

# Curriculum Vitae

## **Cathie Spino, Sc.D.**

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## **Education**

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Sc.D., Biostatistics, Harvard University School of Public Health, Boston, MA (1989)

M.S., Biostatistics, Harvard University School of Public Health, Boston, MA (1985)

B.S., Mathematics and Statistics, Miami University, Oxford, OH (1983)

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## **Professional Experience**

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**University Of Michigan School Of Public Health**

**2007 to present**

**Department Of Biostatistics**

Ann Arbor, Michigan

Director, Statistical Analysis of Biomedical & Educational Research unit (SABER) 2007 to present  
Associate Research Professor

- Grow SABER's capabilities and reputation in statistical and data management practices, leading to continued funding as a premier data coordinating center for multiple NIH-funded networks and multicenter clinical studies.
- Direct staff of data-entry specialists, data managers, clinical study monitors/project managers, database and web programmers, statisticians and research administrative staff (10 to 24 FTEs).
- Develop infrastructure and stability of funding for SABER.
- Enhance clinical research capabilities and reputation of UM faculty through high-quality academic and industry grant submissions for clinical studies, support of study conduct according to Good Clinical Practice, delivery of reliable, valid data, and analysis and interpretation of study results.

Faculty Lead for Biostatistics, Michigan Institute for Clinical and Health Research 2017 to present

- Provide biostatistical perspective and expertise to the MICHR cabinet and clinical and translational investigators.
- Represent MICHR at national Biostatistics, Epidemiology and Research Design activities.
- Provide leadership to MICHR Biostatistics Affiliated staff.

**Pfizer Global Research And Development**

**1999 to 2007**

Ann Arbor, Michigan

Director, Clinical Biostatistics, Dermatology, Inflammation & Phase 1

2006 to 2007

- Led statistical efforts at regulatory meetings in the US and Europe.
- Supervised five PhD- and MS-level statisticians and several statistical contractors; interacted with Therapeutic Area Development Teams on drug development strategies and Technical Review Committees on design and analysis issues; and led global statistical initiative on operational excellence.

Director, Clinical Biostatistics, Cardiovascular and Metabolism

2004 to 2006

- Supervised two MS-level statisticians; interacted with CV/MET Development Operations managers to ensure proper prioritization, focus and alignment; and, set direction for CV/MET Clinical Biostatistics department in collaboration with other managers.

Associate Director, Clinical Biostatistics, Cardiovascular

1999 to 2004

- Participated in the preparation of INDs, NDAs, and other special reports; represented statistical line during regulatory interactions.
- Performed biostatistical project management activities. Oversaw all and personally conducted biostatistical activities for the design, implementation, statistical analysis and reporting of clinical evaluations.
- Provided consultation to development of clinical research support processes, and resource estimation, allocation and management tracking systems.

**Astra Usa, Inc.**

**1997 to 1999**

Westborough, Massachusetts

Senior Biostatistician

- Provided statistical support in the design, analysis, and reporting of clinical trials in asthma and hypertension, including preparation of an sNDA.

**Statistical And Data Analysis Center  
Of The Aids Clinical Trials Group**

**1990 to 1997**

Boston, Massachusetts

Assistant Director, Pediatric Division

1995 to 1997

- Managed operational aspects of the Division of 18 MS and PhD statisticians. Developed job descriptions and career ladder for master's-level statisticians and research associates. Led grant renewal activities. Coordinated statistical and data management center activities. Interacted with SDAC, ACTG and NIH leadership on goals. Supervised staff, participated in hiring and training decisions. Provided statistical support in the design, analysis, and reporting of Phase I-III pediatric AIDS clinical trials in national AIDS clinical trials group.

Statistician, Adult Division, Women's Health, Immunology

1990 to 1997

- Section Head of Women's Health Committee. Designed, analyzed, and reported on Phase I-III clinical trials and epidemiological cohort studies. Head of Statistical Computing. Organized set-up of computing for newly-formed SDAC, including hiring and supervising of staff, 1990-1991.

## Harvard School Of Public Health

1990 to 1996

Boston, Massachusetts

Assistant Professor, Department of Biostatistics

- Instructor in Statistical Computing and Statistical Methods for Health Policy & Management courses. Supervised students. Member of Thesis Committees. Head of Departmental Computing Committee.

## Cancer And Leukemia Group B

1989 to 1990

Boston, Massachusetts

Statistician (post-doctoral fellowship)

- Responsible for statistical support of adult acute lymphoblastic leukemia studies and analyses.

## North Charles Mental Health Research & Training Foundation

1986 to 1987

Cambridge, Massachusetts

Statistical Programmer and Systems Analyst

- Wrote SAS and C code for statistical analyses. Responsible for computer (PC) system integrity.

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## Professional Memberships

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American Statistical Association

International Biometric Society, Eastern North American Region

Drug Information Association

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## Honors and Awards

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1979-1983	Alumni Merit, Ohio Academic and National Merit Scholarships
1981	Pi Mu Epsilon National Mathematics Honorary
1983	Elected to Phi Beta Kappa
1983-1986	National Cancer Institute Research Service Traineeship
1987-1988	Biomedical Computing Traineeship
1991	Innovations in Teaching Methods Grant
1994	Departmental Pfizer Award for “Issues in Statistical Computing” Research

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## Grants

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Below I list current, pending and past grants funded at SABER under my leadership. Grants for which I am the DCC Director or UM PI are in bold font.

*Current Grants (including those for which I have effort and those that support other members of SABER)*

- **PI, Director of DCC. Pulmonary Fibrosis Patient Registry DCC (PI: Spino, 11/01/15-10/31/20, funded by Pulmonary Fibrosis Foundation) (10% effort)**

- **PI, Director of DCC. RA-ILD (PI: Spino, 3/1/16 to 2/28/20, investigator-initiated study [I Rosas, Harvard] funded by Genentech) (5% effort)**
- **Director of DCC, Co-Investigator, Senior Statistician. ASSET: A pilot study to evaluate subcutaneous abatacept vs. placebo in diffuse cutaneous systemic sclerosis- -a double-blind, placebo-controlled, randomized controlled trial (PI: Khanna, 06/17/14 – 06/17/24, investigator-initiated study [D Khanna, UM] funded by BMS) (15% support)**
- **Director of DCC, Co-Investigator, Senior Statistician. Childhood Liver Disease Research Network Data Coordinating Center (PI: Magee, 08/20/14 – 05/31/19, funded by NIH) (15% support)**
- **Co-Director of DCC, Co-Investigator. PERL: A multicenter clinical trial of allopurinol to prevent GFR loss in T1D (PI: Doria, 09/30/13 – 06/30/18, funded by NIH) (10% effort)**
- **Director of DCC, Co-Investigator, Senior Statistician. PH-2013-010 Pilot Study to Assess the Efficacy and Safety of Riociguat vs Placebo in Scleroderma-Associated Digital Ulcers (PI: Khanna, 07/01/16-06/30/17, investigator-initiated study [D Khanna, UM] funding requested from Bayer HealthCare) (5% effort)**
- **Senior Statistician, Co-Investigator. Randomized Evaluation of VAD InterVENTion before Inotropic Therapy (REVIVE-IT) Pilot Trial- Additional Funding - (REVIVAL) (PI: Aaronson, 01/15/11 – 06/30/16, funded by NIH) (5% effort)**
- **Co-Director of Biostatistics and Data Management Core, Co-Investigator. University of Michigan Udall Center - Cholinergic Mechanisms of Gait Dysfunction in Parkinson's Disease (PI: Dauer, 09/30/14 – 06/30/19, funded by NIH) (5% effort)**
- **Senior Statistician. NephCure Accelerating Cures Institute (PI: Gipson, 04/01/15 – 03/31/16, funded by NephCure Kidney International) (7.9% effort)**
- **Co-Director of Biostatistics and Data Management Core, Co-Investigator. Alpha4Beta2 Nicotinic Agonist for Treatment of L-Dopa Refractory Gait and Balance Disorders in Parkinson Disease. (PI: Albin, 11/01/15 – 10/31/18, funded by Michael J. Fox Foundation) (supports Udall effort)**
- **Senior Statistician, Co-Investigator,. Improving Respiratory Health for Low-Income Elderly in Urban Communities (PI: Morishita, 07/01/16-06/30/21, NIH) (2.5% effort)**
- **Senior Statistician, Co-Investigator. Pediatric Implantable Artificial Lung (PI: Hirschl, 07/01/17 – 06/30/22, NIH) (5% support years 3-5)**
- **SABER DCC. BASIC4 (Brain Attack Surveillance in Corpus Christi). (PI: Morgenstern & Lizbeth, 4/1/14 – 3/31/17, funded by NIH) (0% Spino effort)**
- **SABER DCC. Sleep Apnea Health Disparities in Mexican-Americans. (PI: Morgenstern & Lizbeth, 4/1/11 – 4/30/17, funded by NIH) (0% Spino effort)**
- **SABER DCC. Sleep apnea after stroke: Implications for Screening. (PI: Morgenstern & Lizbeth, 12/15/15 – 11/30/19, funded by NIH) (0% Spino effort)**
- **SABER DCC. Outcomes Among Surrogate Decisions Makers in Stroke (PI: Zahuranec, 9/1/15 – 07/31/20, funded by NIH) (0% Spino effort)**
- **SABER DCC. ReTHINC. Multi-Site clinical Trials for the Pulmonary Trials Cooperative (PTC). (PI: Han, 09/09/15 – 07/31/19, funded by NIH) (0% Spino effort)**
- **SABER DCC. Small Defect Project. (PI: Feinberg, 08/01/13 – 09/26/17 NCE, funded by DOD) (0% Spino effort)**

- PI, Director of DCC, Senior Statistician. Scleroderma Lung Study III (PI: Spino, 7/1/2017 to 6/31/2022, investigator-initiated study [M Roth, UCLA] funded by Genentech) (20% effort)

***Pending Grants or Those Submitted in Last Year (including those for which I have effort or those that support other members of SABER)***

- PI, Director of DCC, Senior Statistician. A Multicenter Randomized Controlled Trial of the Effectiveness of Magnetic Resonance Angiography (MRA) versus CT angiography (CTA) for Pulmonary Embolism (PI: Spino, 12/01/17 – 11/30/22, NIH) (10% support)
- PI, Co-Director of DCC, Senior Statistician. Preventing Early Renal Loss in Diabetes Follow-Up Study (PERLage) (PI: Spino, 07/01/17 – 12/31/19, NIH) (10% support)
- PI, Director of DCC, Co-Investigator. The CAPTURE Study: Validating a unique COPD screening tool in primary care (PI: Spino [F Martinez, Weill Cornell], 09/01/17 – 08/31/21, NIH) (10% support)
- Co-PI, Director of DCC, Senior Statistician. TAPER: Tapering Antidepressants in Pregnancy and Emergence of Relapse (PI: Spino & Muzik, 04/01/18 – 03/31/24, NIH) (40% support)
- Director of DCC, Co-Investigator, Senior Statistician. Treat-to-target and personalized approach to periodontal therapy (PI: Ioannidou, 12/01/17 – 11/31/22, NIH) (5-10%)
- Director of DCC, Co-Investigator, Senior Statistician. MiACL: Michigan Initiative for Anterior Cruciate Ligament Rehabilitation (PI: Palmieri-Smith, 09/01/17 – 08/30/22, NIH) (10-20%) – not funded
- PI, Director of DCC. Measuring Glomerular Filtration Rate Using Dried Blood Spots in the PERL Study (PI: Spino [Maahs, Stanford], 09/01/17 - 08/31/19, NIH) (0% Spino effort; SABER DCC.)
- PI, Director of DCC. Study to Assess Predictive Value of CGM for Microvascular Complications of Diabetes (PI: Spino [Hirsch, U Washington], 07/01/17 - 11/3/19, Helmsley Trust) (1% effort)
- Co-PI, Director of DCC. NACI Coordinating Center Proposal: Complexa Phase 2 FSGS Trial (PI: Gipson, Spino, 03/01/17 – 03/31/19, Complexa) (10% support)
- Director of DCC. Reversing Synchronized Brain Circuits with Targeted Auditory-Somatosensory Stimulation to Treat Tinnitus (PI: Shore, 09/01/17 - 08/31/22, NIH) (1% support)
- Senior Statistician, Co-Investigator. Citalopram as an anti-amyloid therapy in Parkinson disease (PI: Kotagal, 12/01/17 – 11/30/22, NIH) (30% support)
- Senior Statistician, Co-Investigator. JAK inhibitor as therapy for Recurrent FOCal segmental glomerulosclerosis in the US, REFOCUS (PI: Savin, 04/01/18 – 03/31/2023, DOD) (10% support)
- Senior Statistician, Co-Investigator. Dietary prevention of hypertensive heart failure with preserved ejection fraction in salt-sensitive postmenopausal women - R61/R33 (PI: Hummel, 12/01/17 – 11/31/22, NIH) (10% support)
- Director of DCC, Co-Investigator. Cognitive Impairment in Mexican Americans: a population-based study (PI: Morgenstern, 04/01/2017 – 03/31/2022, NIH) (0% Spino effort) – not funded

- Co-Investigator. Integrated Big Data Science Research, Predictive Analytics, Clinical Practice, and Health Education T32 Training Grant (PI: Dinov, Fall 2017 – Fall 2022, NIH) (5% support) – not funded
- Director of DCC, Co-Investigator. Prospective Multicenter Natural History Study of Genetic Lipodystrophy Syndromes to Determine Prevalence, Incidence and Predictors of Diabetes and Severe Hypertriglyceridemia, and their Complications (PI: Oral, 09/01/17 – 08/31/22, FDA) (5% support) – not funded
- Senior Statistician, Co-Investigator. Functional Resistance Training during Gait: A Novel Intervention to Improve Knee Function after ACL Reconstruction (PI: Krishnan, 07/01/17 – 06/30/19, NIH) (3% support) – not funded
- Senior Statistician, Co-Investigator. Effect of LED Based Skylight Emulators on Cardiometabolic Risk (PI: Baylin, 12/01/17 – 11/31/19, AHA) (5% support) – not funded

***Previous Grants (including those for which I have effort or those that support other members of SABER)***

- PI, Director of DCC, Senior Statistician. Pelvic Floor Disorders Network – Data Coordinating Center (PI: Spino, 07/01/2006 – 06/30/2011, funded by NIH) (40% effort)
- PI, Senior Statistician. Placebo Controlled Trial of Sertaline and IPT for Postpartum Depression (PI: Spino, 09/01/11-05/31/13, funded by NIH) (5% effort)
- PI, Senior Statistician. Improving Mental Health Research Infrastructure and Collaboration for Women’s Depression (PI: Spino, 06/01/13 – 11/30/14, funded by NIH) (10% effort)
- Director of DCC, Co-Investigator, Senior Statistician. Rare Liver Disease Network (PI: Magee, 08/01/08 – 07/10/10, funded by NIH) (10% effort)
- Director of DCC, Co-Investigator, Senior Statistician. Biliary Atresia Research Consortium – Data Coordinating Center (PI: Magee, 06/01/09 – 05/31/14, funded by NIH) (10% support)
- Director of DCC, Co-Investigator, Senior Statistician. Childhood Liver Disease and Education Network Data coordinating Center (PI: Magee, 06/01/09 – 05/31/14, funded by NIH) (24% effort)
- DCC Director, Co-Investigator. COMET (Molecular Phenotypes of rapidly progressive idiopathic pulmonary fibrosis) (PI: Martinez, 09/30/09 – 09/29/11, funded by NIH) (5% effort)
- Director of DCC, Co-Investigator. A Multi-Center International Study of the Lung Microbiome in COPD (PI: Gyetko, 04/01/13 – 03/31/14, funded by NIH) (2% effort)
- Director of DCC, Co-Investigator, Senior Statistician. Stent vs. indomethacin for preventing post-ERCP pancreatitis (SVI study). (PI: Elmunzer, 08/15/13 – 07/31/14, funded by NIH) (5% effort)
- Director of DCC, Co-Investigator. Michigan Alzheimer's Disease Core Center (PI: Gilman, 08/01/10 – 05/31/11, funded by NIH) (10% effort)
- Co-Director of Data and Coordinating Center. National Network of Depression Centers Data Registry (PI: Spino, 08/23/12 – 08/22/14, funded by National Network of Depression Centers) (13.7% effort)

- Co-Director of Integrative Biostatistics and Informatics Core, Co-Investigator. Nutrition Obesity Research Centers (P30) (PI: Burant, 07/01/10 – 06/30/15, funded by NIH) (5% effort)
- Co-Director of Biostatistics and Data Management Core, Co-Investigator. Great Lakes Air Center for Integrative Environmental Research (GLACIER) (PI: Harkema, 12/01/10 – 11/30/15, funded by NIH) (5% effort)
- Co-Director of Data Management Core, Co-Investigator. Lifestage Exposures and Adult Disease (PI: Hu / Loch-Carusio, 04/01/11 – 03/31/15, funded by NIH) (5-8% effort)
- Co-Investigator. GlaxoSmithKline Research Collaborative Agreement (PI: Abecasis, 12/01/08 – 11/30/11, funded by GSK) (10% effort)
- Senior Statistician, Co-Investigator. Benign Prostatic Hyperplasia Registry Data Generation and Communications (PI: Wei, 11/30/09 – 12/31/10, funded by Sanofi-Aventis) (5% effort)
- Senior Statistician, Co-Investigator. Michigan Institute for Clinical and Health Research (MICHHR) - U-award (PI: Shanley, 09/17/07 – 05/31/14, funded by NIH) (5% effort)
- Senior Statistician, Co-Investigator. Randomized Evaluation of VAD InterVENTion before Inotropic Therapy (REVIVE-IT) Pilot (PI: Aaronson, 11/15/13 – 08/31/14, funded by NIH) (20% effort)
- SABER DCC. Large Defect Project. (PI: Feinberg, 09/01/13 – 09/26/16, funded by DOD) (0% Spino effort)
- Senior Statistician, Co-Investigator. Retrophin: Proteinuria as a surrogate for long-term nephroprotection in primary FSGS (PI: Gipson, 01/20/16 – 03/31/16, funded by Retrophin) (2.1% support)

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## Publications – Peer-Reviewed

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† indicates that I was senior statistician of the publication

†† indicates a publication where a student or junior staff member whom I co-mentored was an author

1. McAuliffe, WE, Breer, P, White Ahmadifar, N, and **Spino**, C. Assessment of Drug Abuser Treatment Needs in Rhode Island, *American Journal of Public Health* 1991; 81:365-371. [PMID: 1847277]
2. **Spino**, C, and Pagano, M. Efficient Calculation of the Permutation Distribution of Robust Two-Sample Statistics, *Computational Statistics and Data Analysis* 1991; 12:349-365.
3. **Spino**, C, and Pagano, M. Efficient Calculation of the Permutation Distribution of Trimmed Means, *Journal of the American Statistical Association* 1991; 86:729-737.
4. †Westbrook, CA, Hooberman, AL, **Spino**, C, Dodge, RK, Larson, RA, Davey, F, WursterHill, DH, Sobol, RE, Schiffer, C, and Bloomfield, CD. Clinical Significance of the BCR-ABL Fusion Gene in Adult Acute Lymphoblastic Leukemia: A Cancer and Leukemia Group B Study (8762), *Blood* December 1992; 80:2983-2990. [PMID: 1467514]

5. †Villari, P, **Spino**, C Chalmers, TC, Lau, J, and Sacks, HS. Cesarean Section to Reduce Perinatal Transmission of Human Immunodeficiency Virus: A Metaanalysis. *The Online Journal of Current Clinical Trials* July 1993, Document no. 74. [PMID: 8306011]
6. †Connelly, MC, Knight, M, Giorgi, JV, Kagan, J, Landay, AL, Parker, JW, Page, E, **Spino**, C, Wilkening, C, Mercolino, TJ. Standardization of Absolute CD4+ Lymphocyte Counts Across Laboratories: An Evaluation of the Ortho Cytoron Absolute Flow Cytometry System on Normal Donors, *Cytometry (Communications in Clinical Cytometry)* 1995; 22:200-210. [PMID: 8556951]
7. †,†† Korvick, JA, Stratton, P, **Spino**, C, Huang, J, Bardeguez, A, Wolfsy, C. Women's Participation in AIDS Clinical Trials Group (ACTG) Trials in the USA: Enough or Still Too Few? *Journal of Women's Health* 1996; 5(2):129-136.
8. †Valentine, FT, Kindu, S, Haslett, PAJ, Katzenstein, D, Beckett, L, **Spino**, C, Borucki, M, Vasquez, M, Smith, G, Korvick, J, Kagan, J, Merigan, TC. A Randomized, Placebo-Controlled Blinded Study of the Immunogenicity of HIV rgp160 Vaccine in HIV-Infected Individuals with Greater Than 400 CD4 T Lymphocytes (ACTG 137). *Journal of the Infectious Disease* 1996; 173(6):1336-46. [PMID: 8648205]
9. Baglivo, J, Pagano, M and **Spino**, C. Permutation Distributions via Generating Functions with Applications to Sensitivity Analysis of Discrete Data. *Journal of the American Statistical Association* 1996; 91(435):1037-1046.
10. †Wolfe, EJ, Cavacini, LA, Samore, MH, Posner, MR, Kozial, C, **Spino**, C, Trapnell, CB, Ketter, N, Hammer, S, and Gambertoglio, JG. Pharmacokinetics of F105, A Human Monoclonal Antibody, In Persons Infected with Human Immunodeficiency Virus Type 1. *Clinical Pharmacology and Therapeutics* June 1996; 59(6):662-667. [PMID: 8681491]
11. †Kundu, SK, Katzenstein, D, Valentine, FT, **Spino**, C, Efron, B, and Merigan, TC. Effect of Therapeutic Immunization with Recombinant gp160 HIV-1 Vaccine on HIV-1 Proviral DNA and Plasma RNA: Relationship to Cellular Immune Responses. *JAIDS* 1997; 15(4):269-74. [PMID: 9292585]
12. †**Spino**, C, Kahn, J, Dolin, R, and Phair, JP. Predictors of Survival in HIV-infected Persons with 50 or Fewer CD4+ Cells/mm<sup>3</sup>, *JAIDS* 1997; 15(5):346-355. [PMID: 9344254]
13. †Veronikis, DK, Nichols, DH, and **Spino**, C. The Noble-Mengert-Fish Operation - Revisited. A Composite Approach for Persistent Rectovaginal Fistulas and Complex Perineal Defects. *American Journal of Obstetrics and Gynecology* 1998; 179(6 Pt 1): 1411-6; discussion 1416-7. [PMID: 9855574]
14. †,††Watts, DH, **Spino**, C, Zaborski, L, Katzenstein, D, Hammer, S, and Benson, C. Comparison of Gynecologic History and Laboratory Results in HIV-positive Women with CD4+ Lymphocyte Counts between 200 and 500 cells/microl and below 100 cells/microl. *Journal of Acquired Immune Deficiency Syndromes* 1999; 20(5): 455-62. [PMID: 10225227]

15. ††Howland LC, Gortmaker, SL, Mofenson, LM, **Spino**, C, Gardner, JD, Gorski, H, Fowler, MG, and Oleske, J. Effects of Negative Life Events on Immune Suppression in Children and Youth Infected with HIV-1. *Pediatrics* 2000; 106(3):540-546. [PMID: 10969100]
16. †,††Currier, JS, **Spino**, C, Grimes, J, Wofsy, CB, Katzenstein, DA, Hughes, MD, Hammer, SM, and Cotton, DJ. Differences Between Women and Men in Adverse Events and CD4 Responses to Nucleoside Analogue Therapy for HIV Infection. The AIDS Clinical Trials Group 175 Team. *JAIDS* 2000; 24(4):316-24. [PMID: 11015147]
17. †Schooley, RT, **Spino**, C, Kuritzkes, D, Walker, BD, Valentine, FT, Hirsch, MS, Cooney, E, Friedland, G, Kundu, S, Merigan, Jr, TC, McElrath, MJ, Collier, A, Plaeger, S, Mitsuyasu, R, Kahn, J, Haslett, P, Uherova, P, deGruttola, V, Chiu, S, Zhang, B, Jones, G, Bell, D, Ketter, N, Twadell, T, Chernoff, D, Rosandich, M, and the AIDS Clinical Trials Group 209 and 214 Study Teams. Two Double-Blinded, Randomized, Comparative Trials of 4 Human Immunodeficiency Virus Type 1 (HIV-1) Envelope Vaccines in HIV-1-Infected Individuals across a Spectrum of Disease Severity: AIDS Clinical Trials Groups 209 and 214. *The Journal of Infectious Diseases* 2000; 182(5):1357-64. [PMID: 110234569]
18. †Britton, JR, Baker, A, **Spino**, C, and Bernstein, H. Postpartum Discharge Preferences of Pediatricians: Results from a National Survey. *Pediatrics* 2002; 110(1):53-60. [PMID: 12093946]
19. †Bernstein, HH **Spino**, C, Baker, A, Slora, EJ, Touloukian, CL, and McCormick, MC. Postpartum Discharge: Do Varying Perceptions of Readiness Impact Health Outcomes? *Journal of Ambulatory Pediatrics* 2002; 2(5):388-95. [PMID: 12241135]
20. †Bird, Shawn J, Brown, Mark J, **Spino**, C, Watling, S, and Foyt, Howard L. Value of Repeated Measures of Nerve Conduction and Quantitative Sensory Testing in a Diabetic Neuropathy Trial. *Muscle and Nerve* 2006; 34(2):214-24. [PMID: 16708368]
21. †,††Symonds, T, **Spino**, C, Sisson, M, Soni, P, Martin, M, Gunter, L, and Patrick, D. Methods to Determine the Minimum Important Difference for a Sexual Event Diary Used by Postmenopausal Women with Hypoactive Sexual Desire Disorder. *Journal of Sexual Medicine* 2007; 4(5):1328-1355. [PMID: 17727352]
22. †,††Bernstein, HH, **Spino**, C, Finch, S, Wasserman, R, Slora, E, Lalama, C, Touloukian, C, Lilienfeld, H, and McCormick, MC. Decision-Making for Postpartum Discharge of 4,300 Mothers and Their Healthy Infants: The Life Around Newborn Discharge Study. *Pediatrics* 2007; 120(2):e391-e400. [PMID: 17636111]

From 1997 – 2007, I was employed in the pharmaceutical industry where publications were discouraged. Papers during this period reflect those begun during my tenure at Harvard (with two exceptions for publications #20 and #21 for work carried out at Pfizer).

23. †,††Finch, SA, Lalama, C, **Spino**, C, Schwartz, HC, Wasserman, RC, McCormick, MC, and Bernstein, HH. Practice-Based Research Network Solutions To Methodological Challenges Encountered In A National, Prospective Cohort Study Of Mothers And Newborns. *Paediatric and Perinatal Epidemiology* 2008; 22:87-98. [PMID: 18173787]

24. †Perrone, G, Ruffini, PA, Catalano, V, **Spino**, C, Santini, D, Muretto, P, Zingaretti, C, Spoto, C, Sisti, V, Alessandroni, P, Cicetti, A, Ruzzo, A, Magnani, M, Tonini, G, Giordani, P, Rabitti, C, and Graziano, F. Intratumoral FOXP3-positive Regulatory T Cells Are Associated with Adverse Prognosis in Radically Resected Stage II-III Gastric Cancer. *European Journal of Cancer* 2008; 1875-1882. [PMID: 18617393]
25. †Nygaard, I, Barber, MD, Burgio, KL, Kenton, K, Meikle, S, Schaffer, J, **Spino**, C, Whitehead, WE, Wu, J, Brody, DJ, for the Pelvic Floor Disorders Network. Prevalence of Symptomatic Pelvic Floor Disorders in Women in the United States, 2005-2006. *The Journal of the American Medical Association* 2008; 300(11):1311-1316. [PMC2918416]
26. †Barber, MD, Brubaker, L, Menefee, S, Norton, P, Borello-France, D, Varner, E, Schaffer, J, Weidner, A, Xu, X, **Spino**, C, Weber, A for the Pelvic Floor Disorders Network. Operations and Pelvic Muscle Training in the Management of Apical Support Loss (OPTIMAL) Trial: Design and Methods. *Contemporary Clinical Trials* 2009; 30:178–189. [PMC2646798]
27. †Barber, MD, **Spino**, C, Janz, NK, Brubaker, L, Nygaard, I, Nager, CW, and Wheeler, TL for the Pelvic Floor Disorders Network. The Minimum Important Differences for the Urinary Scales of the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire. *American Journal of Obstetrics and Gynecology* 2009; 200:580e1-7. [PMC2680021]
28. †Nager, CW, Richter, HE, Nygaard, I, Paraiso, MF, Wu, JM, Kenton, K, Atnip, SD, and **Spino**, C for the Pelvic Floor Disorders Network. Incontinence Pessaries: Size, POPQ Measures, and Successful Fitting. *International Urogynecology Journal* 2009; 20:1023-8. [PMC2721123]
29. †,††Barber, MD, Brubaker L, Nygaard I, Wheeler II, TL, Schaffer, J, Chen, Z, and **Spino**, C for the Pelvic Floor Disorders Network. Defining “Success” after Surgery for Pelvic Organ Prolapse. *Obstetrics and Gynecology* 2009; 114:600-609. [PMC2904469]
30. †,††Bradley, CS, Rahn, DD, Nygaard, IE, Barber, MD, Kenton, KS, Siddiqui, NY, Abel, RB, **Spino**, C, and Richter, HE. The Questionnaire for Urinary Incontinence Diagnosis (QUID): Validity and Responsiveness to Change in Women Undergoing Non-surgical Therapies for Treatment of Stress Predominant Urinary Incontinence. *Neurourology and Urodynamics* 2010 Jun; 29(5):727-34. [PMC2891326]
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Short Form Versions of the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ). *Neurourology and Urodynamics*,2011 Apr;30(4):541-6. [PMC3759146]

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Hampstead, BH, Dauer, W, Toga, AW. Predictive Big Data Analytics: A Study of Parkinson's Disease Using Large, Complex, Heterogeneous, Incongruent, Multi-Source and Incomplete Observations. *PLoS ONE* 2016; 11(8):e0157077 . [PMCID: PMC4975403]

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62. †Pagani FD, Aaronson KD, Kormos R, Mann DL, **Spino, C**, Jeffries N, Taddei-Peters WC, Mancini DM, McNamara DM, Grady KL, Gorcsan J 3rd, Petrucci R, Anderson AS, Glick HA, Acker MA, Eduardo Rame J, Goldstein DJ, Pamboukian SV, Miller MA, Timothy Baldwin J; REVIVE-IT Investigators. The NHLBI REVIVE-IT Study: Understanding its Discontinuation in the Context of Current Left Ventricular Assist Device Therapy. *Journal of Heart and Lung Transplantation*. 2016 Nov;35(11):1277-1283. [PMID: 27836022].
63. Wei JT, Dunn R, Nygaard I, Burgio K, Lukacz ES, Markland A, Wren PA, Brubaker L, Barber MD, Jelovsek JE, **Spino, C.** (2017). Development and Validation of a Quantitative Measure of Adaptive Behaviors in Women With Pelvic Floor Disorders. *Female Pelvic Medicine & Reconstructive Surgery*, 23(4), 232-237. [PMID: 28650896]

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## Publications – Non-Peer-Reviewed

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1. Pagano, M, and **Spino, C.** The Role of Randomization. In: *Research Designs and Methods in Psychiatry*. Fava, M. and Rosenbaum, J.F., eds. Amsterdam: Elsevier, 1992.
2. Pagano, M and **Spino, C.** Stratification and Blocking. *Nutrition* 1994; 10:432. [PMID: 7819662]
3. **Spino, C**, and Stratton, P. Obstetrical and Gynecological Issues in AIDS. In: *AIDS Clinical Trials: Guidelines for Design and Analysis*. Finkelstein, D.M., and Schoenfeld, D.A., eds. Wiley-Liss, Inc., 1995.
4. **Spino, C**, LaMoreaux, L, Paulissen, J, Juneau, P, Chartier, K, Abel, R, Yan, C, and Bycott, P. Book Review of *Encyclopedia of Biopharmaceutical Statistics*, 1<sup>st</sup> ed., by Shein-Chung Chow. *Controlled Clinical Trials* 2001.

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## Manuscripts in Preparation or Submitted

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1. Mueller, ER, Corton, M, **Spino, C**, and the PFDN Endoanal Work Group. Multi-center, Multispecialty Certification for 2-D Ultrasound of Anal Sphincter Anatomy. Submitted to *Female Pelvic Medicine and Reconstructive Surgery*.
2. Loomes, K, Spino, C, for the Childhood Liver Disease Research Network. DXA analysis in ALGS, A1AT and BASD subjects. To be submitted to *Hepatology*.
3. Teckman, J, Spino, C, for the Childhood Liver Disease Research and Education Network. Longitudinal Analysis of Portal Hypertension, Liver Transplantation and Death in a Cohort of Young Patients with Alpha-1-Antitrypsin Deficiency Liver Disease. In Process.
4. Siegel, M, Jahnke, J, Spino, C, Narkewicz, M, Ye, W. Validation and Optimization of an Ultrasound Scoring System for Prediction of the Risk of Hepatic Cirrhosis in Cystic Fibrosis. In Process.
5. Bove, KE, Fei, L, Chung, CT, Finegold, MJ, Lovell, M, Russo, P, Shehata, B, White, F, Spino, C, Sheridan, R, Anders, R, Cummings, OW, Finn, L, Ranganathan, S, Magid, MS, Melin-Aldana, H, Wang, L, Chen, Z, Magee, JC. Hepatic hilar lymph node reactivity at Kasai portoenterostomy: correlations with age, outcome, and histology of proximal biliary remnant and liver. *Human Pathology*. Submitted 2016 Apr.
6. Pagani, FD, Kormos, R, Mann, DL, Spino, CA, Jeffries, N, Taddei-Peters, WC, Mancini, DM, McNamara, DM, Grady, KL, Gorscan III, J, Petrucci, R, Anderson, AS, Glick, HA, Acker, MA, Rame, JE, Goldstein, DJ, Pamboukian, SV, Miller, MA, Baldwin JT. Trial Design for the Randomized Evaluation of VAD Intervention Before Inotropic Therapy (REVIVE-IT) Study. *Journal of Heart and Lung Transplantation*. Submitted 2016 Jul 24.
7. Flynn, HA, Spino, C, Guille, C, Deligiannidis, KM, Maki, P, Jahnke, J, Rosenblum, K, Epperson, CN, Weiss, SJ. A Collaborative, Network-based Approach to Advance Women's Depression Research in the U.S.: Preliminary Findings. *Journal of Women's Health*. Re-Submitted 2017 April.

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## Professional Activities

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### ***Data and Safety Monitoring Boards***

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| 2010-2017    | NIDDK Data Safety and Monitoring Board, Irritable Bowel Syndrome Outcome Study   |
| 2011-2012    | Data Safety and Monitoring Board, Placebo-controlled RCT of Rectal Indomethacin in Prevention of Post-ERCP Pancreatitis    |
| 2013-2015    | Data Safety and Monitoring Board; Beneficial Effects of Quercetin in COPD - A Preliminary Clinical Trial                   |
| 2017-present | Data Safety and Monitoring Board, Chair; Interventional Radiology vs. ERC for Perihilar Biliary Tumors: The INTERCPT Trial |

### ***Editorial Boards***

2011-2016 Biostatistical Editor, *Gastroenterology*  
2014-present Biostatistical Editor, *Clinical Diabetes and Endocrinology*  
2016-present Biostatistical Editor, *Female Pelvic Medicine and Reconstructive Surgery*

### ***NIH Study Sections***

2013 Member, NIAID Special Emphasis Panel for RFA-AI-12-023 (Development of Medical Countermeasures for Post-Exposure Mitigation/Treatment of Injuries Resulting from a Radiation/Nuclear Incident)  
2014 Member, NIDDK Longitudinal Assessment of Bariatric Surgery (LABS) External Scientific Consultant Panel, February 13, 2014  
2015 Member, NICHD Maternal-Fetal medicine Units (MFMU) Network Special Emphasis Panel, November 19-20, 2015  
2016 Member, NICHD/ECHO IDeA Pediatric Network Special Emphasis Panel, June 23-24, 2016

### ***Other***

2010-2014 Consultant, the 33<sup>rd</sup> to 36<sup>th</sup> Annual Midwest Biopharmaceutical Statistics Workshop, 2010-2014, Muncie, Indiana  
2006 PhRMA Working Group on Adaptive Clinical Trial Designs

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## **Presentations and Invited Seminars**

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1. "Efficient Calculation of the Permutation Distribution for Trimmed Means," Joint Statistical Meetings, 1989.
2. "Efficient Calculation of the Permutation Distribution for Trimmed Means," University of Connecticut Statistics Department Seminar, 1991.
3. "Design of Combination Drug Trials," Society for Clinical Trials Meeting, 2003.
4. "Basic Statistics for Pathologists," University of Michigan Pathology Lectures, 2012.
5. "Advanced Training Course in Clinical Research Design and Protocol Development", Peking University Clinical Research Institute, 2013 [This is a 10-day course in Beijing for mid-career clinicians who are interested in developing expertise in research design and statistical analysis. I developed and provided lectures on biostatistics and epidemiology.]
6. "The Minimal Important Difference is of Maximal Importance", University of Michigan Biopsychology Speaker Series, 2014.
7. "Introduction to Biostatistics," University of Michigan Translational Pharmacology Lectures, 2014, 2015, 2016.
8. "Some Modern Statistical Ideas about Solutions to Hamlet's Lament," University of Michigan Rheumatology Grand Rounds, 2015.
9. "Comparing and Communicating Adaptive Designs for a Dose-Ranging Study," Miami University Statistical Department Seminar, 2015.
10. "Clinical Trials 101," University of Michigan Woodson Faculty Scholars Program, 2016.

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## **Biostatistics Department Service**

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- Computing Committee, 2009-2012
- Statistics in the Community at Michigan (STATCOM), 2012 - present

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## Teaching

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On Job/On Campus Program in Clinical Research Design and Statistical Analysis -- The On Job/On Campus Master's in Clinical Research Design and Statistical Analysis Program was developed to provide a means for physicians, dentists, pharmacists, pharmacologists and others who are involved in clinical research to develop expertise in research design and statistical analysis appropriate to such research while remaining in their existing employment.

- Clinical Trials and Study Design (Instructor 2010, 2012)
  - *A review of the ways clinical trials are used as a research tool: design of clinical trials; randomization; sample size; compliance; blinding; analysis of clinical trials data; stopping rules. The course also considers advantages and limitations of alternative types of quasi-experimental designs; nonequivalent control group designs; interrupted time-series designs; case series; crossover designs; meta-analysis.*
  - My mean scores were 4.19 (2010) and 4.55 (2012) to the statement “Overall, the instructor was an excellent teacher” on a Likert scale from “Strongly agree” (5) to “Strongly disagree” (1); average class size = 33.
- Planning and Funding Clinical Research (Co-Instructor 2011, 2013)
  - *This course will encompass four main areas of exploration. The preparation of a written document whose focus is on an integrated research plan including specific aims, background and significance, design, methods, logistical implementation and statistical analysis, and fiscal requirements. The evaluation of clinical research plans. Identification of funding sources and their requirements. And identification of the role of the research administrator in facilitating clinical research.*
  - My mean scores were 3.86 (2011) and 4.31 (2013) to the statement “Overall, the instructor was an excellent teacher” on a Likert scale from “Strongly agree” (5) to “Strongly disagree” (1); average class size = 33.

Statistical Computing, Harvard University School of Public Health (Instructor 2 terms)

Introduction to Biostatistics for Health Policy and Management, Harvard University School of Public Health (Instructor 2 terms)

Introduction to Computing, Harvard University School of Public Health (Instructor 1 term)

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## Mentoring and Advising

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I have mentored the following junior faculty in BORC/SABER on clinical trials design, conduct and analysis:

- Wen Ye
- Yun Li
- Lu Wang
- Min Zhang

I have mentored the following clinical researchers through the OJ/OC program or through K awards:

- Mark Peterson
- Vikas Kotagal

I have supported (partially or fully) the following Biostatistics GSRA's:

- Doug Lehmann, Summer 2011
- Fang Xiang, 2010-2012
- Hui Yang, 2012-2013
- Su Chu, Summer 2013
- Ritabrata Das, 2013-2014
- Jordan Jahnke, 2013-2015
- Yin-Hsiu Chen, 2015
- Ming Tang, 2016-present

I was academic advisor for the following Biostatistics students:

- Lauren Ziemba, 2013
- YiFan Wu, 2013

I served on the thesis committee for the following students:

- Pedro Saturno, DrPH, 1994
- Lois Howland, MS, 1994