gene expression signature for sensitive patients. *Clinical Cancer Research* 11:7872-7878, 2005
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41. Korn EL, **Freidlin B**. The likelihood as statistical evidence in multiple comparisons in clinical trials: No free lunch. *Biometrical Journal* 48: 346-355, 2006
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44. Korn EL, **Freidlin B**. A posterior tale. *Biometrical Journal* 49: 346-50, 2007
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- estimation. *Clinical Trials* 6:119-25, 2009
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 59. **Freidlin B**, McShane LM, Korn EL. Randomized Clinical Trials With Biomarkers: Design Issues. *Journal of the National Cancer Institute* 102:152-160, 2010
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 62. Korn EL, **Freidlin B**, Mooney M, Abrams JS. Accrual experience of National Cancer Institute Cooperative Group phase III trials activated from 2000 to 2007. *Journal of Clinical Oncology* 28:5197-201, 2010
 63. **Freidlin B**, Korn EL. Biomarker-adaptive clinical trial designs. *Pharmacogenomics* 11:1679-1682, 2010
 64. Korn EL, Dodd LE, **Freidlin B**. Measurement error in the timing of events: effect on survival analyses in randomized clinical trials. *Clinical Trials* 7: 626-633, 2010
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73. Korn EL, **Freidlin B**, Abrams JS and Halabi S. Design issues in randomized phase II/III trials. *Journal of Clinical Oncology* 30:667-671, 2012
74. Korn EL, **Freidlin B** and Abrams JS. Bevacizumab in ovarian cancer (letter). *New England Journal of Medicine* 366:1256, 2012
75. **Freidlin B**, Korn EL. Assessing causal relationships between treatments and clinical outcomes: always read the fine print. *Bone Marrow Transplantation* 47:626-632, 2012
76. **Freidlin B**, McShane LM, Polley M-Y, and Korn EL. Randomized phase II trial designs with biomarkers. *Journal of Clinical Oncology* 30:3304-3309, 2012
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79. **Freidlin B**, Korn EL. Borrowing Information Across Subgroups: Is It Useful? *Clinical Cancer Research* 19:1326-1334, 2013
80. **Freidlin B**, Korn EL. Adaptive randomization versus interim Monitoring. *Journal of Clinical Oncology* 31:969-970, 2013
81. Korn EL, McShane LM, **Freidlin B**. Statistical challenges in the evaluation of treatments for small patient populations *Science Translational Medicine*, 5 (178), art. no. 178sr3, 2013
82. **Freidlin B**, Sun Z, Gray R, Korn EL. Phase III clinical trials that integrate treatment and biomarker evaluation. *Journal of Clinical Oncology* 31: 3158-3161, 2013
83. **Freidlin B**, Abrams JS, Korn EL. New challenges for comparative effectiveness in oncology: Choice of primary end points for randomized clinical trials. *Journal of Comparative Effectiveness Research*, 2: 469-481, 2013

84. Dodd LE, Korn EL, **Freidlin B**, Gu W, Abrams JS, Bushnell WD, Canetta R, Doroshow JH, Gray RJ, Sridhara R. An audit strategy for time-to-event outcomes measured with error: Application to five randomized controlled trials in oncology. *Clinical Trials*, 10:754-760, 2013
85. Polley M-Y, **Freidlin B**, Korn EL, Conley BA, Abrams JS, McShane LM. Statistical and practical considerations for clinical evaluation of predictive biomarkers. *Journal of the National Cancer Institute*, 105:1677-1683, 2013
86. **Freidlin B**, Korn EL. Biomarker enrichment strategies: Matching trial design to biomarker credentials *Nature Reviews Clinical Oncology*, 11: 81-90, 2014
87. **Freidlin B**, Korn EL, Gray R. Marker Sequential Test (MaST) design *Clinical Trials*, 11: 19-27, 2014
88. **Freidlin B**, Korn EL. Transparency in interim monitoring *Journal of Clinical Oncology*, 32:2387-2388, 2014
89. **Freidlin B**, Sun Z, Gray R, Korn EL. Reply to Goteti et al. *Journal of Clinical Oncology* 32: 856, 2014
90. **Freidlin B**, Korn EL. A model too far. *Journal of the National Cancer Institute*, 106(2):djt638, 2014
91. **Freidlin B**, Korn EL. Response to Etzioni and Gulati. *Journal of the National Cancer Institute*, 106(4):dju059, 2014
92. Polley MY, Polley EC, Huang EP, **Freidlin B**, Simon R. Two-stage adaptive cutoff design for building and validating a prognostic biomarker signature. *Statistics in Medicine*, 33:5097-110, 2014
93. Korn EL, Dignam JJ, **Freidlin B**. Assessing treatment benefit with competing risks not affected by the randomized treatment. *Statistics in Medicine*, 34:265-80, 2015
94. Korn EL, **Freidlin B**. Commentary on Hey and Kimmelman. *Clinical Trials*, 12: 122-124, 2015
95. Korn EL. **Freidlin B**. Evaluation of chemoresponse assays as predictive marker. *British Journal of Cancer* 112:621-623, 2015
96. Korn EL. **Freidlin B**. Response to Comment on: Evaluation of chemoresponse assays as predictive marker. *British Journal of Cancer* 112:1978, 2015

97. **Freidlin B**, Little RF, Korn L. Design issues in randomized clinical trials of maintenance therapies. *Journal of the National Cancer Institute* 107(11): djv225, 2015
98. **Freidlin B**, Korn EL, RE: Impact of a biomarker-based strategy on oncology drug development: A meta-analysis of clinical trials leading to FDA approval. (letter) *Journal of the National Cancer Institute* 108:djv430, 2016
99. **Freidlin B**, Othus M, and Korn EL. Information time scales for interim analyses of randomized clinical trials. *Clinical Trials* 13:391-399, 2016
100. Korn EL and **Freidlin B**. Non-factorial analyses of two-by-two factorial trial designs. *Clinical Trials* 13: 651-659, 2016
101. Korn EL, **Freidlin B**. Reader reaction on estimation of treatment effects in all-comers randomized clinical trials with a predictive marker. *Biometrics* 73:706-708, 2017
102. Zhang Q, **Freidlin B**, Korn EL, Halabi S, Mandrekar S, and Dignam JJ. Comparison of futility monitoring guidelines using completed phase III oncology trials. *Clinical Trials* 14:48-58, 2017
103. Little RF, McShane LM, **Freidlin B**. Myeloma minimal residual disease and surrogacy (letter). *JAMA Oncology* doi: 10.1001/jamaoncol.2016.5660, 2017
104. **Freidlin B** and Korn EL. Sample size adjustment designs with time-to-event outcomes: a caution. *Clinical Trials* 14:597-604, 2017
105. **Freidlin B** and Korn EL. Rejoinder to Dr. Mehta. *Clinical Trials* 14:609-610. 2017
106. Korn EL, Othus M, Chen T-T and **Freidlin B**. Assessing treatment efficacy in the subset of responders in a randomized clinical trial. *Annals of Oncology* 28:1640-1647, 2017
107. Korn EL and **Freidlin B**. Adaptive Clinical Trials: Advantages and disadvantages of various adaptive design elements. *Journal of the National Cancer Institute* 109: dlx013, 2017
108. **Freidlin B** and Korn EL. Two-by-two factorial cancer treatment trials: Is sufficient attention being paid to possible interactions? *Journal of the National Cancer Institute* 109:djx146, 2017
109. Korn EL, **Freidlin B**. Quantitative assessment of a prognostic or predictive biomarker panel. *Journal of Biopharmaceutical Statistics* 28:264-281, 2018

110. Korn EL, **Freidlin B**. Interim monitoring for non-inferiority trials: minimizing patient exposure to inferior therapies. *Annals of Oncology* 29:573-577, 2018
111. Korn EL, **Freidlin B**. Surrogate and intermediate endpoints in randomized trials: what's the goal? *Clinical Cancer Research* 24:2239-40, 2018
112. **Freidlin B**, Korn EL, Abrams JS. Bias, operational bias, and generalizability in phase II/III trials. *Journal of Clinical Oncology* 36:1902-04, 2018
113. Korn EL, **Freidlin B**. Interim futility monitoring assessing immune therapies with a potentially delayed treatment effect. *Journal of Clinical Oncology* 36:2444-49, 2018
114. Yee LM, McShane LM, **Freidlin B**, Mooney MM, Korn EL. Biostatistical and Logistical Considerations in the Development of Basket and Umbrella Clinical Trials. *Cancer Journal* 25:254-263, 2019
115. Korn EL, Gray RJ, **Freidlin B**. Noninferiority trials with nonadherence to the assigned randomized treatment. *Clinical Trials* 16:673-681, 2019
116. **Freidlin B**, Korn EL. Methods for Accommodating Nonproportional Hazards in Clinical Trials: Ready for the Primary Analysis? *Journal of Clinical Oncology* 37:3455-3459, 2019
117. Polley M-YC, Korn EL, **Freidlin B**. Phase III precision medicine clinical trial design that integrates treatment and biomarker evaluation *JCO Precision Oncology* 3:1-9, 2019
118. Foster JC, **Freidlin B**, Kunos CA, Korn EL. Single-Arm Phase II Trials of Combination Therapies: A Review of the CTEP Experience 2008-2017. *Journal of the National Cancer Institute* 112:128-135, 2020
119. **Freidlin B**, Allegra CJ, Korn EL. Moving Molecular Profiling to Routine Clinical Practice: A Way Forward? *Journal of the National Cancer Institute* 112:773-778 2020
120. **Freidlin B**, Korn EL. Reply to H Uno et al and B Huang et al. *Journal of Clinical Oncology* 38: 2003-2004, 2020
121. Foster JC, **Freidlin B**, Korn EL, and Smith M. Evaluation of the contribution of randomized cancer clinical trials evaluating agents without documented single-agent activity. *ESMO Open* 5:e000871, 2020
122. **Freidlin B**, Hu, C, Korn EL. Are restricted mean survival time methods especially useful for Noninferiority Trials? *Clinical Trials* 18:188-196, 2021

123. Dodd LE, **Freidlin B**, and Korn EL. Platform trials – Beware the noncomparable control group. *New England Journal of Medicine* 384:1572-1573, 2021
124. **Freidlin B**, Hu C, and Korn EL. Reply to Quartagno et al. *Clinical Trials* 18:746, 2021
125. **Freidlin B** and Korn EL. A problematic biomarker trial design. *Journal of the National Cancer Institute* 114:187-190, 2022
126. Korn EL and **Freidlin B**. Time trends with response adaptive randomization: the inevitability of inefficiency. *Clinical Trials* 19:158-161, 2022
127. Korn EL, Allegra CJ, and **Freidlin B**. Clinical benefit scales and trial design: some statistical issues. *Journal of the National Cancer Institute* 114:1222-1227, 2022
128. Kumar S, Baizer L, Callander NS, Giralto SA, Hillengass J, **Freidlin B**, Hoering A, Richardson PG, Schwartz EI, Reiman A, Lentzsch S, McCarthy PL, Jagannath S, Yee AJ, Little RF, Raje NS. Gaps and opportunities in the treatment of relapsed-refractory multiple myeloma: Consensus recommendations of the NCI Multiple Myeloma Steering Committee. *Blood Cancer Journal* 12(6) 98, 2022
129. Sridhara R, Barksdale E, Marchenko O, Jiang Q, Ando Y, Bloomquist E, Coory M, Crouse M, Degtyarev E, Framke T, **Freidlin B**, Gerber DE, Gwise T, Josephson F, Hess L, Kluetz P, Li D, Mandrekar S, Posch M., Rantell K, Ratitch B, Raven A, Roes K, Rufibach K, Sarac SB, Simon R, Singh H, Theoret M, Thomson A, Zuber E, Shen YL, Pazdur R. Cancer Clinical Trials beyond Pandemic: Report of an American Statistical Association Biopharmaceutical Section Open Forum Discussion. *Statistics in Biopharmaceutical Research* DOI: 10.1080/19466315.2022.2103181, 2022
130. **Freidlin B** and Korn EL. Augmenting randomized clinical trial data with historical control data: Precision medicine applications. *Journal of the National Cancer Institute* (in press)
131. LoRusso PM, **Freidlin B**. Improving Precision Oncology through Better Designs and Reporting of Biomarker-Driven Randomized Clinical Trials. *Journal of the National Cancer Institute* (in press)
132. Korn EL, Moscow JA, and **Freidlin B**. Dose optimization during drug development: whether and when to optimize. *Journal of the National Cancer Institute* (in press)

Book Chapters:

1. Simon R, Dixon D, **Freidlin B**. A Bayesian model for evaluating specificity of treatment effects in clinical trials. *Recent Advances In Clinical Trial Design*, Thall P. editor, Kluwer Academic Publishers, Boston, 1995
2. Simon R, Dixon D, **Freidlin B**. Bayesian subset analysis of a clinical trial for the treatment of HIV infection. *Bayesian Biostatistics*, Berry D and Stangl D. (eds.), Marcel-Dekker, New-York, 1996
3. **Freidlin B**, and Gastwirth JL. The application of change point tests to data occurring in fair hiring cases. *Asymptotic Methods in Probability and Statistics (ICAMPS)*, Szyszkowicz B. editor, Elsevier Science, Amsterdam, 1998
4. Gastwirth JL, **Freidlin B**, Miao W. The Shonubi case as an example of the legal system's failure to appreciate statistical evidence. *Statistical Science in the Courtroom*, Gastwirth JL editor, Springer, New-York, 2000
5. Zheng G, **Freidlin B**, and Gastwirth JL. Comparison of robust test for genetic association using case-control studies. *IMS Lecture Notes-Monograph Series*, 2006
6. Dancey J, **Freidlin B**, and Rubinstein L. Accelerated titration designs. *Statistical Methods in Dose-Finding Studies*, Chevret S. editor, Wiley, New-York, 2006
7. **Freidlin B**. Futility analysis. *Encyclopedia of Clinical Trials*, Wiley, New-York, 2007
8. Korn EL, **Freidlin B**. Interim analysis of phase III trials. *Oncology Clinical Trials*, Kelly and Halabi S (eds.), Demos Medical, New York, 2010
9. McShane LM, Korn EL, **Freidlin B**. Statistical considerations in the development and evaluation of therapeutic biomarkers in cancer. In *Handbook of Therapeutic Biomarkers in Cancer*, Yang, Dancey (eds.), Pan Stanford, Singapore, 2013.
10. **Freidlin B**. Futility analysis. In *Methods and Applications of Statistics in Clinical Trials: Planning, Analysis, and Inferential Methods*. Balakrishnan N editor, Wiley, New York, 2014.
11. Korn EL, **Freidlin B**. Outcome-adaptive randomization in early clinical trials. In *Design and Analysis of Clinical Trials for Predictive Medicine*, Matsui S, Buyse ME and Simon R (eds.), Chapter 7, CRC Press, Boca Raton, FL, 2015
12. **Freidlin B**. and Simon R. Adaptive clinical trial designs with biomarker development and validation In *Design and Analysis of Clinical Trials for*

- Predictive Medicine*, Matsui S, Buyse ME and Simon R (eds.), Chapter 18, CRC Press, Boca Raton, FL, 2015
13. **Freidlin B.** Korn EL. Ethics of outcome adaptive randomization. *Wiley Statistics Reference Online*, Wiley, New York, 2016
 14. Korn EL and **Freidlin B.** Clinical Trial Designs in Oncology. In *Abeloff's Clinical Oncology*, Sixth Edition Niederhuber JE, Armitage JO, Doroshow JH, Kastan MB, and Tepper JE (eds.), New York: Elsevier, 2019
 15. **Freidlin B** and Korn EL. Adaptive Phase II trials. *Principles and Practice of Clinical Trials*, S. Piantadosi, C. Meinert (eds.), Springer, New-York, 2020
 16. **Freidlin B** and Korn EL. Futility Analysis. *Wiley StatsRef: Statistics Reference Online*, John Wiley 2021

Book reviews:

Ellenberg SS, Fleming TR, and DeMets DL. *Data Monitoring Committees in Clinical Trials*, 2002; New York: Wiley. *Biometrics*, 59:457-458, 2003