

SCHOLARLY ACTIVITIES

PART I ADVANCEMENT OF KNOWLEDGE (RESEARCH)

NAME: Stephen D. Simon

Completion of Scholarly Activities- Advancement of Knowledge (Research)

Applicants must demonstrate excellence in two (2) of the three (3) recognized areas of scholarly activity. Candidates may elect not to submit data for the optional area, or they may submit information in all three (3) areas and allow the SOM Faculty Appointment and Promotion Committee to independently consider their strengths in those areas. The following areas should be described with sufficient detail to allow the Committee to assess the merit of each listed activity. **All activities described below should occur since the applicant's affiliation with UMKC or the applicant's last promotion.** Where applicable, brief narrative descriptions of the research activity should be included. Citations for publications should be in a standard bibliographic format: Author(s), Title, Journal, Volume, Page(s), Date.

- 1. AWARDS AND GRANTS:** In reverse chronological order, beginning with the most recent, list all awards and/or external/internal grants received since affiliated with UMKC or last promotion. The listing should include the title, funding agency, principal investigator and amount and funded or unfunded. For each award/grant provide a brief explanation of the project(s) it supports.

I am listed as a consultant, collaborator, or co-investigator on numerous grants, but I do not track this information. The one grant worth noting here is "Estimating delays in completion of IRB approved and KBR supported research studies" because I am the principal investigator. This grant was funded in December 2006 for \$4,245 by the Katherine B. Richardson Foundation. Here is the abstract of this grant:

As the research biostatistician at Children's Mercy, Dr. Simon has supported the development of literally hundreds of clinical trials across just about every branch of pediatric medicine. In his experience and in the experience of many of the people he works with, the greatest practical problem in conducting medical research is slow accrual of patients. It is not unusual to see a research project that has gone a full year past its completion date and yet the researcher still has less than half of the subjects originally planned for. Slow accrual causes serious difficulty for researchers, for groups that fund research, and for groups that review research, such as Institutional Review Boards (IRBs) and Data and Safety Monitoring Committees.

There is little appreciation, however, in the research community for the problem caused by slow patient accrual. This lack of concern is caused, in large part, by the lack of hard data on scope and magnitude of the problem with slow patient accrual. This research proposal asks for \$4,245 for a pilot study to evaluate a random sample of 100 studies approved by the Children's Mercy IRB. This sample will produce an estimate of the proportion of studies that fall behind schedule, the proportion that end with fewer patients than originally planned, and the average shortfall in those studies. A qualitative analysis of the interim and final reports will help identify the major factors that cause slow patient accrual. The results of this research will serve as preliminary data for an R03 or R21 grant to produce quantitative tools for planning and monitoring accrual rates in clinical trials. These tools will help researchers plan appropriate and realistic accrual rates and

monitor them regularly, so that corrective action can be taken early to get a study back on track.

- 2. ORIGINAL RESEARCH, PEER REVIEWED PUBLICATIONS:** In reverse chronological order, beginning with the most recent publication since affiliated with UMKC or last promotion, list all published original research in peer reviewed journals and indicate if primary author. In addition, list the number of times these works have been cited in other publications (see Citation Index). Provide three (3) published reprints which best represent your published works. You may select reprints from this, or Other Publications or both areas, as long as the copies total three (3).

The number of citations of these articles, as of August 30, 2007 appears at the end of the reference. If no number appears, then this article has no citations, according to the Citation Index.

Resource utilization and expenditures for overweight and obese children. Hampl SE, Carroll CA, Simon SD, Sharma V. Arch Pediatr Adolesc Med. 2007 Jan; 161(1): 11-4. (Cited 1 time)

Prevention of peritonitis in children receiving peritoneal dialysis. Auron A, Simon S, Andrews W, Jones L, Johnson S, Musharaf G, Warady BA. Pediatr Nephrol 2007 Apr; 22(4): 578-85.

Use of the multipurpose drainage catheter for the provision of acute peritoneal dialysis in infants and children. Auron A, Warady BA, Simon S, Blowey DL, Srivastava T, Musharaf G, Alon US. Am J Kidney Dis. 2007 May;49(5):650-5.

X chromosome gene expression in human tissues: Male and female comparisons. Talebizadeh Z, Simon SD, Butler MG. Genomics 2006 Dec; 88(6): 675-81. (Cited 1 time)

The link between the Hippocratic Oath and evidence-based medicine. Dinakar C, Simon S. Ann Allergy Asthma Immunol 2006; 96(4); 511-3.

Tracking Trichophyton tonsurans through a large urban child care center: defining infection prevalence and transmission patterns by molecular strain typing. Abdel-Rahman SM, Simon SD, Wright KJ, Ndjountche L, Gaedigk A. Pediatrics 2006 Dec; 118(6); 2365-73. (Cited 1 time)

A time to be promoted. The Prospective Study of Promotion in Academia (Prospective Study of Promotion in Academia). Beasley BW, Simon SD, Wright SM. J Gen Intern Med 2006; 21(2); 123-9.

Impact of rapid influenza testing at triage on management of febrile infants and young children. Abanses JC, Dowd MD, Simon SD, Sharma V. Pediatr Emerg Care 2006; 22(3); 145-9. (Cited 4 times)

Timing of follow-up voiding cystourethrogram in children with primary vesicoureteral reflux: development and application of a clinical algorithm. Thompson M, Simon SD, Sharma V, Alon US. *Pediatrics* 2005; 115(2); 426-34. (Cited 13 times)

Random urine calcium/osmolality in the assessment of calciuria in children with decreased muscle mass. Richmond W, Colgan G, Simon S, Stuart-Hilgenfeld M, Wilson N, Alon US. *Clin Nephrol* 2005; 64(4); 264-70. (Cited 2 times)

Development of a new standard laboratory protocol for estimation of the field attenuation of hearing protection devices: Sample size necessary to provide acceptable reproducibility. Murphy WJ, Franks JR, Berger EH, Behar A, Casali JG, Dixon-Ernst C, Krieg EF, Mozo BT, Royster JD, Royster LH, Simon SD, Stephenson C. *J. Acoust. Soc. Am.* 2004; 115(1); 311-323.

Can an alternative umbilical arterial catheter solution and flush regimen decrease iatrogenic hemolysis while enhancing nutrition? A double-blind, randomized, clinical trial comparing an isotonic amino acid with a hypotonic salt infusion. Jackson JK, Biondo DJ, Jones JM, Moor PJ, Simon SD, Hall RT, Kilbride HW. *Pediatrics* 2004; 114(2); 377-383.

Lack of seasonal variations in urinary calcium/creatinine ratio in school-age children. Hilgenfeld MS, Simon S, Blowey D, Richmond W, Alon US. *Pediatr Nephrol* 2004; 19(10); 1153-5. (Cited 3 times)

Comparison of two formulae for estimation of glomerular filtration rate in children. Hellerstein S, Berenbom M, DiMaggio S, Erwin P, Simon SD, Wilson N. *Pediatr Nephrol* 2004; 19; 780-784. (Cited 6 times)

When should cranial magnetic resonance imaging be used in girls with early sexual development? Grunt JA, Midyett LK, Simon SD, Lowe L. *J Pediatr Endocrinol Metab.* 2004; 17(5); 775-780. (Cited 2 times)

Adverse effects of systemic glucocorticosteroid therapy in infants with hemangiomas. George ME, Sharma V, Jacobson J, Simon S, Nopper AJ. *Arch Dermatol* 2004; 140; 963-969. (Cited 10 times)

Low levels of tissue inhibitors of metalloproteinases with a high matrix metalloproteinase-9/tissue inhibitor of metalloproteinase-1 ratio are present in tracheal aspirate fluids of infants who develop chronic lung disease. Ekekezie II, Thibeault DW, Simon SD, Norberg M, Merrill JD, Ballard RA, Ballard PL, Truog WE. *Pediatrics* 2004; 113(6); 1709-14. (Cited 15 times)

Influence of the news media on diagnostic testing in the emergency department. Sharma V, Dowd MD, Swanson DS, Slaughter AJ, Simon SD. *Arch Pediatr Adolesc Med* 2003; 157(3); 257-60. (Cited 3 times)

Baby boomer nurses bearing the burden of care: A four-site study of stress, strain, and coping for inpatient registered nurses. Santos SR, Carroll CA, Cox KS, Teasley SL, Simon SD, Bainbridge L, Cunningham M, Ott L. J Nurs Adm 2003: 33(4); 243-50. (Cited 5 times)

Is 3-mm Less Drowsiness Important? Portnoy JM, Simon SD. Annals of Allergy, Asthma and Immunology 2003: 91(4); 324-5. (Cited 3 times)

Vagal nerve stimulation in refractory epilepsy: the first 100 patients receiving vagal nerve stimulation at a pediatric epilepsy center. Murphy JV, Torkelson R, Dowler I, Simon S, Hudson S. Arch Pediatr Adolesc Med 2003: 157(6); 560-4. (Cited 8 times)

Evaluating the Benefit of Speech Recoding Hearing Aids in Children. Miller-Hansen D, Nelson PB, Widen J, Simon SD. American Journal of Audiology 2003: 12(2); 106-113.

Human Sperm Survival Assay as a Bioassay for the Assisted Reproductive Technologies Laboratory. De Jonge CJ, Centola GM, Reed ML, Shabanowitz RB, Simon SD, Quinn P. Journal of Andrology 2003: 24(1); 16-18.

Effect of rapid diagnosis of influenza virus type a on the emergency department management of febrile infants and toddlers. Sharma V, Dowd MD, Slaughter AJ, Simon SD. Arch Pediatr Adolesc Med 2002: 156(1); 41-3. (Cited 26 times)

A breast-feeding assessment score to evaluate the risk for cessation of breast-feeding by 7-10 days of age. Hall RT, Mercer AM, Teasley SL, McPherson DM, Simon SD, Santos SR, Meyers BM, Hipsh NE. J Pediatr 2002: 141(5); 659-664. (Cited 12 times)

Growth Hormone Responsiveness in Two Groups of Children With Significantly Short Stature. Grunt JA, Schwartz ID, Simon SD, Howard CP. The Endocrinologist 2002: 12; 58-65.

Using standard desk-top tools to monitor medical error rates. Carroll CA, Cox KS, Santos SR, Simon SD. Seminars for Nurse Managers 2002: 10(2); 95-99.

Normal urinary calcium/creatinine ratios in african-american and caucasian children. So NP, Osorio AV, Simon SD, Alon US. Pediatr Nephrol 2001: 16(2); 133-9. (Cited 15 times)

Understanding the odds ratio and the relative risk. Simon SD. J Androl 2001: 22(4); 533-6. (Cited 1 time)

Is the randomized clinical trial the gold standard of research? Simon SD. Journal of Andrology 2001: 22(6); 938-43. (Cited 5 times)

Interpreting positive studies. Simon SD. J Androl 2001: 22(3); 358-9. (Cited 1 time)

Interpreting negative studies. Simon SD. J Androl 2001: 22(1); 13-6. (Cited 1 times)

Creatinine excretion rates for renal clearance studies. Hellerstein S, Simon SD, Berenbom M, Erwin P, Nickell E. *Pediatr Nephrol* 2001; 16(8); 637-43. (Cited 7 times)

Allergenic materials in the house dust of allergy clinic patients. Barnes C, Tuck J, Simon S, Pacheco F, Hu F, Portnoy J. *Annals of Allergy, Asthma, & Immunology* 2001; 86(5); 517-23. (Cited 14 times)

Factors influencing infant visits to emergency departments. Sharma V, Simon SD, Bakewell JM, Ellerbeck EF, Fox MH, Wallace DD. *Pediatrics* 2000; 106(5); 1031-1039. (Cited 25 times)

Comparison of the Burkard and Allergenco MK-3 volumetric collectors. Portnoy J, Landuyt J, Pacheco F, Flappan S, Simon S, Barnes C. *Annals of Allergy, Asthma and Immunology* 2000; 84; 19-24. (Cited 8 times)

Readmission of breastfeeding infants in the first 2 weeks of life. Hall RT, Smith MT, Simon S. *J Perinatol* 2000; 20(7); 432-437. (Cited 13 times)

Semen Quality and Hormone Levels Among Radiofrequency Heat Sealer Operators. Grajewski B, Cox C, Schrader SM, Murray SM, Edwards RM, Turner TW, Smith JM, Shekar SS, Evenson DP, Simon SD, Conover DL. *J Occup Environ Med* 2000; 42(10); 993-1005. (Cited 11 times)

High incidence of focal segmental glomerulosclerosis in nephrotic syndrome of childhood. Srivastava T, Simon SD, Alon US. *Pediatr Nephrol* 1999; 13(1); 13-8. (Cited 42 times)

Transitioning preterm infants with nasogastric tube supplementation: increased likelihood of breastfeeding. Kliethermes PA, Cross ML, Lanese MG, Johnson KM, Simon SD. *J Obstet Gynecol Neonatal Nurs* 1999; 28(3); 264-73. (Cited 5 times)

Optimization of cytochrome p450 2D6 (CYP2D6) phenotype assignment using a genotyping algorithm based on allele frequency data. Gaedigk A, Gotschall RR, Forbes NS, Simon SD, Kearns GL, Leeder JS. *Pharmacogenetics* 1999; 9(6); 669-682.

Reproductive function in relation to duty assignments among military personnel. Schrader SM, Langford RE, Turner TW, Breitenstein MJ, Clark JC, Jenkins BL, Lundy DO, Simon SD, Weyandt TB. *Reprod Toxicol* 1998; 12(4); 465-8. (Cited 5 times)

Male reproductive effects of lead, including species extrapolation for the rabbit model. Moorman WJ, Skaggs SR, Clark JC, Turner TW, Sharpnack DD, Murrell JA, Simon SD, Chapin RE, Schrader SM. *Reprod Toxicol* 1998; 12(3); 333-46. (Cited 15 times)

Skin carcinogenicity of condensed asphalt roofing fumes and their fractions following dermal application to mice. Sivak A, Niemeier R, Lynch D, Beltis K, Simon S, Salomon R,

Latta R, Belinky B, Menzies K, Lunsford A, Cooper C, Ross A, Bruner R. *Cancer Letters* 1997; 117(1); 113-123. (Cited 30 times)

Semen analysis of military personnel associated with military duty assignments. Weyandt TB, Schrader SM, Turner TW, Simon SD. *Reprod Toxicol* 1996; 10(6); 521-8. (Cited 11 times)

Combining reproductive studies of men exposed to 2-ethoxyethanol to increase statistical power. Schrader SM, Turner TW, Ratcliffe JM, Welch LS, Simon SD. *Occupational Hygiene* 1996; 2; 411-415. (Cited 1 time)

[20 peer reviewed publications from 1985 to 1995 not listed.]

- 3. OTHER PUBLICATIONS:** In reverse chronological order, beginning with the most recent, list all other research publications including book chapters, letters to the editor, monographs and abstracts published in non-peer reviewed journals since affiliated with UMKC or last promotion. Identify each publication by its type (abstract, book chapter, *etc.*). Please refer to #2 regarding three (3) reprint selections.

Statistical Evidence in Medical Trials. What Do the Data Really Tell Us? Stephen D. Simon (2006) Oxford, UK: Oxford University Press. This book did undergo peer-review prior to publication. A blurb from the back cover of this book provides a nice summary.

Statistical Evidence in Medical Trials is a lucid, well-written and entertaining text that addresses common pitfalls in evaluating medical research. Including extensive use of publications from the medical literature and a non-technical account of how to appraise the quality of evidence presented in these publications, this book is ideal for health care professionals, students in medical or nursing schools, researchers and students in statistics, and anyone needing to assess the evidence published in medical journals.

Nine reviews have been published about this book in various peer-reviewed medical and statistical journals. The reviews are generally, but not uniformly, positive. Here are the review citations and brief excerpts. Some of these reviews have full free text on the net, and you can find these links at www.childrensmercy.org/stats/evidence/reviews.asp.

Julian JA. *Statistics in Medicine* 2007; 26: 3825-2826. doi: 10.1002/sim.2908.

Stephen Simon's *Statistical Evidence in Medical Trials* is an enjoyable book that attempts to provide a simple guide for the consumer of the medical research literature. In general, he has accomplished this, but I think a number of important topics have not been covered. For the statistician with little or no experience or training in medical research, this book will be an easy read. For the student of epidemiology, the book is useful as a gentle introduction, and the paperback edition is priced reasonably. Its worth as a reference book, though, is limited.

Karlsson A. *Pharmaceutical Statistics* 2007 (June); 6(2): 149. doi: 10.1002/pst.278.

To conclude, although it has some shortcomings, this is a very interesting and useful book, especially for consumers of research with a limited knowledge of statistics, but even for producers of research. The main message is the importance of aspects of statistics other than formulas or calculations, such as selection of the right control group and avoidance of bias, which make the formulas more or less useless according to how they are implemented. Most practical statisticians in the pharmaceutical industry will find this book very useful.

Davis JW. *The American Statistician* 2007 (May); 61(2): 186

This book is the perfect remedy for those in the medical profession who took a statistics class but came away wondering how all the pieces fit together.

The author does a good job of conveying the lessons in a very understandable manner, peppering the text with stories, analogies, and the occasional joke. I found the book quite enjoyable to read, and sometimes hard to put down, even though I knew "how the story would end." This book is a real gem, and its intended audience will benefit from it immensely.

Martin J. *Evidence-Based Medicine* 2007; 12: 59; doi:10.1136/ebm.12.2.59. [Full text] [PDF]

Clearly this book is not "just another statistics book." Rather, it borders on the side of being revolutionary—a statistics book without numbers! While this might be considered near sacrilege in the world of pure statistics, for the purposes of inciting balanced, practical, evidence-based clinical decision making, it is nearly a 5 star resource. The tasteful humour injected throughout the text is just the perfect spoonful of sugar to make the medicine go down.

Dhar SK. *Journal of Biopharmaceutical Statistics* 2007: 5

The author uses conversational language with a good sense of humor and is able to explain complex concepts using simple stories and amusing anecdotes. This makes the book beneficial, not just for clinical researchers or students, but also as a valuable teaching tool for biostatistics trainers.

Sabin CA. *HIV Clinical Trials* 2007 (further publication details unknown)

Despite its title, 'Statistical Evidence in Medical Trials' (Stephen D Simon, Oxford Statistics) is not a statistics textbook – instead, it aims to provide the reader with a list of the most important questions that should be asked of any research to ensure that the quality of the evidence provided has been thoroughly assessed and that the conclusions are interpreted with appropriate caution. As a result, the book is ideal for those who wish to be able to read and appreciate the broad statistical concepts contained within the medical literature. It is assumed that the reader is familiar with the most common statistical techniques (although a chapter is provided in which some of these are discussed) and readers hoping to learn more about these would be better advised to read a

more specialised textbook. However, for those who are familiar with the general principles of statistical analysis, this book provides an additional guide to some of the 'softer' issues that are often ignored in statistics texts, most notably a detailed description of bias and clinical relevance. Non-medics will also benefit from reading the book – although the many examples cited are largely medical, they have been chosen so that most reasonably educated readers will understand the concepts and the issues discussed have wider applicability. Indeed, the author suggests that the book may be suitable to journalists and lawyers, as well as to patients who wish to find out more about their own illnesses.

Goldstein R. *Technometrics* 2007 (February); 49(1): 107-108.

Notwithstanding my negative comments and tone above, there are valuable points here; they are, however, generally too hard to find and some of them are undercut the author's misguided attempt to be "fair." If the author were to clean up the typographical errors and omissions and highlight the main points, the result would be a much better book.

Hamilton C. *Baylor University Medical Center Proceedings* 2006 (October): 19(4); 419.

Simon's text does a wonderful job of presenting and explaining the relevance of statistical issues in a manner understandable even to those with no statistical training whatsoever.

Rooney R. *International Journal of Epidemiology* 2006; 35(5):1368-1369;
doi:10.1093/ije/dyl182

This book is a clear, concise, and interesting read and should prove to be a useful guide. The examples and case studies make it easy to understand difficult concepts and the jokes and stories make it fun. There are some salient points and hopefully the reader will be enthused about looking at the published research and be more confident about distinguishing between the good and the bad.

This book has sold approximately 1,000 copies as of August 2007.

- 4. EDITORIAL/REVIEW:** If you have served as an editor or manuscript reviewer for a journal or other publication since affiliated with UMKC or last promotion, list those positions. Include journal/publication title, your position and the dates of service. If you have sat on a study section or scientific review committee for a funding/research agency or foundation, list those positions, the name of the agency and the dates of service.

I have refereed three research papers for *BMJ* in 2006 and 2007, two for the *Annals of Allergy, Asthma & Immunology* in 2003 and 2004, one for *BMC Medical Research Methodology* in 2002, and two for the *Journal of Andrology* in 1999 and 2000.

5. **HONORS AND AWARDS:** In reverse chronological order, beginning with the most recent, list any honors or awards you have received for your research activities since affiliated with UMKC or last promotion. List awards by title, date of award and location. A brief description of the award and what it recognizes should be included.

Co-author of a research presentation (Nopper et al. Bone Density in Children With Hemangiomas Treated With Systemic Glucocorticoids) which received the ISSVA "R Schobinger Award" for best clinical paper presented during the 16th International Workshop on Vascular Anomalies, June 2006, Milano, Italy.

Co-author of a research paper (Miller et al. Am J Audiology 2003; 24(1): 16-18) which received the Editor's Award for the American Journal of Audiology for the most outstanding publication in the calendar year 2003.

Co-author of a research paper (Moorman et al. Reproductive Toxicology 1998; 12(3): 333-46) which was the winner of the Alice Hamilton Award for 1999 for the best research paper in occupational safety and health (Biological Sciences Category).

Please note additional award under Teaching, Section 4.

6. **PRESENTATIONS:** In reverse chronological order, list all presentations that have resulted from your research since affiliated with UMKC or last promotion. This listing should include the title of the presentation, date, who presented to and where presented.

I do not track all presentations on my resume because there are too many of them. Please note, however, the award for the 2006 presentation by Nopper et al noted in Advancement of Knowledge (Research), section 5. The only presentations I track are those where I am first author. There is an uncertain dividing line between a training class (listed in Teaching, Section 3) and a research presentation (this section). I have adopted the arbitrary rule that anything that is 45 minutes or shorter is a research presentation and anything that is 60 minutes or longer is a training class. For the most part, this is a reasonable choice, but a case can be made that some of the material in this section might fit better in Teaching, Section 3 and vice versa.

* Simon SD. "Control charts for continuous monitoring of the number needed to harm," an **invited 35 minute oral research presentation** for the December 2007 Signal Detection and Risk Management Conference in **Amsterdam, the Netherlands** sponsored by Informa Life Sciences. I am also being asked to give a four hour training class at the same conference (see Teaching, Section 3).

* Simon SD "Use of Diagnostic Tests for Making Clinical Decisions," an **invited 30 minute oral research presentation** for the November 2007 Annual Scientific Meeting of the American College of Allergy, Asthma & Immunology in **Dallas TX**.

* Simon SD and Gajewski B "Predicting Accrual in Clinical Trials: Bayesian Posterior Predictive Distribution," a **contributed poster presentation** at the July/August 2007 Joint Statistical Meeting in **Salt Lake City, UT**.

* Simon SD. "Control charts for continuous monitoring of the number needed to harm," an **invited 45 minute oral research presentation** for the December 2006 Signal Detection and Data Mining Conference in **London England** sponsored by PharmaIQ, a branch of the International Quality and Productivity Center. I was also invited to give a three hour training class at the same conference (see Teaching, Section 3).

* Simon SD. "Four Tips for Developing an Educational Web Site." A **contributed poster presentation** for the Joint Statistical Meetings, August 1998, **Dallas TX**.

* Simon SD. "Medical Statistics Case Studies on the Web." A **contributed 15 minute oral presentation** at the Joint Statistical Meetings, August 1997, **Anaheim CA**. Note the award for this presentation cited in Teaching, Section 4.

[1 invited and 7 contributed first author oral research presentations from 1984 to 1995 not included.]

- 7. OTHER RESEARCH:** In this section, the faculty member may list other research activities. The applicant is referred to Appendix B, *Guidelines for Promotion of SOM Full-Time Non-Regular (Non-Tenure) Non-Physician and Non-Clinical Physician Faculty* for suggestions on the types of other or innovative activities which may be included. These suggestions are not all-inclusive however. Faculty members who have other unique or innovative research activities are encouraged to describe those in this section. Each activity must be listed by title, date(s) of activity, location and with a narrative description as mentioned above. Candidates may attach additional documentation which clarifies the faculty member's activities for up to two (2) of these activities.

Co-inventor on U.S. Patent, A System and Method for Monitoring and Analyzing Data Trends of Interest Within an Organization, filed 12/29/2000 and currently under review.

The actual text of the patent was written by lawyers, here is a summary from the perspective of Statistics. Many health-care organizations **monitor events related to safety**, such as medication errors, employee accidents, and patient complaints. A common thread is that these events are summarized as counts over time (typically months, quarters, or years). This patent suggests that a control chart based not on the count but on the **date gap (waiting time) between successive events** represents a superior approach to monitoring safety. The date gap allows you to react quickly to a sudden surge of events, rather than forcing you to wait to the end of an arbitrary calendar boundary. This approach is also useful for rapid assessment of an intervention that starts in the middle of a calendar period. A second innovation is the **adjustment of these date gaps for workload** (hospital census, number of full time equivalent employees, number of medications dispensed). This workload adjustment can, in some circumstances, be shown to be equivalent to the Number Needed to Harm (NNH), a commonly used measure of absolute risk. By plotting the adjusted date gaps on a control chart, you gain the ability **to monitor NNH on a continuing and on-going basis**.

I am currently examining extensions to this patent to monitor accrual problems in clinical trials, which has been funded by a small grant, as mentioned in Advancement of Knowledge (Research), Section 1. Another extension that I am studying is the monitoring of adverse events in clinical trials, which has led to two invited international oral presentations described in Advancement of Knowledge (Research), Section 6.