

---

---

## Mary F. Johnson, PhD

411 Monmouth Avenue  
Spring Lake, NJ 07762-1130  
(732) 359-6802  
e-mail: mary.johnson@mjbostat.com

---

---

### Publications

Kelsey, J.L.; Greenberg, R.A.; Hardy, R.J.; **Johnson, M.F.**: Pregnancy and the Syndrome of Herniated Lumbar Intervertebral Disc: An Epidemiological Study. Yale Journal of Biology and Medicine, 48: 361-368, 1975.

Makuch, R.W.; Freeman, D.H.; **Johnson, M.F.**: Justification for the Log-normal Distribution as a Model for Blood Pressure. Journal of Chronic Disease, 32: 245-250, 1979.

**Johnson, M.F.**: Inter-Species Extrapolation of Radiation-Induced Cancer Effects Using a Generalized Weibull Model. Biometrics, 25(4): 889, 1979.

Troendle, G.; Gueriguian, J.; Sobel, S.; **Johnson, M.F.**: Letter to the Editor: Probucol and Cardiac Toxicity. Lancet 1: 1179, 1982.

Makuch, R.W.; **Johnson, M.F.**: Biostatistical Considerations for Head and Neck Cancer Research. In Head and Neck Oncology, pp. 473-502; Wolf, F.T. (ed.), Martinus Nijhoff, Boston, Massachusetts, 1984.

Johnson, M.F.: Comments on the Design and Analysis of Plaque and Gingivitis Trials. Proceedings of the Conference on Clinical Trials in Periodontal Disease in Chicago, Illinois, 21-23 May 1985.

Makuch, R.W.; **Johnson, M.F.**: Some Issues in the Interpretation of "Negative" Clinical Studies. Arch. Intern. Med. 146: 986-989, 1986.

Makuch, R.W.; **Johnson, M.F.**: Avoiding Pitfalls in the Design and Analysis of Head and Neck Cancer Clinical Trials. In Cancers of the Head and Neck, pp. 193-222; Jacobs, C. (ed.), Martinus Nijhoff, Boston, Massachusetts, 1987.

Makuch, R.W.; **Johnson, M.F.**: Dilemmas in the Use of Active Control Groups in Clinical Research. IRB Journal 11(1): 1-5, 1989.

Makuch, R.W.; **Johnson, M.F.**: Issues in Planning and Interpreting Active Control Equivalence Studies, J. Clinical Epidemiology 42 (6): 503-511, 1989.

Senior, J.R.; **Johnson, M.F.**; DeTurck, D.M.; Bazzoli, F.; Roda, E.: In Vivo Kinetics of Radiolucent Gallstone Dissolution by Oral Dihydroxy Bile Acids, Gastroenterology 99: 243-251, 1990.

**Johnson, M.F.**: Design of Clinical Trials-Active Control (Equivalence) Trials, JAIDS 3(2): 589-90, 1990.

Brown, W.A.; **Johnson, M.F.**; Chen, M.: Clinical Features of Depressed Patients Who Do and Do Not Improve with Placebo. Psychiatry Research 41(3): 203-214, 1992.

**Johnson, M.F.**: Comparative Efficacy of NaF and SMFP Dentifrices in Caries Prevention: A Meta-Analytic Overview. Caries Res 27: 328-336, 1993.

Frishman, W.H.; Glasser, S.; Stone, P.; Deedwania, P.C.; **Johnson, M.F.**; Fakouhi, D.T.: Comparison of Controlled-Onset Extended Release Verapamil to Amlodipine and Amlodipine plus Atenolol on Exercise Performance and Ambulatory Ischemia in Patients with Chronic Stable Angina Pectoris. Amer. J. Cardiology 83: 507-514, 1999.

White, W.B.; **Johnson, M.F.**: Heart Rate and the Rate-Pressure Product in Patients with Hypertension: the Usefulness of Chronotherapy. Eur. Heart J. 20: Suppl B, 1999.

Malcolm, P.N.; Brown, J.J.; Hahn, P.F.; Stillman, A.E.; King, C.P.; Kawamura, Y.; Tanaka, T.; Noel, J.K.; Molony, B.A.; **Johnson, M.F.**; Hildebolt, C.F.: The Clinical Value of Ferric Ammonium Citrate: A Positive Oral Contrast Agent for T1-Weighted MR Imaging of the Upper Abdomen. JMRI 12: 702-707, 2000.

Glasser, S.P.; Frishman, W.; White, W.P.; Stone, P.; **Johnson, M.F.**; Circadian Heart Rate Response to Chronotherapy versus Conventional Therapy in Patients with Hypertension and Myocardial Ischemia. Clin. Cardiol. 23: 524-529, 2000.

White, W.B.; **Johnson, M.F.**; Black, H.R.; Elliott, W.J.; Sica, D.A.: Gender and Age Effects on the Ambulatory Blood Pressure and Heart Rate Responses to Antihypertensive Therapy. Amer. J. Hypertension 14: 1239-1247, 2001.

White, W.B.; Elliott, W.J.; **Johnson, M.F.**; Black, H.R.: Chronotherapeutic Delivery of Verapamil in Obese versus Non-Obese Patients with Essential Hypertension. J. Human Hypertension 15: 135-141, 2001.

White, W.B.; **Johnson, M.F.**; Anders, R.J.; Elliott, W.J.; Black, H.R.: Safety of Controlled-Onset Extended-Release (COER)-Verapamil in Middle-Aged and Older Patients with Hypertension and Coronary Artery Disease. Amer. Heart Journal 142: 1010-1015, 2001.

Laster, L.L.; **Johnson, M.F.**: Non-Inferiority Trials: The 'At Least As Good As' Criterion. Statistics in Medicine 22: 187-201, 2003.

Laster, L.L.; **Johnson, M.F.**; Kotler, M.L.: Non-Inferiority Trials: The 'At Least As Good As' Criterion With Dichotomous Data. Statistics in Medicine 25: 1115-1130, 2006.

## **Presentations**

**Johnson, M.F.**; Kelsey, J.L.; Holeman, G.R.: The Health Effects of Exposure to Low-Level Radiation from Nuclear Power Plants: A Feasibility Study. Meeting of the Health Physics Society, Buffalo, July 1975.

**Johnson, M.F.:** The Inter-Species Extrapolation of Radiation Induced Cancer Effects Using a Generalized Weibull Model. Meeting of the Biometric Society, the Institute of Mathematical Statistics and the American Statistical Association, New Orleans, Louisiana, 8-11 April 1979.

**Johnson, M.F.:** Statistical Guidelines for Protocol Development and NDA Submissions: The FDA's Perspective. Meeting of the Pharmaceutical Special Interest Group, Cherry Hill, New Jersey, 22-24 March 1981.

**Johnson, M.F.:** Statistical Approaches to Multiplicity in the Analysis of Intervention Trials. Invited presentation to the Biostatistics Subsection of the Pharmaceutical Manufacturer's Association Meeting, Naples, Florida, 11-14 October 1981.

**Johnson, M.F.;** Makuch, R.W.: Current Controversies in Clinical Trials. Invited presentation to Biostatistics department at the Medical College of Virginia in Richmond 15 October 1982.

**Johnson, M.F.:** Considerations in Planning an Aspirin-Controlled Trial: Is Aspirin Effective for Stroke Prevention? Invited presentation at the Fourth Annual Meeting of the Society for Clinical Trials in St. Louis, Missouri, 9-11 May 1983.

**Johnson, M.F.:** Invited Panel Discussant on Analytic Methods at the Conference on Caries Clinical Trials, sponsored by the American Dental Association in Chicago, Illinois, 17-19 May 1983.

**Johnson, M.F.:** Alternative Design Strategies for Cancer Clinical Trials. Invited presentation for the 1984 Biopharmaceutical Research Unit Spring Seminar Series at the University of Massachusetts in Amherst, Massachusetts, 9-11 April 1984.

**Johnson, M.F.:** Heterogeneity Among Patient Subgroups in Combination Drug Trials. Invited presentation at the Fifth Annual Meeting of the Society for Clinical Trials in Miami, Florida, 13-16 May 1984.

**Johnson, M.F.:** Drop-Outs and Exclusions. Invited presentation at an FDA Symposium entitled "Current Issues in the Design, Conduct and Interpretation of Clinical Trials" in Bethesda, Maryland, 11-12 September 1984.

**Johnson, M.F.:** Comments on the Design and Analysis of Plaque and Gingivitis Trials. Proceedings of the Conference on Clinical Trials in Periodontal Disease in Chicago, Illinois, 21-23 May 1985.

**Johnson, M.F.:** Statistical and Clinical Interpretation of Data. Invited workshop lecture for a course entitled "Clinical Interpretation of Investigational Data" at the Institute of Applied Pharmaceutical Sciences, East Brunswick, New Jersey, 10-12 June 1985.

**Johnson, M.F.:** FDA Perspective on Positive Control Trials. Invited presentation at a seminar entitled "The Use of Placebos and the Protection of the Human Subject in Clinical Trials" sponsored by the Western Institutional Review Board in Napa Valley, California, 13-14 October 1985.

**Johnson, M.F.:** Guest Lecturer. Statistical Evaluation of Data. FAES Graduate School course

in Pharmacology at NIH, 25 November 1985.

**Johnson, M.F.:** The NDA Review Process at FDA. PMA Working Group on Electronic Data Transmission, Raritan, New Jersey, October 1986.

**Johnson, M.F.:** Drop-Outs and Non-Evaluable Patient Data. Midwest Biopharmaceutical Statistics Workshop, Muncie, Indiana, May 1988.

**Johnson, M.F.:** Issues in Planning Interim Analyses. Drug Information Association Workshop, Hilton Head, South Carolina, 6-7 March 1989.

**Johnson, M.F.:** Study Design Considerations. Seminar of the Regulatory Affairs Professional Society: How to Prepare for and Conduct a Clinical Investigation, San Diego, California, 8-9 August 1989.

**Johnson, M.F.:** Interpreting Active-Controlled Trials: Comparisons with a Hypothetical Placebo Control. Drug Information Association, Baltimore, Maryland, 27 June-1 July 1999.

**Johnson, M.F.:** Review of Existing Methods for Indirect Comparisons to Historical Control. Drug Information Association, San Diego, CA 11-15 June 2000.

**Johnson, M.F.:** Invited Speaker. Statistical Trial Design and How It Affects You. Regulatory Affairs Professional Society Annual Conference and Exhibition, Boston, MA 23-26 September 2007.

**Johnson, M.F.:** Invited Speaker. Novel Statistical Methods for Clinical Development: Acceptance by the Regulatory Biostatistician. Annual Conference of the Indian Society for Clinical Research, Bangalore, India, 8-9 January 2010.

Gabardi, S.; Nigro, V.; **Johnson, M.F.**; Nachtrieb, R; Weinberg, J. Poster presentation. Evaluation of Steady-State Pharmacokinetic Parameters of LCP-Tacro™ and Advagraf® in Healthy Volunteers using a Systems Dynamic Model. 16<sup>th</sup> Congress of the European Society for Organ Transplantation (ESOT), Vienna, Austria, 8-11 September 2013.