

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
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NAME Shuster, Jonathan J.	POSITION TITLE		
eRA COMMONS USER NAME JSHUSTER	Professor		
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
McGill University, Montreal, Canada	B.Sc	1964	Chemistry
McGill University, Montreal, Canada	M.Sc.	1967	Math – Statistics
McGill University, Montreal, Canada	Ph.D.	1969	Math – Statistics

A. PERSONAL STATEMENT

I have been the Director of the Research Design and Analysis Program (RDAP) since 2009. We did not take the name BERD as the national key function committee was established later. Before that, I was the Clinical Research Center biostatistician (2002-2009) and the founding and only group statistician for the Pediatric Oncology Group (POG) (1980-2001), before it merged into the Children's Oncology Group. I was the PI of the statistical and data center for POG, funded by the NCI/NIH for over \$20,000,000 direct. My extensive statistical experience in clinical trial design is reflected in the invited book chapters (i.e. Chapter 13 in John Crowley's 2006 book-second edition, "Handbook of Statistics in Clinical Oncology", "Power and Sample Size for Phase III trials of Survival" and Chapter 12, "Design and Analysis of Experiments" in (then President of the Association of GCRC Biostatisticians) Walter Ambrosius' 2007 book, "Topics in Biostatistics.") and my full CV lists over 350 peer reviewed publications, including well over 50 in statistical/biostatistical journals. I also have been very active in national activities in the BERD key function committee (KFC) which like all KFCs was temporarily discontinued in January 2014. I am also active in the Association of Clinical and Translational Statisticians, which is continuing and enhancing the old KFC. Over the past 35 years, I have mentored hundreds of young clinical and translational researchers in almost every area of medical investigation. I combine good analytical skills with strong communication skills, and the ability to translate a medical question into a research question, both at the study design and data analysis points in time.

B. POSITIONS AND HONORS

POSITIONS:

1968-69	Lecturer, Mathematics, McGill University
1969-2005	University of Florida (UF), Assistant Professor (1969-74), Associate Professor (1974-80), Professor (1980 -2001), Adjunct Professor (2002), Research Professor (2003-5) Department of Statistics
2002-2005	UF General Clinical Research Center Biostatistician
2005-present	UF Professor, Department of Epidemiology and Health Policy Research (Renamed Health Outcomes/Policy 2010)
2009-present	Director, Research Design and Analysis Program, UF Clinical and Translational Science Award (CTSA)

NIH Study Sections:

1988-90	EDCI Study Section (Chairman 1989-90)
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1991-93	CCIRC Study Section Member
2003-5	NIH Epidemiology of Chronic Disease Study Section
2005-2008	Cardiovascular and Sleep Epidemiology Study Section
2010	CTSA Special Emphasis Panel

ELECTED FELLOW: American Statistical Association, 1994.

EDITORIAL: *Sequential Analysis* Associate Editor; *Research Synthesis Methods* Editorial Board

C. SELECTED PUBLICATIONS From a total of 355 (55 statistical methods) This list accents the statistical contributions. I coauthored 15 collaborative papers in 2014 (published or in press) and eight in 2013.

1. Suissa S, **Shuster JJ**. Exact Unconditional Sample Sizes for the 2x2 Binomial Trial. *J. Royal Statistical Society Series A*, 1985, 148:317-327.
2. Krischer JP, Hurley C, Pillalamarri M, Pant S, Bleichfeld C, Opel M, **Shuster JJ**. An automated patient registration and treatment randomization system for multicenter clinical trials. *Control Clin Trials*. 1991 12:367-77.
3. Suissa S, **Shuster JJ**. The 2X2 matched-pairs trial: exact unconditional design and analysis. *Biometrics* 1991, 47:361-372.
4. **Shuster JJ**. Fixing the Number of Events in Large Comparative Trials with Low Event Rates: A Binomial Approach. *Controlled Clinical Trials* 1993, 14:198-208.
5. **Shuster JJ**. Optimal Two-Stage Designs for Single Arm Phase II Cancer Trials. *Journal of Biopharmaceutical Statistics*, 2002, 12:39-51.
6. **Shuster JJ**, Chang MN, Tian L. Design of Group Sequential Trials with Ordinal Categorical Data based on the Mann-Whitney-Wilcoxon Test. *Sequential Analysis* (Wald Centennial Issue), 2004, 23:413-426.
7. **Shuster JJ**. Diagnostics for assumptions in moderate to large simple clinical trials: Do they really help? *Statistics in Medicine* 2005, 24:2431-2438.
8. **Shuster JJ**, Chang MN. Second guessing clinical trial designs. *Sequential Analysis*. 2008, 27:2-20
9. **Shuster JJ**, Theriaque D, Ilfeld B. Applying Hodges-Lehmann Scale Parameter Estimates to Hospital Discharge Times. *Clinical Trials*, 2008, 5:631-634. PMID: PMC2745104.
10. **Shuster JJ**. Student T-tests for potentially abnormal data. *Statistics in Medicine*, 2009, 28:2170-2184.
11. Haller MJ, Wasserfall CH, Hulme MA, Cintron M, Brusko TM, McGrail KM, Sumrall TM, Wingard JR, Theriaque DW, Shuster JJ, Atkinson MA, Schatz DA. Autologous umbilical cord blood transfusion in young children with type 1 diabetes fails to preserve C-peptide. *Diabetes Care*. 2011 Dec;34(12):2567-9. doi:10.2337/dc11-1406. Epub 2011 Oct 19. PubMed PMID: 22011412; PubMed Central PMCID:PMC3220832.
12. **Shuster JJ**, Guo JD, Skyler JS. Meta-analysis of safety for low event-rate binomial trials. *Res Synth Methods*. 2012 Mar;3(1). doi: 10.1002/jrsm.1039. PubMed PMID: 24339834; PubMed Central PMCID: PMC3856441.
13. **Shuster JJ**. Sample size verification for clinical trials. *Clin Transl Sci*. 2014 Feb;7(1):60-2. doi: 10.1111/cts.12115. Epub 2013 Oct 3. PubMed PMID:24119049; PubMed Central PMCID: PMC3945059.
14. Borst SE, **Shuster JJ**, Zou B, Ye F, Jia H, Wokhlu A, Yarrow JF. Cardiovascular risks and elevation of serum DHT vary by route of testosterone administration: a systematic review and meta-analysis. *BMC Med*. 2014 Nov 27;12:211. doi: 10.1186/s12916-014-0211-5. PubMed PMID: 25428524; PubMed Central PMCID: PMC4245724.
15. **Shuster JJ**, Neu J. A Pocock approach to sequential meta-analysis of clinical trials. *Res Synth Methods*. 2013 Sep;4(3). doi: 10.1002/jrsm.1088. PubMed PMID:24348752; PubMed Central PMCID: PMC3856440.

Free Statistical Study Design Software developed for GCRC and CTSA Biostatisticians Nationwide: Go to <http://ags.bwh.harvard.edu/> and click on Jon Shuster's SAS sample size programs.

D. RESEARCH SUPPORT

Ongoing Research Support

(Nelson/Shuster)

CTSI-RDAP Core Program	04/01/13-03/31/15	3.08 calendar months
UF Research Foundation/NIH	\$247,711	
Role: Program Director		

00078924	07/01/10-6/30/15	1.62 calendar months
FL Legislature (Dewar)	\$33,790	
Low Income Pool (LIP)		

The primary goal of the CARE Medical Home Program is to investigate whether a Health Coach helps to reduce patients' potentially preventable-admissions (PPAs), -readmissions (PPRs), and emergency department –visits (PPVs). The program also investigates whether patients' satisfaction with care and health outcomes differ by their group.

Role: Investigator and Biostatistician

University of Florida (Nelson)	Ongoing	3.00 calendar months
UF Clinical and Translational Science Institute		

The University of Florida makes a substantial institutional commitment to the CTSA awards above.

Role: Co-Investigator and Biostatistician

Pfizer Inc. (Hurley)	10/01/13-9/30/15	.72 calendar months
\$27,140		

An Integrative and Sustainable Approach to Pain Management

Serves as statistician on the project analyzing data obtained from this study.

Role: Biostatistician

DP3 DK101120 (Campbell-Thompson)	09/20/16-08/31/16	.48 calendar months
NIH/NIDDK	\$25,899	

Pancreatic Volume in Preclinical Type 1 Diabetes

Serves as statistician on the project analyzing data obtained from this study.

Role: Biostatistician

PRT-01/R43DK089787 (Toskes)	09/01/10-9/01/16	.28 calendar months
Metabolic Solutions/NIH	\$5,120	

Novel Breath Test to Detect Early Stage Chronic Pancreatitis

A clinical trial

Role: Biostatistician

1R01NR014019 (Parker)	03/18/13-01/31/17	1.32 calendar months
NIH/NINR	\$26,080	

Routine Aspiration of Residual Gastric Contents in Very Low Birth Weight Infants

Serves and advisor and statistician for this study on routine aspiration that routinely occurs in very low weight infants.

VA Medical Center (Shuster)	06/01/14-05/31/15	1.20 calendar months
Brain Rehabilitation Research Center	\$27,751	

Assisting with analysis and interpretation of statistics as well as experimental design.

Role: Biostatistician

Pending Support
None Disclosed

Overlap

None/coverage will never exceed 100%. CTSA coverage would drop if award made.