

Bruce E. Rodda, Ph.D., M.B.A.

Curriculum Vitae

EDUCATION

M.B.A. - Fairleigh Dickinson University, Teaneck, NJ, 1982
(Thesis title: The Impact of Governmental Regulations Governing Transborder Data Flow on Multinational Pharmaceutical Companies)

Ph.D., Biostatistics - Tulane University, New Orleans, LA, 1969
(Dissertation title: An Analytic System for the Statistical Analysis of Markov Chains)

M.S., Biostatistics - Tulane University, New Orleans, LA, 1967

B.A., Mathematics - Alfred University, Alfred, NY, 1965

Other universities attended from which course credit was received:

Bucknell University
Yale University
Louisiana State University
Indiana University
Somerset County Community College
Bucks County Community College

INDUSTRIAL POSITIONS HELD

- 1969-1973 Senior Statistician, Lilly Research Laboratories
Eli Lilly and Company, Indianapolis, IN
- 1974-1976 Research Scientist, Lilly Research Laboratories
Eli Lilly and Company, Indianapolis, IN
- 1976-1977 Associate Director, Clinical Biostatistics and Research Data Systems
International, Merck Sharp and Dohme Research Laboratories
Merck and Company, Rahway, NJ
- 1977-1982 Director, Clinical Biostatistics and Research Data Systems International
Merck Sharp and Dohme Research Laboratories
Merck and Company, Rahway, NJ
- 1982-1987 Senior Director, Clinical Biostatistics and Research Data Systems
International, Merck Sharp and Dohme Research Laboratories
Merck and Company, Rahway, NJ
- 1987-1988 Vice President, Clinical Operations
Ayerst Laboratories, New York, NY
and
Assistant Vice President, Overseas Clinical Operations
Wyeth-Ayerst Research, Philadelphia, PA
Both companies are divisions of American Home Products, Inc.
- 1988-1994 Vice President, Biostatistics and Data Management
Bristol-Myers Squibb Pharmaceutical Research Institute,
Princeton, NJ
- 1994-1997 Vice President, Research Administration
Schering-Plough Research Institute, Kenilworth, NJ
- 1998-1999 Vice President, Operations-Americas
PPD Development, Austin, TX
- 2001-2003 Global Head, Medical Development Strategy
Pharmacia Corporation, Peapack, NJ
- 2003- Principal, Strategic Statistical Consulting LLC
Spicewood, TX

ACADEMIC POSITIONS HELD

- 1965-1967 NIH (General Medical Sciences) Trainee and Teaching Assistant,
Tulane University Medical School, New Orleans, LA
- 1967-1968 Statistical Research Assistant, Biostatistics Department,
Tulane University Medical School, New Orleans, LA
- 1968-1969 Public Health Service Predoctoral Research Fellow,
Tulane University Medical School, New Orleans, LA
- 1972-1974 Instructor, Department of Pharmacology and Toxicology,
Indiana University Medical School, Indianapolis, IN
- 1975-1976 Assistant Professor,
Department of Pharmacology and Toxicology,
Indiana University Medical School, Indianapolis, IN
- 1977-1978 Guest Investigator,
The Rockefeller University, New York, NY
- 1979-1990 Assistant Professor of Community Medicine,
University of Illinois School of Medicine, Rockford, IL
- 1991-1998 Member, Industrial Advisory Committee
Rutgers University, New Brunswick, NJ
(Chair 1995-1998)
- 2000-2001 Adjunct Associate Professor of Statistics
McNeese State University, Lake Charles, LA
- 2000-2005 Associate Professor of Clinical Research and Biostatistics,
Texas State University, San Marcos, TX
- 2005 - Adjunct Professor of Biostatistics, The University of Texas School of
Public Health, The University of Texas Health Science Center at Houston,
Houston, TX and Adjunct Professor of Public Health, Austin Regional
Campus

In addition to academic appointments, invited seminars have been presented at:

American University	Louisiana State University
University of Connecticut	McNeese State University
Indiana University Medical Center	Columbia University
University of Illinois Medical School at Chicago	University of Buffalo
University of Illinois Medical School at Rockford	Rutgers University
Medical University of South Carolina	Food and Drug Administration
University of Massachusetts	The University of Texas

MISCELLANEOUS POSITIONS HELD

- 1973 – 1976 Consultant to the Veterans Administration Hospital in Indianapolis, IN and the Veterans Administration Hospital in Shreveport, LA
- 1975 Consultant -- Indianapolis Department of Education
- 1979 Guest Faculty – Epidemiology Survey Course – Sponsored by the University of Illinois School of Medicine
- 2004 – 2011 Member, TheraSphere Medical Advisory Board
- 2004 – 2005 Member, Scientific Advisory Board, Daiichi Medical Research, Inc.
- 2012 – 2015 Member, Scientific Advisory Board, Pam Labs LLC
- 2012 – 2015 Board of Directors, Global Outcomes Inc.
- 2012 – 2013 Member, Arginine Review Expert Panel, U.S. Pharmacopeia

Consultant to NIH Special Study Sections:

1. Human health effects of polybrominated biphenyls
2. Immunotoxicology of environmental agents
3. Response surface methodology in cancer chemotherapy
4. Genetic and environmental factors in disease
5. Clinical and postmortem evaluation of Alzheimer's disease
6. Computer systems for clinical trials
7. Information networks for cognitive scientists

PHARMACEUTICAL REGULATORY EXPERIENCE

Personal presentations have been made to the pharmaceutical regulatory agencies of:

Sweden	France
Belgium	Germany
Spain	United States
England	European Medicines Agency
Canada	India

Participated in an Orientation for FDA Statistical Advisors – September 2000

PROFESSIONAL ASSOCIATIONS

International Society of Clinical Biostatistics

American Statistical Association

Fellow (Elected 1991)

Member Bioavailability Committee, 1971-1972

Executive Committee, Biopharmaceutical Section, 1991-1994

Chair, Biopharmaceutical Section, 1993-1994

Executive Committee, Princeton-Trenton Chapter, 1994

Chair, Corporate Representatives Committee, 1996-1999

Accredited Professional Statistician (PStat), 2011 - present

Biometric Society

Member, Regional Advisory Board, 1986-1988

Drug Information Association

Food and Drug Law Institute

American Society for Clinical Pharmacology and Therapeutics

Vice Chairman, Section on Biostatistics and Clinical Trial Methodology, 1986-1989

Chairman, Council III (Biostatistics and Clinical Trial Methodology, Medico-Legal
Matters, and R&D Administration), 1987-1988

Board of Directors, 1987 - 1988

Society for Clinical Trials

Nominating Committee, 1992-1994 (Chair-1994)

Society of the Sigma XI

Delta Mu Delta (National Business Honorary)

Listed in American Men and Women of Science

Listed in Who's Who in the East

Editorial Board – Controlled Clinical Trials, 1983-1987

Editorial Board – Journal of Chronic Diseases, 1975-1987

Editorial Board – Journal of Clinical Epidemiology, 1988 – 2018

PROFESSIONAL ASSOCIATIONS (continued)

Associate Editor – Journal of the American Statistical Association, Biopharmaceutical Statistics, Special Applications Section, 1989

Editorial Advisory Board – Pharmaceutical Medicine, 1988 - 1991

Editorial Board – Journal of Biopharmaceutical Statistics, 1990 – 1997

Editorial Board – Biostatistics and Biometrics Open Access Journal, 2017 – present

Pharmaceutical Research and Manufacturers of America (formerly Pharmaceutical Manufacturers Association)

Biostatistics Subsection

Member, Steering Committee, 1981 - 1985

Chairman, Long Range Planning Committee, 1982 -1984

Vice Chairman, 1983 - 1984

Chairman, 1984 - 1985

Advisor, 1986 - 1988

Member, Ad Hoc Committee on Drugs in the Elderly, 1983 - 1988

Member, Bioavailability/Bioequivalence Committee, 1985 - 1988

Member, Biostatistics Guidelines Committee, 1985 - 1986

Member, PMA/FDA/ASCPT Committee on Drug Level Monitoring, 1985 - 1988

Member, Bioavailability Guidelines Committee, 1985 - 1986

Member, PMA/FDA Joint Committee on Computerized Biopharmaceutics Submissions, 1987 - 1990

Member, Ad Hoc Committee on ANDA Regulations, 1989

HONORS AND QUALIFICATIONS

Recipient of FDA Commissioner's Special Citation (CANDA Guidance Task Force), 1993

Recipient of PhRMA Career Achievement Award, 2002

Fellow, Royal Statistical Society

Chartered Statistician (CStat), Royal Statistical Society

Fellow, American Statistical Association

Accredited Professional Statistician (PStat), American Statistical Association

RESEARCH INTERESTS

Experimental design, strategic aspects of clinical research.

PUBLICATIONS

1. Rodda, B.E.: "An Analytic System for the Statistical Analysis of Markov Chains." Ph.D. Dissertation, Tulane University, 1969. University Microfilms, Ann Arbor, MI (1969).
2. Rodda, B.E. and Miller, M.C.: "Analysis and Simulation of Biological Processes Using Finite Markov Chains." Biometrics 25:201 (1969) (Abstract).
3. Wolen, R.L. and Rodda, B.E.: "Automated Determination of Protein Binding by Ultrafiltration." The Pharmacologist, 12:244 (1970) (Abstract).
4. Kiplinger, G.F.; Manno, J.E.; Rodda, B.E.; and Forney, R.B.: "Dose-Response Analysis of the Effects of Tetrahydrocannabinol in Man." Clin. Pharmacol. Ther., 12:650-657 (1971).
5. Rodda, B.E.; Scholz, N.E.; Gruber, C.M.; and Wolen, R.L.: "Evaluation of Plasma Concentration of Propoxyphene Utilizing a Hybrid Principal Components -- Analysis of Variance Technique: Case I -- Equimolar Doses." Toxicol. Appl. Pharmacol., 19:563-571 (1971).
6. Rodda, B.E.; Scholz, N.E.; Gruber, C.M.; and Wolen, R.L.: "Evaluation of Plasma Concentration of Propoxyphene Utilizing a Hybrid Principal Components -- Analysis of Variance Technique: Case II -- Equipotent Doses." Toxicol. Appl. Pharmacol., 19:572-582 (1971).
7. Rodda, B.E.; Miller, M.C.; and Bruhn, J.G.: "Prediction of Anxiety and Depression Patterns Among Coronary Patients Using a Markov Chain Analysis." Behavioral Sci., 16:482-489 (1971).
8. Crabtree, R.E.; Young, E.C.; Galloway, J.A.; and Rodda, B.E.: "The Use of Highly Purified 'Single Component' Insulins in Insulin Resistance." Diabetes, 20:352 (1971) (Abstract).
9. Matsuda, A.; Galloway, J.A.; Diller, E.R.; Rodda, B.E.; and Young, E.C.: "The Effect of Weight Change and Sulfonylurea Treatment on Circadian Blood Glucose and Serum Insulin in Maturity Onset Diabetes." Diabetes, 20:366 (1971) (Abstract).
10. Rodda, B.E.: "Sustained Release Preparations: Estimation of Plasma Concentration in the One Compartment Open Model When Release is Both Immediate and Zero Order." Arch. Int Pharmacodyn., 194:290-296 (1971).

PUBLICATIONS (continued)

11. Rubin, A.; Rodda, B.E.; Warrick, P.; Rudolfo, A.S.; and Gruber, C.M.: "Physiologic Disposition of Fenopropfen in Man: I - Pharmacokinetic Comparison of the Calcium and Sodium Salts Administered Orally." J. Pharm. Sci., 60:1797-1801 (1971).
12. Rubin, A.; Rodda, B.E.; Warrick, P.; Rudolfo, A.S.; and Gruber, C.M.: "Physiologic Disposition of Fenopropfen in Man: II - Plasma and Urine Pharmacokinetics After Oral and Intravenous Administration." J. Pharm. Sci., 61:739-745 (1972).
13. Manno, J.E.; Kiplinger, G.F.; Rodda, B.E.; Forney, R.B.; and Manno, B.R.: "Dose-dependent Alterations in Human Motor and Mental Performance After Smoking Marijuana Cigarettes." Drug Addiction, Vol. II, Futura Publishing Co., Mt. Kisco, NY (1972).
14. Chernish, S.M.; Wolen, R.L.; and Rodda, B.E.: "Adsorption of Propoxyphene Hydrochloride by Activated Charcoal." Clinical Toxicology, 5:317-329 (1972).
15. Chernish, S.M.; Rubin, A.; Rodda, B.E.; Ridolfo, A.S.; and Gruber, C.M.: "Physiologic Disposition of Fenopropfen in Man: IV - The Effects of Position of Subject, Food Ingestion, and Antacid Ingestion on the Plasma Levels of Orally Administered Fenopropfen." J. Med., 3:249-257 (1972).
16. Martz, R.; Brown, D.J.; Forney, R.B.; Bright, T.P.; Kiplinger, G.F.; and Rodda, B.E.: "Propranolol Antagonism of Marijuana Induced Tachycardia." Life Sciences, 11:999-1006 (1972).
17. Martz, R.; Sunday, F.L.; Rodda, B.E.; Brown, D.J.; Kiplinger, G.F.; and Forney, R.B.: "The Effects of Marijuana on Auditory Thresholds." J. Aud. Res., 12:146-148 (1972).
18. Rubin, A.; Rodda, B.E.; Warrick, P.; Gruber, C.M.; and Ridolfo, A.S.: "Interactions of Aspirin with Nonsteroidal Anti-inflammatory Drugs in Man." Arthritis Rheum., 16:635-645 (1973).
19. Miller, R.E.; Chernish, S.M.; Rosenak, B.D.; and Rodda, B.E.: "Hypotonic Duodenography with Glucagon." Radiology, 108:35-42 (1973).
20. Lemberger, L.; Martz, R.; Rodda, B.E.; Forney, R.B.; and Rowe, H.: "Comparative Pharmacology of Delta-9-THC and its Metabolite, 11-OH-9-THC." J. Clin. Inv., 52:2411-2417 (1973).

PUBLICATIONS (continued)

21. Chernish, S.M.; Miller, R.E.; Rosenak, B.D.; Skucas, J.; and Rodda, B.E.: "Hypotonic Duodenography: A Double-blind Comparison of Glucagon to Placebo and to Two Anticholinergics." Gastroenterology, 64:709 (1973) (Abstract).
22. Evans, M.A.; Martz, R.; Rodda, B.E.; Brown, D.J.; Kiplinger, G.F.; Lemberger, L.; and Forney, R.B.: "Impairment of Performance with Low Doses of Marijuana." Clin. Pharmacol. Ther., 144:936-940 (1973).
23. Trygstad, C.W.; Bang, N.U.; Heidenreich, R.O.; Csiscko, B.M.; and Rodda, B.E.: "A Controlled Trial of Aspirin in Childhood Glomerular Disorders." Thrombos. Diasthes. Haemorrh. 30:12-16 (1973).
24. Evans, M.A.; Martz, R.; Rodda, B.E.; Brown, D.J.; Lemberger, L.; and Forney, R.B.; "Effects of d-Amphetamine on Psychomotor Skills." The Pharmacologist, 15:219 (1973) (Abstract).
25. Job, D.D.; Griffing, W.J.; and Rodda, B.E.: "A Possible Origin of Intestinal Gradients and Their Relation to Motility." Am. J. Physiol., 226:1510-1515 (1974).
26. Evans, M.A.; Martz, R.; Rodda, B.E.; Kiplinger, G.F.; and Forney, R.B.: "Quantitative Relationship Between Blood Alcohol Concentration and Psychomotor Performance." Clin. Pharmacol. Ther., 15:253-260 (1974).
27. Miller, R.E.; Chernish, S.M.; and Rodda, B.E.: "Cholecystography: A Cost Reduction Study." Radiology, 110:61-65 (1974).
28. Beall, A.C., et al: "The Development and Introduction of New Cardiovascular Drugs." Am. J. Cardiology, 34:457-486 (1974).
29. Miller, R.E.; Chernish, S.M.; Skucas, J.; Rosenak, B.D.; and Rodda, B.E.: Hypotonic Roentgenography with Glucagon." Am. J. Radiol., 121:264-274 (1974).
30. Gruber, C.M.; Waife, S.O.; and Rodda, B.E.: "Should Clinical Evaluation of Analgesia be Based on Single Doses? – Some Pharmacokinetic Considerations." Clin. Pharmacol. Ther., 15:208 (1974) (Abstract).
31. Helleberg, L.; Rubin, A.; Wolen, R.L.; Rodda, B.E.; Ridolfo, A.S.; and Gruber, C.M.: "A Pharmacokinetic Interaction in Man Between Phenobarbitone and Fenoprofen, A New Anti-inflammatory Agent." Brit. J. Clin. Pharm., 1:371-374 (1971).

PUBLICATIONS (continued)

32. Rodda, B.E.: "Sequential Analysis in Phase 1 and Phase 2 Clinical Trials." in McMahon, F.G. (ed.) Principles and Techniques of Human Research and Therapeutics. Vol IV - Importance of Experimental Design, Futura Publishing Co., Mt. Kisco, NY (1974).
33. Wolen, R.L.; Rubin, A.; Rodda, B.E.; Ridolfo, A.S.; and Gruber, C.M.: "Problems Associated with Bioavailability and Dosage Regimen Studies in Man." J. Pharmacokinetics and Biopharmaceutics, 2:365-377 (1974)
34. Kiplinger, G.F.; Sokol, G.; and Rodda, B.E.: "Effect of Combined Alcohol and Propoxyphene on Human Performance." Arch. Int. Pharmacodyn., 212:175-180 (1974).
35. Miller, R.E.; Chernish, S.M.; Skucas, J.; Rosenak, B.D.; and Rodda, B.E.: "Hypotonic Colon Examination with Glucagon." Radiology, 113:555-561 (1974).
36. Dalton, W.; Martz, R.; Lemberger, L.; Rodda, B.E.; and Forney, R.B.: "Clinical Effects of Marijuana Combined with Secobarbital." Clin. Pharmacol. Ther. 18:298-304 (1975).
37. Waife, S.O.; Gruber, C.M.; Rodda, B.E.; and Nash, J.F.: "Problems and Solutions to Single-Dose Testing of Analgesics: Comparison of Propoxyphene, Codeine, and Fenpropfen." Internat. J. Clin. Pharmacol., 12:301-304 (1975).
38. Rodda, B.E.: "Multiclinic and Multi-investigator Trials of Cardiovascular Agents -- A Statistical Enigma." Biometrics, 31:600 (1975) (Abstract).
39. Nash, J.F.; Bechtol, L.D.; Lowary, L.R.; Rodda, B.E.; and Rose, H.A.: "The Relationship Between the Particle Size of Dicumarol and its Bioavailability in Dogs: Part I - Capsules." Drug Development Communications, 1:443-458 (1975).
40. Rodda, B.E.; Sampson, C.B.; and Smith, D.W.: "The One Compartment Open Model: Some Statistical Aspects of Parameter Estimation." J. Roy. Stat. Soc. Series C, 24:309-318 (1975).
41. Dalton, W.S.; Martz, R.; Rodda, B.E.; Lemberger, L.; and Forney, R.B.: "Combined Effects of Delta-9-Tetrahydrocannabinol and Cannabidiol in Man." Forensic Science, 5: 118 (1975). (Abstract)

PUBLICATIONS (continued)

42. Cockerill, E.M.; Miller, R.E.; Chernish, S.M.; McLaughlin, G.C.; and Rodda, B.E.: "Optimal Visualizaion of Esophageal Varices." American J. Roentgenol. Rad. Therapy and Nuclear Med., 126: 516-523 (1976).
43. Dalton, W.S.; Martz, R.; Lemberger, L.; Rodda, B.E.; and Forney, R.B.: "The Influence of Cannabidiol on the Effects of Delta-9-Tetrahydrocannabinol in Man." Clin. Pharmacol. Ther. 19: 300-309 (1976).
44. Evans, M.A.; Martz, R.; Lemberger, L.; Rodda, B.E.; and Forney, R.B.: "Effects of Dextroamphetamine on Psychomotor Skills." Clin. Pharmacol. Ther., 19: 777-781 (1976).
45. Rodda, B.E.; Chernish, S.M.; and Nash, J.F.: "Pharmacokinetic Method of Designing Sustained Release Formulations - Propoxyphene Hydrochloride." J. Pharmacokinetics and Biopharmaceutics, 4: 243-253 (1976).
46. Rodda, B.E.; Chernish, S.M.; and Nash, J.F.: "Delayed Release Propoxyphene - Pharmacokinetic Design." Clin. Pharmacol. Ther., 19: 114 (1976) (Abstract).
47. Waife, S.O.; Gruber, C.M.; Rodda, B.E.; and Nash, J.F.: "Analgesia, Plasma Levels and Dosage of Propoxyphene." Int. J. Clin. Pharmacol., 13: 177-181 (1976).
48. Lemberger, L.; Dalton, W.; Martz, R.; Rodda, B.E., and Forney, R.B.: "Clinical Studies on the Interaction of Psychopharmacologic Agents with Marijuana." Annals N.Y. Academy Sci., 281: 219-228 (1976).
49. Rubin, A.; Chernish, S.M.; Crabtree, R.; Gruber, C.M.; Helleberg, L.; Rodda, B.E.; Warrick, P.; Wolen, R.L.; and Ridolfo, A.S.: "A Profile of the Physiological Disposition and Gastrointestinal Effects of Fenoprofen in Man." Curr. Med. Res. Opin., 2: 529-544 (1974).
50. Evans, M.A.; Martz, R.; Wimbish, G.; Griffis, L.; Rodda, B.E.; Brown, D.J.; Lemberger, L.; and Forney, R.B.: "Subjective Response and Excretion Patterns of Dextroamphetamine after the Administration of Therapeutic Doses." J. Forensic Sci., 2: 197-201 (1977).
51. Evans, M.A.; Martz, R.; Rodda, B.E.; Lemberger, L.; and Forney, R.B.: "Effects of Marijuana-Dextroamphetamine Combination." Clin. Pharmacol. Ther., 20: 350-358 (1976).

PUBLICATIONS (continued)

52. Dalton, W.S.; Martz, R.; Rodda, B.E.; Lemberger, L.; and Forney, R.B.: "Influence of Cannabidiol on Secobarbital Effects and Plasma Kinetics." Clin. Pharmacol. Ther., 20: 695-700 (1976).
53. Forney, R.B.; Martz, R.; Lemberger, L.; Rodda, B.E.; and Evans, M.A.: "The Combined Effect of Marijuana and Dextroamphetamine." Annals N.Y. Academy Sci., 281: 162-170 (1976).
54. Van Winzum, C. and Rodda, B.E.: "Diflunisal - Efficacy in Postoperative Pain." Br. J. Clin. Pharm., 4: 39S - 43S (1977).
55. Andrew, A.; Rodda, B.E.; Verhaest, L.; and Van Winzum, C.: "Diflunisal - Six Month Experience in Osteoarthritis." Br. J. Clin. Pharm., 4: 45S-52S (1977).
56. Kleber, J.W.; Galloway, J.A.; and Rodda, B.E.: "GLC Determination of Acetohexamide and Hydroxyhexamide in Biological Fluids." J. Pharm.Sci., 66: 635-638 (1977).
57. Nash, J.F.; Galloway, J.A.; Garner, A.D.; Johnson, D.W.; Kleber, J.W.; and Rodda, B.E.: "In Vivo and In Vitro Availability of Acetohexamide from Tablets." Can. J. Pharm. Sci. 12: 59-64 (1977).
58. Rodda, B.E. and Davis, R.L.: "Application of Bayesian Methods to the Evaluation of Data from Pharmacokinetic and Bioavailability Studies." Biometrics, 34: 534 (1978) (Abstract).
59. Rodda, B.E. and Davis, R.L.: "Determining the Probability of an Important Difference in Bioavailability." Clin. Pharmacol. Ther., 28: 247-252. (1980).
60. Rodda, B.E. and Huber, P.B.: "Statistical Considerations in Drug Absorption and Disposition Studies - Current Practices." Albert, K.S. (ed.) Statistical Considerations in Drug Absorption and Disposition Studies., A.Ph.A. Press (1980).
61. Rodda, B.E.: "Analysis of Sets of Estimates from Pharmacokinetic Studies." in Endreny, L. (ed.), Kinetic Data Analysis; Design and Analysis of Enzyme and Pharmacokinetic Experiments., Plenum Press, NY (1981).
62. Rodda, B.E.: "Consideracoes Biostatisticos no Desenho de Ensaio de Prevencao Secundaria do Infarto do Miocardio e Morte Subita." Gomes, A.J. ed., Anais do Symposio Internacional Sobre Infarto Myocardio, Unipress Editorial Ltda., Sao Paulo (1981).

PUBLICATIONS (continued)

63. Rodda, B.E.: "The Timolol Myocardial Infarction Study - An Evaluation of Selected Variables." Circulation, 67: 1101-1106 (1983).
64. Rodda, B.E.: "Pooled Inferences from Multiclinic Drug Trials." Biometrics, 39: 810 (1983). (Abstract).
65. Abrams, W.B. and Rodda, B.E.: "Clinical Trial Design - Industry Perspective." Cutler, N.R. (ed.), Methodological Concerns for Clinical Trials in Geriatrics., Plenum Press, NY (1986).
66. Rodda, B.E.: "Quantitative and Statistical Analysis of Data from Bioequivalence Studies." In Bioequivalence of Solid Oral Dosage Forms: A Presentation to the U.S. Food and Drug Administration Hearing on Bioequivalence of Solid Oral Dosage Forms, Pharmaceutical Manufacturers Association (1986).
67. Rodda, B.E.; Tsianco, M.C.; Bolognese, J.A.; and Kersten, M.K.: "Clinical Development." in Peace, K.E. (ed.), Biopharmaceutical Statistics for Drug Development, Marcel-Dekker, NY (1988).
68. Boissel, J.P., et al (The Beta-Blocker Pooling Project Research Group): "The Beta-Blocker Pooling Project (BBPP): Subgroup Findings from Randomized Trials in Post-Infarction Patients." Eur. Heart J., 9: 8-16 (1988).
69. Rodda, B.E.: "Bioavailability: Designs and Analysis." in Berry, D.A. (ed.), Statistical Methodology in Pharmaceutical Science, Marcel-Dekker, NY (1989).
70. Hwang, I.K. and Rodda, B.E.: "Interim Analysis in the Norwegian Multicenter Study." in Peace, K.E. (ed.), Biopharmaceutical Sequential Statistical Applications, Marcel-Dekker, NY (1991).
71. Rodda, B.E.; Brooks, C.; Reynolds, G.: "Statistics and Clinical Trials." Clin. Pharmacol. Ther., 52: 104-105 (1992).
71. Waldo, A.L., et al: "Survival with Oral d-Sotalol in Patients with Left Ventricular Dysfunction after Myocardial Infarction: Rationale, Design, and Methods (the SWORD Trial)." Am. J. Cardiol., 75: 1023-1027 (1995).
72. Jukema, J.W., et al: "Effects of Lipid Lowering by Pravastatin on Progression and Regression of Coronary Artery Disease in Symptomatic Men with Normal to Moderately Elevated Serum Cholesterol Levels." Circulation, 91: 2528-2540 (1995).

PUBLICATIONS (continued)

73. Rodda, B.E.; Hajjan, G.; Tsai, K.T.; Mellars, L.; and Capece, L.: "Analysis of 24-Hour Blood Pressure Data." J. Biopharm. Stat., 6(4): 495-513 (1996).
74. Rodda, B.E.; Millard, S.P.; and Krause, A.: "Statistics and the Drug Development Process" in Millard, S.P. and Krause, A. (ed.), Applied Statistics in the Pharmaceutical Industry, Springer-Verlag, Heidelberg (2001).
75. Williams, R.C., et al: "Treatment of Periodontitis by Local Administration of Minocycline Microspheres: A Controlled Trial." J. Periodontol., 72: 1535-1544 (2001).
76. Recht, L.; Mechtler, L.L.; Wong, E.T.; O'Connor, P.C.; and Rodda, B.E.: "Steroid-Sparing Effect of Corticorelin Acetate in Peritumoral Cerebral Edema Is Associated with Improvement in Steroid-Induced Myopathy." J. Clin. Oncology, Mar 20, 2013:1182-1187.
77. Brooks, J.R., et al: "Safety and performance benefits of arginine supplements for military personnel: a systematic review." Nutrition Reviews, 74: 708-721 (2016).
78. Rodda, B.E.: "Synergy or Additivity – The Importance of Defining the Primary Endpoint" in Peace, K.E., Chen, D-G, and Menon, S. (eds.), Biopharmaceutical Applied Statistics Symposium – Volume 3, Statistical Applications, Springer, Singapore (2018).

PRESENTATIONS

1. Rodda, B.E. and Miller, M.C.: "An Analytic System for Finite Markov Chains." Presented at the VII Annual Symposium on Biomathematics and Computer Science in the Life Sciences, Houston, TX (March, 1969).
2. Rodda, B.E. and Miller M.C.: "Analysis and Simulation of Biological Processes Using Finite Markov Chains." Presented at the Joint Statistical Meetings (American Statistical Association, Biometric Society, Institute of Mathematical Statistics), New York, NY (August, 1969).
3. Rodda, B.E.: "Sequential Analysis of Clinical Trials." Invited lecture, Pharmaceutical Manufacturers Association training session for new industry physicians, Skytop, PA (April, 1972).
4. Rodda, B.E.: "Enumeration Data." Invited lecture, Pharmaceutical Manufacturers Association training session for new industry physicians, Skytop, PA (April, 1972).
5. Rodda, B.E.; Sampson, C.B.; and Smith, D.W.: "The One Compartment Open Model: Some Statistical Aspects of Parameter Estimation." Invited paper presented at the Joint Statistical Meetings (American Statistical Association, Biometric Society, Institute of Mathematical Statistics), Montreal, Quebec (August, 1972).
6. Rodda, B.E.: "Current Status of Sequential Design and Analysis of Clinical Trials." Invited paper presented to the Medical Section of the Pharmaceutical Manufacturers Association, Washington, DC (November, 1972).
7. Rodda, B.E.: "Sequential Design and Analysis in Phase I and Phase II Clinical Trials." Invited paper presented at the Symposium on Clinical Pharmacological Methods - Phase I and II, New Orleans, LA (March, 1973).
8. Rodda, B.E.: "Games People Play with Blood Level Curves." Presented to the Central Indiana Chapter, American Statistical Association, Indianapolis, IN (February, 1974).
9. Rodda, B.E.: "Multiclinic and Multi-investigator Trials of Cardiovascular Agents - A Statistical Enigma." Invited paper presented at the Joint Statistical Meetings (American Statistical Association, Biometric Society, Institute of Mathematical Statistics), St. Louis, MO (August, 1974).
10. Rodda, B.E.; Chernish, S.M.; and Nash, J.F.: "Delayed Release Propoxyphene - Pharmacokinetic Design." Presented at the annual meetings of the American Society of Clinical Pharmacology and Therapeutics, Seattle, WA (March, 1976).

PRESENTATIONS (continued)

11. Rodda, B.E. and Davis, R.L.: "Application of Bayesian Methods to the Evaluation of Data from Pharmacokinetic and Bioavailability Studies." Invited paper presented at the Biometric Society (ENAR) meetings, Lexington, KY (March, 1978).
12. Rodda, B.E. and Davis, R.L.: "Is There a Clinically Significant Difference? -- Answering the Right Question." Presented at the annual meeting of the American Society for Clinical Pharmacology and Therapeutics, Kansas City, MO (March, 1979).
13. Rodda, B.E. and Huber, P.B.: "Statistical Considerations in Drug Absorption and Disposition Studies." Presented at the annual meeting of the Academy of Pharmaceutical Sciences of the American Pharmaceutical Association, Washington, DC (April, 1980).
14. Rodda, B.E.: "Biostatistical Considerations in the Design of Secondary Prevention Trials of Myocardial Infarction and Sudden Death." Presented at the Simposio Internacional Sobre Infarto do Miocardio, Rio de Janeiro, Brazil (May, 1981).
15. Rodda, B.E.: "International Statistical and Data Processing Support of Clinical Trials." Invited paper presented to the Pharmaceutical Manufacturers Association, Naples, FL (October, 1981).
16. Rodda, B.E.: "The Timolol Myocardial Infarction Study – An Evaluation of Selected Variables." Invited paper presented at the Symposium on the Implications of Recent Beta-blocker Trials for Post-MI Patients, Bethesda, MD (May, 1982).
17. Rodda, B.E.: "Multinational Clinical Trials: Organizational and Operational Considerations." Invited paper presented at the Conference on Changing Concepts in Bioavailability and Clinical Trials, Baltimore, MD (October, 1982).
18. Rodda, B.E.: "Problems of Inference in Multiclinic Trials." Invited paper presented at the annual meeting of the Biostatistics Subsection of the Pharmaceutical Manufacturers Association, New Orleans, LA (October, 1982).
19. Rodda, B.E.: "Sequential Methods in Clinical Trials." Invited paper presented to the annual meeting of the American Society for Clinical Pharmacology and Therapeutics, San Diego, CA (March, 1983).
20. Rodda, B.E.: "Pooled Inferences in Multiclinic Drug Trials." Invited paper presented at the Biometric Society (ENAR) meetings, Nashville, TN (March, 1983).

PRESENTATIONS (continued)

21. Rodda, B.E.: "Planning, Processing, and Quality Control of International Clinical Trials." Invited paper presented at the annual meeting of the Science Information Subsection of the Pharmaceutical Manufacturers Association, Tarpon Springs, FL (May, 1983).
22. Rodda, B.E.: "Statisticians in the U.S. Pharmaceutical Industry – Organization and Issues." Presented at the annual meeting of Statisticians in the Pharmaceutical Industry (U.K.), Bristol, England (September, 1983).
23. Rodda, B.E. "Foreign Clinical Trials – Design, Logistics, and Processing." Invited paper presented at the Medical Section meeting of the Pharmaceutical Manufacturers Association, Arlington, VA (November, 1983).
24. Rodda, B.E.: "Population Pharmacokinetics." Invited paper presented at the annual meeting of the American Society for Clinical Pharmacology and Therapeutics, Atlanta, GA (March, 1984).
25. Rodda, B.E.: "Concepts and Issues in Establishing Bioavailability and Bioequivalence." Invited paper presented at the Midwest Pharmaceutical Statisticians Workshop, Muncie, IN (May, 1984).
26. Rodda, B.E.: "Statistical Considerations in Multinational Clinical Trials." Invited paper presented at the annual meeting of the Drug Information Association, San Diego, CA (June, 1984).
27. Rodda, B.E.: "Statistical Evaluation of Bioequivalence Trials." Invited paper presented at the annual meeting of the Drug Metabolism Discussion Group, Plymouth Meeting, PA (May, 1985).
28. Rodda, B.E.: "Clinical Data Management: A Domestic and International Perspective." Invited paper presented at the annual meeting of the Drug Information Association, Atlanta, GA (June, 1985).
29. Rodda, B.E.: "FDA Clinical and Statistical Guidelines." Invited presentation at the Drug Information Association meeting on the FDA Guidelines, Washington, DC (May, 1986).
30. Rodda, B.E.: "The Future of Statistics and Data Processing in Pharmaceutical Development." Invited paper presented at the Project Management Subsection meeting of the Pharmaceutical Manufacturers Association, Atlanta, GA (May, 1986).

PRESENTATIONS (continued)

31. Rodda, B.E.: "Statistical Considerations in Multinational Clinical Trials from the Perspective of a U.S. Sponsor." Invited paper presented at the annual meeting of the Pharmaceutical Manufacturers Association Biostatistics Subsection, Washington, DC (September, 1986).
32. Rodda, B.E.: "Pharmaceutical Industry Statisticians' Response to the FDA Statistical/Clinical Guidelines." Invited paper presented at the annual meeting of Statisticians in the Pharmaceutical Industry (U.K.), Southampton, England (September, 1986).
33. Rodda, B.E.: "Quantitative and Statistical Analysis of Data from Bioequivalence Studies." Testimony at the U.S. Food and Drug Administration Hearing on Bioequivalence of Solid Oral Dosage Forms, Washington, DC (September, 1986).
34. Rodda, B.E.: "Centralized and Distributed Data Entry and Data Processing of Foreign Clinical Trials." Invited presentation at the Pharmaceutical Manufacturers Association Data Processing Workshop, Washington, DC (September, 1986).
35. Rodda, B.E.: "An Overview of the Statistical Methodologies used in the Evaluation of Bioequivalence Studies." Invited presentation at the International Society of Clinical Biostatistics Meetings, Gothenburg, Sweden (September, 1987).
36. Rodda, B.E.: "Higher Opportunities for Statisticians in the Pharmaceutical Industry." Invited presentation at the Biometric Society (ENAR) meetings, Boston, MA (March, 1988).
37. Rodda, B.E.: "Update on the FDA Bioequivalence Task Force Recommendations." Invited presentation at the annual meeting of the Pharmaceutical Manufacturers Association Biostatistics Subsection, Clearwater, FL (October, 1988).
38. Rodda, B.E.: "Dose-Ranging Studies." Invited presentation at the Forty-fourth Annual Conference on Applied Statistics and Quality Control, Atlantic City, NJ (December, 1988).
39. Rodda, B.E.: "International Clinical Data Management - Global Centralization of a Logically Decentralized Function." Invited presentation at the Drug Information Association annual meetings, Washington, DC (June, 1991).

PRESENTATIONS (continued)

40. Rodda, B.E.: "Administrative Considerations Involved in Multinational Mergers of Data Management Departments." Invited presentation at the DIA Workshop on Technical and Organizational Challenges in Clinical Data Management, Noordwijk, The Netherlands (November, 1992).
41. Rodda, B.E.: "Harmonization and Opportunities for Cost Reduction in Multinational Clinical Development." Invited presentation at the DIA Annual Meeting, Chicago, IL (July, 1993).
42. Rodda, B.E.: "Regulatory Issues in Bioequivalence Studies." Presentation at the Joint Annual Statistics Meetings, San Francisco, CA (August, 1993).
43. Rodda, B.E.: "Generalized Estimating Equations in Longitudinal Data Analysis of Clinical Trials." Presentation at the Biometric Society Meetings (ENAR), Cleveland, OH (March, 1994).
44. Rodda, B.E.: "The Role of the Non-clinical Statistician in the Pharmaceutical Industry." Training program at the Joint Annual Statistics Meetings, Toronto, Canada (August, 1994) and at the Winter Statistics Meetings, Raleigh, NC (January, 1995) at the Joint Annual Statistics Meetings, Anaheim, CA (August 1997), and at the Joint Annual Statistics Meetings, Baltimore, MD (August, 1999).
45. Rodda, B.E.: "New Initiatives in the IND to NDA Process – The Paperless Future." Invited presentation to the Annual Meeting of the American Association of Pharmaceutical Sciences, Miami, FL (November, 1995).
46. Rodda, B.E.: "Statistical Considerations in 24-hour Blood Pressure Monitoring." Invited presentation to the Second Annual Biopharmaceutical Applied Statistics Symposium, San Diego, CA (December, 1995).
47. Rodda, B.E.: "Evolution of the Statistics Profession in the Pharmaceutical Industry." Invited presentation to the International Biometric Society Meeting (ENAR), Memphis, TN (March, 1997).
48. Rodda, B.E.: "Natural Selection or Intelligent Design – The Evolution of the Statistics Profession in the Pharmaceutical Industry." Keynote address, Midwest Biopharmaceutical Statisticians Workshop, Muncie, IN (May 2006).

PRESENTATIONS (continued)

49. Rodda, B.E.: "The Role of the Statistical Consultant in Strategic Planning and Development in the Pharmaceutical and Biotechnology Industries." Invited presentation to the International Biometrics Society (ENAR), San Antonio, TX (March 2009).
50. Rodda, B.E.: "Synergy – Patient or Patent." Invited presentation to the Houston Chapter of the American Statistical Association, Houston, TX (February 2011).