Frank W. Rockhold, Ph.D.

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Profile

Frank has had diverse research interests and consulting experience in industry and academia including clinical trials design, data monitoring, benefit/risk, and most recently, safety and pharmacovigilance. He has been a leader in the scientific community in promoting data disclosure and transparency in clinical research.

Frank is a full-time Professor of Biostatistics and Bioinformatics at Duke Clinical Research Institute and Managing Partner of HunterRockhold, Inc., (www.hunterrockhold.com). His 40+-year career includes senior research positions at Lilly, Merck, and GlaxoSmithKline, where he recently retired as Senior Vice President of Global Clinical Safety and Pharmacovigilance. He has also held faculty appointments at six different universities. Frank served for 9 years on the board of directors of the non-profit CDISC, most recently as Chairman, and is past president of the Society for Clinical Trials. He is a past member of the PCORI Clinical Trials Advisory Panel and is on the board of the Frontier Science and Technology Research Foundation.

Frank holds a BA in Statistics from The University of Connecticut, an ScM in Biostatistics from The Johns Hopkins University, and a PhD in Biostatistics from the Medical College of Virginia at Virginia Commonwealth University. Frank is a Fellow of both the American Statistical Association and the Society for Clinical Trials and an Accredited Professional Statistician, PStat®. He is widely published in major scientific journals across a wide variety of research topics.

PROFESSIONAL EXPERIENCE

Duke University

Professor of Biostatistics and Bioinformatics 2016-present
Duke Clinical Research Institute
Duke University School of Medicine

- Clinical Trial Design
- Senior Biostatistics Faculty on Mega-Trials
- Faculty and staff advisor
- IDMC Membership and Training
- Data Sharing and Transparency
- Safety and Pharmacovigilance

HunterRockhold, Inc. (www.hunterrockhold.com)

Managing Partner 2016-present

Provide strategic advice on clinical development, trial designs, data transparency, pharmacovigilance, and data standards. Serves on Independent Data Monitoring Committees and Scientific Advisory Boards.

GlaxoSmithKline Pharmaceuticals (1987-2016)

Senior Vice President, Global Clinical Safety and Pharmacovigilance 2009-2016

$80 million budget; staff of 350 at 10+ sites worldwide

- Responsible for safety and Pharmacovigilance of all R&D and marketed products worldwide including serious adverse event and regulatory reporting, signal detection and management and risk management strategies.
- The staffs of physicians and scientists monitor 1000+ pharmaceutical, vaccine and consumer health products.
- Orchestrated a change program in 2010 to expand the scope of the department to include all new GSK business and absorb a tripling of workload by 2015 including implementing a new safety system.
- Co-Chairman of the Global Safety Board, and Product Recall Board.
- Chief Statistician for all of GSK
- Chairman, GSK Data Disclosure Steering Committee

Senior Vice President, Drug Development Sciences 2000-2010

$200 million budget; staff of 1,200+ at 10 sites worldwide

- Directed statistics and programming, epidemiology, clinical data management, decision sciences, health care database, and data exploration across all areas of R&D and all phases of development.
- Successfully combined overlapping departments following major merger while continuing industry leadership in cycle times and achieving synergy targets on schedule.
- Initiated, created and managed the company's first protocol review board.
- He created the industry's largest epidemiology department to enhance understanding of disease, improve safety, and increase efficiency of patient recruitment.
- Member of Global Safety Board
- Director of the GSK Clinical Trial Register, the industry's first clinical trial register to enhance public access to clinical trial results for every marketed product.

Senior Vice President, Cardiovascular and Metabolic Medicine Development Center 2008-2009

$200+ million budget; staff of 150

- Responsible for clinical development, clinical research, and life cycle management of all GSK assets in the cardiovascular and metabolic disease research worldwide.

SmithKline Beecham Pharmaceuticals

Vice President and Director, Biostatistics and Data Sciences 1998-2000

Staff of 600+

- Directed worldwide R&D departments in clinical data management, clinical biometrics, non-clinical statistics, clinical pharmacology statistics, statistical research, epidemiology, disease modeling, Phase IV statistics, and contract management.
- Created the industry's first unit dedicated to data mining technology and internal statistical research.
- Led the development of the "healthcare information factory" a 200 million patient database to better characterize relevant patient populations to assist in epidemiology and clinical trial design.

Vice President and Director, Biometrics & Research Statistics 1997-1998

- Directed the analysis and reporting for all R&D clinical trials worldwide including clinical pharmaceutical statistics, and research statistics in the US and the UK.

Merck Research Laboratories

Executive Director, Clinical Biostatistics and Research Data Systems 1994-1997

Project Co-chair for Protease Inhibitor Development

- Led the development of the first protease inhibitors (Crixivan) from clinical trials to market, the shortest time of any pharmaceutical product in history (approximately 41 days from end of trials to approval).
- Directed worldwide data management and statistical analysis and reporting for the Blue Bell Medical department. Directed worldwide health economic and remote data entry support for all clinical programs.

SmithKline Beecham Pharmaceuticals

Vice President and Director, Biometrics 1991-1994

- Directed analysis and reporting for all R&D clinical trials worldwide. Directly led clinical statistics and clinical applications programming in the US and the UK.

Vice President and Director, Operations - US Medical Affairs & Clinical Development 1988-1991

- Directed the implementation, monitoring, data collection, safety review, and data processing for US and Canadian clinical trials.

Smith Kline & French Laboratories

Acting Group Director, Planning & Scientific Administration - Medical & Regulatory Affairs 1988

- Directed operations components of trials for the U.S. pharmaceutical business.

Director of Biostatistics - Medical and Regulatory Affairs 1987-1988

Lilly Research Laboratories (1979-1987)

Research Scientist 1984-1987
Senior Statistician 1979-1983

ACADEMIC APPOINTMENTS

University of Pennsylvania 2000 to 2010
Adjunct Scholar, Epidemiology and Biostatistics
Penn State College of Medicine 1995 to 2010
Adjunct Professor, Department of Public Health Sciences
Medical College of Virginia/Virginia Commonwealth University 1990 to 2000
Graduate Faculty, Department of Biostatistics
Affiliate Professor of Biostatistics, VCU Medical Center 2012-Present
Indiana University School of Business Administration 1983 to 1985
Lecturer, Department of Quantitative Business Analysis
Butler University School of Business Administration 1979 to 1985
Lecturer, Department of Management Science
Duke University School of Medicine, Adjunct Professor of Biostatistics and Bioinformatics 2014-2016
Duke University School of Medicine, Professor of Biostatistics and Bioinformatics 2016-Present

EDUCATION

Medical College of Virginia, Ph.D. Biostatistics	1979
Johns Hopkins University, Sc.M. Biostatistics	1976
University of Connecticut, B.A. Statistics	1974

PROFESSIONAL AFFILIATIONS

American Statistical Association - Fellow, 2000, Committee on Committees 2008-2010
Biometric Society - Regional Advisory Board, 1989-1991;
Midwest Biopharmaceutical Statistics Workshop; Clinical Co-Chair, 1990 Workshop; Chair 1992
Society for Clinical Trials - President, 1996-1997; Board of Directors, 1989-1993; Chair Student Scholarship Committee, 1986-1991; Associate Editor for *Controlled Clinical Trials*, 1986-1999; Chair, Development Committee, 1998-2001; Policy Committee, 2000-2001; Fellows Committee, 2005-2006, Elected Fellow, 2008
Pharmaceutical Research Manufacturers of America - Biostatistics Steering Committee, 1994-1997; Vice-Chair (Chair-Elect), 1997-1998; Chair, 1999-2000; Advisor, 2001-2007; Clinical Steering Committee, 1999-2000, 2005-2008
ICH Expert Working Group – Member, ICH Expert Working Group (E1) on Extent of Population Exposure, 1992-1994; Member, ICH Expert Working Group (E9) on Biostatistics Guidelines for Clinical Trials, 1996-1998; Member, ICH Expert Working Group (E10) on Choice of a Control Group, 1997-2000
Institute of Medicine -- Panel on Developing a National Registry of Pharmacologic and Biologic Clinical Trials, 2005. Planning Committee Member and Session Chair Sharing Clinical Research Data: An IOM Workshop
World Health Organization – Scientific Advisory Group for the International Clinical Trials Registry Project, 2005-2008
Clinical Data Interchange Standards Consortium (CDISC), Member Board of Directors, 2006 -2007, Chair Elect 2008-2009, Chairman of the Board 2010-2011, Past Chairman 2012-2013
National Library of Medicine Board of Regents Clinical Trial Working Group, 2007 – 2010
Patient Centered Outcomes Research Institute Advisory Panel on Clinical Trials, Member 2014-2017
Frontier Science and Technology Research Institute, Board of Directors, 2015-

AWARDS, HONORS AND RECOGNITION

Elected Fellow, American Statistical Association**,** 2000
Elected Fellow, Society for Clinical Trials**,** 2008
ACCREDITED PROFESSIONAL STATISTICAN™, PStat® **,**2012
Career Achievement Award, PhRMA**,** 2009
Chairman's Leadership Award, GlaxoSmithKline 2004
Chairman's Award for Most Successful Process Improvement Team, "Reducing Cycle Time for Statistical Reporting," SmithKline Beecham**,** 1994
Named Outstanding Alumnus from Medical College of Virginia, Graduate School of Health Sciences, 1993

PAPERS, TECHNICAL REPORTS AND ABSTRACTS

Papers

Rockhold, F.W. Acute Myocardial Infarction and the Evaluation of Anticoagulants in Vermont, 1969-1973. Master of Science Thesis, Department of Biostatistics, The Johns Hopkins University School of Hygiene and Public Health, Baltimore, MD, 1977.

Boyle, R.M., Rockhold, F.W., Mitchell, G.S., and VanHorn, S. The Age/Sex Register: Estimation of the Practice Population. The Journal of Family Practice 5(6):999-1003, 1977.

Rockhold, F.W. and Boyle, R.M. Family Practice in Virginia: A Comparative Analysis of Two Years Data. The Journal of Family Practice 6(4):793-797, 1978. Reprinted in Clinical Medicine 85(11):29, November, 1978.

Rockhold, F.W. Discrimination Among Stochastic Models of the Negative Binomial: An Application to Episodes of Illness. Ph.D. Dissertation, Department of Biostatistics, Medical College of Virginia/Virginia Commonwealth University, Richmond, VA, December, 1978.

Boyle, R.M. and Rockhold, F.W. An Analysis of Returning Patients in Family Practice. The Journal of Family Practice 8(5):1029-1036, 1979.

Ridolfo, A.S., Crabtree, R.E., Johnson, D.W., Rockhold, F.W. Gastrointestinal Microbleeding: Comparisons Between Benoxaprofen and Other Nonsteroidal Anti-Inflammatory Agents. Journal of Rheumatology 7(Suppl. No. 6):36-47, 1980.

Rockhold, F.W. and Kilpatrick, S.J. Methods of Discrimination Among Stochastic Models of the Negative Binomial Distribution with an Application to Medical Statistics. Biometrical Journal 23(7):681-692, 1981.

Steinberg, M.I., Sullivan, M., Weist, S., Rockhold, F.W., Molloy, B.B. Cellular Electrophysiology of Clofilium, A New Anti-Fibrillatory Agent in Normal and Ischemic Canine Purkinje Fibers. Journal of Cardiovascular Pharmacology 3:881-895, 1981.

Ridolfo, A.S., Carmichael, R.H., DeSante, K.A., Bergstrom, R.F., Rockhold, F.W., Nash, J.F., Fineberg, S.E. Clinical Pharmacology of Benoxaprofen, European Journal of Rheumatology and Inflammation 5(2):98-112, 1982.

Ridolfo, A.S., Ashbrook, E.M., Schmid, G.E., Vogel, J.A., Rockhold, F.W., Offen, W.W. A Double-Blind Study Comparing Benoxaprofen, Aspirin, and Benoxaprofen Plus Aspirin in Patients with Rheumatoid Arthritis. European Journal of Rheumatology and Inflammation 5(2):239-245, 1982.

Enas, G.G., Hardison, C.D., and Rockhold, F.W. Technical Exposition of Graphical Tools in Survival Analysis: Proceedings of the Ninth Annual SAS Users Group Conference pp. 546-551, 1984.

Rockhold, F.W. and Kilpatrick, S.J. Estimation of the Population at Risk in General Practice Using Truncated Information from the Negative Binomial. Primary Care Research (Kilpatrick & Boyle Editors), Praeger, Chapter 5, pp. 65-81, 1985.

Enas, G.G. and Rockhold, F.W. Some Useful Pictures and Methods in Survival Analyses of Oncology Data. Proceedings of the Biopharmaceutical Section of the American Statistical Association pp. 266-275, 1987.

Goldberg, M.R., Sushak, C.S., Rockhold, F.W., Thompson, W.L. The Multi-Center Investigator Group: Vasodilator Monotherapy in the Treatment of Hypertension. I. Comparative Efficacy and Safety of Pinacidil, a Potassium Channel Opener, and Prazosin. Clinical Pharmacology and Therapeutics 44:78-92, 1988.

Goldberg, M.R., Rockhold, F.W., Offen, W.W. Factorial Design: An Approach to the Assessment of Therapeutic Drug Interactions in Clinical Trials. Journal of Clinical Research and Drug Development 2:215-225, 1988.

Enas, G.G., Rockhold, F.W., Dornseif, B.E., Sampson, C.B, Wuu, J. Monitoring and Interim Analysis of Clinical Trials: A Perspective from the Pharmaceutical Industry. Controlled Clinical Trials 10(1):57-70, 1989.

Goldberg, M.R., Rockhold, F.W., Offen, W.W., Dornseif, B.E. Assessment of Dose-Effect and Concentration-Effect Relationships of Pinacidil and Hydrochlorothiazide in Hypertension. Clinical Pharmacology and Therapeutics 46(2):208-218, 1989.

Rockhold, F.W., Goldberg, M.R., Thompson, W.L. Beneficial Effects of Pinacidil on Blood Lipids: Comparisons with Prazosin and Placebo in Hypertensive Patients. Journal of Laboratory and Clinical Medicine 114:646-654, 1989.

Goldberg, M.R., Rockhold, F.W., Thompson, W.L., DeSante, K.A. Clinical Pharmacokinetics of Pinacidil, A Potassium Channel Opener, in Hypertension. Journal of Clinical Pharmacology 29(1):33-40, 1989.

Frank, W.O., Karlstadt, R.G., Rockhold, F.W., Palmer, R.H., Malone, M., Young, M.D. Comparison Between Continuous and Intermittent Infusion Regimens of Cimetidine in Ulcer Patients. Clinical Pharmacology and Therapeutics 46:234-239, 1989. Erratum: Clinical Pharmacology and Therapeutics 46(5):500, 1989.

Frank, W.O., Karlstadt, R.G., Rockhold, F.W., Palmer, R.H., Young, M.D. Comparative Effects on Intragastric pH of Cimetidine Intermittent Injections and Primed Continuous Infusion in Patients with a History of Peptic Ulcer Disease. Clinical Pharmacology and Therapeutics.

Maroko, P.R., McDevitt, J.T., Silber, S.A., Fox, M.J., Young, M.D., Beg, M.A., Rockhold, F.W., Free, S.M., Herron, J.R., Gray, J.M., Schnaper, H.W., Hoffman, M.J., Matlin, J.S., Hamilton, B.P., Oberman, A.F., Hollifield, J.W. Antihypertensive Effectiveness of Very Low Doses of Hydrochlorothiazide - Results of the PHICOG I Trial. Clinical Therapeutics 11(1):94-119, 1989.

Frank, W.O., Wallin, B.A., Berkowitz, J., Kimmey, M., Fox, M.J., Palmer, R.H., Rockhold, F., Young, M.D. Reduction of Indomethacin-Induced Gastroduodenal Mucosal Injury and Gastrointestinal Symptoms with Cimetidine in Normal Subjects, Journal of Rheumatology 16(9):1249-1252, 1989.

Young, M.D., Frank, W.O., Karlstadt, R.G., O'Connell, S., Palmer, R.H., Rockhold, F.W., Kogut, D.G., Loiudice, T.A., Orchard, J.L., Stone, R.C. The Efficacy of Cimetidine in the Treatment of "Resistant" Duodenal Ulcers. Clinical Therapeutics 11(4):521-528, 1989.

Young, M.D., Frank, W.O., Karlstadt, R.G., O'Connell, S., Palmer, R.H., Rockhold, F.W., Kogut, D.G., Loiudice, T.A., Orchard, J.L., Stone, R.C. Efficacy of Once-Daily Cimetidine in Preventing Recurrence of Duodenal Ulcer. Clinical Therapeutics 11(4):529-538, 1989.

Frank, W.O., Young, M.D., Palmer, R., Rockhold, F., Karlstadt, R., Mounce, W., O'Connell, S. Acute Treatment of Benign Gastric Ulcer with Once-Daily Bedtime Dosing of Cimetidine Compared with Placebo. Alimentary Pharmacology and Therapeutics 3:573-584, 1989.

Frank, W.O., Young, M., Palmer, R.H., Karlstadt, R., Rockhold, F., Mounce, W. Once-Daily Bedtime Dosing Regimen of Cimetidine in the Treatment of Gastric Ulcer. Clinical Therapeutics 11(5):595-603, 1989.

Karlstadt, R.G., Iberti, T.J., Silverstein, J., Lindenberg, L., Bright-Asare, P., Rockhold, F.W., Young, M.D. Comparison of Cimetidine and Placebo for the Prophylaxis of Upper Gastrointestinal Bleeding Due to Stress-Related Gastric Mucosal Damage in the Intensive Care Unit. Journal of Intensive Care Medicine 5:26-32, 1990.

Palmer, R.H., Frank, W.O., Rockhold, F.W., Wetherington, J.D., Young, M.D., Cimetidine 800 mg BID for Healing Erosions and Ulcers in Gastroesophageal Reflux Disease. Journal of Clinical Gastroenterology 12(Suppl 2):S29-S34, 1990.

Rockhold, F.W., Enas, G.G. Practical Approaches to the Design and Conduct of Interim Analyses. Chapter 1.2 in Biopharmaceutical Sequential Statistical Applications Peace, K.E. (ed.), Marcel Dekker, 1992.

Martin, L.F., McL. Booth, F.V., Karlstadt, R.G., Silverstein, J.H., Jacobs, D.M., Hampsey, J., Bowman, S.C., D'Ambrosio, C.A., Rockhold, F.W. Continuous Intravenous Cimetidine Decreases Stress-Related Upper Gastrointestinal Hemorrhage Without Promoting Pneumonia. Critical Care Medicine 21(1):19-30, January, 1993.

Rockhold, F.W, Enas, GG. Data Monitoring and Interim Analyses in the Pharmaceutical Industry: Ethical and Logistical Considerations. Statistics in Medicine, 12:471-479, 1993.

Rockhold, F.W., Goldberg, M.R. An Approach to the Assessment of Therapeutic Drug Interactions With Fixed Combination Drug Products. Journal of Biopharmaceutical Statistics 6(3):231-240, 1996.

Knatterud, G.L., Rockhold, F.W., George, S.L., Barton, F.B., Davis, C.E., Fairweather, W.R., Honohan, T., Mowery, R., O'Neill, R. Guidelines for Quality Assurance Procedures for Multicenter Trials - A Position Paper. Controlled Clinical Trials 19(5):477-493, October, 1998.

Rockhold, F.W. Strategic Use of Statistical Thinking in Drug Development, Statistics in Medicine 19:3211-3217, 2000.

Dragalin, V., Fedorov, V., Jones, B., Rockhold, F. Estimation of the Combined Response to Treatment in Multicenter Trials. BDS Technical Report 2000-06.

Lewis, J., Louv, W., Rockhold, F., Sato, T. The Impact of the International Guideline entitled Statistical Principles for Clinical Trials (ICH E9), Statistics in Medicine 20:2549-2560, 2001.

Dragalin, V., Fedorov, V., Jones, B., Rockhold, F. Estimation of the Combined Response to Treatment in Multicenter Trials, Journal of Biopharmaceutical Statistics 11(4):275-295, 2001.

Rockhold, F.W. Industry Perspectives on ICH Guidelines, Statistics in Medicine 21:2949-2957, 2002.

DeMets, D., Califf, R., Dixon, D., Ellenberg, S., Fleming, T., Held, P., Julian, D., Kaplan, R., Levine, R., Neaton, J., Packer, M., Pocock, S., Rockhold, F., Seto, B., Siegel, J., Snapinn, S., Stump, D., Temple, R., Whitley, R. Issues in Regulatory Guidelines for Data Monitoring Committees, Clinical Trials 1:1-8, 2004.

DeMets, D.L., Fleming, T.R., Rockhold, F., Massie, B., Merchant, T., Meisel, A., Mishkin, B., Wittes, J., Stump, D., Califf, R. Liability Issues for Data Monitoring Committee Members, Clinical Trials 1(6):525-531, 2004.

Krall, R., Rockhold F. More on Compulsory Registration of Clinical Trials: GSK has Created A Useful Register. British Medical Journal 330 (7489):479-480, Letter to the Editor, February 26, 2005.

Krall, R., Rockhold, F. Trial Registration: Ignored to Irresistible. PMID: 15644534 [PubMed – indexed for MEDLINE]. Letter to the Editor.

Rockhold, F., Freeman, A., Metz, C., Merchant, T., Fuell, D., Gallacher, T., Krall, R. CTR Act. From Study Initiation to Publication – the Role of Clinical Trial Registers. Applied Clinical Trials. 14 (9), 38-46, September, 2005.

Krall, R.L., Rockhold, F. Clinical Trials Report Card. Letter to the Editor. New England Journal of Medicine 354 (13), 1427, March 30, 2006.

Rockhold, F.W., Krall, R.L. Trial Summaries on Results Databases and Journal Publication. The Lancet 367 (9523), 1635-1636, May, 2006.

Rockhold, F.W. Requiring 'Independent' Statistical Analyses for Industry Sponsored Trials? Pharmaceutical Statistics, May 5-6, 2006.

Begg, C.B., Brawley, O., Califf, R.M., DeMets, D.L., Ellenberg, S.S., Kaplan, R.S., Rockhold, F.W. The Society for Clinical Trials Opposes US Legislation to Permit Marketing of Unproven Medical Therapies for Seriously Ill Patients. Position Paper, Clinical Trials 3: 154-157, 2006.

Rockhold, F., Segreti, T. Secondary Efficacy Endpoints. Wiley Encyclopedia of Clinical Trials 2007.

Rockhold, F.W., Snapinn, S. Improving the Image of Pharmaceutical Industry Research: Transparency is Not Always Clear. Biopharmaceutical Report, 15 (1), 2007.

Metz, C.A., Rockhold, F., Freeman, A. GSK Clinical Study Results Database: Site Utilization Metrics for a Large Public Database, Drug Information Journal, (42), 247-252, 2008.

Kush, R.D., Helton, E., Rockhold, F.W., Hardison, CD, Electronic Health Records, Medical Research, and the Tower of Babel, New England Journal of Medicine, 358;16 April 17, 2008.

Ghersi, D., Clarke, M., Berlin, J., Gulmezoglu, M., Lumbiganon, P., Moher, D., Rockhold, F., Sim, I., Wager, E. Reporting the Findings of Clinical Trials: A Discussion Paper, Bulletin of the World Health Organization; Perspectives Article DOI: 10.2471/08.053769.

Rockhold, F., Ruberg, S. ICH-E9 Reflections and Considerations, Pharmaceutical Statistics, 7(4):233-235, 2008.

Strahlman, E., Rockhold, F., Freeman, A. Public Disclosure of Clinical Research. The Lancet, Comment DOI: 10.1016/S0140-6736(09)60613-9, March 24, 2009.

Rockhold, F.W., Freeman, A.J., Metz, C.A. Public Disclosure of Clinical Trial Results: A Necessary Step on the Path to Transparency and Trust. Pharmaceutical Medicine, 23(3): 131-137, 2009.

Chuang-Stein, C., Bain, R., Branson, M., Burton, C., Hoseyni, C., Rockhold, F., Ruberg, S., Zhang, J. Statisticians in the Pharmaceutical Industry: The 21st Century. Statistics in Biopharmaceutical Research, Vol. 2, No. 2: 145 -152, May 2010.

Rockhold F.W., Enas, G. 10 Years with ICH E10: Choice of Control Groups. Pharmaceutical Statistics, 10(5): 407-409, 2011.

Rockhold, F.W., Bishop, S. Extracting the value of Standards: The role of CDISC in a pharmaceutical research strategy. Clinical Evaluation, 40 (1): 91-96, 2012

Chan, A-W., Tetzlaff, J.M., Altman, D.G., Laupacis, A., Gøtzsche, P.C., Krlež̆a-Jeric´, K., Bjartsson, A.H., Mann, H. Dickersin, K., Berlin, J.A., Dore, C.J., Parulekar, W.R., Summerskill, W.S.M., Groves, T., Schulz, K.F., Sox, H.C., Rockhold, F.W., Rennie, D. and Moher, D. SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. Ann Intern Med., 158:200-207, 2013,

Nisen P., Rockhold F. Opening a Gate to the Walled Garden: Providing Access to Patient Level Data from Clinical Trials, New England Journal of Medicine, 369;5 , August 1, 2013

Berlin, J.A., Morris, S., Rockhold, F.W., Askie, L., Ghersi, D., Waldstreicher, J. Bumps and Bridges on the Road to Responsible Sharing of Clinical Trial Data, Clinical Trials 2014; 11: 7–12

Rockhold, F., Nisen, P., and Freeman, A., Data Sharing at a Crossroads. New England Journal of Medicine, 2016. **375**(12): p. 1115-1117

Rockhold, F., Comments on 'Estimands in clinical trials – broadening the perspective'. Statistics in Medicine, 2017. **36**(1): p. 24-26.

Rockhold, F.W. A Critical Juncture for Clinical Data Sharing. For The Record, Vol. 28 No. 12 P. 5, 2016 http://www.fortherecordmag.com/archives/1216p5.shtml

Ohman, E.M., Roe, M.T., Steg, P.G., James, S.K., Povsic, T.J., White, J., Rockhold, F., et al., Clinically significant bleeding with low-dose rivaroxaban versus aspirin, in addition to P2Y12 inhibition, in acute coronary syndromes (GEMINI-ACS-1): a double-blind, multicentre, randomised trial. Lancet, 2017

Rockhold, F.W., Statistical controversies in clinical research: data access and sharing—can we be more transparent about clinical research? Let's do what's right for patients. Annals of Oncology, 2017. **28**(8): p. 1734-1737.

Rockhold, F.W., Data Sharing: Stakeholder Perspectives On Transparency In Clinical Trials, Clinical Informatics, August 22, 2017 http://www.clinicalinformaticsnews.com/2017/08/22/data-sharing-stakeholder-perspectives-on-transparency-in-clinical-trials.aspx

Abstracts 2015 - present (1977- 2014 Abstracts upon request)

Rockhold, F.W., Access to Anonymised Patient Level Data: Experience from GSK, AAAS Annual Meeting, San Jose, CA February 15, 2015

Rockhold, F.W. Providing Access To Patient Level Clinical Trial Data, White House Workshop on Accelerating Data Collaborative, Washington DC, 20 March 2015

Rockhold, F.W., Clinical Study Data Request Platform, Promoting Clinical Trial Data Transparency Conference, Harvard MRCT, Boston, MA, 30 March 2015

Rockhold, F.W., The expanding role of statistical science in medicines safety and pharmacovigilance, World Drug Safety Conference, Chicago, IL, 23 April 2015,

Rockhold, F.W., Putting the patient first – benefit and risk considerations in Drug Development, International Society for Pharmacoeconomics and Outcomes Research, Philadelphia, PA, 19 May 2015

Rockhold, F.W., The Evolving Role of Quantitative Clinical Trial Science in Medicine Development, Duke Department of Biostatistics and Bioinformatics Seminar Series Durham, NC September 17 2015

Rockhold, F.W., ICH-E9+ Statistical Principles for Clinical Trials, American Course on Drug Development and Regulatory Sciences, University of California, San Francisco, Washington DC February 23, 2016

Rockhold, F.W., The Role of Quantitative Science in Medicine Safety and Pharmacovigilance, American Course on Drug Development and Regulatory Sciences, University of California, San Francisco, Washington DC February 23, 2016

Rockhold, F.W., The Evolving Role of Quantitative Clinical Data Science in Medicine Development, MCV Department of Biostatistics Seminar Series, Richmond, VA March 25, 2016

Rockhold, F.W., The Role of Quantitative Science in Medicine Safety and Pharmacovigilance, Trends and Innovations in Clinical Trial Statistics, Durham, NC May 4, 2016

Rockhold, F.W. Benefit to risk considerations in ongoing monitoring of clinical trials, Duke-Industry Statistics Symposium, Durham, NC September 16, 2016

Rockhold, F.W., Experiences in sharing of individual patient data from clinical trials: Making disclosure transparent, Experiences and Methods in Sharing Clinical Trial Data, Philadelphia, 24 October 2016

Rockhold, F.W. Open Access, Data Sharing: Benefits and Challenges, CardioVascular Clinical Trialists (CVCT) Workshop, French Embassy Washington DC, Dec 4-5th, 2016

Rockhold, F.W. Data Monitoring in Clinical Trials: Considerations in a Seamless Drug Development Paradigm, National Cancer Policy Forum, National Academy of Science, Washington, DC, December 13 2016

Rockhold, F.W. Open Access & Data Sharing: The Changing Clinical Data Disclosure and Transparency Landscape, Keynote Address, Clinical Data Disclosure and Transparency Conference Jan 18-19, 2017 Philadelphia, PA

Rockhold, F.W. Open Access and Data Sharing: Where are we on the Clinical Data Disclosure and Transparency Journey? Keynoite Address, Midwest Biopharmaceutical Statistics Workshop May 22, 2017 Ball State University, Muncie, Indiana

Rockhold, F.W. Clinical Data Access and Sharing: Where are we on the Journey?, Consequential and Reproducible Clinical Research: Charting the Course for Continuous Improvement June 15, 2017 National Library of Medicine, Bethesda MD

Rockhold, F.W. Quantitative Safety Monitoring: Regulatory Landscape, Statistical Methodology and Cross-Disciplinary Scientific Engagement, Joint Statistics Meetings, August 2, 2017, Baltimore MD

Rockhold, F.W. Open Patient Data Access and Sharing: Where Are We on the Journey and Is the Destination Worth the Cost of the Trip?, Keynote Address, Disclosure and Transparency for Clinical Data Summit August 7, 2017 Philadelphia, PA