CURRICULUM VITAE

Donald A. Berry <dberry@mdanderson.org>

March 2022

I. BIOGRAPHICAL DATA

A. Education:

Yale University, Statistics, PhD (1971)
PhD Thesis: Bernoulli Two-armed Bandits; Advisors: LJ Savage and JB Kadane
Yale University, Statistics, M.A. (1967)
Dartmouth College, Mathematics, A.B. (1965)

B. Professional Employment and Endowed Positions:

Professor, Department of Biostatistics, The University of Texas M.D. Anderson Cancer Center (2010-present)
Head, Division of Quantitative Sciences, The University of Texas M.D. Anderson Cancer Center (2006-2010)
Chairman, Department of Biostatistics, The University of Texas M.D. Anderson Cancer Center (2006-2010)
Chairman, Department of Biostatistics and Applied Mathematics, The University of Texas M.D. Anderson Cancer Center (1999-2006)
Frank T. McGraw Memorial Chair of Cancer Research at The University of Texas M.D. Anderson Cancer Center (1999-2010)
Professor, Graduate School of Biomedical Sciences, The University of Texas, Houston, TX (2000-present)
Edger Thompson Professor of Statistics in Trinity College of Arts and Sciences, Duke University (1999).
Professor, Institute of Statistics and Decision Sciences, and Cancer Center Biostatistics, Duke University (1991-1999).
Acting Director, Institute of Statistics and Decision Sciences, Duke University (1995)
Faculty member, School of Statistics, University of Minnesota (1970-1993, Professor from 1981)
Chairman, Department of Theoretical Statistics, School of Statistics, University of Minnesota (1981-1989)
Statistical Analyst, Center for Naval Analyses of the University of Rochester, Arlington, VA (1968-1970)

C. Adjunct and Visiting Positions and Advisory Boards:

Scientific Advisory Board, National Biomarker Development Alliance, Arizona State University, Phoenix, AZ (2014-present)
Scientific Advisory Board, Medidata, New York, NY (2013-2017)
Biostatistics Advisory Board, Bristol-Myers Squibb, Princeton, NJ (2010-present)
Adjunct Professor, Department of Statistics, Rice University (2000-present)
Visiting Professor, Institüt fur Mathematische Stochastik, University of Göttingen, West Germany (1986)

I. BIOGRAPHICAL DATA (Cont'd)

D. Consultantships:

Berry Consultants, LLC, Austin, TX (2000-present)
Advanced Tissue Sciences, San Diego, CA (2000)
BioNumerik Pharmaceuticals, San Antonio, TX (1999-2000)
Synthes Corporation, Paoli, PA (1999-2000)
Spinal Dynamics Corporation, Seattle, WA (1999-2000)
Roche Diagnostics, Indianapolis, IN (1999)
Pioneer Hybrid International, Des Moines, IA (1998-2000)
Bristol Myers Squibb, Inc., Princeton, NJ (1998-2000)
Theradex, Inc., Princeton, NJ (1998-2000)
Pfizer UK, Inc., Sandwich, England (1998-2000)
AstraZeneca Pharmaceuticals, Wilmington, DE (1998-1999)
Medtronic Sofamor Danek, Memphis, TN (1998-1999)
Health Protection Department of the U.S. Department of Energy, Pacific Northwest National Laboratory, Richland, WA (1997-1998)
Center for Devices and Radiological Health, Food and Drug Administration of the U.S. Department of Health, Education and Welfare, Rockville, MD (1996-1998)
Pfizer Inc., Groton, CT (1996-1999)
Berlex Laboratories, Richmond, CA (1996-1997)
Wyeth-Ayerst Laboratories, Philadelphia, PA (1995-1996)
US Environmental Protection Agency, Research Triangle Park, NC (1995-1996)
Matrix Pharmaceuticals, Inc., Menlo Park, CA (1994-1995)
American Sterilizer Company, Apex, NC (1992-1997)
Santa Barbara Cancer Foundation, Santa Barbara, CA (1992-1995)
Immunotech, Orange, CA (Scientific Advisory Board, 1992-1993)
Glaxo Inc. Research Institute, Research Triangle Park, NC (1991-1992)
Health Industry Manufacturing Association, Washington, DC (1991-1992)
Food and Drug Administration of the U.S. Department of Health, Education and Welfare, Washington, D.C. (1991-1992)
Statistician to Breast Cancer Committee of Cancer and Leukemia Group B (now the Alliance for Clinical Trials), Chicago, IL. (1990-present)
Sarns/3M, Ann Arbor, MI (1990-1999)
University Diagnostics Laboratory, University College London, England (1990-1991)
Miragen Corporation, Irvine, CA (1990-1994)
SeisMed Instruments, Inc., Minneapolis, MN (1988-1991)
Hennepin County Medical Center, Minneapolis, MN (1987-1990)
Eli Lilly Company, Indianapolis, IN (1987-1991)
National Research Associates, Arden Hills, MN (1985-1989)
Boehringer-Ingelheim, Ridgefield, CT (1985)
3M Corporation (Pharmaceutics Division, Orthopedics Division, Biosciences Laboratory, Health Care Division) St. Paul, MN (1980-1997)
First Phoenix American Corporation, Minneapolis, MN (1980-1984)
The Bureau of Mines, U.S. Department of Interior, Minneapolis, MN (1978-1980)
Sperry-Univac Corporation, St. Paul, MN (1978-1979)

Carlson Marketing Group, Carlson Companies, Minneapolis, MN (1976-1991)
Operations Research, Inc., Silver Spring, MD (1971-1973)

II. PROFESSIONAL HONORS AND RECOGNITIONS

A. Societies:

Institute of Mathematical Statistics (Fellow)
American Statistical Association (Fellow, 1986)
International Society of Bayesian Analysis (Fellow 2016)

B. Distinguished Lectures and Awards:

2004 Presidential Invited Address, Western North American Region of the International Biometric Society, Albuquerque, New Mexico.
2005 Wallace C. Epstein Lecture in Rheumatology, University of California at San Francisco, California.
2006 Biostatistics Presidents' Special Invited Speaker for the Canadian Statistical Society, Ottawa, Canada.
2006 Robert C. Knapp Lecture in Obstetrics and Gynecology, Harvard University, Cambridge, MA.
2008 Presidential Invited Address, Eastern North American Region of the International Biometric Society, Washington, DC.
2010 Dana-Farber Cancer Institute/Frontier Science and Technology Research Foundation Annual Lecture on Biostatistics in Cancer, sponsored by the Friends of DFCI, Cambridge, MA.
2010 Donna J. Brogan Annual Lecture at Emory University, Atlanta, Georgia.
2010 Thomas W. Teal Award for Excellence in Statistics Publishing, Drug Information Association.
2010 National Institutes of Health Award of Merit, presented to Donald A. Berry, Ph.D., PDQ Screening and Prevention Editorial Board.
2012 Sixth Annual Distinguished Professor S. James Press Endowed Lecture. University of California at Riverside.
2013 Keynote Address. The Ohio State-Cleveland Clinic Foundation-Case Western Reserve Biostatistics Symposium. Columbus, OH. Apr 2014.
2014 Thomson Reuters Highly Cited Researcher. In recognition of ranking among the top 1% of researchers for most cited documents, in Clinical Medicine.
2014 The World's Most Influential Scientific Minds. ScienceWatch.com.
2015 President's Symposium Presentation. Annual Meeting of American Society of Pediatric Hematology/Oncology (ASPHO). Phoenix, AR. May 2015.
2015 Keynote Address. The 20th Annual Scientific Meeting of the Society of Neuro-Oncology (SNO). San Antonio, TX. Nov 2015.
2017 Keynote Address: Shifting the Clinical Trial Paradigm to Keep Pace with Rapidly Changing Cancer Biology. The 7th WIN Symposium. Paris, France. Jun 2017.
2019 Robert W. Makuch Distinguished Lecture series in Biostatistics at the University of Connecticut, Storrs, CT. Apr 2019.

II. PROFESSIONAL HONORS AND RECOGNITIONS (CONT'D)

C. Grants (as Principal Investigator):

NCI 1U01 CA187945 01 (2015-2020) (Principal Investigator) Modeling the Impact of Targeted Therapy Based on Breast Cancer Subtypes
NCI 5U01 CA152958 (2010-2015) (Principal Investigator) Breast Cancer Intervention and Surveillance Modeling (CISNET)
NCI Specialized Program of Research Excellence (SPORE) Grant in Breast Cancer to M.D. Anderson Cancer Center (2005-2009) (Principal Investigator of Biostatistics and Data Management Core)
NCI Specialized Program of Research Excellence (SPORE) Grant in Melanoma to M.D. Anderson Cancer Center (2004-2015) (Principal Investigator of Biostatistics and Data Management Core)
NCI Specialized Program of Research Excellence (SPORE) Grant in Leukemia to M.D. Anderson Cancer Center (2003-present) (Principal Investigator of Biostatistics and Data Management Core)
NCI U01CA088278-01, 5U01CA088278-04, 1U01CA152958-01 (2000-present) (Principal Investigator) Breast Cancer Intervention and Surveillance Modeling (CISNET)
NCI Specialized Program of Research Excellence (SPORE) Grant in Breast Cancer to Duke University Medical Center, P50 CA68438 (1995-2000) (Principal Investigator of Project No. 4, Decision Analyses in Breast Cancer, and Principal Investigator of Biostatistics Core)
NSF Grant DMS 94-04200 (1994-1996) (Principal Investigator)
NCI U01 CA64061 (1994-1998) (Statistician)
NCI U01 CA64057 (1994-1998) (Co-Principal Investigator)
NCI 1 PO1 CA47741 (1993-1997) (Principal Investigator of Statistical Core)
NCI 7 U10 CA33601-14 (1993-1998) (Statistician)
NIH Grant HS 06475 (1990-1993) (Principal Investigator)
NSF Grant DMS 89-11548 (1989-1992) (Principal Investigator)
Bush Sabbatical Fellowship (1989-1990)
NSF Grant DMS 88-03087 (1988-1990) (Principal Investigator)
University of Minnesota Single Quarter Leave (Winter, 1986-1987)
NSF Grant DMS 85-05023 (1985-1988) (Principal Investigator)
NSF Grant MCS 83-01450 (1983-1985) (Principal Investigator)
NSF Grant MCS 82-41091 (1982-1983) (Principal Investigator)
NSF Grant MCS 81-02477 (1981-1982) (Principal Investigator)
University of Minnesota Single Quarter Leave (Winter, 1980-1981)
NSF Grant MCS 80-01800 (1980-1981) (Principal Investigator)
NSF Grant MCS 78-02694 (1978-1980) (Principal Investigator)
University of Minnesota Graduate School Research Grant (1976-1977)
NIH Grant GM 2234 (1975-1977) (Principal Investigator)
University of Minnesota Faculty Summer Research Grant (1974)
NDEA IV Fellowship, Yale University (1965-1968)

III. TEACHING

A. Courses Taught at University of Minnesota and Duke University:

1. Undergraduate

Introduction to the Ideas of Statistics
Probability and Statistics
Introductory Managerial Statistics
Probability and Statistics in Games and Sports

2. Graduate, Masters Level

Theory of Statistics
Introduction to Decision Theory
Statistical Methods
Introduction to Multivariate Methods
History of Statistics
Bayesian Decision Making
Designing Experiments
Mathematical Statistics
Theory of Inference
Statistical Decision Theory
Bayesian Decision Making
Sequential Analysis
Distribution Theory
Survival Analysis and Reliability
Sequential Decision Making
Experimental Design
Bayesian Biostatistics
Various special topics

B. MS Advisees:

at the University of Minnesota:

1. Dorothee P. Aeppli (1976)—Properties of some Random Distributions
2. Ronald R. Christensen (1976)—Empirical Bayes Estimation via Mixtures of Dirichlet Processes
3. Gregory Grandits (1982)—Optimal Sequential Plans for Sampling without Replacement
4. Julie Wild Legler (1982)—The Randomized Response Technique: Warner's Model, Extensions, and a Bayesian Approach
5. Kenneth H. Svendsen (1982)—Survivorship Analysis and the Proportional Hazards Model
6. Chih-Kung Wu (1982)—Bayes Decision Theory and Optimal Sample Size Determination
7. Katherine G. Johnson (1983)—Analyzing Exponential Survival Times
8. David E. Polansky (1984)—A Simple Bernoulli Two-Armed Bandit

III. TEACHING (CONT'D)

B. MS Advisees (cont'd):

at the University of Minnesota (cont'd):

9. Dennis M. Heisey (1985)—Dynamic Bayesian Birds: Discounting vs. Rate Maximization
10. Bradley Dain (1986)—Computer Simulations of Sequential Clinical Trials with Two Exponential Groups
11. Timothy Allard (1988)—Predicting World Series Outcomes: Is a Baseball Game like Tossing a Coin?
12. Steven Wickstrom (1988)—Group Sequential Designs in Clinical Trials: Advantages and Disadvantages
13. Jon Seltzer (1989)—Statistical Inference in DNA Fingerprinting
14. Panayota Palli (1989)—Modeling Electrical Loads by Use Sector

at Duke University:

15. Wei Liu (1997)—Inferences Using Splines: Assessing the Role of Age and Other Prognostic Factors in Node-Positive Breast Cancer
16. Lan Liang (1997)—The Impact of Data Errors in Clinical Trials

C. PhD Advisees:

at the University of Minnesota:

1. John S. Croucher (1974)—Game Theoretic Models with Applications
2. Dorothee P. Aeppli (1980)—The Concept of Information and Ferguson's Distribution
3. Larry M. Pearson (1980)—Treatment Allocation for Clinical Trials in Stages
4. Roy F. Mensch (1981)—A Search Problem with Directional Information
5. Ronald R. Christensen (1983)—Searching for the Lowest Price when the Unknown Distribution of Prices is Modeled with a Dirichlet Process
6. Jeffrey A. Witmer (1983)—Bayesian Multistage Decision Problems
7. Murray K. Clayton (1983)—Bayes Sequential Sampling for Choosing the Better of Two Populations
8. Stephen G. Eick (1985)—Sequential Experimentation with Delayed Responses
9. Chih-Hsiang Ho (1986)—One-sided Sequential Stopping Boundaries for Clinical Trials: Classical and Bayesian Approaches
10. Steven N. MacEachern (1988)—Sequential Bayesian Bioassay Design
11. John S. Andersen (1988)—Allocating Experiments in Stages
12. Kumarasiri Samaranayake (1988)—Bernoulli k-Armed Bandits with Dependent Arms
13. Manas K. Chattopadhyay (1991)—Dirichlet Bandit Problems
14. Shipei Weng (1991)—Sequential Allocation to Maximize the Probability of Achieving a Number of Successes
15. Yi Cheng (1992)—Group Sequential Strategies in Two-Armed Bandit Problems
16. Kris Gillingham (1993)—Bayesian Hierarchical Models for Metaanalysis of Dichotomous Response Studies

III. TEACHING (CONT'D)

C. PhD Advisees (cont'd):

at Duke University:

17. Zhengning Lin (1993)—Statistical Methods for Combining Historical Controls with Clinical Trial Data
18. Ram Gopalan (1994)—Bayesian Multiple Comparisons
19. Chengchang Li (1994)—Metaanalysis of Survival Data
20. Jiang Qian (1994)—A Bayesian Weibull Survival Model
21. Fusheng Su (1996)—Limit Theorems on Deviation Probabilities with Applications to Two-Armed Clinical Trials
22. Lurdes Inoue (1999)—Bayesian Design and Analysis of Clinical Experiments
23. Heidi Ashih (2000)—Bayesian Models of Tumor Growth in Breast Cancer

at Rice University:

24. Shu Han (2005)—Modeling Auxiliary Information in Clinical Trials

at University of Texas Graduate School of Biomedical Sciences:

25. Lin Yang (2011)—Efficient Phase I Cancer Trials

IV. SERVICE

A. Professional:

Presentation on Irreproducible Research to President's Council of Advisors in Science and Technology (PCAST). (2014)
Chair, Biostat/Pharma Section, International Society of Bayesian Analysis (2012-2014)
Member, Institute of Medicine Committee on Cancer Clinical Trials and the NCI Cooperative Group Program (2008-2010)
Editorial Board, Journal of Clinical Oncology (2008-2012)
Member, Cancer Steering Committee of Biomarker Consortium, Foundation of the National Institutes of Health (2007-present)
Member, External Advisory Board, Winship Cancer Institute of Emory University (2007-2016)
Member, Education Committee of the American Association of Cancer Research (2007-2008)
Member, Clinical Trials Group of the AACR-FDA-NCI Cancer Biomarkers Collaborative (2007-2009)
Member, Cancer Research Committee of the American Society of Clinical Oncology (2006-2009)
Member, Investigational Drug Steering Committee of the National Cancer Institute (2006-2011), Co-chair of Clinical Trial Design Task Force (2009-2011)
Chair, American Statistical Association Excellence in Statistical Reporting Committee (2003-2008)
Member, External Advisory Board, University of Chicago Cancer Research Center (2003-present)
Biostatistical Reviewer, American Society of Clinical Oncology abstracts (2001-2003)
IOM Committee: Shortening the Timeline for New Cancer Treatments (2001)
Statistical Consultant, International Journal of Gynecological Cancer (2001-2002)
Chair, Treatment Effects Monitoring Committee of Alzheimer's Disease Anti-inflammatory Prevention Trial (ADAPT) (2001-2002)
Editorial Board, Clinical Cancer Research (2000-2015)
Member, Cancer Genetics Advisory Board of the National Cancer Institute (2000-2005)
Member, Breast Task Force, American Joint Committee on Cancer (2000-2012)
Elected Member, Council of the Institute of Mathematical Statistics (1999-2000)
Member, Advisory Committee of the Cooperative Family Registry for Breast Cancer Studies, National Cancer Institute (1999-2003)
Member, Editorial Board, Breast Cancer Research and Treatment (1998-2016)

IV. SERVICE (CONT'D)

A. Professional (cont'd):

Member, Immunology Devices Panel, and consultant to other panels of the Medical Devices Advisory Committee, Food and Drug Administration of the U.S. Department of Health, Education and Welfare, Rockville, MD. (Special Government Employee) (1998-present)

Member, US Food and Drug Administration's Senior Biomedical Research Service Credentials Committee (1998-present)

President, Section on Bayesian Statistical Science of the American Statistical Association (1998)

Member, Editorial Board of the International Cancer Information Center; Physicians Data Query (PDQ), Screening & Prevention (1997-present)

Co-Leader, Cancer Control Breakout Group of the Prostate Cancer Progress Review Group of National Cancer Institute (1997)

Co-chair, National Institutes of Health Consensus Development Conference Panel on Breast Cancer Screening for Women Ages 40-49 (1997)

Member, Scientific Advisory Committee of Clinical Trials Evaluation Group, National Cancer Institute, National Institutes of Health (1997)

Member, Data Safety Monitoring Committee of DCLHb in the Treatment of Severe Traumatic Hemorrhagic Shock (1997-1998)

Representative, Institute of Mathematical Statistics to the Section of Biological Sciences of the American Association for the Advancement of Science (1996-1999)

Member, NSF panel for Minority and Women's Career Advancement Awards and Research Planning Grants (1996)

Statistical Editor, Journal of the National Cancer Institute (1995-2016)

Chair, Nominating Committee of the Institute of Mathematical Statistics (1995-1996)

Chair, Council of Scientists of the International Society of Bayesian Analysis (1994-1995)

Faculty Statistician, Solid Tumor Correlative Sciences Committee of the Cancer and Leukemia Group B (1993-present)

Program Chair, Section on Bayesian Statistical Science of the American Statistical Association (1992-1993)

Faculty Statistician, Pathology Committee of the Cancer and Leukemia Group B (1990-present)

Faculty Statistician, Breast Cancer Committee of the Cancer and Leukemia Group B (1990-2016)

Advisory Editor, Marcel Dekker Publishers (1990-1996)

Associate Editor, Journal of Biopharmaceutical Statistics (1990-2002)

Associate Editor, Journal of the American Statistical Association (1987-1993)

Member, RA Fisher Lecture and Award Committee of the Joint Statistical Societies (1987-1993, Chair in 1992-1993)

IV. SERVICE (CONT'D)

A. Professional (cont'd):

Member, Publications Board of the Institute of Mathematical Statistics (1990-1992, Chair in 1992)
Nominating Committee for the Committee of Presidents of Statistical Societies Award (1984)
President, Twin Cities Chapter of the American Statistical Association (1978-1980)
Associate Editor, The Annals of Statistics (1975-1983)

B. University of Minnesota:

College of Liberal Arts Civil Service Merit Pay Committee (1988-1989)
College of Liberal Arts Committee on Awards (1988-1990)
Student Academic Support Services Committee (1985-1987)
Search Committee for Executive Officer/Associate Dean, College of Liberal Arts (1984)
Promotion and Tenure Committee, College of Liberal Arts, University of Minnesota (1982-1985)
Director of Graduate Studies, School of Statistics (1977-1979)
University Senate (1975-1977)
All-University Council on Liberal Education (1973-1979)

C. Duke University:

Duke University Cancer Center Steering Committee (1998 to present)
Faculty Compensation Committee (1997-2000)
Acting Director, Institute of Statistics and Decision Sciences (Jan - Jun 1995)
Provost's Advisory Committee on Appointments, Promotion and Tenure (1992-1995—Chair, 1993-1995)
Translational Research Review Committee of the Comprehensive Cancer Center (1993-1995)

D. University of Texas M.D. Anderson Cancer Center:

Molecular Markers Advisory Committee (2004-2009)
Executive Internet Steering Committee (2003-2004)
Leukemia SPORE Advisory Committee (2003-present)
Ovarian SPORE Advisory Committee (2001-present)
Multidisciplinary Research Advisory Committee (2001-2004)
Endowed Positions and Awards Committee (2001-2004)
Gulf Coast Consortia Oversight Committee (2001-2003)
Prostate SPORE Advisory Committee (2001-present)
Deputy Director, Community Clinical Oncology Program (2000-2003)
Research Strategies Advisory Committee (2001-2009)
Center of Research for Minority Health Breast Cancer Working Gp (2001-2003)
Advisory Committee: Institutional K12 Grant for Patient-Oriented Research (2001-2003)

IV. SERVICE (CONT'D)

D. University of Texas M.D. Anderson Cancer Center (cont'd):

Steering Committee of Brain Tumor Program (2001-2003)
Information Services Steering Committee (2000-2003)
Representative for Keck Center Executive Committee (2000-2002)
Data Monitoring Committee (1999-2009, Chair 2004-2009)
Surveillance Committee (IRB) (1999-2004)
Executive Committee for Science Faculty (1999-2009)
Research Council (1999-2009)
Search Committee for Health Services Research Chair (1999-2000)
Search Committee for Head, Division of Cancer Medicine (1999-2000)
Cancer Genomics Advisory Committee (1999-2005)

V. PUBLICATIONS

A. Textbooks:

1. Lindgren BW, McElrath GW, **Berry DA** (1978). Introduction to Probability and Statistics, 4th ed. 365 pp, New York: Macmillan.
2. Lindgren BW, **Berry DA** (1981). Elementary Statistics. 530 pp, New York: Macmillan.
3. **Berry DA**, Lindgren BW (1996). Statistics: Theory and Methods (Second Edition). 702 pp, Belmont, California: Duxbury Press.
4. **Berry DA** (1996). Statistics: A Bayesian Perspective. 518 pp, Belmont, California: Duxbury Press.

B. Edited Volumes:

5. **Berry DA** (1989). Statistical Methodology in the Pharmaceutical Sciences. 580 pp, New York: Marcel Dekker.
6. **Berry DA**, Chaloner KM, Geweke JF (1996). Bayesian Analysis in Statistics and Econometrics: Essays in Honor of Arnold Zellner. 577 pp, New York: Wiley-Interscience.
7. **Berry DA**, Stangl DK (1996). Bayesian Biostatistics. 681 pp, New York: Marcel Dekker.
8. Halloran ME, **Berry DA** (1999). Statistical Models in Epidemiology, the Environment and Clinical Trials. 274 pp, New York: Springer-Verlag.
9. Stangl DK, **Berry DA** (2000). Meta-Analysis in Medicine and Health Policy. 398 pp, New York: Marcel Dekker.

C. Professional Monograph:

10. **Berry DA**, Fristedt B (1985). Bandit Problems: Sequential Allocation of Experiments. 275 pp. London: Chapman-Hall. Reprinted as Springer Monograph on Statistics and Applied Probability, ISBN: 978-94-015-3713-1 (Print) 978-94-015-3711-7 (Online)

D. Professional Articles—Theory and Methods:

11. **Berry DA** (1972). A Bernoulli two-armed bandit. The Annals of Mathematical Statistics 43:871-897.
12. **Berry DA**, Sobel M (1973). An improved procedure for selecting the better of two Bernoulli populations. Journal of the American Statistical Association 68:979-984.
13. **Berry DA**, Heath DE, Sudderth WD (1974). Red-and-black with unknown win probability. The Annals of Statistics 2:602-608.
14. **Berry DA** (1974). Optimal sampling schemes for estimating system reliability by testing components—I: Fixed sample sizes. Journal of the American Statistical Association 61:485-491.
15. **Berry DA** (1974). A class of optimal stopping problems for sampling without replacement. Biometrika 61:361-368.
16. **Berry DA** (1977). A modern statistical approach to model assessment. Political Development and Change: A Policy Approach 462-486. New York: Free Press. (Ed: Brewer G, Brunner R.)

V. PUBLICATIONS (CONT'D)

D. Professional Articles—Theory and Methods (cont'd):

17. **Berry DA**, Young DH (1977). A note on inverse sampling procedures for selecting the best binomial population. The Annals of Statistics 5:235-236.
18. **Berry DA**, Regal RR (1978). Probabilities of winning a certain carnival game. The American Statistician 32 126-129.
19. **Berry DA** (1978). Modified two-armed bandit strategies for certain clinical trials. Journal of the American Statistical Association 73:339-345.
20. **Berry DA**, Christensen RR (1979). Empirical Bayes estimation of a binomial parameter via mixtures of Dirichlet processes. The Annals of Statistics 7:558-568.
21. **Berry DA**, Fristedt B (1979). Bernoulli one-armed bandits—arbitrary discount sequences. The Annals of Statistics 7:1086-1105.
22. **Berry DA** (1979). Detecting trends in arrangements of ordered objects: A likelihood approach. The Scandinavian Journal of Statistics 6:169-174.
23. **Berry DA**, Fristedt B (1980). Two-armed bandits with a goal, I. One arm known. Advances in Applied Probability 12:775-798.
24. **Berry DA**, Fristedt B (1980). Two-armed bandits with a goal, II. Dependent arms. Advances in Applied Probability 12:958-971.
25. **Berry DA** (1980). Statistical inference and the design of clinical trials. Biomedicine 32:4-7.
26. **Berry DA**, Viscusi WK (1981). Bernoulli two-armed bandits with geometric termination. Stochastic Processes and Their Applications 11:35-45.
27. **Berry DA**, Wang P-C (1982). Optimal stopping regions with islands and peninsulas. The Annals of Statistics 10:634-636.
28. **Berry DA**, Fristedt B (1983). Maximizing the length of a success run for many-armed bandits. Stochastic Processes and Their Applications 15:317-325.
29. **Berry DA**, Fox TL (1983). Regression analysis applied to PVC histories: A statistical procedure for evaluating antiarrhythmic drug efficacy. Statistics in Medicine 2:331-343.
30. **Berry DA** (1983). Bandit Problems with Random Discounting. In Mathematical Learning Models—Theory and Algorithms 12-25. New York, Springer-Verlag. (Ed: Herkenrath U, Kalin D, Vogel W.)
31. **Berry DA** (1983). Statistics of Disputed Paternity Cases. Invited paper: Proceedings of the Social Statistics Section of the American Statistical Association 131-138.
32. **Berry DA** (1984). Some Gambling Problems with Nonintuitive Solutions. Invited paper: Proceedings of the Seventh Conference in Probability Theory 41-49. Utrecht, Holland: VNU-Science Press. (Ed: Iosifescu M.)
33. **Berry DA**, Eaton ML, Ekholm BP, Fox TL (1984). Assessing differential drug effect. Biometrics 40:1109-1115.
34. **Berry DA** (1985). One- and Two-armed Bandit Problems. Encyclopedia of Statistical Sciences, Vol. VI, 418-422. New York: John Wiley & Sons. (Ed: Kotz S, Johnson NL.)
35. **Berry DA**, Berry TD (1985). The probability of a field goal: Rating kickers. The American Statistician 39:152-155.

36. **Berry DA** (1985). Interim analysis in clinical trials: Classical vs. Bayesian approaches. Statistics in Medicine 4:521-526.
37. Clayton MK, **Berry DA** (1985). Bayesian nonparametric bandits. The Annals of Statistics 13:1523-1534.
38. **Berry DA**, Mensch RF (1986). Discrete search with directional information. Operations Research 34:470-477.
39. **Berry DA**, Pearson LM (1985). Optimal designs for two-stage clinical trials with dichotomous responses. Statistics in Medicine 4:497-508.
40. **Berry DA**, Geisser S (1986). Inferences in Cases of Disputed Paternity. In Statistics and the Law 353-382. New York: Wiley. (Ed: DeGroot MH, Fienberg SE, Kadane JK.)
41. **Berry DA** (1987). Interim analysis in clinical trials: The role of the likelihood principle. The American Statistician 41:117-122.
42. **Berry DA** (1987). Logarithmic transformations in ANOVA. Biometrics 43:439-456.
43. **Berry DA** (1987). Statistical inference, clinical trials, and pharmaceutical company decisions. The Statistician 36:181-189.
44. **Berry DA** (1988). Interim analysis in clinical research. Cancer Investigation 5:469-477.
45. Berger JO, **Berry DA**. The Relevance of Stopping Rules in Statistical Inference (with discussion). Statistical Decision Theory and Related Topics IV, 1(1988):29-72. New York: Springer-Verlag. (Ed: Berger JO, Gupta S.)
46. Fristedt B, **Berry DA** (1988). Optimality of myopic stopping times with geometric discounting. Journal of Applied Probability 25:437-443.
47. Berger JO, **Berry DA** (1988). Statistical analysis and the illusion of objectivity. The American Scientist 76:159-165.
48. **Berry DA** (1988). Multiple Comparisons, Multiple Tests, and Data Dredging: A Bayesian Perspective (with discussion). In Bayesian Statistics 3:79-94. Oxford, England: Oxford University Press. (Ed: Bernardo JM, DeGroot MH, Lindley DV, Smith AFM.)
49. **Berry DA**, Ho C-H (1988). One-sided sequential stopping boundaries for clinical trials: A decision-theoretic approach. Biometrics 44:219-227.
50. **Berry DA** (1988). Invited paper: Inferences Concerning Adverse Experiences in Pharmaceutical Trials. Proceedings of the Pharmaceutical Section of the American Statistical Association 15-17.
51. **Berry DA** (1989). Basic Principles in Designing and Analyzing Clinical Studies. In Statistical Methodology in the Pharmaceutical Sciences 1-55. New York: Marcel Dekker. (Ed: **Berry DA**.)
52. **Berry DA** (1989). Monitoring accumulating data in a clinical trial. Biometrics 45:1197-1211.
53. **Berry DA** (1989). Invited paper: Inferential Aspects of Adaptive Allocation Rules. Proceedings of the Pharmaceutical Section of the American Statistical Association 1-8.

V. PUBLICATIONS (CONT'D)

D. Professional Articles—Theory and Methods (cont'd):

54. **Berry DA** (1989). Invited paper: Challenge of the Future of Statisticians in the Pharmaceutical Field: Academic Perspective. Proceedings of the Pharmaceutical Section of the American Statistical Association 217-219.
55. **Berry DA** (1990). DNA fingerprinting: Can it prove guilt? Chance 3 (3):15-25.
56. **Berry DA** (1990). Subgroup analyses. Biometrics 47:1227-1230.
57. **Berry DA**, Kertz RP (1991). Worth of perfect information in Bernoulli bandits. Advances in Applied Probability 23:1-23.
58. **Berry DA** (1990). Invited paper: A Bayesian Approach to Metaanalysis and Multicenter Trials. Proceedings of the Pharmaceutical Section of the American Statistical Association 1-10.
59. **Berry DA** (1991). Bayesian methodology in Phase III trials. Drug Information Journal 25:345-368.
60. **Berry DA** (1991). Inferences using DNA profiling in forensic identification and paternity cases (with discussion). Statistical Science 6:175-205.
61. **Berry DA** (1991). Experimental design for drug development: A Bayesian approach. Journal of Biopharmaceutical Statistics 1:81-101.
62. **Berry DA** (1991). Probability of Paternity. In The Use of Statistics in Forensic Science 150-156. New York: Ellis Horwood Limited. (Ed: Aitken CGG, Stoney DA.)
63. **Berry DA**, Evett IW, Pinchin R (1992). Statistical inferences in crime investigations using deoxyribonucleic acid profiling (Read paper, with discussion). Journal of the Royal Statistical Society, Series C 41:499-531.
64. **Berry DA**, Wolff MC, Sack D (1992). Public Health Decision Making: A Sequential Vaccine Trial (with discussion). In Bayesian Statistics 4:79-96. Oxford, England: Oxford University Press. (Ed: Bernardo JM, Berger JO, Dawid AP, Smith AFM.)
65. **Berry DA** (1992). Statistical Issues in DNA Identification. In DNA on Trial: Genetic Identification and Criminal Justice 91-108. Cold Spring Harbor, NY: Cold Spring Harbor Laboratory Press. (Ed: Billings PR.)
66. **Berry DA** (1993). A case for Bayesianism in clinical trials (with discussion). Statistics in Medicine 12:1377-1404.
67. **Berry DA**, Hardwick J (1994). Using historical controls in clinical trials: Application to ECMO. Statistical Decision Theory and Related Topics V 141-156. New York: Springer-Verlag. (Ed: Berger JO, Gupta S.)
68. **Berry DA**, Wolff MC, Sack D (1994). Decision making during a phase III randomized controlled trial. Controlled Clinical Trials 15:360-379.
69. Parmigiani G, **Berry DA** (1994). Applications of Lindley information measure to the design of clinical experiments. In Aspects of Uncertainty: A Tribute to DV Lindley 329-348. Chichester, England: Wiley. (Ed: Freeman PR, Smith AFM.)
70. Lewis RJ, **Berry DA** (1994). Group sequential clinical trials: A classical evaluation of Bayesian decision-theoretic designs. Journal of the American Statistical Association 89:1528-1534.

V. PUBLICATIONS (CONT'D)

D. Professional Articles—Theory and Methods (cont'd):

71. George SL, Li CC, **Berry DA**, Green MR (1994). Stopping a clinical trial early: Frequentist and Bayesian approaches applied to a CALGB trial in non-small cell lung cancer. Statistics in Medicine 13:1313-1327.
72. **Berry DA** (1994). DNA, Statistics and the Simpson Case. Chance 7(4):9-12.
73. Lewis RJ, **Berry DA** (1994). Bayesian group sequential clinical trial designs based on a quadratic loss function. Proceedings of the Section on Bayesian Statistical Science of the American Statistical Association 23-28.
74. Cheng Y, **Berry DA** (1995). Optimal designs for clinical trials in stages. In Adaptive Designs. Hayward, CA: Institute of Mathematical Statistics Monograph Series, 25:124-138. (Ed: Flournoy N, Rosenberger WF.)
75. **Berry DA**, Eick SG (1995). Adaptive assignment versus balanced randomization in clinical trials: A decision analysis. Statistics in Medicine 14:231-246.
76. Rosner GL, **Berry DA** (1995). A Bayesian group sequential design for a multiple arm randomized clinical trial. Statistics in Medicine 14:381-394.
77. **Berry DA**, Thor A, Cirrincione C, Edgerton S, Muss H, Marks J, Liu E, Wood W, Budman D, Perloff M, Peters W, Henderson IC (1995). Scientific Inference and Predictions; Multiplicities and Convincing Stories: A Case Study in Breast Cancer Therapy (with discussion). In Bayesian Statistics 5:45-67. Oxford, England: Oxford University Press. (Ed: Bernardo JM, Berger JO, Dawid AP, Smith AFM.)
78. **Berry DA** (1995). Decision Analysis and Bayesian Methods in Clinical Trials. In Recent Advances in Clinical Trial Design and Analysis. 125-154. New York: Kluwer Press. (Ed: Thall P.)
79. **Berry DA**, Stangl DK (1996). Bayesian Methods in Health-Related Research. In Bayesian Biostatistics. 1-66. New York: Marcel Dekker. (Ed: **Berry DA**, Stangl DK.)
80. **Berry DA**, Parmigiani G, Sanchez J, Schildkraut J, Winer E (1997). Probability of carrying a mutation of breast-ovarian cancer gene BRCA1 based on family history. Journal of the National Cancer Institute 89:227-238.
81. **Berry DA**, Chen RW, Zame A, Heath DE, Shepp LA (1997). Bandit problems with infinitely many arms. The Annals of Statistics 25:2103-2116.
82. **Berry DA** (1997). Teaching elementary Bayesian statistics with real applications in science (with discussion). The American Statistician 51:241-274.
83. Gopalan R, **Berry DA** (1998). Bayesian multiple comparisons using Dirichlet process priors. Journal of the American Statistical Association 93:1130-1139.
84. Parmigiani G, **Berry DA**, Aguilar O (1998). Determining carrier probabilities for breast cancer susceptibility genes BRCA1 and BRCA2. The American Journal of Human Genetics 62:145-158.
85. Stangl D, **Berry DA** (1998). Bayesian statistics in medicine: Where we are and where we should be going. Sankhya 60:176-195.
86. **Berry DA**, Parmigiani G (1998). Assessing the benefits of testing for breast cancer susceptibility genes: A decision analysis. Breast Disease 10(1,2): 115-125.

V. PUBLICATIONS (CONT'D)

D. Professional Articles—Theory and Methods (cont'd):

87. Lewis RJ, **Berry DA** (1998, 2005). Decision Theory. In Encyclopedia of Biostatistics, Vol 2, 1109-1118 (1393-1402 in 2nd Ed). New York: John Wiley & Sons. (Ed: Armitage P, Colton T.)
88. **Berry DA**, Hochberg Y (1999). Bayesian perspectives on multiple comparisons. Journal of Statistical Planning and Inference 82:215-227.
89. Parmigiani G, **Berry DA**, Iversen E, Müller P, Schildkraut J, Winer E (1999). Modeling risk of breast cancer and decisions about genetic testing. In Case Studies in Bayesian Statistics IV 415-436. (Ed: Carlin B, Carriquiry A, Gatsonis C, Gelman A, Kass RE, Verdinelli I, West M.)
90. Iversen ES, Parmigiani G, **Berry DA**, Schildkraut JM (2000). Genetic susceptibility and survival: Application to breast cancer. Journal of the American Statistical Association 95:28-42.
91. Iversen ES, Parmigiani G, **Berry DA** (1999). Validating Bayesian prediction models: A case study in genetic susceptibility to breast cancer. In Case Studies in Bayesian Statistics IV 321-338. (Ed: Carlin B, Carriquiry A, Gatsonis C, Gelman A, Kass RE, Verdinelli I, West M.)
92. Stangl DK, **Berry DA** (2000). Meta-Analysis: Past and Present Challenges. In Meta-Analysis in Medicine and Health Policy. 1-28. New York: Marcel Dekker. (Ed: Stangl DK, **Berry DA**.)
93. **Berry DA**, Müller P, Grieve AP, Smith M, Parke T, Blazek R, Mitchard N, Krams M (2001). Adaptive Bayesian Designs for Dose-Ranging Drug Trials. In Case Studies in Bayesian Statistics V 99-181. New York: Springer-Verlag. (Ed: Gatsonis C, Kass RE, Carlin B, Carriquiry A, Gelman A, Verdinelli I, West M.)
94. **Berry DA** (2001). Sequential Statistical Methods. In International Encyclopedia of Social and Behavioral Sciences 20:13922-13927. Oxford, UK: Elsevier. (Ed: Smelser NJ, Baltes PB.)
95. **Berry DA** (2002). Adaptive Clinical Trials and Bayesian Statistics (with Discussion). Pharmaceutical Report 9(2):1-11. American Statistical Association.
96. **Berry DA**, Seltzer JD, Xie C, Wright DL, Smith JSC (2002). Assessing probability of ancestry using simple sequence repeat profiles: Applications to maize hybrids and inbreds. Genetics 161:813-824.
97. Inoue LYT, Thall P, **Berry DA** (2002). Seamlessly expanding a randomized phase II trial to phase III. Biometrics 58:264-272.
98. **Berry DA**, Berry SM, McKellar JJ, Pearson T (2003). Bayesian dose-response meta-analysis comparing LDL-C lowering of rosuvastatin and atorvastatin. American Heart Journal. 145:1036-1045.
99. Cheng Y, Su F, **Berry DA** (2003). Choosing sample size for a clinical trial using decision analysis. Biometrika 90:923-936.
100. **Berry DA**, Seltzer JD, Xie C, Wright DL, Jones ES, Sebastian S, Smith JSC (2003). Assessing probability of ancestry using simple sequence repeat profiles: Applications to maize inbred lines and soybean varieties. Genetics 165:331-342.

V. PUBLICATIONS (CONT'D)

D. Professional Articles—Theory and Methods (cont'd):

101. **Berry DA** (2003). The difficult and ubiquitous problems of multiplicities. International Chinese Statistical Association Bulletin, Jul, 42-45.
102. **Berry DA** (2003). Statistical Innovations in Cancer Research. In Cancer Medicine e.6. Ch 33, pp 465-478. London: BC Decker. (Ed: Holland J, Frei T et al.)
103. **Berry DA** (2004). Bayesian statistics and the efficiency and ethics of clinical trials. Statistical Science 19:175-187.
104. Berry SM, **Berry DA** (2004). Accounting for multiplicities in assessing drug safety: A three-level hierarchical mixed model. Biometrics 60:418-426.
105. Berry SM, **Berry DA**, Natarajan K, Lin C-S, Hennekens CH, Belder R (2004). Bayesian survival analysis with nonproportional hazards: Metanalysis of pravastatin-aspirin. Journal of the American Statistical Association 99:36-44.
106. Inoue LYT, **Berry DA**, Parmigiani G (2005). Relationship between Bayesian and frequentist sample size determination. The American Statistician 59:79-87.
107. Krams M, Lees KR, **Berry DA** (2005). The past is the future: innovative designs in acute stroke therapy trials. Stroke 36:1341-1347.
108. **Berry DA**, Wright DL, Xie C, Seltzer JD, Smith JSC (2005). Using molecular sizes of simple sequence repeats versus discrete binned data in assessing probability of ancestry: Application to maize hybrids. Genetics 170:365-374.
109. Biswas S, Lin S, **Berry DA** (2005). A new Bayesian approach incorporating covariate information for heterogeneity and its comparison with HLOD. BMC Genetics 6:S138.
110. Biswas S, **Berry DA** (2005). Determining joint carrier probabilities of cancer-causing genes using Markov chain Monte Carlo methods. Genetic Epidemiology 29:141-154.
111. **Berry DA** (2005). Introduction to Bayesian methods III: Use and interpretation of Bayesian tools in design and analysis. Clinical Trials 2:295-300.
112. **Berry DA** (2005). Statistical Innovations in Cancer Research. In Cancer Medicine e.7. Ch 29, pp 411-425. London: BC Decker. (Ed: Holland J, Frei T et al.)
113. **Berry DA** (2006). One- and Two-armed Bandit Problems. Methods and Applications of Statistics in the Life and Health Sciences. New York: John Wiley & Sons. (Ed: Balakrishnan N.)
114. **Berry DA**, Ayers GD (2006). Symmetrized percent change for treatment comparisons. The American Statistician 60:27-31.
115. Huang X, Biswas S, Estey EH, **Berry DA** (2006). Building and validating a prognostic index for biomarker studies. Disease Markers 2:97-101.
116. Gaydos B, Krams M, Perevozskaya I, Bretz F, Liu Q, Gallo P, **Berry DA**, Chuang-Stein C, Pinheiro J, Bedding A (2006). Adaptive dose-response studies. Drug Information Journal 40:451-461.
117. Mueller P, **Berry DA**, Grieve AP, Krams M (2006). A Bayesian decision-theoretic dose-finding trial. Decision Analysis 3:197-207.

V. PUBLICATIONS (CONT'D)

D. Professional Articles—Theory and Methods (cont'd):

118. Lewis RJ, Lipsky AM, **Berry DA** (2007). Bayesian decision-theoretic group sequential clinical trial design based on a quadratic loss function: a frequentist evaluation. Clinical Trials 4:5-14.
119. Mueller P, **Berry DA**, Grieve AP, Smith M, Krams M (2007). Simulation-based sequential Bayesian design. Journal of Statistical Planning and Inference 137:3140-3150.
120. Huang X, Biswas S, Oki Y, Issa J-P, **Berry DA** (2007). A parallel phase I/II clinical trial design for combination therapies. Biometrics 63:429-436.
121. Cheng Y, **Berry DA** (2007). Optimal adaptive randomized designs for clinical trials. Biometrika 94:673-689.
122. **Berry DA** (2007). The difficult and ubiquitous problems of multiplicities. Pharmaceutical Statistics 6:155-160.
123. Gaydos B, Anderson K, **Berry D**, Burnham N, Chuang-Stein C, Dudinak J, Fardipour P, Gallo P, Givens S, Maca J, Pinheiro J, Pritchett Y, Lewis R, Krams M (2009). Good practices for adaptive clinical trials. Drug Information Journal 43:539-556.
124. Smith JSC, Hoeft E, Cole G, Lu H, Jones ES, Wall SJ, **Berry DA** (2009). Genetic diversity among US sunflower inbreds and hybrids: Assessing probability of ancestry and potential for use in plant variety protection. Crop Science 49:1295-1303.
125. **Berry DA**, Wathen JK, Newell MA (2009). Bayesian model averaging in meta-analysis: Vitamin E supplementation and mortality (with discussion). Clinical Trials 6:28-41.
126. Huang X, Ning J, Li Y, Estey E, Issa J-P**, Berry DA** (2009). Using short-term response information to facilitate adaptive randomization for survival clinical trials. Statistics in Medicine 28:1680-1689.
127. Biswas S, Liu DD, Lee JJ, **Berry DA** (2009). Bayesian clinical trials at the University of Texas M. D. Anderson Cancer Center. Clinical Trials 6:205-216.
128. **Berry DA**. Statistical Innovations in Cancer Research. In Cancer Medicine e.8 (2009). Ch 35, pp 446-463. London: BC Decker. (Ed: Holland J, Frei T et al.)
129. Broglio KR, **Berry DA**. Detecting an overall survival benefit that is derived from progression-free survival. Journal of the National Cancer Institute 101(2009):1642-1649.
130. Berry SM, Broglio KR, **Berry DA**. Addressing the incremental benefit of histamine dihydrochloride when added to interleukin-2 in treating acute myeloid leukemia: A Bayesian meta-analysis. Cancer Investigation 29(2011):293-299.
131. Berry SM, Broglio KR, Groshen S, **Berry DA**. Bayesian hierarchical modeling of patient subpopulations: Efficient designs of phase II oncology clinical trials. Clinical Trials 10(2013):720-734.
132. Broglio KR, Stivers DN, **Berry DA**. Predicting clinical trial results based on announcements of interim analyses. Trials 15:73(2014). DOI: 10.1186/1745-6215-15-73.

V. PUBLICATIONS (CONT'D)

D. Professional Articles—Theory and Methods (cont'd):

133. Fischer K, **Berry DA**. Statisticians introduce science to international doping agency: The Andrus Veerpalu case. Chance 27.3(2014):10-16.
134. Xu Y, Müller P, Tsimberidou AM, **Berry D**. A nonparametric Bayesian basket trial design. Biometrical Journal (2019).

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications:

135. The Flecainide-Quinidine Research Group (including **Berry DA**). (1983). Flecainide versus quinidine for treatment of chronic ventricular arrhythmias: A multicenter trial. Circulation 67:1117-1123.
136. Holtzman JL, **Berry DA**, Kvam DC, Mottonen L, Borrell G (1984). The application of second-order polynomial equations to the study of pharmacodynamic interactions: The effect of flecainide acetate and propranolol on cardiac output and vascular resistance. The Journal of Pharmacology and Experimental Therapeutics 231:286-290.
137. **Berry DA** (1986). Invited paper: Marshall/MacIntosh LAD vs. Nonaugmented Controls. Proceedings from the Symposium on Prosthetic Augmentation of Autogenous Grafts II 54-74. St. Paul, Minn.:3M.
138. Salerno DM, Granrud G, Sharkey P, Krejci J, Larson T, Erlien D, **Berry DA**, Hodges M (1986). Pharmacodynamics and side effects of flecainide acetate. Clinical Pharmacology and Therapeutics 40:101-107.
139. Holtzman JL, Finley DK, Johnson BW, **Berry DA**, Sirgo MA (1986). The effects of single dose atenolol, labetalol, and propranolol on cardiac and vascular function. Clinical Pharmacology and Therapeutics 40:268-273.
140. Holtzman JL, Kvam DC, **Berry DA**, Mottonen L, Borrell G, Harrison LI, Conard GJ (1987). The pharmacodynamic and pharmacokinetic interaction of flecainide acetate with propranolol: Effects on cardiac function and drug clearance. European Journal of Clinical Pharmacology 33:97-99.
141. Holtzman JL, Weeks CE, Kvam DC, **Berry DA**, Mottonen L, Ekholm BP, Chang SF, Conard GJ (1989). Identification of drug interactions by meta-analysis of premarketing trials: The effect of smoking on the pharmacokinetics and dosage requirement for flecainide acetate. Clinical Pharmacology and Therapeutics 46:1-8.
142. **Berry DA** (1989). Ethics and ECMO: Comment on a paper by Ware. Statistical Science 4:306-310.
143. Holtzman JL, Finley D, Mottonen L, **Berry DA**, Ekholm BP, Kvam DC, McQuinn RL, Miller AM (1989). The pharmacodynamic and pharmacokinetic interaction between single doses of flecainide and verapamil: Effects on cardiac function and drug clearance. Clinical Pharmacology and Therapeutics 46:26-32.
144. Salerno DM, Gillingham K, **Berry DA**, Hodges M (1990). A comparison of antiarrhythmic drugs for suppression of ventricular ectopic depolarizations: A meta-analysis. American Heart Journal 120:340-353.
145. Hillman D, Fernández JR, Cornélissen G, **Berry DA**, Halberg J, Halberg F (1990). Bounded limits and statistical inference in chronobiometry. Chronobiology: Its Role in Clinical Medicine, General Biology, and Agriculture, Part B. 417-428.
146. Gitter MJ, Salerno DM, **Berry DA**, Fifield JH, Farmer CK (1990). Variability of different methods for measurement of ECG interval temporal variation. The Journal of Electrocardiology 22 (Suppl):125-126.
147. Enas NH, Dies F, Gonzales CR, **Berry DA** (1991). Bayesian methods for monitoring survival in congestive heart failure. In Biopharmaceutical Sequential Statistical Applications 201-217. New York: Marcel Dekker. (Ed: Peace KE.)

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

148. Agee J, McCarroll HR, Tortosa R, **Berry DA**, Szabo RM, Peimer C (1992). Endoscopic release of the carpal tunnel: A randomized prospective multicenter study. The Journal of Hand Surgery 17:987-995.
149. **Berry DA** (1993). Clinical research in the critical care environment. Critical Care Medicine. 21 (suppl):S400-S402.
150. Muss HB, Thor A, **Berry DA**, Kute T, Liu ET, Koerner F, Cirrincione C, Budman DR, Wood WC, Barcos M, Henderson IC (1994). c-erbB-2 expression predicts response to adjuvant therapy in women with node positive early breast cancer. New England Journal of Medicine 330:1260-1266.
151. Marks JR, Humphrey PA, Wu K, **Berry DA**, Kerns BJM, Iglehart JD (1994) Overexpression of the p53 and HER-2/neu proteins as prognostic markers in early breast cancer. Annals of Surgery 219:332-341
152. Perry JJ, **Berry DA**, Weiss RB, Hayes DM, Duggan DB, Henderson IC (1995). High dose toremifene for estrogen and progesterone receptor negative metastatic breast cancer: A phase II trial of the Cancer and Leukemia Group B. Breast Cancer Research and Treatment 36:35-40.
153. Costanza ME, **Berry DA**, Henderson IC, Ratain MJ, Wu K, Shapiro C, Duggan D, Kalra J, Berkowitz I, Lyss AP (1995). Amonafide: An active agent in the treatment of previously untreated advanced breast cancer: A Cancer and Leukemia Group B study (CALGB 8642). Clinical Cancer Research 1:699-704.
154. Kute TE, Quadri Y, Muss H, Zbieranski N, Cirrincione C, **Berry DA**, Barcos M, Thor AP, Liu E, Koerner F, et al. (1995). Flow cytometry in node-positive breast cancer: cancer and leukemia group B protocol 8869. Cytometry 22:297-306.
155. Hussein AM, Petros WP, Ross M, Vredenburgh JJ, Affronti ML, Jones RB, Shpall EJ, Rubin P, Elkordy M, Gilbert C, Cupton C, Egorin M, Soper J, Berchuck A, Clarke-Pearson D, **Berry DA**, Peters WP (1996). A phase I/II study of high-dose cyclophosphamide, cisplatin, and thiotepa followed by autologous bone marrow and granulocyte colony-stimulating factor-primed peripheral blood progenitor cells in patients with advanced malignancies. Cancer Chemotherapy and Pharmacology 37:561-569.
156. Roach M, Cirrincione CT, Budman D, Hayes DF, **Berry DA**, Younger J, Hart R, Henderson IC (1997). Race is not an independent prognostic factor for women receiving adjuvant chemotherapy for stage II breast cancer: An analysis based on CALGB 8541. The Cancer Journal of Scientific American 3:107-112.
157. Inouye P, Schnaper LA, Buyske J, Shank BM, Shapiro CL, **Berry DA**, Wilder KLM, Hughes KS (1997). Carcinoma of the breast in the geriatric population. Surgical Rounds. Jan 1997, 16-20.
158. Gordis L, **Berry DA**, Chu SY, Fajardo LL, Hoel DG, Laufman LR, Rufenbarger CA, Scott JR, Sullivan DC, Wasson JH, Westhoff CL, Zern RT (1997). Breast cancer screening for women ages 40-49. Journal of the National Cancer Institute 89:1015-1026. (Reprinted in Monograph of the Journal of the National Cancer Institute (1997) 22:vii-xii.)

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

159. Fisher DC, Vredenburgh JJ, Hussein A, **Berry DA**, Petros WP, Elkordy M, Rubin P, Gilbert C, Ross M, Peters WP (1998). Reduced mortality following bone marrow transplantation for breast cancer with the addition of peripheral blood progenitor cells is primarily due to a marked reduction in veno-occlusive disease of the liver. Bone Marrow Transplantation 21:117-122.
160. Vredenburgh JJ, Silva O, Broadwater G, **Berry DA**, DeSombre K, Tyer C, Petros WP, Peters WP, Bast RC Jr. (1997). The significance of tumor contamination in the bone marrow from high risk primary breast cancer patients treated with high dose chemotherapy and hematopoietic support. Biology of Blood and Marrow Transplantation. Biology of Blood and Marrow Transplantation 3:91-97.
161. Peters WP, Dansey R, Klein J, **Berry D** (1997). High-dose chemotherapy for high-risk primary breast cancer. In: Salmon SE, ed. Adjuvant Therapy of Cancer VIII, Philadelphia: Lippincott-Raven. 117 – 122.
162. Alpert LC, Schecter RL, **Berry DA**, Melnychuk D, Peters WP, Caruso JA, Townsend AJ, Batist G (1997). Relation of glutathione S-transferase α and μ isoforms to response to therapy in human breast cancer. Clinical Cancer Research 3:661-667.
163. Budman DR, **Berry DA**, Cirrincione CT, Henderson IC, Wood W, Weiss RB, Ferre C, Muss H, Cannelos G, Green M, Silver R, Carey R, Holland J, Norton L, Frei E (1998). Dose and dose intensity as determinants of outcome in the adjuvant treatment of breast cancer. Journal of the National Cancer Institute 90:1205-1211. doi: 10.1093/jnci/90.16.1205.
164. Thor A, **Berry DA**, Budman D, Muss H, Kute T, Henderson IC, Barcos M, Cirrincione C, Edgerton S, Allred C, Norton L, Liu E (1998). erbB-2, p53 and efficacy of adjuvant therapy in lymph node-positive breast cancer. Journal of the National Cancer Institute 90:1346-1360.
165. **Berry DA** (1998). Benefits and risks of screening mammography for women in their forties: A statistical appraisal. Journal of the National Cancer Institute 90:1431-1439.
166. Kupfer DJ, Baltimore RS, **Berry DA**, Breslau N, Ellinwood EH, Ferre J, Ferriero DM, Fuchs LS, Guze SB, Hamburg BA, McGlothlin J, Turner SM, Vonnegut M. Diagnosis and Treatment of Attention Deficit Hyperactivity Disorder. NIH Consensus Statement 1998 Nov 16-18; 16(2): 1-37.
167. Peters KG, Coogan A, **Berry DA**, Marks J, Iglehart JD, Kontos CD, Trogan E, Rao P (1998). Expression of Tie-2/Tek in breast tumor vasculature provides a new marker for evaluation of tumor angiogenesis. British Journal of Cancer 77:51-56.
168. Mark HFL, McCarthy M, **Berry DA** (1998). Advances in breast cancer genetics. Recent Advances in Laboratory Medicine 81:183-186.
169. Millikan RC, Kornblith AB, McIntyre OR, **Berry DA**, Broadwater GJ, Sandler DP, Karas K, Dressler L, Gross LS, Collyar DE, Schilsky RL (1998). Genetic testing in breast cancer cooperative clinical trials: Barriers and opportunities. Cancer Therapeutics 1:95-99.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

170. Gilbert CJ, Petros WP, Vredenburgh J, Hussein A, Ross M, Rubin P, Fehdrau R, Cavanaugh C, **Berry D**, McKinstry C, Peters WP (1998). Pharmacokinetic interaction between ondansetron and cyclophosphamide during high-dose chemotherapy for breast cancer. Cancer Chemotherapy and Pharmacology 42:497-503.
171. Vredenburgh JJ, Tyer C, DeSombre K, Broadwater G, **Berry DA** (1998). The Detection and Significance of Tumor Cell Contamination of the Bone Marrow. Proceedings of the Ninth Symposium of Bone and Marrow Transplantation.
172. Laughlin MJ, McGaughey DS, Crews JR, Chao N, Rizzieri D, Ross M, Gockerman J, Cirrincione C, **Berry DA**, Mills L, Defusco P, Legrande S, Peters WP, Vredenburgh JJ (1998). Secondary myelodysplasia and acute leukemia in breast cancer patients following autologous bone marrow transplant. Journal of Clinical Oncology 16:1008-1012.
173. Iglehart JD, Miron A, Rimer BK, Winer EP, **Berry DA**, Schildkraut JM (1998). Overestimation of hereditary breast cancer risk. Annals of Surgery 228:375-384.
174. Ashih H, Gustilo-Ashby T, Myers ER, Andrews J, Clarke-Pearson DL, **Berry DA**, Berchuck A (1999). Cost-effectiveness of treatment of early stage endometrial cancer. Gynecologic Oncology 74:208-216.
175. Tengs TO, **Berry DA** (2000). The cost-effectiveness of testing for the BRCA1 and BRCA2 breast-ovarian cancer susceptibility genes. Disease Management and Clinical Outcomes Winter:15-24.
176. **Berry DA**, Muss H, Thor AD, Dressler L, Liu ET, Broadwater G, Budman DR, Henderson IC, Barcos M, Hayes D, Norton M (2000). HER-2/neu and p53 expression vs tamoxifen resistance in estrogen-receptor-positive node-positive breast cancer. Journal of Clinical Oncology 18:3471-3479.
177. Claus EB, Schildkraut J, Iversen ES, **Berry DA**, Parmigiani G (1998). The effect of BRCA1 and BRCA2 on the association between breast cancer risk and family history. Journal of the National Cancer Institute 90:1824-1829.
178. **Berry DA** (1998). Screening mammography for women in their forties. Breast Disease 10(3,4): 23-32.
179. Parmigiani G, **Berry DA**, Winer EP, Tebaldi C, Iglehart JD, Prosnitz L (1999). Is axillary lymph node dissection indicated for early stage breast cancer?—A decision analysis. Journal of Clinical Oncology 17:1465-1473.
180. Tengs TO, Winer EP, Paddock S, Aguilar-Chavez O, **Berry DA** (1999). Testing for BRCA1 breast-ovarian cancer susceptibility gene: A decision analysis. Medical Decision Making 18:365-375.
181. Abrams J, Aisner J, Cirrincione C, **Berry DA**, Cooper MR, Henderson IC, Panasci L, Kirshner J, Ellerton J, Norton L (1999). A dose-response trial of megestrol acetate in advanced breast cancer: Cancer and Leukemia Group B phase III study 8741. Journal of Clinical Oncology 17:64-73.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

182. Bluman LG, Rimer BK, **Berry DA**, Borstelmann N, Regan K, Schildkraut J, Winer E (1999). Attitudes, knowledge and risk perceptions of women with breast cancer considering testing for BRCA1 and BRCA2. Journal of Clinical Oncology 17:1040-1046.
183. Costanza ME, Weiss RB, Henderson IC, Norton L, **Berry DA**, Cirrincione C, Wood WC, Frei E III, McIntyre OR, Schilsky RL (1999). The safety and efficacy of using a single agent or phase II agent before instituting standard combination chemotherapy in previously untreated metastatic breast cancer patients: Report of a randomized study: CALGB 8642. Journal of Clinical Oncology 17:1397-1406.
184. Rizzieri DA, Vredenburgh JV, Jones R, Shpall EJ, Hussein A, Broadwater G, **Berry DA**, Petros WP, Gilbert C, Affronti ML, Coniglio D, Rubin P, Elkordy M, Long GD, Chao NJ, Peters WP (1999). Prognostic and predictive factors for patients with metastatic breast cancer undergoing aggressive induction therapy followed by high dose chemotherapy with autologous stem-cell support. Journal of Clinical Oncology 17:3064-3074.
185. Guidi AJ, **Berry DA**, Broadwater G, Perloff M, Norton L, Barcos M, Hayes DF (2000). Association of angiogenesis in lymph node metastases with outcome of breast cancer. Journal of the National Cancer Institute 92:486-492.
186. Harris LN, Liotcheva V, Broadwater G, Ramirez MJ, Maimonis P, Anderson S, Everett T, Harpole D, Moore MB, **Berry DA**, Vredenburgh JJ, Rizzeri D, Bentley RC (2001). Comparison of methods of measuring HER2 in metastatic breast cancer patients treated with high-dose chemotherapy. Journal of Clinical Oncology 19:1698-1706.
187. Blackwell K, Broadwater G, Haroon Z, **Berry DA**, Harris L, Iglehart JD, Dewhirst M, Greenberg C (2000). Plasma D-dimer levels in operable breast cancer patients correlate with extent of disease involvement. Journal of Clinical Oncology 18:600-608.
188. Tengs TO, **Berry DA** (2001). Overconfident physician opinion on the effectiveness of BRCA1 risk reduction measures. Breast Cancer Research 3.2:E001. http://breast-cancer-research.com/content/3/2/E001.
189. Lewis RJ, **Berry DA**, Cryer H, Fost N, Krome R, Washington GR, Houghton J, Blue J, Bechhofer R, Cook T, Fisher, M (2001). Monitoring a clinical trial conducted under the new FDA regulations allowing a waiver of prospective informed consent: The DCLHb traumatic shock efficacy trial. Annals of Emergency Medicine 38.4: 397-404.
190. Zhang W, Labordé PM, Coombes KR, **Berry DA**, Hamilton S (2001). Cancer genomics: Promises and complexities. Clinical Cancer Research 7:2159-2167.
191. Pecora AL, Lazarus HM, Stadtmauer EA, Winter J, Van Vilet A, **Berry DA**, Gray R, Jennis A, Goldberg S, Cooper BW, Preti R (2001). Effect of induction chemotherapy and tandem cycles of high-dose chemotherapy on outcomes in autologous stem cell transplant for metastatic breast cancer. Bone Marrow Transplantation 27:1245-1253.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

192. Hayes DF, Yamauchi H, Broadwater GJ, Cirrincione CT, Rodrigue SP, **Berry DA**, Younger J, Panasci LL, Millard F, Duggan DB, Norton L, Henderson IC (2001). Circulating HER2/c-neu extra cellular domain (ECD/HER2) as a prognostic factor in patients with metastatic breast cancer: Cancer & Leukemia Group B study 8662. Clinical Cancer Research 7:2703-2711.
193. Guidi AJ, **Berry DA**, Broadwater G, Dressler L, Helmchen G, Bleiweiss I, Budman DR, Henderson IC, Norton L, Hayes DF (2002). Association of angiogenesis and disease outcome in node-positive breast cancer patients treated with adjuvant CAF chemotherapy: A Cancer and Leukemia Group B Correlative Science Study from Protocol 8541/8869. Journal of Clinical Oncology 20:732-742.
194. **Berry DA**, Broadwater G, Klein JP, Antman K, Aisner J, Bitran J, Costanza M, Freytes CO, Gale RP, Henderson IC, Lazarus HM, McCarthy PL, Norton L, Parnes H, Pecora A, Perry MC, Rowlings P, Spitzer G, Stadtmauer E, Horowitz MM (2002). High-dose vs standard chemotherapy in metastatic breast cancer: Comparison of Cancer and Leukemia Group B trials with data from the Autologous Blood and Marrow Transplant Registry. Journal of Clinical Oncology 20:743-750.
195. Buzdar AU, Singletary SE, Valero V, Booser DJ, Ibrahim NK, Rahman Z, Theriault RL, Walters R, Rivera E, Smith TL, Holmes FA, Hoy E, Frye DK, Manuel N, Kau S-W, NcNeese MD, Strom E, Thomas E, Hunt K, Ames F, **Berry DA**, Hortobagyi GN (2002). Evaluation of paclitaxel in adjuvant chemotherapy for patients with operable breast cancer: Preliminary data of a prospective randomized trial. Clinical Cancer Research 8:1073-1079.
196. **Berry DA**, Iversen E, Gudbjartsson DF, Hiller E, Garber J, Peshkin B, Lerman C, Watson P, Lynch H, Hilsenbeck S, Rubinstein W, Hughes K, Parmigiani G (2002). BRCAPRO validation, sensitivity of genetic testing of BRCA1/BRCA2, and prevalence of other breast cancer susceptibility genes. Journal of Clinical Oncology 20:2701-12.
197. Petros WP, Broadwater G, **Berry DA**, Jones RB, Vredenburgh JJ, Gilbert CJ, Gibbs JP, Colvin MO, Peters WP (2002). Association of high-dose cyclophosphamide, cisplatin and carmustine pharmacokinetics with survival, toxicity and dosing weight in patients with primary breast cancer. Clinical Cancer Research 8:698-705.
198. Skinner CS, Schildkraut J, **Berry D**, Calingaert B, Marcom PK, Sugarman J, Winer E, Iglehart JD, Futreal PA, Rimer BK (2002). Pre-counseling education materials for BRCA testing: does tailoring make a difference? Genetic Testing 6:93-105.
199. **Berry DA** (2002). The Utility of Mammography for Women 40 to 50 Years of Age (Con). In Progress in Oncology 2002 233-259. Sudbury MA, Jones and Bartlett. (Ed: DeVita VT, Hellman S, Rosenberg SA.)

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

200. Singletary SE, Allred C, Ashley P, Bassett LW, **Berry DA**, Bland KI, Borgen PI, Clark G, Edge SB, Hayes DF, Hughes LL, Hutter RVP, Morrow M, Page DL, Hecht A, Theriault RL, Thor A, Weaver DL, Wieand HS, Greene FL (2002). Revision of the American Joint Committee on Cancer staging system for breast cancer. Journal of Clinical Oncology.20:3628-3636. (Reprinted as Staging System for Breast Cancer: Revisions for the 6th Edition of the AJCC Cancer Staging Manual, In The Surgical Clinics of North America. Breast Cancer: New Concepts in Management. 83 (4) Aug 2003:803-819. Philadelphia PA, W.B. Saunders Company. Ed: Jatoi I, Singletary SE.)
201. **Berry DA** (2003). Clinical Trial Design. Gynecologic Oncology 88:S114-S116. doi: http://dx.doi.org/10.1006/gyno.2002.6951.
202. Henderson IC, **Berry DA**, Demetri GD, Cirrincione CT, Goldstein LJ, Martino S, Ingle JN, Frei ME III, Schilsky RL, Wood WC, Muss HB, Norton L (2003). Improved outcomes from adding sequential paclitaxel but not from escalating doxorubicin dose in an adjuvant chemotherapy regimen for patients with node-positive primary breast cancer. Journal of Clinical Oncology 21:976-983.
203. Citron ML, **Berry DA**, Cirrincione C, Hudis C, Winer EP, Gradishar WJ, Davidson NE, Martino S, Livingston R, Ingle JN, Perez EA, Carpenter J, Hurd D, Holland JF, Smith BL, Sartor CI, Leung EH, Abrams J, Schilsky RL, Muss HB, Norton L (2003). Randomized trial of dose-dense versus conventionally scheduled and sequential versus concurrent combination chemotherapy as postoperative adjuvant treatment of node-positive primary breast cancer: First report of Intergroup C9741/Cancer and Leukemia Group B Trial 9741. Journal of Clinical Oncology 21:1431-1439.
204. Giles FJ, Kantarjian HM, Cortes JE, Garcia-Manero G, Verstovsek S, Faderl S, Thomas DA, Ferrajoli A, O'Brien S, Wathen JK, Xiao L-C, **Berry DA**, Estey EH (2003). Adaptive randomized study of idarubicin and cytarabine versus troxacitabine and cytarabine versus troxacitabine and idarubicin in untreated patients 50 years or older with adverse karyotype acute myeloid leukemia. Journal of Clinical Oncology 21:1722-1727.
205. Parnes H, Cirrincione C, Aisner J, **Berry DA**, Allen SL, Abrams J, Cooper MR, Perry MC, Duggan DB, Szatrowski TP, Henderson IC, Norton L (2003). Phase III study of cyclophosphamide, doxorubicin, and fluorouracil (CAF) plus leucovorin versus CAF for metastatic breast cancer: Cancer and Leukemia Group B 9140. Journal of Clinical Oncology 21:1819-1824.
206. Weiss RB, Woolf SH, Demakos E, Holland JF, **Berry DA**, Falkson G, Cirrincione CT, Robbins A, Bothun S, Henderson IC, Norton L (2003). Natural history of more than 20 years of node-positive primary breast carcinoma treated with cyclophosphamide, methotrexate, and fluorouracil-based chemotherapy: A Study by the Cancer and Leukemia Group B. Journal of Clinical Oncology 21:1825-1835.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

207. Rosner G, **Berry DA** (2003). Designs for Phase II and Phase III Cancer Drug Studies. Chapter 26 in Handbook of Anticancer Drug Development. pp. 379-392. Lippincott Williams & Wilkins (Ed: Budman D.)
208. Kimmick G, Ratain MJ, **Berry DA**, Woolf S, Norton L, Muss HB (2004). Subcutaneously administered recombinant human interleukin-2 and interferon alfa-2a for advanced breast cancer: A phase II study of the Cancer and Leukemia Group B (CALGB 9041). Investigational New Drugs 22:83-89.
209. Hennekens CH, Sacks FM, Tonkin A, Jukema JW, Byington RP, Pitt B, **Berry DA**, Berry SM, Ford NF, Walker AJ, Natarajan K, Lin C-S, Fiedorek FT, Belder R (2004). Additive benefits of pravastatin and aspirin to decrease risks of cardiovascular disease: Randomized and observational comparisons of secondary prevention trials and their meta-analysis. Archives of Internal Medicine 164:40-44.
210. **Berry DA**, Chastain LA (2004). Inferences about testosterone abuse among athletes. Chance 17(2):5-8.
211. Winer E, **Berry DA**, Woolf S, Duggan D, Kornblith A, Henderson IC, Hudis C, Muss H, Norton L (2004). Failure of higher-dose paclitaxel to improve outcome in patients with metastatic breast cancer: Results from CALGB 9342. Journal of Clinical Oncology 22:2061-8.
212. Buchholz TA, Huang EH, **Berry DA**, Puzstai L, Strom EA, McNeese MD, Perkins GH, Schechter N, Kuerer HM, Buzdar AU, Valero V, Hunt KK, Hortobagyi GN, Sahin AA (2004). HER2/neu disease does not increase risk of locoregional recurrence for patients treated with neoadjuvant doxorubicin-based chemotherapy, mastectomy, and radiotherapy. International Journal of Radiation Oncology*Biology*Physics 59:1337-1342.
213. Hughes KS, Schnaper LA, **Berry DA**, Cirrincione C, McCormick B, Shank B, Wheeler J, Champion LA, Smith TJ, Smith BL, Shapiro C, Muss H, Winer E, Hudis C, Wood W, Sugarbaker D, Henderson IC, Norton L (2004). A randomized comparison of lumpectomy plus tamoxifen with and without irradiation in women 70 years of age or older who have clinical stage 1, estrogen receptor positive carcinoma of the breast: Results of CALGB study 9343. New England Journal of Medicine 351:971-977.
214. Dressler L, **Berry DA**, Broadwater G, Cowan D, Cox K, Griffith S, Miller A, Tse J, Novotny D, Persons DL, Barcos M, Henderson IC, Liu ET, Thor A, Budman D, Muss H, Norton L, Hayes DF (2005). Comparison of HER2 status by fluorescent in situ hybridization and immunohistochemistry to predict benefit from dose escalation of adjuvant doxorubicin-based therapy in node-positive breast cancer patients. Journal of Clinical Oncology 23:4287-4297.
215. Parke T, Krams M, Mueller P, **Berry D** (2005). Efficient Dose-Response Finding Strategies for Acute Neuroscience Populations. In Handbook of Neuroemergency Clinical Trials. Ch 9, pp 179-204. New York: Elsevier. (Ed: Alves WM, Skolnick BE.)

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

216. Shen L, Kantarjian H, Saba H, Lin E, **Berry D**, Ahmed S, Jelinek J, Issa J-P (2005). CpG island methylation is a poor prognostic factor in myelodysplastic syndrome patients and is reversed by decitabine therapy: Results of a phase III randomized study. Blood 106:790.
217. Abe O, Abe R, Enomoto K, Kikuchi K, Koyama H, Masuda H, …, **Berry D**, …, R Sauer R. Effects of radiotherapy and of differences in the extent of surgery for early breast cancer on locl recurrences and 15-year survival: an overview of the randomised trials. Lancet 366:2087-2106.
218. Jimenez C, Yang Y, Kim H-W, Al-Sagier F, **Berry DA**, El-Naggar AK, Patel S, Vassilopoulou-Sellin R, Gagel RF (2005). Primary hyperparathyroidism and osteosarcoma: Examination of a large cohort identifies three cases of fibroblastic osteosarcoma. Journal of Bone and Mineral Research 20:1562-8.
219. Buzdar AU, Ibrahim NK, Francis D, Booser DJ, Thomas ES, Theriault RL, Pusztai L, Green MC, Arun BK, Giordano SH, Cristofanilli M, Frye DK, Smith TL, Hunt KK, Sahin AA, Ewer MS, Buchholz TA, **Berry DA**, Hortobagyi GN (2005). Significantly higher pathological complete remission rate following neoadjuvant therapy with trastuzumab, paclitaxel and epirubicin-containing chemotherapy: results of a randomized trial in human epidermal growth factor receptor 2-positive operable breast cancer. Journal of Clinical Oncology 23:3676-3685.
220. **Berry DA**, Cronin KA, Plevritis SK, Fryback DG, Clarke L, Zelen M, Mandelblatt JS, Yakovlev AY, Habbema JDF, Feuer EJ for the Cancer Intervention and Surveillance Modeling Network (CISNET) (2005). Effect of screening and adjuvant therapy on mortality from breast cancer. New England Journal of Medicine 353:1784-1792.
221. Lipscomb B, Ma G, **Berry DA** (2005). Bayesian predictions of final outcomes: regulatory approval of a spinal implant. Clinical Trials 2:325-333.
222. Rouzier R, Pusztai L, Delaloge S, Gonzalez-Angulo AM, André F, Hess KR, Buzdar AU, Garbay JR, Spielmann M, Mathieu M-C, Symmans WF, Wagner P, Valero V, Atallah D, Valero V, **Berry DA**, Hortobagyi GN (2005). Nomograms to predict pathologic complete response and metastasis-free survival after preoperative chemotherapy for breast cancer. Journal of Clinical Oncology 23:8331-8339.
223. Muss HB, Woolf S, **Berry DA**, Cirrincione C, Weiss RB, Budman D, Wood WC, Henderson IC, Hudis C, Winer E, Cohen H, Wheeler J, Norton L (2005). Adjuvant chemotherapy in older and younger women with lymph node–positive breast cancer. Journal of the American Medical Association 293:1073-1081.
224. Shen Y, Yang Y, Inoue LYT, Munsell MF, Miller AB, **Berry DA** (2005). Role of detection method in predicting breast cancer survival: Analysis of randomized screening trials. Journal of the National Cancer Institute 97:1195-1203.
225. **Berry DA**. A guide to drug discovery: Bayesian clinical trials. Nature Reviews Drug Discovery 5(2006):27-36.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

226. **Berry DA**, Cirrincione C, Henderson IC, Citron ML, Budman DR, Goldstein LJ, Martino S, Perez EA, Muss HB, Norton L, Hudis C, Winer EP (2006). Estrogen-receptor status and outcomes of modern chemotherapy for patients with node-positive breast cancer. Journal of the American Medical Association 295:1658-1667.
227. **Berry DA**, Inoue L, Shen Y, Venier J, Cohen D, Bondy M, Theriault R, Munsell MF (2006). Modeling the Impact of Treatment and Screening on Breast Cancer Mortality: A Bayesian Approach. Monograph of the Journal of the National Cancer Institute Number 36:30-36.
228. Rouzier R, Pusztai L, Garbay JR, Delaloge S, Hunt KK, Hortobagyi GN, **Berry D**, Kuerer HM (2006). Development and validation of nomograms for predicting residual tumor size and the probability of successful conservative surgery with neoadjuvant chemotherapy for breast cancer. Cancer 107:1459-66.
229. Chen S, Iversen ES, Friebel T, Finkelstein D, Weber BL, Eisen A, Peterson LE, Schildkraut JM, Isaacs C, Peshkin BN, Corio C, Leondaridis L, Tomlinson G, Dutson D, Kerber R, Amos CI, Strong LC, **Berry DA**, Euhus DM, Parmigiani G (2006). Characterization of BRCA1 and BRCA2 mutations in a large United States sample. Journal of Clinical Oncology 24(6):863-871.
230. Rincon M, Broadwater G, Harris L, Crocker AM, Weaver D, Dressler L, **Berry DA**, Sutton L, Michaelson R, Messino M, Kirshner J, Fleming G, Winer E, Hudis C, Appel S, Norton L, Muss HB (2006). Interleukin-6, multidrug resistance protein-1 expression and response to paclitaxel in women with metastatic breast cancer: results of Cancer and Leukemia Group B Trial 159806. Breast Cancer Research and Treatment 100:301-308.
231. **Berry DA** (2006). Interpreting adjuvant breast cancer data in 2006 and beyond. European Journal of Cancer. Supplements Vol 4, No. 13:17-22
232. Harris LN, Broadwater G, Lin NU, Miron A, Schnitt SJ, Cowan D, Lara J, Bleiweiss I, **Berry DA**, Ellis M, Hayes DF, Winer EP, Dressler L (2006). Molecular subtypes of breast cancer in relation to paclitaxel response and outcomes in women with metastatic disease: results from CALGB 9342. Breast Cancer Research 8:R66.
233. Yang J-Y, Zong CS, Xia W, Wei Y, Ali-Seyed M, Li Z, Broglio K, **Berry DA**, Hung M-C (2006). MDM2 promotes cell motility and invasiveness by regulating E-cadherin degradation. Molecular and Cellular Biology 26:7269-7282.
234. Ravdin PM, Cronin KA, Howlader N, Berg CD, Chlebowski RT, Feuer EJ, Edwards BK, **Berry DA** (2007). The decrease in breast-cancer incidence in 2003 in the United States. The New England Journal of Medicine 356:1670-1674.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

235. Parmigiani G, Chen S, Iversen ES, Friebel TM, Finkelstein D, Anton-Culver H, Ziogas A, Weber BL, Eisen A, Malone KE, Daling JR, Hsu L, Ostrander EA, Peterson LE, Schildkraut JM, Isaacs C, Corio C, Leondaridis L, Tomlinson G, Amos CI, Strong LC, **Berry DA**, Weitzel JN, Sand S, Dutson D, Kerber R, Peshkin BN, Euhus DM (2007). Validity of models for prediction of BRCA1 and BRCA2 mutations. Annals of Internal Medicine 147:441-450.
236. Bhardwaj S, Duggan D, Kirshner JJ, Woolf S, Holland JF, **Berry DA**, Norton L, Henderson IC (2007). An intensive sequenced adjuvant chemotherapy regimen for breast cancer, a pilot study of the Cancer and Leukemia Group B. Cancer Therapy 5:117-124.
237. Singh B, **Berry DA**, Shoher A, Ayers GD, Wei C, Lucci A (2007). COX-2 involvement in breast cancer metastasis to bone. Oncogene 26:3789-3796.
238. Pujol JL, Paul S, Chouaki N, Peterson P, Moore P, **Berry DA**, Salzberg M. (2007). Survival without common toxicity criteria grade 3/4 toxicity for pemetrexed compared with docetaxel in previously treated patients with advanced non-small cell lung cancer (NSCLC): a risk-benefit analysis. Journal of Thoracic Oncology 2:397-401.
239. **Berry DA** (2007). Biomarker studies and other difficult inferential problems: Statistical caveats. Seminars in Oncology 34(suppl 3):S17–S21.
240. **Berry DA**, Smith T, Buzdar A (2007). Breast Cancer. Chapter 6 in Textbook of Clinical Trials, 2nd Ed. New York: John Wiley & Sons (Ed: Machin D, Day S.)
241. Muss HB, **Berry DA**, Cirrincione C, Budman DR, Henderson IC, Citron ML, Norton L, Winer EP, Hudis C (2007). Toxicity of older and younger patients treated with adjuvant chemotherapy for node-positive breast cancer: The Cancer and Leukemia Group B Experience. Journal of Clinical Oncology 25:3699-3704.
242. Hayes DF, Thor AD, Dressler LG, Weaver D, Edgerton S, Cowan D, Broadwater G, Goldstein LJ, Martino S, Ingle JN, Henderson IC, Norton L, Winer EP, Hudis CA, Ellis MJ, **Berry DA** (2007). HER2 and response to paclitaxel in node-positive breast cancer. New England Journal of Medicine 357:1496-1506.
243. Liu M, Demetri GD, **Berry DA**, Norton L, Broadwater G, Robert NJ, Duggan DB, Hayes DF, Henderson IC, Winer EP, Hudis CA (2008). Dose-escalation of filgrastim does not improve efficacy: Clinical tolerability and long-term follow-up on CALGB study 9141, adjuvant chemotherapy for node-positive breast cancer patients using dose-intensified doxorubicin plus cyclophosphamide followed by paclitaxel. Cancer Treatment Reviews 34:223-230.
244. Wolff AC, **Berry D**, Carey L, Colleoni M, Dowsett M, Ellis M, Garber JE, Mankoff D, Paik S, Pusztai L, Smith ML, Zujewski J (2008). Research issues affecting preoperative systemic therapy for operable breast cancer. Journal of Clinical Oncology 26:806-813.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

245. Seidman AD, **Berry DA**, Cirrincione C, Harris L, Muss H, Marcom PK, Gipson G, Burstein H, Lake D, Shapiro CL, Ungaro P, Norton L, Winer E, Hudis C (2008). Randomized phase III trial of weekly compared with every-3-weeks paclitaxel for metastatic breast cancer, with trastuzumab for HER-2 overexpressors and random assignment to trastuzumab or not in HER-2 nonoverexpressors: Final results of Cancer and Leukemia Group B protocol 9840. Journal of Clinical Oncology 26:1642-1649.
246. DiGiovanna MP, Stern DF, Edgerton S, Broadwater G, Dressler L, Budman DR, Henderson IC, Norton L, Liu ET, Muss HB, **Berry DA**, Hayes DF, Thor AD. Influence of activation state of ErbB-2 (HER2) on response to adjuvant cyclophosphamide/doxorubicin/fluorouracil for stage II, node-positive breast cancer: Cancer and Leukemia Group B Study 8541. Journal of Clinical Oncology 26(2008):2364-2372.
247. Polite BN, Cirrincione C, Fleming, GF, **Berry DA**, Seidman A, Muss H, Norton L, Shapiro C, Bakri K, Marcom K, Lake D, Schwartz JH, Hudis C, Winer EP (2008). Racial differences in clinical outcomes from metastatic breast cancer: A pooled analysis of Cancer and Leukemia Group B trials 9342 and 9840. Journal of Clinical Oncology 26:2659-2665.
248. Julian TB, Blumencranz P, Deck K, Whitworth P, **Berry DA**, Berry SM, Rosenberg A, Chagpar AB, Reintgen D, Beitsch P, Simmons R, Saha S, Mamounas EP, Giuliano A (2008). A novel intra-operative molecular test for sentinel lymph node metastases in early stage breast cancer patients. Journal of Clinical Oncology 26:3338-3345.
249. Dong W, **Berry DA**, Bevers TB, Kau S-W, Hsu L, Theriault RL, Shen Y (2008). Prognostic role of detection method and its relationship with tumor biomarkers in breast cancer: The University of Texas M. D. Anderson Cancer Center experience. Cancer Epidemiology Biomarkers & Prevention 17:1096-1103.
250. Kimmick GG, Cirrincione C, Duggan DB, Bhalla K, Robert N, **Berry D**, Norton L, Lemke S, Henderson IC, Hudis C, Winer E, on Behalf of the Cancer and Leukemia Group B. Fifteen-year median follow-up results after neoadjuvant doxorubicin, followed by mastectomy, followed by adjuvant cyclophosphamide, methotrexate, and fluorouracil (CMF) followed by radiation for stage III breast cancer: a phase II trial (CALGB 8944). Breast Cancer Research and Treatment 113(2009):479-490.
251. Muss HB, **Berry DA**, Cirrincione CT, Theodoulou M, Mauer AM, Kornblith AB, Partridge AH, Dressler LG, Cohen HJ, Becker HP, Kartcheske PA, Wheeler JD, Perez EA, Wolff AC, Gralow JR, Burstein HJ, Mahmood AA, Magrinat G, Parker BA, Hart RD, Grenier D, Norton L, Hudis CA, Winer EP, for the Cancer and Leukemia Group B (2009). Adjuvant chemotherapy in older women with early-stage breast cancer. New England Journal of Medicine 360:2055-2065.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

252. Harris LN, Broadwater G, Abu-Khalaf MM, Cowan DW, Thor AD, Cirrincione CT, **Berry DA**, Winer EP, Hudis CA, Hayes DF, Friedman P, Ellis MJ, Dressler LG, for the Cancer and Leukemia Group B (2009). Topoisomerase II&[alpha] amplification does not predict benefit from dose-intense cyclophosphamide, doxorubicin and 5FU (CAF) therapy in HER2 amplified, early breast cancer: Results of CALGB 8541/150013. Journal of Clinical Oncology 27:3430-3436.
253. Gonzalez-Angulo AM, Litton JK, Broglio KR, Rakkhit R, Meric-Bernstam F, Cardoso F, Peintinger F, Hanrahan EO, Sahin A, Guray M, Larsimont D, Feoli F, Stranz H, Buchholz TA, Valero V, Theriault R, Piccart-Gebhart M, Ravdin PM, **Berry DA**, Hortobagyi GN (2009). High risk of recurrence for breast cancer Patients with HER2-positive node negative tumors 1 cm or smaller. Journal of Clinical Oncology 27:5700-5706.
254. Barker AD, Sigman CC, Kelloff GJ, Hylton NM, **Berry DA**, Esserman LJ (2009). I-SPY 2: An adaptive breast cancer trial design in the setting of neoadjuvant chemotherapy. Clinical Pharmacology & Therapeutics 86:97-100.
255. Borthakur G, Huang X, Kantarjian H, Faderl S, Ravandi-Kashani F, Ferrajoli A, Torma R, **Berry D**, Issa J-P (2009). Report of a Phase 1/2 study of a combination of azacitidine and cytarabine in acute myelogenous leukemia and high-risk myelodysplastic syndromes. Leukemia and Lymphoma 51:73-78.
256. Allred DC, Carlson RW, **Berry DA**, Burstein HJ, Edge SB, Goldstein LJ, Gown A, Hammond ME, Iglehart JD, Moench S, Pierce LJ, Ravdin P, Schnitt SJ, Wolff AC. NCCN Task Force Report: Estrogen receptor and progesterone receptor testing in breast cancer by immunohistochemistry. Journal of the National Comprehensive Cancer Network. 7 Suppl 6:S1-S21(2009);quiz S22-23.
257. Mandelblatt JS, Cronin KA, Bailey S, **Berry DA**, de Koning HJ, Draisma G, Huang H, Lee SJ, Munsell M, Plevritis SK, Ravdin P, Schechter CB, Sigal B, Stoto MA, Stout NK, van Ravesteyn NT, Venier J, Zelen M, Feuer EJ for the Breast Cancer Working Group of the Cancer Intervention and Surveillance Modeling Network (CISNET). Effects of mammographic screening under different screening schedules: Model estimates of potential benefits and harms. Annals of Internal Medicine 151(2009):738-747.
258. Wilber DJ, Pappone C, Neuzil P, De Paola A, Marchlinski FE, Natale A, Macle L, Daoud EG, Calkins H, Hall B, Reddy V, Augello G, Reynolds MR, Vinekar C, Liu CY, Berry SM, **Berry DA** for the ThermoCool AF Trial Investigators (2010). Comparison of antiarrhythmic drug therapy and radiofrequency catheter ablation in patients with paroxysmal atrial fibrillation: A randomized controlled trial. Journal of the American Medical Association 303(2010):333-340.
259. Berry SM, Ishak J, Luce B, **Berry DA**. Bayesian meta-analysis for comparative effectiveness and informing coverage decisions. Medical Care 48(2010):S137-S144.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

260. Hamaoka T, Costelloe CM, Madewell JE, Liu P, **Berry DA**, Islam R, Theriault RL, Hortobagyi GN, Ueno NT. Tumour response interpretation with new tumour response criteria vs the World Health Organisation criteria in patients with bone-only metastatic breast cancer. British Journal of Cancer 102(2010):651-657.
261. Shen L, Kantarjian H, Guo Y, Lin E, Shan J, Huang X, **Berry D**, Ahmed S, Zhu W, Pierce S, Kondo Y, Oki Y, Jelinek J, Saba H, Estey E, Issa J-P. DNA methylation predicts survival and response to therapy in patients with myelodysplastic syndromes. Journal of Clinical Oncology 28(2010):605-613.
262. Partridge AH, Archer L, Kornblith AB, Gralow J, Grenier D, Perez E, Wolff AC, Wang X, Kastrissios H, **Berry D**, Hudis C, Winer E, Muss H. Adherence and persistence with oral adjuvant chemotherapy in older women with early stage breast cancer in CALGB 49907: Adherence Companion Study 60104. Journal of Clinical Oncology 28(2010):2418-2422.
263. Berry SM, Spinelli W, Littman GS, Liang JZ, Fardipour P, **Berry DA**, Lewis RJ, Krams M. A Bayesian dose-finding trial with adaptive dose expansion to flexibly assess efficacy and safety of an investigational drug. Clinical Trials 7(2010):121-135.
264. Seymour L, Ivy P, Sargent D, Spriggs D, Baker L, Rubinstein L, Ratain M, Le Blanc M, Stewart D, Crowley J, Groshen S, Humphrey J, West P, **Berry D**. The design of Phase II clinical trials testing cancer therapeutics: Consensus recommendations from the clinical trial design task force of the National Cancer Institute Investigational Drug Steering Committee. Clinical Cancer Research 16(2010):1764-1769.
265. **Berry DA**. Adaptive and Bayesian Approaches to Study Design. In Redesigning the Clinical Effectiveness Research Paradigm: Innovation and Practice-Based Approaches: Workshop Summary. Institute of Medicine. Washington, DC: The National Academies Press. 2010. pp 174-180.
266. Parmar S, Andersson BS, Couriel D, Munsell MF, Fernandez-Vina M, Jones RB, Shpall EJ, Popat U, Anderlini P, Giralt S, Alousi A, Cano P, Bosque D, Hosing C, de Padua Silva L, Westmoreland M, Wathen JK, **Berry D**, Champlin RE, de Lima M. Prophylaxis of graft-versus-host disease in unrelated donor transplantation with pentostatin, tacrolimus, and mini-methotrexate: A Phase I/II controlled, adaptively randomized study. Journal of Clinical Oncology 29(2011):294-302.
267. Rimm DL, Nielsen TO, Jewell SD, Rohrer D, Broadwater G, Waldman F, Mitchell KA, Singh B, Tsongalis GJ, Frankel SL, Magliocco A, Lara JF, His ED, Bleiweiss I, Badve SS, Chen B, Ravdin P, Schilsky R, Thor A, **Berry DA**. CALGB Pathology Committee Guidelines for Tissue Microarray Construction representing Multi-Center Prospective Clinical Trial Tissues. Journal of Clinical Oncology 29(2011):2282-2289.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

268. Schuster SJ, Neelapu SS, Gause BL, Janik JE, Muggia FM, Gockerman JP, Winter JN, Flowers CR, Nikcevich DA, Sotomayor EM, McGaughey DS, Jaffe ES, Chong EA, Reynolds CW, **Berry DA**, Santos CF, Popa MA, McCord AM, Kwak LW, on behalf of the BV301 Phase III Study Investigators. Vaccination with patient-specific tumor-derived antigen in first remission improves disease-free survival in follicular lymphoma. Journal of Clinical Oncology 29(2011):2787-2794.
269. **Berry DA**, Ueno NT, Johnson MM, Lei X, Caputo J, Rodenhuis S, Peters WP, Leonard RC, Barlow WE, Tallman M, Bergh J, Nitz UA, Gianni AM, Basser RL, Zander AR, Coombes RC, Roché H, Tokuda Y, de Vries EGE, Hortobagyi GN, Crown JP, Pedrazzoli P, Bregni M, Demirer T. High-dose chemotherapy with autologous stem cell support as adjuvant therapy in breast cancer: Overview of 15 randomized trials. Journal of Clinical Oncology 29(2011):3214-3223.
270. **Berry DA**, Ueno NT, Johnson MM, Lei X, Caputo J, Smith DA, Yancey LJ, Crump M, Stadtmauer EA, Biron P, Crown JP, Schmid P, Lotz JP, Rosti G, Bregni M, Demirer T. High-dose chemotherapy with autologous hematopoietic stem cell transplantation in metastatic breast cancer: Overview of six randomized trials. Journal of Clinical Oncology 29(2011):3224-3231.
271. Lara JF, Thor AD, Dressler LG, Broadwater G, Bleiweiss IJ, Edgerton S, Cowan D, Goldstein LJ, Martino S, Ingle JN, Henderson IC, Norton L, Winer WP, Hudis CA, Ellis MJ, **Berry DA**, Hayes DF. p53 expression in node positive breast cancer patients: Results from the Cancer and Leukemia Group B (CALGB) 9344 Trial (159905). Clinical Cancer Research 17(2011):5170-5178.
272. **Berry DA**. Adaptive clinical trials in oncology. Nature Reviews Clinical Oncology 9(2012):199-207.
273. **Berry DA**. Next generation clinical trials. Clinical Advances in Hematology & Oncology 9(2011):601-603.
274. Mandelblatt JS, Cronin KA, **Berry DA**, Chang Y, de Koning HJ, Lee SJ, Plevritis SK, Schechter CB, Stout NK, van Ravesteyn NT, Zelen M, Feuer EJ. Modeling the impact of population screening on breast cancer mortality in the United States. The Breast 20(2011);Suppl.3:S75-S81.
275. **Berry DA**. Bayesian approaches for comparative effectiveness research. Clinical Trials 9(2012):37-47.
276. Ji Y, Feng L, Liu P, Shpall E, Kebriaei P, Champlin R, **Berry D**, Cooper L. Bayesian continual reassessment method for dose-finding trials infusing T cells with limited sample size. Journal of Biopharmaceutical Statistics 22(2012):1206-1219.
277. Esserman LJ, **Berry DA**, DeMichele A, Carey L, Davis SE, Buxton MB, Hudis C, Gray JW, Perou C, Yau C, Livasy C, Krontiras H, Montgomery L, Tripathy D, Lehman C, Liu MC, Olopade OI, Rugo HS, Carpenter JT, Dressler L, Chhieng D, Singh B, Mies C, Rabban J, Chen YY, Giri D, van 't Veer L, Hylton N. Pathologic complete response predicts recurrence-free survival more effectively by cancer subset: Results from the I-SPY 1 TRIAL—CALGB 150007/150012, ACRIN 6657. Journal of Clinical Oncology 30(2012):3242-3249. PMID: 22649152. PMCID: PMC3434983.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

278. Esserman LJ, **Berry DA**, Cheang MC, Yau C, Perou CM, Carey L, DeMichele A, Gray JW, Conway-Dorsey K, Lenburg ME, Buxton MB, Davis SE, van 't Veer LJ, Hudis C, Chin K, Wolf D, Krontiras H, Montgomery L, Tripathy D, Lehman C, Liu MC, Olopade OI, Rugo HS, Carpenter JT, Livasy C, Dressler L, Chhieng D, Singh B, Mies C, Rabban J, Chen YY, Giri D, Au A, Hylton N; I-SPY 1 TRIAL Investigators. Chemotherapy response and recurrence-free survival in neoadjuvant breast cancer depends on biomarker profiles: Results from the I-SPY 1 Trial (CALGB 150007/150012; ACRIN 6657). Breast Cancer Research and Treatment 132(2012):1049-1062. PMID: 22198468. PMCID: PMC3332388.
279. Lin C, Buxton MB, Moore D, Krontiras H, Carey L, DeMichele A, Montgomery L, Tripathy D, Lehman C, Liu M, Olapade O, Yau C, **Berry D**, I-SPY TRIAL Investigators, Esserman L. Locally advanced breast cancers are more likely to present as interval cancers: Results from the I-SPY 1 TRIAL (CALGB 150007/150012, ACRIN 6657, InterSPORE Trial). Breast Cancer Research and Treatment 132(2012):871-879. PMID: 21796368. PMCID: PMC3975048.
280. **Berry DA**, Herbst RS, Rubin EH. Design strategies for personalized therapy trials. Clinical Cancer Research 18(2012):638-644.
281. Collins SP, Lindsell CJ, Pang PS, Storrow AB, Peacock WF, Levy P, Rahbar MH, Del Junco D, Gheorghiade M, **Berry DA**. Bayesian adaptive trial design in acute heart failure syndromes: Moving beyond the mega trial. American Heart Journal 164(2012):138-145.
282. **Berry DA**. Multiplicities in cancer research: Ubiquitous and necessary evils. Journal of the National Cancer Institute 104(2012):1125-1133.
283. O'Brien S, Rizzieri DA, Vey N, Ravandi F, Krug UO, Sekeres MA, Dennis M, Venditti A, **Berry DA**, Jacobsen TF, Staudacher K, Bergeland T, Giles FJ. Elacytarabine has single-agent activity in patients with advanced acute myeloid leukemia. British Journal of Haematology 158(2012):581-588.
284. Bach PB, Mirkin JN, Oliver TK, Azzoli CG, **Berry DA**, Brawley OW, Byers T, Colditz GA, Gould MK, Jett JR, Sabichi AL, Smith-Bindman R, Wood DE, Qaseem A, Detterbeck FC. Benefits and Harms of CT Screening for Lung Cancer: A Systematic Review. Journal of the American Medical Association 307(2012): 2418-2429.
285. Meurer WJ, Lewis RJ, Tagle D, Fetters MD, Legocki L, Berry S, Connor J, Durkalski V, Elm J, Zhao W, Frederiksen S, Silbergleit R, Palesch Y, **Berry DA**, Barsan WG. An overview of the Adaptive Designs Accelerating Promising Trials Into Treatments (ADAPT-IT) project. Annals of Emergency Medicine 60(2012):451-457.
286. Lips EH, Mukhtar RA, Yau C, de Ronde JJ, Livasy C, Carey LA, Loo CE, Vrancken-Peeters MJ, Sonke GS, **Berry DA**, van 't Veer LJ, Esserman LJ, Wesseling J, Rodenhuis S, Hwang SE, I-SPY TRIAL Investigators. Lobular histology and response to neoadjuvant chemotherapy in invasive breast cancer. Breast Cancer Research and Treatment 136(2012):35-43. PMID: 22961065.
287. Meurer WJ, Lewis RJ, **Berry DA**. Adaptive clinical trials: A partial remedy for the therapeutic misconception? Journal of the American Medical Association 307(2012):2377-2378.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

288. Younes A, **Berry DA**. From drug discovery to biomarker-driven clinical trials in lymphoma. Nature Reviews Clinical Oncology 9(2012):643-653.
289. Shulman LN, Cirrincione CT, **Berry DA**, Becker HP, Perez EA, O'Regan R, Martino S, Atkins JN, Mayer E, Schneider CJ, Kimmick G, Norton L, Muss J, Winer EP, Hudis C. Six cycles of doxorubicin and cyclophosphamide or paclitaxel are not superior to four cycles as adjuvant chemotherapy for breast cancer in women with zero to three positive axillary nodes: Cancer and Leukemia Group B 40101. Journal of Clinical Oncology 30(2012):4071-4076.
290. Janku F, **Berry D**, Gong J, Parsons H, Stewart D, Kurzrock R. Outcomes of phase II clinical trials with single-agent therapies in advanced/metastatic non-small cell lung cancer published between 2000 and 2009. Clinical Cancer Research 18(2012):6356-6363.
291. Tsimberidou A, Iskander NG, Hong DS, Wheler JJ, Falchook GS, Fu S, Piha-Paul SA, Naing A, Janku F, Luthra R, Ye Y, Wen S, **Berry DA**, Kurzrock R. Personalized medicine in a phase I clinical trials program: The MD Anderson Cancer Center Initiative. Clinical Cancer Research 18(2012):6373-6383.
292. Skrivanek Z, Berry S, **Berry D**, Chien J, Geiger MJ, Anderson JH Jr, Gaydos B. Application of adaptive design methodology in development of a long-acting glucagon-like peptide-1 analog (dulaglutide): Statistical design and simulations. Journal of Diabetes Science and Technology 6(2012):1305-1318.
293. Geiger MJ, Skrivanek Z, Gaydos B, Chien J, Berry S, **Berry D**, Anderson JH. An adaptive, dose-finding, seamless phase 2/3 study of a long-acting glucagon-like peptide-1 analog (dulaglutide): trial design and baseline characteristics. Journal of Diabetes Science and Technology 6(2012):1319-1327.
294. Esserman L, Barker A, Woodcock J, Buxton M, **Berry DA**, Patterson R, Jolly K, DeMichele A, Hylton N, Rubin E, Parkinson D, Wholley D, van 't Veer L, Yee D, Park J, Tripathy D, Perlmutter J, Buetow B, Hogarth M, Gray J, Dilts D. A model for accelerating identification and regulatory approval of effective investigational agents. Curēus (2012).
295. Hughes KS, Schnaper LA, Bellon JR, Cirrincione CT, **Berry DA**, McCormick B, Muss HB, Smith BL, Hudis CA, Winer EP, Wood WC. Lumpectomy plus tamoxifen with or without irradiation in women age 70 years or older with early breast cancer: Long-term follow-up of CALGB 9343. Journal of Clinical Oncology 31(2013):2382-2387. doi: 10.1200/JCO.2012.45.2615.
296. DeMichele A, **Berry DA**, Yee D, Zujewski J, Hunsberger S, Rubenstein L, Tomaszewski J, Kelloff G, Perlmutter J, Buxton M, Lyandres J, Albain KS, Benz C, Chien AJ, Haluska P, Leyland-Jones B, Liu MC, Munster P, Olopade O, Park JW, Parker BA, Pusztai L, Tripathy D, Rugo H, Yee D, Esserman L. Developing safety criteria for introducing new agents into neoadjuvant trials. Clinical Cancer Research 19(2013):2817-2823.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

297. Martín M, Prat A, Rodríguez-Lescure Á, Caballero R, Ebbert MTW, Munárriz B, Ruiz-Borrego M, Bastien RRL, Crespo C, Davis C, Rodríguez CA, López-Vega JM, Furió V, García AM, Casas M, Ellis MJ, **Berry DA**, Pitcher BN, Harris L, Ruiz A, Winer E, Hudis C, Stijleman IJ, Tuck DP, Carrasco E, Perou CM, Bernard PS. PAM50 proliferation score as a predictor of weekly paclitaxel benefit in breast cancer. Breast Cancer Research and Treatment 138(2013):457-466. doi: 10.1007/s10549-013-2416-2.
298. Johnson CM, Wei C, Ensor JE, Smolenski DJ, Amos CI, Levin B, **Berry DA**. Meta-analyses of colorectal cancer risk factors. Cancer Causes & Control 24(2013):1207-1222.
299. Alexander BM, Wen PY, Trippa L, Reardon DA, Yung WKA, Parmigiani G, **Berry DA**. Biomarker-based adaptive trials for patients with glioblastoma: Lessons from I-SPY 2. Neuro-Oncology 15(2013):972-978.
300. Campbell MJ, Wolf D, Mukhtar RA, Tandon V, Yau C, Au A, Baehner F, Van 't Veer L, **Berry D**, Esserman LJ. The prognostic implications of macrophages expressing proliferating cell nuclear antigen in breast cancer depend on immune context. PLOS One 8(2013)(10):e79114. PMID: 24205370. PMCID: PMC3812150.
301. **Berry DA**, Coombes KR. Biostatistics and Bioinformatics in Clinical Trials**.** In Abeloff's Clinical Oncology: 5th Edition (2013):282-294. Chennai, India: Elsevier. (Ed: Niederhuber JE, Armitage JO, Doroshow JH, Kastan MB, Tepper J.)
302. **Berry DA**. Breast cancer screening: controversy of impact. The Breast 22(2013):S73-S76. PMID: 24074796.
303. Esserman LJ, Thompson IM, Reid B, Nelson P, Ransohoff DF, Welch HG, Hwang S, **Berry DA**, Kinsler KW, Black WC, Bissell M, Parnes H, Srivastava S. Addressing overdiagnosis and overtreatment in cancer: a prescription for change. The Lancet Oncology 15(2014):e234-e242. doi:10.1016/S1470-2045(13)70598-9.
304. Skrivanek Z, Gaydos BL, Chien JY, Geiger MJ, Heathman MA, Berry S, Anderson JH, Forst T, Milicevic Z, **Berry D**. Dose-finding results in an adaptive, seamless, randomized trial of once-weekly dulaglutide combined with metformin in type 2 diabetes patients (AWARD-5). Diabetes, Obesity and Metabolism 16(2014):748-756.
305. Wu W, Merriman K, Nabaah A, Seval N, Lin H, Wang M, Qazilbash H, Baladandayuthapani V, **Berry D**, Orlowski RZ, Lee M-H, Yeung S-C J. The association of diabetes and anti-diabetic medications with clinical outcomes in multiple myeloma. British Journal of Cancer 111(2014):628–636. doi:10.1038/bjc.2014.307
306. Ajani JA, Wang X, Song S, Suzuki A, Taketa T, Sudo K, Wadhwa R, Komaki R, Maru DM, Lee JH, Bhutani MS, Weston B, Baladandayuthapani V, Yao Y, Skinner HD, Johnson RL, **Berry DA**. ALDH-1 expression levels predict response or resistance to preoperative chemoradiation in resectable esophageal cancer patients. Molecular Oncology 8(2014):142-149. doi:10.1016/j.molonc.2013.10.007.
307. Legocki LJ, Meurer WJ, Frederiksen S, Lewis RJ, Durkalski VL, **Berry DA**, Barsan WG, Fetters MD. Clinical trialist perspectives on the ethics of adaptive clinical trials: A mixed-methods analysis. BMC Medical Ethics 16(2015):27-38. doi:10.1186/s12910-015-0022-z. PMCID: PMC4424427.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

308. Munsell MF, Sprague BL, **Berry DA**, Chisholm GB, Trentham-Dietz A. Body mass index and breast cancer risk according to postmenopausal estrogen-progestin use and hormone receptor status. Epidemiologic Reviews 36(2014):114-136. doi: 10.1093/epirev/mxt010.
309. Stout NK, Lee SJ, Schechter CB, Kerlikowske K, Alagoz O, **Berry DA**, Buist DSM, Cevik M, Chisholm G, de Koning HJ, Huang H, Hubbard RA, Miglioretti DL, Munsell MF, Trentham-Dietz A, van Revesteyn NT, Tosteson ANA, Mandelblatt JS. Benefits, harms and costs for breast cancer screening in the US following implementation of digital mammography. Journal of the National Cancer Institute 106(6)(2014). doi:10.1093/jnci/dju092.
310. Shulman, LN, **Berry DA**, Cirrincione C, Becker HP, Perez EA, O'Regan R, Martino S, Shapiro CL, Atkins JN, Schneider CJ, Kimmick G, Burstein HJ, Norton L, Muss H, Hudis CA, Winer EP, Cancer and Leukemia Group B. Comparison of doxorubicin and cyclophosphamide (AC) versus single agent paclitaxel (T) as adjuvant therapy for breast cancer in women with 0-3 positive axillary nodes: CALGB 40101. Journal of Clinical Oncology 32(2014):2311-2317 doi:10.1200/JCO.2013.53.7142
311. Munoz D, Near AM, van Ravesteyn NT, Lee SJ, Schechter CB, Alagoz O, **Berry DA**, Burnside ES, Chang Y, Chisholm G, de Koning HJ, Ergun MA, Heijnsdijk EAM, Huang H, Stout N, Sprague BL, Trentham-Dietz A, Mandelblatt JS, Plevritis SK. Effects of screening and adjuvant therapy on specific US breast cancer mortality by estrogen receptor status. Journal of the National Cancer Institute 106(11)(2014): doi:10.1093/jnci/dju289.
312. Sikov WM, **Berry DA**, Perou CM, Singh B, Cirrincione CT, Tolaney SM, Kuzma CS, Pluard TJ, Somlo G, Port ER, Golshan M, Bellon JR, Collyar D, Hahn OM, Carey LA, Hudis CA, Winer EP. Impact of the addition of carboplatin and/or bevacizumab to neoadjuvant once-per-week paclitaxel followed by dose-dense doxorubicin and cyclophosphamide on pathologic complete response rates in stage II to III triple-negative breast cancer: CALGB 40603 (Alliance). Journal of Clinical Oncology 33(1)(2015):13-21. doi:10.1200/JCO.2014.57.0572.
313. Venook AP, Arcila ME, Benson AB, **Berry DA**, Camidge DR, Carlson RW, Choueiri TK, Guild V, Kalemkerian GP, Kurzrock R, Lovly CM, McKee AE, Morgan RJ, Olszanski AJ, Redman MW, Stearns V, Birkeland ML. NCCN Working Group Report: Designing clinical trials in the era of multiple biomarkers and targeted therapies. Journal of the National Comprehensive Cancer Network 12(2014):1629-1649.
314. Stephenson D, Perry D, Bens C, Bain LJ, **Berry D**, Krams M, Sperling R, Dilts D, Luthman J, Hanna D, McKew J, Temple R, Fields FO, Salloway S, Katz R. Charting a path toward combination therapy for Alzheimer's disease. Expert Review of Neurotherapeutics 15(2015):107-113.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

315. Perry D, Sperling R, Katz R, **Berry D**, Dilts D, Hanna D, Salloway S, Trojanowski J, Bountra C, Krams M, Luthman J, Potkin S, Gribkoff V, Temple R, Wang Y, Carrillo M, Stephenson D, Snyder H, Liu E, Ware T, McKew J, Fox A, Fields F, Bain L, Bens C. Building a roadmap for developing combination therapies for Alzheimer's disease. Expert Review of Neurotherapeutics 15(2015):327-333. doi: 10.1586/14737175.2015.996551.
316. Lenz RA, Pritchett YL, Berry SM, Llano DA, Han S, **Berry DA**, Sadowsky CH, Abi-Saab WM, Saltarelli MD. An adaptive, dose-finding Phase 2 trial evaluating the safety and efficacy of ABT-089 in mild-to-moderate Alzheimer disease. Alzheimer Disease & Associated Disorders 29(2015):192-199. PMID: 25973909. doi: 10.1097/WAD.0000000000000093.
317. **Berry DA**. The Brave New World of clinical cancer research: Adaptive biomarker-driven trials integrating clinical practice with clinical research. Molecular Oncology 9(2015):951-959. doi:10.1016/j.molonc.2015.02.011.
318. Trippa L, Wen PY, Parmigiani G, **Berry DA**, Alexander BM. Combining PFS and OS in neuro-oncology trials. Neuro-Oncology 17(2015):1106-1113. doi: 10.1093/neuonc/nou345.
319. Jones ES, Burke JP, Nelson B, Wall S, **Berry DA**, Wright DL, Smith JSC. Assessing probability of ancestry using Bayesian likelihood methods, random effects modeling and single nucleotide polymorphism (SNP) profiles: Applications to inbred lines of maize and varieties of soybean (2015). (Submitted for publication)
320. Tsimberidou AM, Wen S, Hong DS, Wheler JJ, Falchook GS, Fu S, Piha-Paul SA, Naing A, Janku F, Aldape KD, Ye Y, Kurzrock R, **Berry DA**. Personalized medicine for patients with advanced cancer in the phase I program at MD Anderson: Validation analysis. Clinical Cancer Research 20(2014):4827-4836. PMID: 24987059.
321. Ligibel JA, Cirrincione CT, Liu M, Citron M, Ingle JN, Gradishar W, Martino S, Sikov W, Michaelson R, Mardis E, Perou CM, Ellis M, Winer EP, Hudis CA, **Berry D**, Barry WT. Body mass index, PAM50 subtype, and outcomes in node-positive breast cancer: CALGB 9741. Journal of the National Cancer Institute 107(2015)(9). doi:10.1093/jnci/djv179.
322. Bates SE, **Berry DA**, Balasubramaniam S, Bailey S, LoRusso PM, Rubin EH. Advancing clinical trials to streamline drug development. CCR Focus. Clinical Cancer Research 21(2015):4527-4535.
323. Chang JY, Senan S, Paul MA, Mehram RJ, Louie AV, Balter P, Groen HJM, McRae SE, Widder J, Feng L, van den Borne B, Munsell MF, Hurkmans C, **Berry DA**, van Werkhoven E, Kersl JJ, Dingemans, A-M, Dawood O, Haasbeek CJA, Carpenter LS, De Jaeger K, Komaki R, Slotman BJ, Smit EF, Roth JA. Stereotactic ablative radiotherapy versus lobectomy for operable stage I non-small-cell lung cancer: a pooled analysis of two randomised trials. Lancet Oncology 16(2015):630-637. doi: 10.1016/S1470-2045(15)70168-3. Erratum in: Lancet Oncol. 2015 Sep;16(9):e427.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

324. Kang B, Slosberg E, Snodgrass S, Lebedinsky C, **Berry DA**, Corless C, Stein S, Salvado A. The Signature Program: Bringing the protocol to the patient. Clinical Pharmacology & Therapeutics 98(2015):124-126.
325. ICECaP Working Group (Sweeney C, Andren O, Armstrong J, **Berry D**, et al.) The development of intermediate clinical endpoints in cancer of the prostate (ICECaP). Journal of the National Cancer Institute 107(12)(2015). doi:10.1093/jnci/djv261.
326. Golshan M, Cirrincione CT, Sikov WM, **Berry DA**, Jasinski S, Weisberg TF, Somlo G, Hudis C, Winer E, Ollila DW for the Alliance for Clinical Trials in Oncology. Impact of neoadjuvant chemotherapy in stage II–III triple negative breast cancer on eligibility for breast-conserving surgery and breast conservation rates: Surgical results from CALGB 40603 (Alliance). Annals of Surgery 262(2015):434-439. Discussion 438-9. doi: 10.1097/SLA.0000000000001417. PMID: 26222764.
327. Levin VA, Tonge PJ, Gallos JM, Birtwistle MR, Dar AC, Iavarone A, Paddison PJ, Heffron TP, Elmquist WF, Lachowitz JE, Johnson TW, White FM, Sul J, Smith QR, Shen W, Sarkaria JN, Samala R, Wen PY, **Berry DA**, Petter RC. CNS Anticancer Drug Discovery and Development Conference White Paper. Neuro-Oncology 2015;17(Suppl 6):vi1-vi26. doi:10.1093/neuonc/nov169.
328. Raghav K, Mahajan S, Yao J, Hobbs B, **Berry D**, Pentz R, Tam A, Hong W, Ellis L, Abbruzzese J, Overman M. From protocols to publications: A study in selective reporting of outcomes in randomized trials in oncology. Journal of Clinical Oncology 33 (2015):3583-3590.
329. Guetterman TC, Fetters MD, Legocki LJ, Mawocha S, Barsan WG, Lewis RJ, **Berry DA**, Meurer WJ. Reflections on the Adaptive Designs Accelerating Promising Trials Into Treatments (ADAPT-IT) process—Findings from a qualitative study. Clinical Research and Regulatory Affairs 2(2015):121-130. doi: 10.3109/10601333.2015.1079217.
330. Alexander BM, Galanis E, Yung WK, Ballman KV, Boyett JM, Cloughesy TF, Degroot JF, Huse JT, Mann B, Mason W, Mellinghoff IK, Mikkelsen T, Mischel PS, O'Neill BP, Prados MD, Sarkaria JN, Tawab-Amiri A, Trippa L, Ye X, Ligon KL, **Berry DA**, Wen PY. Brain Malignancy Steering Committee clinical trials planning workshop: report from the Targeted Therapies Working Group. Neuro- Oncology 17(2015):180-188. doi: 10.1093/neuonc/nou154. Epub 2014 Aug 26. Review. PMID: 25165194 [PubMed - indexed for MEDLINE]
331. **Berry DA**. State of the Art: Emerging innovations in clinical trial design. Clinical Pharmacology & Therapeutics 99(2016):82-91. PMID:26561040. doi:10.1002/cpt.285.
332. Broglio KR, Quintana M, Foster M, Olinger M, McGlothlin A, Berry SM, Boileau JF, Brezden-Masley C, Chia S, Dent S, Gelmon K, Paterson A, Rayson D, **Berry DA**. Association of pathologic complete response to neoadjuvant therapy in HER2+ breast cancer with long-term outcomes: A meta-analysis. JAMA Oncology 2(2016):751-760. doi: 10.1001/jamaoncol.2015.6113. PMID: 26914222.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

333. Satlin A, Wang J, Logovinsky V, Berry S, Swanson C, Dhadda S, **Berry DA**. Featured Article: Design of a Bayesian adaptive phase 2 proof-of-concept trial for BAN2401, a putative disease-modifying monoclonal antibody for the treatment of Alzheimer's disease. Alzheimer's & Dementia: Translational Research & Clinical Interventions 2(2016):1-12. doi: 10.1016/j.trci.2016.01.001. PMID: 2906729.
334. Carey L, **Berry D**, Cirrincione C, Barry W, Pitcher B, Harris L, Ollila D, Krop I, Henry N, Weckstein D, Anders C, Singh B, Hoadley K, Iglesia M, Cheang M, Perou C, Winer E, Hudis C. Molecular heterogeneity and response to neoadjuvant HER2-targeting in CALGB 40601, a randomized phase III trial of paclitaxel plus trastuzumab with or without lapatinib. Journal of Clinical Oncology 34 (2016):542-549.
335. Mandelblatt JS, Stout NK, Schechter CB, van den Broek JJ, Miglioretti DL, Krapcho M, Trentham-Dietz A, Munoz D, Lee SJ, **Berry DA**, van Ravesteyn NT, Alagoz O, Kerlikowske K, Tosteson ANA, Near AM, Hoeffken A, Chang Y, Heijnsdijk EA, Chisholm G, Huang X, Huang H, Ergun MA, Gangnon R, Sprague BL, Plevritis S, Feuer E, de Koning HJ, Cronin KA for the Breast Cancer Working Group of the Cancer Intervention and Surveillance Modeling Network (CISNET). Collaborative modeling of the benefits and harms associated with different U.S. breast cancer screening strategies. Annals of Internal Medicine 164(2016):215-225.
336. Park JW, Liu MC, Yee D, Yau C, van 't Veer LJ, Symmans WF, Paoloni M, Perlmutter J, Hylton NM, Hogarth M, DeMichele A, Buxton MB, Chien AJ, Wallace AM, Boughey JC, Haddad TC, Chui SY, Kemmer KA, Kaplan HG, Isaacs C, Nanda R, Tripathy D, Albain KS, Edmiston KK, Elias AD, Northfelt DW, Pusztai L, Moulder SL, Lang JE, Viscusi RK, Euhus DM, Haley BB, Khan QJ, Wood WC, Melisko M, Schwab R, Hesten T, Lyandres J, Davis SE, Hirst GL, Sanil A, Esserman LJ, **Berry DA** for the I-SPY 2 Investigators. Adaptive randomization of neratinib in early breast cancer. New England Journal of Medicine 375(2016):11-22. doi: 10.1056/NEJMoa1513750. PMID: 27406346.
337. Rugo HS, Olopade OI, DeMichele A, Yau C, van 't Veer LJ, Buxton MB, Hogarth M, Hylton NM, Paoloni M, Perlmutter J, Symmans WF, Yee D, Chien AJ, Wallace AM, Kaplan HG, Boughey JC, Haddad TC, Albain KS, Liu MC, Isaacs C, Khan QJ, Lang JE, Viscusi RK, Pusztai L, Moulder SL, Chui SY, Kemmer KA, Elias AD, Edmiston KK, Euhus DM, Haley BB, Nanda R, Northfelt DW, Tripathy D, Wood WC, Ewing C, Schwab R, Lyandres J, Davis SE, Hirst GL, Sanil A, **Berry DA**, Esserman LJ, for the I-SPY 2 Investigators. Adaptive randomization of veliparib-carboplatin treatment in breast cancer. New England Journal of Medicine 375(2016):23-34. doi: 10.1056/NEJMoa1513749. PMID: 27406347.
338. **Berry DA**. Right-sizing adjuvant and neoadjuvant clinical trials in breast cancer. Clinical Cancer Research 22(2016):3-5. doi: 10.1158/1078-0432.CCR-15-1903.
339. **Berry DA.** P-values aren't what they're cracked up to be. Online Discussion: ASA Statement on Statistical Significance and P-values. The American Statistician 2016. http://amstat.tandfonline.com/doi/full/10.1080/00031305.2016.1154108.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

340. Meurer WJ, Legocki L, Mawocha S, Frederickson SM, Guetterman TC, Barsan W, Lewis R, **Berry D**, Fetters M. Attitudes and opinions regarding confirmatory adaptive clinical trials: a mixed methods analysis from the Adaptive Designs Accelerating Promising Trials into Treatments (ADAPT-IT) project. Trials 17(2016):373-385. doi: 10.1186/s13063-016-1493-z.
341. Wen S, Ning J, Collins S, **Berry DA**. A response-adaptive design of initial therapy for emergency department patients with heart failure. Contemporary Clinical Trials 52(2016):46–53.
342. Ollila DW, Cirrincione CT, **Berry DA**, Carey LA, Sikov WM, Hudis CA, Winer EP, Golshan M. Axillary management of stage II/III breast cancer in patients treated with neoadjuvant systemic therapy: Results of CALGB 40601 (HER2-positive) and CALGB 40603 (triple-negative). Journal of American College of Surgery. 224(2016):688-694. doi: 10.1016/j.jamcollsurg.2016.12.036. PMID: 28089784.
343. Blumenschein G Jr, Chandler J, Garon EB, Waterhouse D, Goldman JW, Gunuganti VK, Boccia R, Spigel D, Glaspy J, **Berry DA**, Korytowsky B, Zhu J, Lin WH, Bennett K, Reynolds C. CheckMate 370: A master protocol of phase 1/2 studies of nivolumab as maintenance of first-line ± standard-of-care therapies in advanced NSCLC: Journal of Thoracic Oncology 11S(2016):S307. doi: 10.1016/j.jtho.2016.09.094. PMID: 27969526.
344. Golshan M, Cirrincione CT, Sikov WM, Carey LA, **Berry DA**, Overmoyer B, Henry NL, Somlo G, Port E, Burstein HJ, Hudis C, Winer E, Ollila DW for the Alliance for Clinical Trials in Oncology. Impact of neoadjuvant therapy on eligibility for and frequency of breast conservation in stage II-III HER2-positive breast cancer: surgical results of CALGB 40601 (Alliance). Breast Cancer Research and Treatment 160(2016):297-304. PMID: 27704226.
345. Lee JJ, **Berry DA**. Statistical Innovations in Cancer Research. In Holland-Frei Cancer Medicine e.9 (2017). Ch 20. pp 255-270. London: BC Decker. (Ed: Bast RC, Croce CM, Hait WN, et al.) doi:10.1002/9781119000822.hfcm020.
346. Freedman RA, Seisler DK, Foster JC, Sloan JA, Lafky JM, Kimmick GG, Hurria A, Cohen HJ, Winer EP, Hudis CA, Partridge AH, Carey LA, Jatoi A, Klepin HD, Citron M, **Berry DA**, Shulman LN, Buzdar AU, Suman VJ, Muss HB. Risk of acute myeloid leukemia and myelodysplastic syndrome among older women receiving anthracycline-based adjuvant chemotherapy for breast cancer on modern cooperative group trials (Alliance A151511). Breast Cancer Research and Treatment 161(2017):363-373. doi: 10.1007/s10549-016-4051-1. PMID: 27866278.
347. **Berry DA**, Zhou S, Higley H, Mukundan L, Fu S, Reaman GH, Wood BL, Kelloff GJ, Jessup JM, Radich JP. Association of minimal residual disease with clinical outcome in pediatric and adult acute lymphoblastic leukemia: A meta-analysis. JAMA Oncology 3(2017):e170580. doi:10.1001/jamaoncol.2017.0580. PMID: 28494052
348. Mawocha SC, Fetters MD, Legocki LJ, Guetterman TC, Frederiksen S, Barsan WG, Lewis RJ, **Berry DA**, Meurer WJ. A conceptual model for the development process of confirmatory adaptive clinical trials within an emergency research network. Clinical Trials 14(2017):246-254. doi: 10.1177/1740774516688900. PMID: 28135827.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

349. Domenyuk V, Zhong Z, Stark A, Xiao N, O'Neill HA, Wei X, Wang J, Tinder TT, Tonapi S, Duncan J, Hornung T, Hunter A, Miglarese MR, Schorr J, Halbert DD, Quackenbush J, Poste G, **Berry DA**, Mayer G, Famulok M, Spetzler D. Plasma exosome profiling of cancer patients by a next generation systems biology approach. Scientific Reports 7(2017):42741. doi: 10.1038/srep42741. PMID: 28218293.
350. Alagoz O, **Berry DA**, de Koning HJ, Lee SJ, Plevritis SK, Schechter CB, Stout NK, Trentham-Dietz A, Mandelblatt JS. Introduction to the Cancer Intervention and Surveillance Modeling Network (CISNET) breast cancer models. Medical Decision Making 38(2018);S1:3-8. doi: 10.1177/0272989X17737507. PMID: 29554472
351. Huang X, Li Y, Song J, **Berry DA**. A Bayesian simulation model for breast cancer screening, incidence, treatment and mortality. Medical Decision Making 38(2018);S1:78S-88S. doi: 10.1177/0272989X17714473. PMID: 28627297
352. Guetterman TC, Fetters MD, Mawocha S, Legocki LJ, Barsan WG, Lewis RJ, **Berry DA**, Meurer WJ. The life cycles of six multi-center adaptive clinical trials focused on neurological emergencies developed for the Advancing Regulatory Science initiative of the National Institutes of Health and US Food and Drug Administration: Case studies from the Adaptive Designs Accelerating Promising Treatments Into Trials Project. Sage Open Medicine 5(2017). doi:10.1177/2050312117736228. PMID: 29085638.
353. Wadhwa R, Wang X, Baladandayuthapani V, Liu B, Shiozaki H, Shimodaira Y, Lin Q, Elimova E, Hofstetter WL, Swisher SG, Rice DC, Maru DM, Kalhor N, Bhutani MS, Weston B, Lee JH, Skinner HD, Scott AW, Kaya DM, Harada K, **Berry D**, Song S, Ajani AJ. Nuclear expression of Gli-1 is predictive of pathologic complete response to chemoradiation in trimodality treated oesophageal cancer patients. British Journal of Cancer 117(2017):648–655. doi: 10.1038/bjc.2017.225.
354. Wolf DM, Yau C, Sanil A, Glas A, Petricoin E, Wulfkuhle J, Severson TM, Linn S, Brown-Swigart L, Hirst G, Buxton M, DeMichele A, Hylton N, Symmans F, Yee D, Paoloni M, Esserman L, **Berry D**, Rugo H, Olopade O, van 't Veer L. DNA repair deficiency biomarkers and the 70-gene ultra-high risk signature as predictors of veliparib/carboplatin response in the I-SPY 2 breast cancer trial. NPJ Breast Cancer 3(2017). doi: 10.1038/s41523-017-0025-7.
355. Alexander BA, Ba S, Berger MS, **Berry DA**, Cavenee WK, Chang SM, Cloughesy TF, Jiang T, Khasraw M, Li W, Mittman R, Poste GH, Wen PY, Yung WKA, Barker AD, for GBM AGILE Network. Adaptive global innovative learning environment for glioblastoma: GBM AGILE. Clinical Cancer Research 24(2018):737-743. doi: 10.1158/1078-0432.CCR-17-0764. PMID: 28814435.
356. Slosberg ED, Kang BP, Peguero J, Taylor M, Bauer TM, **Berry DA**, Braiteh F, Spira A, Meric-Bernstam F, Stein S, Piha-Paul SA, Salvado A. Signature program: A platform of basket trials. Oncotarget 9(2018):21383-21395. doi: 10.18632/oncotarget.25109.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

357. Tanioka M, Fan C, Parker JS, Hoadley KA, Hu Z, Li Y, Hyslop T, Pitcher BN, Henry LN, Tolaney S, Dang C, Krop IE, Harris L, **Berry DA**, Mardis ER, Winer EP, Hudis CA, Carey LA, Perou CM. Integrated analysis of RNA and DNA from a phase III trial of trastuzumab-based neoadjuvant chemotherapy identifies response predictors in HER2-positive breast cancer. Clinical Cancer Research 24(2018):5292-5304. doi: 10.1158/1078-0432.CCR-17-3431. PMID: 30037817.
358. Plevritis SK, Muñoz D, Kurian A, Stout NK, Alagoz O, Near AM, Lee SJ, van den Broek JJ, Huang X, Schechter CB, Sprague BL, Song J, de Koning HJ, Trentham-Dietz A, van Ravesteyn NT, Gangnon R, Chandler Y, Li Y, Xu C, Ergun MA, Huang H, **Berry DA**, Mandelblatt JS. Association of screening and treatment with breast cancer mortality by molecular subtype in US women, 2000-2012. Journal of the American Medical Association. 319(2018):154-164. doi:10.1001/jama.2017.19130. PMID: 29318276.
359. Jayasekera J, Li Y, Schechter CB, Jagsi R, Song J, White J, Luta G, Chapman JW, Feuer EJ, Zellars RC, Stout N, Julian TB, Whelan T, Huang X, Shelley Hwang E, Hopkins JO, Sparano JA, Anderson SJ, Fyles AW, Gray R, Sauerbrei W, Mandelblatt J, **Berry DA** for the CISNET-BOLD Collaborative Group. Simulation modeling of cancer clinical trials: Application to omitting adjuvant breast radiotherapy in low-risk invasive breast cancer. Journal of the National Cancer Institute 110(2018):1360-1369. doi: 10.1093/jnci/djy059.
360. Jayasekera J, Schechter CB, Sparano JA, Jagsi R, White J, Chapman J-AW, Whelan T, Anderson SJ, Fyles AW, Sauerbrei W, Zellars RC, Li Y, Song J, Huang X, Julian TB, Luta G, **Berry DA**, Feuer EJ, Mandelblatt J. for the CISNET-BOLD Collaborative Group. Effects of Radiotherapy in Early-Stage, Low-Recurrence Risk, Hormone-Sensitive Breast Cancer. Journal of the National Cancer Institute 110(2018):1370-1379. doi: 10.1093/jnci/djy128.
361. Blumenthal GM, Bunn PA Jr, Chaft JE, McCoach CE, Perez EA, Scagliotti GV, Carbone DP, Aerts HJWL, Aisner DL, Bergh J, **Berry DA**, Jarkowski A, Botwood N, Cross DAE, Diehn M, Drezner NL, Doebele RC, Eberhardt WEE, Felip E, Gianni L, Keller SP, Leavey PJ, Malik S, Pignatti F, Prowell TM, Redman MW, Rizvi NA, Rosell R, Rusch V, de Ruysscher D, Schwartz LH, Sridhara R, Stahel R, Swisher S, Taube JM, Travis WD, Keegan P, Wiens JR, Wistuba II, Wynes MW, Kris MG. Current status and future perspectives on neoadjuvant therapy in lung cancer. Journal of Thoracic Oncology 13(2018):1818-18-31. doi: 10.1016/j.jtho.2018.09.017. PMID: 30268698.
362. Domenyuk V, Gatalica Z, Santhanam R, Wei X, Stark A, Kennedy P, Toussaint B, Levenberg S, Wang J, Xiao N, Greil R, Rinnerthaler G, Gampenrieder SP, Heimberger AB, **Berry DA**, Barker A, Quackenbush J, Marshall JL, Poste G, Vacirca JL, Vidal GA, Schwartzberg LS, Halbert DD, Voss A, Magee D, Miglarese MR, Famulok M, Mayer G, Spetzler D. Polyligand profiling differentiates trastuzumab-treated breast cancer patients according to their outcomes. Nature Communications 9(2018):1219-1227. doi:10.1018/s41467-018-03631-z.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

363. Miglarese M, Domenyuk V, Gatalica Z, Stark A, Kennedy P, Hart C, **Berry D**, Barker A, Poste G, Halbert D, Famulok M, Mayer G, Spetzler D. A retrospective analysis of the phase III MAESTRO study by poly-ligand profiling differentiates outcomes and increases the probability of clinical trial success. (Submitted for publication)
364. Chien AJ, Tripathy D, Albain KS, Symmans WF, Rugo HS, Melisko ME, Wallace AM, Schwab R, Helsten T, Forero-Torres A, Stringer-Reasor E, Ellis ED, Kaplan HG, Nanda R, Jaskowiak N, Murthy R, Godellas C, Boughey JC, Elias AD, Haley BB, Kemmer K, Isaacs C, Clark AS, Lang JE, Lu J, Korde L, Edmiston KK, Northfelt DW, Viscusi RK, Yee D, Perlmutter J, Hylton NM, van 't Veer L, DeMichele A, Wilson A, Peterson G, Buxton MB, Paoloni M, Clennell J, Berry S, Matthews JB, Steeg K, Singhrao R, Hirst GL, Sanil A, Yau C, Asare SM, **Berry DA**, Esserman LJ. MK-2206 with paclitaxel-based neoadjuvant therapy improves response in patients with HER2-positive and/or HR-negative breast cancers in the adaptively randomized I-SPY 2 Trial. Journal of Clinical Oncology. 2019. (To appear)
365. Angus DC, Alexander BM, Berry S, Buxton M, Lewis R, Paoloni M, Webb, SAR Arnold, Barker A, **Berry DA**, Bonten MJM, Brophy M, Butler C, Cloughesy TF, Derde LPG, Esserman LJ, Ferguson R, Fiore L, Gaffey SC, Gaziano JM, Giusti K, Goossens H, Heritier S, Hyman B, Krams M, Larholt K, LaVange LM, Lavori P, Lo AW, London AJ, Manax V, McArthur C, O'Neill G, Parmigiani G, Perlmutter J, Petzold EA, Ritchie C, Rowan KM, Seymour CW, Shapiro NI, Simeone DM, Smith B, Spellberg B, Stern AD, Trippa L, Trusheim M, Viele K, Wen PY, Woodcock J. Adaptive platform trials: definition, design, conduct and reporting considerations. Nature Reviews Drug Discovery 2019. doi:10.1038/s41573-019-0034-3
366. Nanda R, Liu MC, Yau C, Shatsky R, Pusztai L, Wallace A, Chien AJ, Forero-Torres A, Ellis E, Han H, Clark A, Albain K, Boughey JC, Jaskowiak NT, Elias A, Isaacs C, Kemmer K, Helsten T, Majure M, Stringer-Reasor E, Parker C, Lee MC, Haddad T, Cohen RN, Asare S, Wilson A, Hirst GL, Singhrao R, Steeg K, Asare A, Matthews JB, Berry S, Sanil A, Schwab R, Symmans WF, van 't Veer L, Yee D, DeMichele A, Hylton NM, Melisko M, Perlmutter J, Rugo H, **Berry DA**, Esserman LJ. Effect of pembrolizumab plus neoadjuvant chemotherapy on pathologic complete response in women with early-stage breast cancer: An analysis of the ongoing phase 2 adaptively randomized I-SPY2 trial. JAMA Oncology. Published online February 13, 2020. doi:10.1001/jamaoncol.2019.6650
367. Liu MC, Oxnard GR, Klein EA, Smith D, Richards D, Yeatman TJ, … (incl **Berry DA**). Sensitive and specific multi-cancer detection and localization using methylation signatures in cell-free DNA. Annals of Oncology 31(2020):745-759.
368. Yee D, DeMichele A, Yau C, Isaacs C, Symmans WF, Albain KS, …, Esserman LJ., **Berry DA** for I-SPY 2 TRIAL Consortium. Disease-free survival correlates with pathologic complete response in the adaptively randomized I-SPY2 trial of stage 2/3 breast cancer. JAMA Oncology 6(2020):1355-1362.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

369. Ip A, **Berry DA**, Hansen E, Goy AH, Pecora AL, Sinclaire BA, Bednarz U, Marafelias M, Berry SM, Berry NS, Mathura S, Sawczuk IS, Sperber S, Piwoz JA, Balani B, Cicogna C, Sebti R, Zuckerman J, Rose KM, Tank L, Jacobs LG, Korcak J, Timmapuri SL, Underwood JP, Sugalski J, Barsky C, Varga DW, Asif A, Landolfi JC, Goldberg SL. Hydroxychloroquine and tocilizumab therapy in COVID-19 patients—An observational study. PLoS ONE 15(2020): e0237693. https://doi.org/10.1371/journal.pone.0237693
370. Fernandez-Martinez A, Krop IE, Hillman DW, Polley MY, Parker JS, Huebner L, Hoadley KA, Shepherd J, Tolaney S, Henry NL, Dang C, Harris L, **Berry D**, Hahn O, Hudis C, Winer E, Partridge A, Perou CM, Carey LA. Survival, pathologic response, and genomics in CALGB 40601 (Alliance), a neoadjuvant phase III trial of paclitaxel-trastuzumab with or without lapatinib in HER2-positive breast cancer. Journal of Clinical Oncology 38(2020):4184-4193. PMID: 33095682.
371. Abraham J, Magee D, Cremolini C, Antoniotti C, Halbert D, Xiu J, Stafford P, **Berry DA**, Oberley M, Shields AF, Marshall JL, Salem M, Falcone A, Grothey AF, Hall M, Venook AP, Lenz H-J, Helmstetter A, Korn WM, Spetzler D. Clinical validation of a machine-learning derived signature predictive of outcomes from first-line oxaliplatin-based chemotherapy in advanced colorectal cancer. Clinical Cancer Research 27(2021):1174-1183. doi:10.1158/1078-0432.CCR-20-3286.
372. Short NJ, Zhou S, Fu C, **Berry DA**, Walter RB, Freeman SD, Hourigan C, Huang X, Nogueras-Gonzalez G, Hwang H, Qi X, Kantarjian H, Ravandi F. Impact of measurable residual disease on survival outcomes in patients with acute myeloid leukemia: A meta-analysis. JAMA Oncology 6(2020):1890-1899. doi: 10.1001/jamaoncol.2020.4600.
373. **Berry DA**, Berry S, Hale P, Isakov L, Lo AW, Siah KW, Wong CH. A cost/benefit analysis of clinical trial designs for COVID-19 vaccine candidates. 2021. PLoS ONE 15(2020): e0244418. https://doi.org/10.1371/journal.pone.0244418.
374. Wolf DM, Yau C, Wulfkuhle J, Brown-Swigart L, Gallagher RI, Magbanua MJM, O'Grady N, Hirst G, Asare S, Tripathy D, **Berry D**, Esserman L, Chien AJ, Petricoin EF, van 't Veer L. Mechanism of action biomarkers predicting response to AKT inhibition in the I-SPY 2 breast cancer trial. NPJ Breast Cancer. 2020;6:48. PMID: 33083527.
375. Clark AS, Yau C, Wolf DM, Petricoin EF, Moulder SL, Wallace AM, Chien AJ, Isaacs C, Albain KS, Tripathy D, Ellis ED, Forero-Torres A, Yung R, Han HS, Lang JE, Viscusi RK, Haley BB, Kemmer K, Elias AD, Nanda R, Boughey JC, Wulfuhle JD, Brown-Swigart L, Gallagher RI, Helsten T, Roesch E, Ewing CA, Alvarado M, Crane EP, Robinson P, Buxton M, Clennell JL, Paolini M, Asare SM, Wilson A, Hirst GL, Singhrao R, Steeg K, Asare AL, Matthews JB, Berry S, Sanil A, Melisko M, Perlmutter J, Rugo HS, Schwab RB, Symmans WF, Hylton NM, Yee D, van 't Veer LJ, **Berry DA**, Esserman LJ, DeMichele. Neoadjuvant T-DM1/pertuzumab and paclitaxel/trastuzumab/pertuzumab for HER2-positive breast cancer in the adaptively randomized I-SPY2 trial. Nature Communications 12, 6428 (2021). https://doi.org/10.1038/s41467-021-26019-y

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

376. Mueller KL, Theoret MR, Lemery SJ, Amiri-Kordestani L, Ariyan CE, Atkins MB, **Berry DA**, Blank CU, DeMichele AM, Forde PM, Ibrahim N, Keegan P, Mitchell TC, Moss RA, Robert C, Sridhara R, Taube JM, Tetzlaff MT, Wargo JA, Flaherty KT, Kaplan MJ, Topalian SL, Ward AF, Hurlbert MS. Neoadjuvant therapy for melanoma: A US Food and Drug Administration—Melanoma Research Alliance Public Workshop. Clinical Cancer Research 27(2021):394-401.PMID: 33188142.
377. Swanson CJ, Zhang Y, Dhadda S, Wang J, Kaplow J, Lai RYK, Lannfelt L, Bradley H, Rabe M, Koyama A, Reyderman L, **Berry DA**, Berry SM, Gordon R, Kramer LD, Cummings JL. A randomized, double-blind phase 2b proof of concept clinical trial in early Alzheimer's disease with lecanemab, an anti-Aβ protofibril antibody. Alzheimer's Research & Therapy 13(2021):80 https://doi.org/10.1186/s13195-021-00813-8)
378. Du L, Yau C, Brown-Swigart L, Gould R, Krings G, Hirst GL, Bedrosian I, Layman RM, Carter JM, Klein M, Venters S, Sonal S, van der Noordaa M, Chien AJ, Haddad T, Isaacs C, Pusztai L, Albain K, Nanda R, Tripathy D, Liu MC, Boughey J, Schwab R, Hylton N, DeMichele A, Permutter J, Yee D, **Berry D**, van 't Veer L, Valero V, Esserman LJ, Symmans WF. Predicted sensitivity to endocrine therapy for stage II-III hormone receptor-positive and HER2-negative (HR+/HER2–) breast cancer before chemo-endocrine therapy. Annals of Oncology 2021. https://doi.org/10.1016/j.annonc.2021.02.011
379. Lin Z, **Berry DA**. Developing and then confirming a hypothesis based on a chronology of several clinical trials: A Bayesian application to pirfenidone mortality results. Journal of Biometrics & Biostatistics 12(2021).
380. Broglio K, Meurer WJ, Durkalski V, Pauls Q, Connor J, **Berry D**, Lewis RJ, Johnston KC, Barsan WG. Prospective comparison of Bayesian and frequentist adaptive clinical trials: The SHADOW-SHINE project. 2021. JAMA Open Network (Submitted for publication)
381. Symmans WF, Yau C, Chen Y-Y, Balassanian R, Klein M, Pusztai L, Nanda R, Parker BA, Datnow B, Krings G, Wei S, Feldman MD, Duan X, Chen B, Tickman R, Sattar H, Khazai L, Zeck JC, Sams S, Mhawech-Fauceglia P, Rendi M, Sahoo S, Ocal I, Fan F, LeBeau LG, Vinh T, Yang S, Adams A, Chien J, Wallace A, Forero-Torres A, Ellis E, Albain K, Murthy R, Boughey JC, Liu M, Haley BB, Elias A, Clark A, Kemmer K, Isaacs C, Lang J, Han H, Edmison K, Viscusi RK, Northfelt D, Khan KJ, Leyland-Jones B, Matthews J, Venters S, Sonal S, Asare S, Buxton M, Asare AL, Rugo H, Schwab R, Helsten T, Hylton N, van 't Veer L, Permutter J, DeMichele A, Yee D, **Berry DA**, Esserman L. Assessment of residual cancer burden and event-free survival in the adaptively randomized I-SPY2 trial of neoadjuvant treatment for high-risk breast cancer. JAMA Oncology. 2021.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

382. Tan A, Bagley S, Wen P, Lim M, Platten M, Colman H, Ashley D, Wick W, Chang S, Galanis E, Mansouri A, Khagi S, Mehta M, Heimburger A, Puduvalli V, Reardon D, Sahebjam S, Simes RJ, Antonia SJ, **Berry D**, Khasraw M. A systematic review of combinations of targeted or immunotherapy in advanced solid tumors. Journal for ImmunoTherapy of Cancer. 2021 Jul;9(7):e002459. doi: 10.1136/jitc-2021-002459.
383. Chang JY, Mehran RJ, Feng L, Verma V, Liao Z, Welsh JW, Lin SH, O'Reilly MS, Jeter MD, Balter PA, McRae SE, **Berry DA**, Heymach JV, Roth JA on behalf of the STARS Lung Cancer Trials Group. Stereotactic ablative radiotherapy for operable Stage I non-small cell lung cancer (revised STARS): Long-term results of a single-arm, prospective trial with prespecified comparison to surgery. Lancet Oncology 2021. DOI: https://doi.org/10.1016/S1470-2045(21)00401-0
384. **Berry DA**, Ip A, Lewis BE, Berry SM, Berry NS, MrKulic M, Gadalla V, Sat B, Wright K, Serna M, Unawane R, Trpeski K, Koropsak M, Kaur P, Sica Z, McConnell A, Bednarz U, Marafelias M, Goy A, Pecora AL, Sawczuk I, Goldberg SL. Development and validation of a prognostic 40-day mortality risk model among hospitalized patients with COVID-19. PLoS ONE 16(2021): e0255228. https://doi.org/10.1371/journal.pone.0255228
385. Onishi N, Li W, Newitt DC, Harnish RJ, Strand F, Nguyen AA-T, Arasu VA, Gibbs J, Jones EF, Wilmes LJ, Kornak J, Joe BN, Price ER, Ojeda-Fournier H, Eghtedari M, Zamora KW, Woodard S, Umphrey HR, Nelson MT, Church AL, Bolan PJ, Kuritza T, Ward K, Morley K, Wolverton D, Fountain K, Paniagua DL, Hardesty L, Brandt KR, McDonald ES, Rosen M, Kontos D, Abe H, Sheth D, Crane E, Dillis C, Sheth P, Hovanessian-Larsen L, Bang DH, Porter B, Oh KY, Jafarian N, Tudorica LA, Niell B, Drukteinis J, Newell MS, Giurescu ME, Berman E, Lehman CD, Partridge SC, Fitzpatrick KA, Borders MH, Yang WT, Dogan B, Goudreau SH, Chenevert T, Yau C, DeMichele A, **Berry DA**, Esserman LJ, Hylton N. Breast MRI during meoadjuvant chemotherapy: Lack of background parenchymal enhancement suppression and inferior treatment response. Radiology 2021. Published Online: Aug 24 2021 https://doi.org/10.1148/radiol.2021203645
386. Hergenroeder GW, Yokobori S, Choi HA, Schmitt K, Detry M, Schmitt LH, McGlothlin A, Puccio AM, Jagid J, Kuroda Y, Yukihiko N, Suidhiro E, Ahmad F, Viele K, Wilde EA, McCauley SR, Kitagawa RS, Temkin NR, Timmons SD, Diringa MN, Dash PK, Bullock R, Okonkwo DO, **Berry DA**, Kim DH. Hypothermia for patients requiring evacuation of subdural hematoma: multicenter randomized clinical trial. Neurocritical Care. (2021) https://doi.org/10.1007/s12028-021-01334-w
387. Yee D, Isaacs C, Wolf DM, Yau C, Haluska P, Geridhar KV, …, **Berry DA**, Esserman LJ. Ganitumab and metformin plus standard neoadjuvant therapy in stage 2/3 breast cancer. NBJ Breast Cancer 7(2021):131; https://doi.org/10.1038/s41523-021-00337-2.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Applications (cont'd):

388. Cudkowicz ME, Lindborg SR, Goyal NA, Miller RG, Burford MJ, Berry JD, Nicholson KA, Mozaffar T, Katz JS, Jenkins LJ, Baloh RH, Lewis RA, Staff NP, Owegi MA, **Berry DA**, Gothelf Y, Levy YS, Aricha R, Kern RZ, Windebank AJ, Brown RH. A randomized placebo-controlled phase 3 Study of mesenchymal stem cells induced to secrete high levels of neurotrophic factors in Amyotrophic Lateral Sclerosis. Muscle and Nerve (2022) Online Jan 6. DOI: 10.1002/mus.27.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Editorials, Letters, and Commentaries:

389. **Berry DA** (1972). Letter to the Editor. The American Statistician 26:47.
390. **Berry DA** (1972). Subjective Inference. The American Statistician 26:195.
391. **Berry DA** (1978). Review of Probability and Statistics by DeGroot MH. Journal of the American Statistical Association 73:218-219.
392. **Berry DA** (1981). Discussion of "Randomized allocation of treatments in sequential experiments" by Bather JA. Journal of the Royal Statistical Society, Series B 43:289.
393. **Berry DA** (1982). Review of Statistical Decision Theory by Berger JO. Technometrics 24:80-82.
394. **Berry DA** (1983). Review of Bayesian Statistics, edited by Bernardo JM, DeGroot MH, Lindley DV, Smith AFM, Technometrics 25:206-207.
395. **Berry DA** (1986). Review of Introduction to Stochastic Dynamic Programming by Ross SM. Journal of the American Statistical Association 81:573.
396. **Berry DA** (1987). Odds Are Against the Twins, but They Aren't Overwhelming (Commentary). Star Tribune (Oct. 16) Minneapolis, Minnesota.
397. **Berry DA** (1988). Discussion of "Bayesian Paleoethnobotany" by Kadane JB, Hastorf CA. In Bayesian Statistics 3:243-259. Oxford, England: Oxford University Press. (Ed: Bernardo JM, DeGroot MH, Lindley DV, Smith AFM.)
398. **Berry DA** (1988). Discussion of "Bayesian Approaches to Clinical Trials" by Spiegelhalter DJ, Freedman LS. In Bayesian Statistics 3:243-259. Oxford, England: Oxford University Press. (Ed: Bernardo JM, DeGroot MH, Lindley DV, Smith AFM.)
399. **Berry DA** (1988). Responses to Letters to the Editor. The American Statistician 42:89.
400. Berger JO, **Berry DA** (1988). Responses to Letters to the Editor. The American Scientist 76. (Various issues.)
401. **Berry DA** (Apr 1989). Significant Statistics. Natural History 6.
402. **Berry DA** (1990). Comments on Kempthorne (1989). The American Statistician 44:187.
403. **Berry DA** (1991). More on "DNA Fingerprinting". Chance 3 (4).
404. **Berry DA** (1991). Review of Probability Models by Ross SM. Journal of Official Statistics 7:133.
405. **Berry DA** (1992). Comment on Hoffman et al. “Transparent Polyurethane Film as a Catheter Dressing.” Journal of the American Medical Association 268:2514-2515.
406. **Berry DA** (1993). Review of Multi-armed Bandit Allocation Indices by JC Gittins. Metrika 40:134-136.
407. **Berry DA** (1993). Editorial: Power of chronobiologic pilots—A statistician's opinion. Chronobiologica 20:213.
408. **Berry DA** (1994). Discussion of "DNA Fingerprinting: A Review of the Controversy" by Roeder K. Statistical Science 9:222-278.
409. **Berry DA** (1994). Discussion of "Bayesian Approaches to Randomized Trials" by Spiegelhalter DJ, Freedman LS, Parmar MKB. Journal of the Royal Statistical Society, Series B 157:357-416.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Editorials, Letters, and Commentaries (cont'd):

410. **Berry DA** (1995). Discussion of "Elicitation, Monitoring, and Analysis for an AIDS Clinical Trial" by Carlin BP, Chaloner KM, Louis TA, Rhame FS. Case Studies in Bayesian Statistics II. 79-85. New York: Springer-Verlag. (Ed: Gatsonis C, Hodges JS, Kass RE, Singpurwalla ND.)
411. **Berry DA** (1995). Editorial comments on "Parametric Survival Analysis of Adjuvant Therapy for Stage II Breast Cancer" by Gamel JW, et al. In Breast Diseases: A Year Book Quarterly 6:201. Chicago: Mosby. (Ed: Balch CM.)
412. **Berry DA** (1996). Editorial: When Is a Confirmatory Randomized Clinical Trial Needed? Journal of the National Cancer Institute 89:1206-1207.
413. **Berry DA** (1997). Review of Quantification and the Quest for Medical Certainty by JR Matthews (Princeton University Press, 1995). The Quarterly Review of Biology 72:359-360.
414. **Berry DA**, Parmigiani G (1997). Response to Daniel Schaid. Journal of the National Cancer Institute 89:1634.
415. **Berry DA**, Budman D (1999). Response to Vollmer Re: Dose and dose intensity as determinants of outcome in the adjuvant treatment of breast cancer. Journal of the National Cancer Institute 91:286-287.
416. **Berry DA** (1999). Response to Kopans-Halpern Re: Benefits and risks of screening mammography for women in their forties: A statistical appraisal. Journal of the National Cancer Institute 91:383-384.
417. **Berry DA**, Thor AD (1999). Response to Cameron-Leonard. Journal of the National Cancer Institute 91:728-729.
418. **Berry DA**, Budman D (1999). Response to Hryniuk Re: Dose and dose intensity as determinants of outcome in the adjuvant treatment of breast cancer. Journal of the National Cancer Institute 91:1425.
419. **Berry DA** (2000). Review of Pharmaceutical Experimental Design by GA Lewis, D Mathieu, R Phan-Tan-Luu, Journal of the American Statistical Association 95:339.
420. Cremin C, Wong N, Buzaglo K, Paradis A-J, Foulkes W, **Berry DA**, Parmigiani G, Rubinstein W, Watson P. Nonovarian pelvic cancers in BRCA1/2 mutation carriers and the BRCAPRO statistical model. Journal of Clinical Oncology 20(2002):3936-3937.
421. **Berry DA**. Editorial: Role of population-based studies in assessing genetic cancer risk. Journal of the National Cancer Institute 93(2001):1188-1189.
422. Henderson IC, Norton L, **Berry DA**. Benefit of paclitaxel in estrogen receptor-negative versus estrogen receptor-positive early breast cancer. Journal of Clinical Oncology 21(2003):4465-4466. DOI: 10.1200/JCO.2003.99.185.
423. **Berry DA**. Commentary: Screening mammography: a decision analysis. International Journal of Epidemiology 33(2004):68.
424. Ibrahim N, Francis D, Booser D, Thomas E, Theriault R, Pusztai L, Green M, Arun B, Giordano S, Cristofanilli M, Frye D, Smith T, Hunt K, Singletary E, Sahin A, Ewer M, Buchholz T, **Berry D**, Hortobagyi G. Herceptin plus chemotherapy combination in preoperative regimen may offer clinical benefit in early stage breast cancer. Cancer Biology and Therapy 4(2005)(5).

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Editorials, Letters, and Commentaries (cont'd):

425. **Berry DA** (2005). Commentary: Clinical Trials—Is the Bayesian approach ready for primetime? Stroke 36:1621-1622.
426. **Berry DA** (2005). Review of Bayesian Approaches to Clinical Trials and Health-Care Evaluation by DJ Spiegelhalter, KR Abrams and JP Myles, John Wiley & Sons, Ltd 2004. Statistics in Medicine 24.
427. **Berry D**, Goodman SN, Louis, TA, Temple R (2005). Floor discussion. Clinical Trials 2(2005):301-304.
428. **Berry DA** (2005). Obituary: Seymour Geisser. Journal of the Royal Statistical Society: Series A 168:245.
429. **Berry DA** (2005). The Bayesian principle: can we adapt? Stroke 36:1623-1624.
430. **Berry DA** (2005). Letter to the Editor: Breast cancer heterogeneity may explain peaks in recurrence. International Journal of Surgery 3:287.
431. **Berry DA** (2005). Editorial comments on "Chemotherapy is more effective in patients with breast cancer not expressing steroid hormone receptors: a study of preoperative treatment" by Colleoni M, et al. In Breast Diseases: A Year Book Quarterly 16. Chicago: Mosby.
432. Buzdar AU, Hunt KK, **Berry D**, Hortobagyi (2005). In reply. Journal of Clinical Oncology 23:6804-6805.
433. Buzdar AU, Hunt KK, **Berry D**, Hortobagyi (2005). In reply. Journal of Clinical Oncology 23:8131-8132.
434. Shen Y, **Berry DA** (2005). Responses to Paci et al. Journal of the National Cancer Institute 97:1853-1854.
435. **Berry DA** (2006). Editorial: Bayesian Statistics. Medical Decision Making 26:429-430.
436. **Berry DA**, Plevritis SK, Fryback DG (2006). The authors reply. New England Journal of Medicine 354:769.
437. **Berry DA** (2007). Commentary: The hazards of survival comparisons. The Oncologist 12:510-511.
438. Parmigiani G, **Berry DA** (2007). Commentary: In reply to "Does search for large genomic rearrangements impact on BRCAPRO carrier prediction?" Journal of Clinical Oncology 25:2634-2635.
439. **Berry DA**, Ravdin PM (2007). Editorial: Breast cancer trends: A marriage between clinical trial evidence and epidemiology. Journal of the National Cancer Institute 99:1139-1141.
440. **Berry DA** (2007). Commentary: Adaptive trial design. Clinical Advances in Hematology & Oncology 5:522-524.
441. Iversen ES, Katki HA, Chen S, **Berry DA**, Parmigiani G (2007). Limited family structure and breast cancer risk. Journal of the American Medical Association 298:2007.
442. Ratain MJ, Humphrey RW, Gordon GB, Fyfe G, Adamson PC, Fleming TR, Stadler WM, **Berry DA**, Peck CC (2008). Editorial Comment: Recommended changes to oncology clinical trial design: Revolution of evolution? European Journal of Cancer 44:8-11.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Editorials, Letters, and Commentaries (cont'd):

443. **Berry DA** (2007). Guest Commentary: Pooling apples, oranges, lemons and limes makes a statistical fruit salad. The Cancer Letter 33;42:5-6.
444. **Berry DA** (2008). Commentary: Does mammography protect against death from breast cancer? OBG Management 20;1:25-26.
445. Hayes DF, **Berry D (**2008). The authors reply. New England Journal of Medicine 358:198.
446. **Berry DA** (2008). Editorial: The screening mammography paradox: Better when found, perhaps better not to find. British Journal of Cancer 98:1729-1730.
447. **Berry DA** (2008). Regional Changes in Hormone Therapy Use and Breast Cancer Incidence in California from 2001 to 2004. Breast Diseases 19:131-132
448. **Berry DA** (2008). Letter to the Editor: The best graph may be no graph. Chance 21(3):6.
449. **Berry DA** (2008). Commentary: The science of doping. Nature 454:692-693.
450. **Berry DA**, Baines CJ, Baum M, Dickersin K, Fletcher SW, Gøtzsche PC, Jørgenson KJ, Junod B, Mæhlen J, Schwartz LM, Thornton H, Welch G, Woloshin S, Zahl P-H (2009). Letter to the Editor: Flawed inferences about screening mammography's benefit based on observational data. Journal of Clinical Oncology 27:639-640.
451. **Berry DA**, Wathen JK, Newell MA (2009). Bayesian model averaging in meta-analysis: Authors' response. Clinical Trials 6:50-51.
452. **Berry DA** (2009). Editorial: Adjuvant chemotherapy for breast cancer in older women. Women's Health 5:453-457.
453. **Berry DA**, Wathen JK, Newell MA (2009). Reply. Clinical Trials 6:394.
454. Muss HB, **Berry DA**, Cirrincione CT. Reply. New England Journal of Medicine 361(2009):1023-1024.
455. Goodman S, **Berry D**, Wittes J (2010). Letter to the Editor: Bias and trials stopped early for benefit. Journal of the American Medical Association 304:157.
456. Baum M, Thornton H, Gøtzsche PC, Bewley S, Jørgensen KJ, Barratt A, Ross N, Woloshin S, Schwartz L, Musiello T, Blennerhassett M, Napoli M, Baines CJ, Vaidya JS, Williams N, Havercroft D, Zahl P-H, Retsky M, Kaplan RM, Dixon-Woods M, **Berry DA**, Isaacson K, Brahams D, Pryke M, Tindall G, Bender DA, Marshall T (2010). Breast cancer awareness month: Still awaiting screening facts. British Medical Journal 341:c6152.
457. **Berry DA** (2010). Editorial: The hazards of endpoints. Journal of the National Cancer Institute 102:1376-1377.
458. **Berry DA** (2011). Editorial: Adaptive clinical trials: The promise and the caution. Journal of Clinical Oncology 29:606-609.
459. **Berry DA**. Editorial: Computer-assisted detection and screening mammography: Where's the beef? Journal of the National Cancer Institute 103(2011):1139-1141.
460. Baggerly KA, **Berry DA** (2011). Reproducible research. AmstatNews, January 2011 #403:16-17.
461. **Berry DA** (2011). Guest Editorial: Comparing survival outcomes across centers—Biases galore. The Cancer Letter 37;11:7-10.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Editorials, Letters, and Commentaries (cont'd):

462. **Berry DA**. Guest Columnist: Alexandria Summit: Oncology 2011 Leads to Neuroscience 2012. <http://www.alexandriasummit.com/guest_columnist_berry.php>
463. **Berry DA**. Responses to Moroni and DeGiorgi/Amadori. Journal of Clinical Oncology 30(2012):759-760.
464. **Berry DA**. Statisticians and clinicians: Collaborations based on mutual respect. AmstatNews, February 2012 #416:27-28.
465. Ellenberg S, Luce B, Fleming T, Siegel J, Strom B, Hernán M, Temple R, Sackett D, Bourguignon C, Bekelman J, **Berry D**, Rotelli M, Judkins D, Schwartz S, Goodman S. Panel discussion 2. Clinical Trials 9(2012):66-79. doi: 10.1177/1740774511433048.
466. **Berry DA**. Discussion of William DuMouchel's "Multivariate Bayesian Logistic Regression for Analysis of Clinical Trial Safety Issues." Statistical Science 27(2012):344-345.
467. Yee D, Haddad T, Albain K, Barker A, Benz C, Boughey J, Buxton M, Chien AJ, DeMichele A, Dilts D, Elias A, Haluska P, Hogarth M, Hu A, Hylton, Kaplan HG, Kelloff GG, Khan Q, Lang J, Leyland-Jones B, Liu M, Nanda R, Northfelt D, Olopade OI, Park J, Parker B, Parkinson D, Pearson-White S, Perlmutter J, Pusztai L, Symmans F, Rugo H, Tripathy D, Wallace A, Wholley D, van 't Veer L, **Berry DA**, Esserman L. Adaptive trials in the neoadjuvant setting: A model to safely tailor care while accelerating drug development. Journal of Clinical Oncology 30(2012):4584-4586.
468. Hughes KS, Schnaper LA, Bellon JR, Cirrincione CT, **Berry DA**, McCormick B, Muss HB, Smith BL, Hudis CA, Winer EP, Wood WC. Reply to P.G. Tsoutsou et al, O. Kaidar-Person et al, and A. Courdi et al. Journal of Clinical Oncology 31(2013):4571-4573.
469. Esserman L, Buxton MB, **Berry D**. Accelerated approval of promising agents in the neoadjuvant setting: A path for facilitating targeted drug development for breast cancer. Breast Diseases: A Year Book Quarterly 24(2013):126-128.
470. **Berry DA**. Editorial: CYP2D6 genotyping and the use of tamoxifen in breast cancer. Journal of the National Cancer Institute 105(2013):1267-1269.
471. **Berry DA**, Berry SM. Comments on "The need for more emphasis on prediction: A 'nondenominational' model-based approach" by David A. Harville. The American Statistician 68(2014):88-89. doi:10.1080/00031305.2014.911546.
472. **Berry DA.** Response to Province and Klein. Journal of the National Cancer Institute 106(2014). doi:10.1093/jnci/djt380.
473. **Berry DA.** Response to Goetz et al. Journal of the National Cancer Institute 106(2014). doi:10.1093/jnci/dju065.
474. **Berry D**, Sledge G. Point-Counterpoint: In NeoALTTO & ALTTO Trials, Neoadjuvant Response Predicts Adjuvant. The Cancer Letter 40(2014);28:1-9.
475. **Berry DA**. Commentary: Failure of researchers, reviewers, editors, and the media to understand flaws in cancer screening studies: Application to an article in Cancer. Cancer 2014. (Published online: 12 Jun 2014, doi:10.1002/cncr.28795)
476. **Berry DA**. Perspective: CYP2D6 genotype and adjuvant tamoxifen. Clinical Pharmacology & Therapeutics 96(2014):138-140; doi:10.1038/clpt.2014.96.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Editorials, Letters, and Commentaries (cont'd):

477. DeMichele A, Yee D, **Berry DA**, Albain KS, Benz CC, Boughey J, Buxton M, Chia SK, Chien AJ, Chui SY, Clark A, Edmiston K, Elias AD, Forero-Torres A, Haddad TC, Haley B, Haluska P, Hylton NM, Isaacs C, Kaplan H, Korde LA, Leyland-Jones B, Liu MC, Melisko M, Minton SE, Moulder SL, Nanda R, Olopade OI, Paoloni M, Park JW, Parker BA, Perlmutter J, Petricoin EF, Rugo H, Symmans WF, Tripathy D, van 't Veer LJ, Viscusi RK, Wallace A, Wolf D, Yau C, Esserman LJ. The neoadjuvant model is still the future for drug development in breast cancer. Clinical Cancer Research 21(2015):2911-2915. doi:10.1158/1078-0432.CCR-14-1760. PMID: 25712686. PMCID: PMC4490043
478. **Berry DA**. Commentary on "Are Outcome-Adaptive Allocation Trials Ethical?" by Spencer Phillips Hey and Jonathan Kimmelman. Clinical Trials 2015. (Published online before print February 3, 2015, doi: 10.1177/1740774515569011)
479. **Berry DA**, Hudis CA. Neoadjuvant therapy in breast cancer as a basis for drug approval. JAMA Oncology 1(2015):875-876. Jul 9. doi: 10.1001/jamaoncol.2015.1293. PMID: 26181139.
480. **Berry DA.** Reply to Burzykowski, Saad, Buyse, "Adoption of pathologic complete response as a surrogate end point in neoadjuvant trials in HER2-positive breast cancer still an open question." JAMA Oncology 3(2016):416-417. doi:10.1001/jamaoncol.2016.3947..
481. **Berry DA.** How to take clinical research to the next level. Fortune Oct 26, 2015.
482. Shulman LN, **Berry DA**, Cirrincione CT, Hudis CA, Winer EP. Reply to V. Amoroso et al. Journal of Clinical Oncology 33(2015):291.
483. **Berry DA.** Commentary on "Impact of screening mammography on breast cancer mortality" by Archie Bleyer, Cornelia Baines and Anthony B. Miller. Breast Diseases: A Year Book Quarterly. 27(2016):276-277.
484. DeMichele A, Yee D, Paoloni M, **Berry D**, Esserman LJ. Neoadjuvant as Future for Drug Development in Breast Cancer—Response. Clinical Cancer Research 22(2016):269-269; doi:10.1158/1078-0432.CCR-15-1643.
485. **Berry DA**, Esserman LJ. In reply to letters regarding "Adaptive randomization of neratinib in early breast cancer." New England Journal of Medicine 375(2016):1592-1593.
486. **Berry DA**. Commentary: A p-value to die for. Journal of the American Statistical Association 112(2017):895-897. doi:10.1080/01621459.2017.1316279.
487. Cronin KA, **Berry DA**. Concern regarding age distribution of breast cancer. JAMA Surgery 153(2018):1060-1061. Doi: 10.1001/jamasurg.2018.2087. PMID: 30046830.
488. Plevritis SK, **Berry DA**, Mandelblatt JS. Contributions of screening and treatment to mortality from breast cancer—Reply. Journal of the American Medical Association 319(2018):2336. doi: 10.1001/jama.2018.4261. PMID: 29896623.
489. **Berry DA**, de Koning HJ, Lee SJ, Mandelblatt JS, Plevritis SK, Schechter CB, Stout NK, Trentham-Dietz A; CISNET Breast Working Group Principal Investigators. Distinguishing between CISNET model results versus CISNET models. Cancer 124(2018):1083-1084. doi: 10.1002/cncr.31150. PMID: 29278430.

V. PUBLICATIONS (CONT'D)

E. Professional Articles—Editorials, Letters, and Commentaries (cont'd):

490. **Berry DA.** Adoption of pathologic complete response as a surrogate end point in neoadjuvant trials in HER2-positive breast cancer still an open question—Reply. JAMA Oncology 3(2017):416-417. doi:10.1001/jamaoncol.2016.3947.
491. **Berry DA**. 6 Versus 12 Months of Adjuvant Trastuzumab for HER2-Positive Early Breast Cancer (PERSEPHONE): 4-Year Disease-Free Survival Results of a Randomised Phase 3 Non-Inferiority Trial. PracticeUpdate website. Available at: https://www.practiceupdate.com/content/6-vs-12-months-of-adjuvant-trastuzumab-for-her2-positive-early-breast-cancer/84999/65/1/1. Accessed July 12, 2019.
492. Faya P, **Berry D**. Bayesian methods in CMC—Has the time come for a regulatory guidance? Biopharmaceutical Report of the American Statistical Association. 28(2021), No. 3:6-9.
493. Jamshidi A, Liu MC, Klein EA, Venn O, Hubbell E Beausang JK, Gross S, Melton C, Fields AP, Liu Q, Zhang N, Fung ET, Kurtzman KN, Amini H, Betts C, Civello D, Freese P, Calef R, Davydov K, Fayzullina S, Hou C, Jiang R, Jung B, Tang S, Demas V, Newman J, Sakarya O, Scott E, Shenoy A, Shojaee S, Steffen KK, Nicula V, Chien TC, Bagaria S, Hunkapiller N, Desai M, Dong Z, Richards DA, Yeatman TJ, Cohn AL, Thiel DD, **Berry DA**, Tummala MK, McIntyre K, Sekeres MA, Bryce A, Aravanis AM, Seiden MV, Swanton C. Evaluation of Cell-Free DNA Approaches for Multi-Cancer Early Detection. (Submitted for publication)

F. Professional Articles—Interviews:

494. Couzin J. "The New Math of Clinical Trials." Science 303(2004):784-786.
495. Piana R. "Can Bayesian Design Streamline Our Sluggish Clinical Trial System?" An interview with **Donald A. Berry**. ASCO Post 2(2011).
496. Stangl D, Inoue LYT, Irony TZ. "Celebrating 70: An Interview with **Don Berry**." Statistical Science 27(2012):144–159.
497. Oncology Live. I-SPY 2 Designer Describes Program's Many Innovations, April 8, 2014. http://www.onclive.com/publications/Oncology-live/2014/March-2014/I-SPY-2-Designer-Describes-Programs-Many-Innovations.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES

1. Red-and-Black with Unknown Win Probability. NBER-NSF Seminar on Bayesian Inference in Econometrics. Minneapolis, MN. May 1973.
2. Adaptive Methods in Clinical Trials. American Mathematical Association. Duluth, MN. Jun 1979.
3. Bandit Problems with Random Discounting. Conference on Mathematical Learning Models—Theory and Algorithms. University of Bonn, West Germany. May 1982.
4. Inferring Effect of Antiarrhythmic Drugs. Midwest Biopharmaceutical Statistics Workshop. Muncie, IN. May 1982.
5. Probability Theory. Brasov, Rumania. Aug 1982.
6. One- and Two-armed Bandit Problems. Midwest Statistics Colloquium. Purdue University, IN. Oct 1982.
7. Optimal Stopping in Bandit Problems. Institute of Mathematical Statistics. Nashville, TN. Mar 1983.
8. Classical vs. Bayesian vs. Ad Hoc Approaches to Interim and Sequential Analysis. Midwest Biopharmaceutical Statistics Workshop. Muncie, IN. May 1983.
9. Statistics of Disputed Paternity Cases. Joint Statistical Meetings. Toronto, Canada, Aug 1983.
10. Calculating a Probability of Paternity: Clarifications and Criticism. Minnesota Trial Lawyers Association. Minneapolis, MN. Dec 1983.
11. Outliers and Transformations. Midwest Biopharmaceutical Statistics Workshop. Muncie, IN. May 1984.
12. Are Clinical Trials Designed to Deliver Good Medicine? Summer Research Conference in Statistics. Arkadelphia, AR. Jun 1984.
13. Some Issues in the Design of Experiments. Midwest Biopharmaceutical Statistics Workshop. Muncie, IN. May 1985.
14. A Converse of the Gittins-Jones Result for Bandit Problems. Operations Research Society of America. Atlanta, GA. Nov 1985.
15. Interim Analysis and Sequential Clinical Trials: The Role of the Likelihood Principle. International Conference on Foundations of Statistical Inference. Tel Aviv, Israel. Dec 1985.
16. Marshall-MacIntosh LAD vs. Nonaugmented Controls. Second Symposium on Prosthetic Augmentation of Autogenous Grafts. St. Paul, MN. Mar 1986.
17. Bandit Problems and Optimal Stopping. International Conference on Gambling and Optimal Stopping. Oberwolfach, West Germany. Jun 1986.
18. The Relevance of Stopping Rules in Statistical Inference. Fourth Symposium on Decision Theory and Related Topics. Purdue University, West Lafayette, IN. Jun 1986.
19. A Bayesian Approach to Pharmaceutical Company Decision Making. International Conference on Practical Bayesian Statistics. Cambridge, UK. Jul 1986.
20. Bandit Problems. Mathematical Sciences Institute Workshop on Deterministic and Stochastic Control. Cornell University. Ithaca, NY. Apr 1987.
21. Prophets and Bandits. Mathematical Sciences Institute Workshop on Deterministic and Stochastic Control. Cornell University. Ithaca, NY. Apr 1987.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

22. Multiple Comparisons, Multiple Tests, and Data Dredging: A Bayesian Perspective. Third International Meeting on Bayesian Statistics. Valencia, Spain. Jun 1987.
23. Bayes's Theorem, Independence, and the Probability of Paternity. International Association of Forensic Sciences. Vancouver, Canada. Aug 1987.
24. Subjectivity in Clinical Trials. Joint Statistical Meetings. San Francisco, CA. Aug 1987.
25. Games, Sports, Gambling and Sex: Who Says Statistics Is Dull? Keynote Address at Ohio Statistics Day. Bowling Green, OH. Nov 1987.
26. Monitoring for Safety in Randomized Clinical Trials. Biometric Society Meetings. Boston, MA. Mar 1988.
27. Adaptive vs. Randomized Allocation in Clinical Trials. Institute of Mathematical Statistics. Honolulu, HI. Jun 1988.
28. Bayesian Methodology in Clinical Trials. International Society of Clinical Biostatistics. Innsbruck, Austria. Aug 1988.
29. Inferences Concerning Adverse Experiences in Pharmaceutical Trials. Joint Statistical Meetings. New Orleans, LA. Aug 1988.
30. Making Decisions in Drug Development. Basel Statistics Association. Basel, Switzerland. Sep 1988.
31. Challenge of the Future of Statisticians in the Biopharmaceutical Field: Academic Perspective. Eastern North American Region of the International Biometric Society. Lexington, KY. Mar 1989.
32. Annual Meeting of the Society for Clinical Trials. Minneapolis, MN. May 1989.
33. Inferential Aspects of Adaptive Allocation Rules. Joint Statistical Meetings. Washington, D.C. Aug 1989.
34. Are Randomized Clinical Trials Ethical If They Withhold ECMO from Newborns with Respiratory Failure? UCLA Conference on Ethics in Clinical Trials. Los Angeles. Oct 1989.
35. Bayesian Methods in Biostatistics. Annual Conference on Applied Statistics. Atlantic City, NJ. Dec 1989.
36. Bayesian Analysis of Phase III Trials. Drug Information Association Biostatistics Workshop. Hilton Head, SC. Mar 1990.
37. Effective Evaluation of DNA Single-Locus Profiles in Crime Investigations. International Conference on Forensic Statistics. Edinburgh, UK. Apr 1990.
38. Some Bandit Problems. IMS-AMS-SIAM Summer Conference in the Mathematical Sciences: Sequential Search and Selection in Real Time. Amherst, MA. Jun 1990.
39. A Bayesian Approach to Metaanalysis and Multicenter Trials. Joint Statistical Meetings. Anaheim, CA. Aug 1990.
40. Quantifying DNA-Based Identification. American Association for the Advancement of Science. Washington, DC. Feb 1991.
41. An Alternative Approach to Drug Development. "State-of-the-art" address invited by President of American Society for Clinical Pharmacology and Therapeutics. San Antonio, TX. Mar 1991.
42. Public Health Decision Making: A Sequential Vaccine Trial. Fourth International Meeting on Bayesian Statistics. Valencia, Spain. Apr 1991.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

43. Alternative Approaches to Clinical AIDS Research. US Food and Drug Administration Workshop on The Role of Alternative Data Sources in AIDS Drug Development: Optimizing the Yield from Observational Data Bases and Expanded Access Protocols through Alternative Study Designs. Washington, DC. May 1991.
44. A Case for Bayesianism in Clinical Trials. Special Conference on Methodology in Clinical Trials at London School of Economics. London, UK. Jun 1991.
45. Statistical Inferences in Crime Investigations Using DNA Profiling. (Presented by Evett IW.) Read before the Royal Statistical Society. London, UK. Nov 1991.
46. Metaanalysis and Using Historical Controls in Clinical Trials. Fifth Symposium on Decision Theory and Related Topics. Purdue University, West Lafayette, IN. Jun 1992.
47. Clinical Research in the Critical Care Environment. First World Congress of Pediatric Intensive Care. Baltimore, MD. Jun 1992.
48. Adaptive Group Sequential Assignment in Clinical Trials. IMS-AMS-SIAM Summer Conference in the Mathematical Sciences: Adaptive Methods. South Hadley, MA. Jul 1992.
49. Bayesian Metaanalysis. Joint Statistical Meetings. Boston, MA. Aug 1992.
50. Multiplicities: Bayesian Attitudes and Methods. Second Merck/Temple Conference in Biostatistics. Philadelphia, PA. Nov 1992.
51. Statistics, Statistical Reasoning and Metaanalysis. Association for Practitioners of Infection Control. Orlando, FL. May 1993.
52. Statistical Potpourri. Graduate Student Seminar Sessions in Statistics and Biostatistics. Pittsburgh, PA. Jul 1993.
53. Bayesian Attitudes and Methods in Clinical Trials: From Design to Handling Multiplicities. Joint Statistical Meetings. San Francisco, CA. Aug 1993.
54. Adaptive Designs for Clinical Trials: An Overview. Pharmaceutical Marketing Association. Seattle, WA. Sep 1993.
55. Discussion of "Elicitation, Monitoring, and Analysis for an AIDS Clinical Trial" by Carlin BP, Chaloner KM, Louis TA, Rhame FS. Workshop in Applied Bayesian Statistics at Carnegie Mellon University. Pittsburgh, PA. Oct 1993.
56. Commentary on DNA Fingerprinting. Workshop of National Institute of Statistical Sciences. Research Triangle Park, NC. Oct 1993.
57. Factorial Designs: Advantages and Disadvantages in Clinical Studies. Cancer and Leukemia Group B Breast Cancer Scientific Session. Chicago, IL. Nov 1993.
58. c-erbB-2 and Doxorubicin Therapy in Node-Positive Early Breast Cancer. National Cancer Institute Conference on Using New Biologic Markers in Breast Cancer Research and Therapy. Washington DC. Nov 1993.
59. Designing Efficient and Informative Clinical Trials. Keynote Address at Drug Information Association Biostatistics Workshop. Hilton Head, SC. Mar 1994.
60. Bayesian Approaches to Designing and Analyzing Experiments. Series of Special Invited Lectures at Taiwan Universities. May 1994.
61. Scientific Inference and Predictions; Multiplicities and Convincing Stories: A Case Study in Breast Cancer Therapy. Fifth International Meeting on Bayesian Statistics. Valencia, Spain. Jun 1994.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

62. Innovative Designs for Clinical Trials. Parke-Davis Distinguished-Speaker Seminar. Ann Arbor, MI. Nov 1994.
63. Therapeutic Significance of Biological Markers in Breast Cancer. Eastern North American Region of the International Biometric Society. Research Triangle Park, NC. Jan 1995.
64. Statistical Analysis and the Illusion of Objectivity. Fifth International Congress on Anti-Cancer Chemotherapy. Paris, France. Feb 1995.
65. Prognostic Factors in High Dose Therapy. American Society of Clinical Oncology. Los Angeles CA. May 1995.
66. Statistical Issues in Health Care. Keynote address at Third Annual Great Lakes Symposium on Statistical Issues in Health Care Medicine. Kalamazoo MI. Jun 1995.
67. Assessing the Probability of Carrying a Breast Cancer Gene Based on Family History. Third World Meeting of the International Society for Bayesian Analysis. Oaxaca, Mexico. Sep 1995.
68. Bayesian Perspective on the Design and Analysis of Clinical Trials. Closing address at Harvard Symposium on Bayesian Approaches to Clinical Trials, Cambridge MA. Mar 1996.
69. Bayesian Biostatistics. Keynote address at Midwest Biopharmaceutical Statistics Workshop. Muncie, IN. May 1996.
70. Flexible Designs for Clinical Trials: A Bayesian Perspective. Schering-Plough/Harvard Workshop in Biostatistics. Cambridge, MA. May 1996.
71. Bayesian Approaches to Problems with Multiplicities: Applications to Multiple Comparisons. International Conference on Multiple Comparisons. Tel Aviv, Israel. Jun 1996.
72. Teaching Introductory Bayesian Statistics with Real Applications in Science: Doing What Comes Naturally. Joint Statistical Meetings. Chicago, IL. Aug 1996.
73. Handling Multiple Comparisons and Other Multiplicities in Clinical Trials. Henry Stewart Conference on Mathematical and Statistical Techniques in Clinical Trials. Rockville, MD. Oct 1996.
74. Benefits and Risks of Screening Mammography Between the Ages of 40 and 49. National Cancer Advisory Board. Bethesda, MD. Feb 1997.
75. Benefits and Risks of Screening Mammography Between the Ages of 40 and 49. National Breast Cancer Coalition Board. New York, NY. Mar 1997.
76. Synthesizing Disparate Sources of Information. Eastern North American Region of the International Biometric Society. Memphis, TE. Mar 1997.
77. Statistical and Decision Making Issues in Breast Cancer. Cancer and Leukemia Group B, Montreal, Canada. Jun 1997.
78. Using Historical Controls, Decision Making, and Adaptive Designs in Clinical Trials. Workshop on Statistics in Medicine at Institute of Mathematics and Its Applications, Minneapolis, MN. Jul 1997.
79. Bayesian Methods in the Design and Analysis of Clinical Trials. Joint Statistical Meetings. Anaheim, CA. Aug 1997.
80. Using a Bayesian Approach in Medical Device Development. Course presentation to the U.S. Food and Drug Administration, Center for Devices and Radiological Health. Washington DC. Sep 1997.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

81. Metaanalysis: Fixed vs. Random Effects. Henry Stewart Conference on Doing and Understanding Meta Analysis. Rockville, MD. Sep 1997.
82. Modeling Risk of Breast Cancer and Decisions about Genetic Testing. Case Studies in Bayesian Statistics Workshop IV. Pittsburgh, PA. Sep 1997.
83. Bayesian Biostatistical Methods. Course presentation to the Swedish Association for Medical Statistics. Lund, Sweden. Oct 1997.
84. Breast Cancer, Genetics, and Clinical Trials. Keynote address, Joint meeting: New England Regional Genetics Group and Rhode Island Commission on Women. Providence RI. Oct 1997.
85. Bayesian Statistics: Attitudes and Methods. Army Applied Statistics Conference, George Mason University. Oct 1997.
86. Assessing the Evidence for Screening Mammography for Women in their Forties. An Era of Hope in Breast Cancer, sponsored by the U.S. Department of Defense. Washington DC. Nov 1997.
87. Using Bayesian Statistics in Assessing Risks of Radiation Exposure. 43rd Annual Conference on Bioassay, Analytical, and Environmental Radiochemistry (BAER), sponsored by the U.S. Department of Energy. Charleston SC. Nov 1997.
88. Efficient and Ethical Designs for Clinical Trials. Drug Information Association. Hilton Head, SC. Mar 1998.
89. Mathematical and Statistical Techniques in Clinical Trials. Rockville, MD. Apr 1998.
90. Ethical Issues in Clinical Trials. Ethics in Clinical Trials and Implications for Biometrics. Basel, Switzerland. May 1998.
91. A CALGB 3x2 Factorial Trial Examining the Use of Doxorubicin (Adriamycin) and Paclitaxel (Taxol) as Adjuvant Therapy in Breast Cancer. Schering-Plough/Harvard Workshop on Monitoring Clinical Trials. Cambridge, MA. May 1998.
92. Analysis of Paired Survival Data. Drug Information Association. Boston, MA. Jun 1998.
93. Pharmaceutical Company Decision Making and the Conduct of Clinical Trials. Drug Information Association. Boston, MA. Jun 1998.
94. Validation of BRCAPRO, Sensitivity of Sequencing BRCA1 and BRCA2, and Implications for the Existence of Other Breast Cancer Susceptibility Genes. SPORE Investigators' Workshop. Rockville, MD. Jul 1998.
95. An Overview of Bayesian Methods in Clinical Research. ASA Biopharmaceutical Section of the American Statistical Association. Arlington, VA. Sep 1998.
96. Bayesian Methods and the Future of Randomized Controlled Trials. Fifty Years of Clinical Trials: Past, Present and Future. British Medical Association/British Medical Journal. London, UK. Oct 1998.
97. Using Bayesian Methods in Medical Device Development. Food and Drug Administration/Health Industry Manufacturers Association Conference. Rockville MD. Nov 1998.
98. Modeling Trial Heterogeneity and Risk/Benefit Analysis of Screening Mammography for Women in Their 40s. Workshop on Methodologic Issues in the Design and Evaluation of Cancer Screening Interventions. Washington, DC. Jan 1999.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

99. Using Surrogate Endpoints in Clinical Trials. Henry Stewart Conference on Understanding, Applying and Not Misusing the Statistical Techniques Used in Clinical Trials. San Diego, CA. Feb 1999.
100. Genetic Risk of Breast Cancer Based on Family History and Decision Making of Genetic Testing. American Society of Clinical Oncology Train-the-Trainer Workshop. New Orleans, LA. Mar 1999.
101. Statistical Inference and the Law. Eastern North American Region of the International Biometric Society. Atlanta, GA. Mar 1999.
102. Using Surrogate Endpoints in Clinical Trials. Institute of Mathematical Statistics. Atlanta, GA. Mar 1999.
103. Biomarkers and Surrogate Endpoints in Cancer Prevention Studies. Biomarkers and Surrogate Endpoints: Advancing Clinical Research and Applications. US Public Health Service. Washington, DC. Apr 1999.
104. Bayesian Designs for Pharmaceutical Studies. Henry Stewart Conference on Mathematical and Statistical Techniques in Clinical Trials. Frankfurt, Germany. Apr 1999.
105. Scientific Inference in Cases of Suspected Athlete Drug Abuse. Duke International Conference on Doping. Durham, NC. May 1999.
106. Conventional- Vs High-Dose Therapy for Metastatic Breast Cancer: Comparison of Cancer and Leukemia Group B and Blood and Marrow Transplant Registry Patients. American Society of Clinical Oncology. Atlanta, GA. May 1999.
107. Statistical Overview of Bone Marrow Transplantation in Breast Cancer. American Society for Blood and Marrow Transplantation. Atlanta, GA. May 1999.
108. Bayesian Designs for Clinical Trials. Schering-Plough/Harvard Workshop on Bayesian Inference in Clinical Trials. Cambridge, MA. Jun 1999.
109. Sequential Methods in Clinical Trials. Biostatistics section of the Statistical Society of Canada. Regina, Saskatchewan, Jun 1999.
110. The Bayesian Approach in the Design of Clinical Trials. Drug Information Association. Tokyo, Japan. Aug 1999.
111. Bayesian Approaches to Sample Size Determination. Joint Statistical Meetings. Baltimore, MD. Aug 1999.
112. Quantifying Evidence in Clinical Trials: A Bayesian Perspective. Joint Statistical Meetings. Baltimore, MD. Aug 1999.
113. Bayesian Designs for Dose-Ranging Drug Trials. Case Studies in Bayesian Statistics Workshop V. Pittsburgh, PA. Sep 1999.
114. Relevance of HER-2/neu Expression for Chemotherapy in Breast Cancer. National Cancer Institute Symposium on HER-2/neu. Washington, DC. Oct 1999.
115. Using Bayesian Methods in Drug and Medical Device Development. Foundational Issues and Their Practical Impact on Survey Sampling and Medical Statistics. Bibbiena, Italy. Oct 1999.
116. Using Bayesian Methods to Put Efficacy and Safety Data in Perspective. PhRMA. Bethesda, MD. Nov 1999.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

117. Bayesian Designs for Pharmaceutical Studies. Henry Stewart Conference on Mathematical and Statistical Techniques in Clinical Trials. Washington, DC. Nov 1999.
118. Using Surrogate Endpoints in Clinical Trials. Henry Stewart Conference on Understanding, Applying and Not Misusing the Statistical Techniques Used in Clinical Trials. Washington, DC. Nov 1999.
119. Using Bayesian Methods in Clinical Trials. Biotechnology 99: Medical Applications of Biotechnology. Havana, Cuba. Nov 1999.
120. Recent Innovations in Clinical Trials. International Conference on Medical Statistics. Oberwolfach, Germany. Feb 2000.
121. When Should They Be Repeated? Conference on Ethical and Value Issues in Clinical Trials. Birmingham AL. Feb 2000.
122. Politics and the Conduct and Interpretation of Clinical Trials: Mammography Screening for Women in Their 40s. Eastern North American Region of the International Biometric Society. Chicago, IL. Mar 2000.
123. Adaptive Designs for Dose Finding and Drug Development. American Society for Clinical Pharmacology and Therapeutics. Los Angeles, CA. Mar 2000.
124. Predictive Probabilities and Data Safety Monitoring Boards. Duke Clinical Research Institute IRB Think-Tank Conference. Durham, NC. May 2000.
125. Recent Developments on the Bayesian Biostatistics Front. Midwest Biopharmaceutical Statistics Workshop. Muncie, IN. May 2000.
126. Using a Bayesian Approach in Drug and Medical Device Development. Joint Statistical Meetings. Indianapolis, IN. Aug 2000.
127. Using the Bayesian Approach in Medical Research and Clinical Trials. Bayesian Workshop of National Institute of Environmental Health Services. Washington, DC. Sep 2000.
128. Innovative Bayesian Designs in Clinical Trials. U.S. Army Conference in Applied Statistics. Rice University, Houston, TX. Oct 2000.
129. Using the Bayesian Approach in Phase II and III Clinical Trials. American Association of Pharmaceutical Sciences. Indianapolis, IN. Oct 2000.
130. Statistical Modeling of Genetics and Screening in Breast Cancer. Cancer Genetics Network Workshop. Houston, TX. Nov 2000.
131. Innovative Bayesian Designs in Clinical Trials. Foundations of Statistical Inference: Applications in Medicine, Social Sciences, and Industry, and the Interface with Computer Science. Jerusalem, Israel. Dec 2000.
132. Role of Clinical Trials in Breast Cancer Research and Treatment. Helene Harris Memorial Trust, 8th Biennial International Forum on Ovarian Cancer. Houston, TX. Mar, 2001.
133. Medical Device Development: Taking a Bayesian Perspective. Society for Clinical Trials. Denver, CO. May 2001.
134. Innovations in Clinical Trial Design and Drug Development Strategies. National Academy of Sciences, Institute of Medicine. Washington, DC. Oct 2001.
135. Novel Clinical Trial Design and Implementation. M D Anderson Clinical Conference. Houston TX. Jan 2002.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

136. Bayesian Statistics and Decision Analysis in Medical Research. First Latin American Bayesian Congress and International Society of Bayesian Analysis. Ubatuba, Sao Paulo, Brazil. Feb 2002.
137. Decision Analysis in the Pharmaceutical Industry. Eastern North American Region of the International Biometric Society. Washington, DC. Mar 2002.
138. Innovations in Clinical Trial Design. American Society of Experimental Neurotherapeutics. Washington, DC. Mar 2002.
139. The Screening Mammography Controversy: Science, Politics and the Press . . . and Women in the Middle. Conference of Texas Statisticians. Houston, TX. Apr 2002.
140. Adaptive Randomization in Clinical Trials: Learning while Delivering Better Treatment. Midwest Biopharmaceutical Statistics Workshop. Muncie, IN. May 2002.
141. Bayesian Adaptive Designs and Monitoring Schemes. Schering-Plough/Harvard Workshop on Emerging Strategies in Designing and Monitoring Clinical Trials. Cambridge, MA. May 2002.
142. Assessing the Benefits and Risks of Mammographic Screening. Global Summit on Mammographic Screening. Milan, Italy. Jun 2002.
143. Bayesian Adaptive Designs. Drug Information Association. Chicago IL. Jun 2002.
144. Statistical Considerations for Using Biomarkers: In the Clinic & Clinical Trials. NCI-EORTC Conference in Tumor Markers. Washington, DC. Jun 2002.
145. Do Mammograms Save Lives? The Future of Breast Cancer: An International Breast Cancer Congress. Bahamas. Jul 2002.
146. Bayesian Approaches to Safety Analyses. Joint Statistical Meetings. New York, NY. Aug 2002.
147. Keynote Address on Cancer Prevention, Control and Epidemiology. Cancer Symposium of the University of California. Sacramento, CA. Sep 2002.
148. The Benefits and Risks of Screening Mammography. Mayo Clinic Medicine and Media Conference. Rochester, MN. Sep 2002.
149. The Promise and Reality of Biomarkers: Hopeful but Cautionary Tales. An Era of Hope in Breast Cancer, sponsored by the U.S. Department of Defense. Orlando, FL. Sep 2002.
150. Risk Trade-offs in Making Decisions about Cancer. American Association of Cancer Research. Boston, MA. Oct 2002.
151. New AJCC Breast Cancer Staging Systems. Trends in Breast Cancer. Boston, MA. Feb 2003.
152. Three-level Hierarchical Modeling of Drug Safety Data. Drug Information Association Biostatistics Workshop. Hilton Head, SC. Mar 2003.
153. Statistical Issues in the Screening Mammography Controversy. Eastern North American Region of the International Biometric Society. Tampa, FL. Mar 2003.
154. Decision Analysis in Clinical Trials. Society of Medical Decision Making. Chicago, IL. Oct 2003.
155. Adaptive Designs for Cancer Clinical Trials. National Coalition for Cancer Survivorship Industry Roundtable. Washington, DC. Nov 2003.
156. If You Want to Publish, Get Your Statistics Right. 4th European Breast Cancer Conference. Hamburg, Germany. Mar 2004.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

157. Early Disclosure of Positive Results of Randomised Trials. 4th European Breast Cancer Conference. Hamburg, Germany. Mar 2004.
158. The Future of Biostatistical Science. Eastern North American Region of the International Biometric Society. Pittsburgh, PA. Mar 2004.
159. Novel Approaches to Data Analysis and Evaluation in Stroke Trials. Baltimore, MD. Stroke Treatment Academic Industry Roundtable. Apr 2004.
160. Basic Bayesian Statistics. FDA/Johns Hopkins Workshop on Bayesian Approaches for Regulatory Decisions. Bethesda, MD. May 2004.
161. Case Study: Spinal Implant PMA. FDA/Johns Hopkins Workshop on Bayesian Approaches for Regulatory Decisions. Bethesda, MD. May 2004.
162. Bayes at the FDA: Efficient Designs and Borrowing Strength. International Society of Bayesian Analysis. Viña del Mar, Chile. May 2004.
163. Data & Safety Monitoring Boards and Early Release of Trial Results. "Meet the Professor." American Society of Clinical Oncology. New Orleans, LA. Jun 2004.
164. Presidential Invited Address, Western North American Region of the International Biometric Society. Albuquerque, NM. Jun 2004.
165. Biomarkers in the Clinical Trial Design for Diagnosis and Early Detection. Joint NCI-FDA Workshop on Research Strategies, Study Designs and Statistical Approaches to Biomarkers Validation for Cancer Diagnosis and Detection. Washington, DC. Jul 2004.
166. Adaptive Clinical Trials. Joint Statistical Meetings. Toronto, Canada. Aug 2004.
167. Bayesian Adaptive Designs and Interim Analyses. FDA/ASA Industry Workshop. Washington, DC. Sep 2004.
168. Adaptive Trial Design: Why, When and How? FDA-PhRMA-DIA Conference on Good Dose-Response—Rewards of Success, Cost of Failure: A Critical Path Opportunity to Focus on Optimizing Benefit/Risk. Arlington, VA. Oct 2004.
169. Innovations in Clinical Trial Design and Analysis. Merck-Temple Conference in Biostatistics. Philadelphia, PA. Oct 2004.
170. Effects of Improvements in Chemotherapy on Disease-free and Overall Survival of Estrogen-receptor Negative, Node-positive Breast Cancer: 20-year Experience of the CALGB & U.S. Breast Intergroup. San Antonio Breast Cancer Symposium. San Antonio, TX. Dec 2004.
171. Advances in Clinical Trial Design Methodology. AAMC/FDA/CDDS Conference on Drug Development Science: Obstacles and Opportunities for Academia, Industry and Government. Washington, DC. Jan 2005.
172. The Vagaries of Using Biomarkers in Early Detection of Cancer. Gordon Conference on New Frontiers in Cancer Detection & Diagnosis. Santa Barbara, CA. Jan 2005.
173. Adaptive Design and Combining Phases: A Bayesian Perspective. Keynote presentation, IBC Conference in Adaptive Designs. Boston, MA. Feb 2005.
174. Clinical Trials Design Challenges Using Biomarker Stratification. NCI/FDA conference: Strategies To Integrate Biomarkers Into Cancer Clinical Trials. Houston, TX. Feb 2005.
175. Biomarkers in Clinical Trial Design: Prognosis and Prediction. IBC Conference in Using Biomarkers in Clinical Research. Boston, MA. Mar 2005.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

176. Bayesian Inference in Pharmaceutical Research. Midwest Biopharmaceutical Statistics Workshop. Muncie, IN. May 2005.
177. Bayesian Approaches in Multiplicities. OBayes: International Conference on Objective Bayesian Methods. Branson, MO. Jun 2005.
178. Clinical Trials of the Future. Era of Hope. Philadelphia, PA. Jun 2005.
179. Bayesian Methods in Clinical Research: Collecting and Using Information Effectively. Society of Toxicology. Washington, DC. Jul 2005.
180. Incorporating Biological Information in Hierarchical Modeling of Many Genetic Disease Markers and Safety Data in Drug Studies. Joint Statistical Meetings. Minneapolis, Minnesota. Aug 2005.
181. Proof of Concept Trials in Pharmaceutical Research. Joint Statistical Meetings. Minneapolis, Minnesota. Aug 2005.
182. Bayesian Trial Design: Drug Case Study. FDA/Industry Biopharm Workshop. Washington, DC. Sep 2005.
183. Proof of Concept Trials in Pharmaceutical Research. The Austrian-Swiss Region (ROeS) of the International Biometric Society (IBS), Graz, Austria. Sep 2005.
184. Innovative Clinical Trial Designs in Prostate Cancer Research. Prostate Cancer Foundation Scientific Retreat. Phoenix AZ. Oct 2005.
185. Bayesian Adaptive Designs for Clinical Trials. IBC Conference in Implementing Adaptive Designs for Drug Development. Princeton, NJ. Nov 2005.
186. Biomarkers and Clinical Trials. Consensus Conference. National Breast Cancer Coalition. Philadelphia PA. Nov 2005.
187. Adaptive Clinical Trials. Forum on Drug Discovery, Development, and Translation. Institute of Medicine. Washington, DC. Dec 2005.
188. Challenges in the Implementation of a New Paradigm in Oncology Development, Part I: Adaptive Study Design. Pharmaceutical Education and Research Institute on Changing the Paradigm in Oncology Drug Development. Washington, DC. Feb 2006.
189. Continuum of Clinical Drug Development. International Conference on Drug Development. Austin, TX. Feb 2006.
190. How Should We Evaluate Adjuvant Breast Cancer Data? European Breast Cancer Conference. Nice, France. Mar 2006.
191. Statistical Issues in the Design, Evaluation, and Monitoring of Clinical Trials with Longitudinal and Survival Endpoints. Eastern North American Region of the International Biometric Society. Tampa, FL. Mar 2006.
192. Bayesian Approaches to Phase II/III Clinical Trials. IBC Conference in Adaptive Designs. Brussels, Belgium. Apr 2006.
193. Weaknesses and Strengths of a Bayesian Approach in Clinical Research. Biostatistics Presidents' Special Invited Speaker at the Canadian Statistical Society 2006 Annual Meeting. London, Ontario, Canada. May 2006.
194. Bayesian Designs for Clinical Trials. Society for Clinical Trials. Orlando, FL. May 2006.
195. Commentary on Sarcoma Trials. American Society of Clinical Oncology. Atlanta, Ga. Jun 2006.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

196. Innovative and Efficient Bayesian Designs for Clinical Trials. Drug Information Association. Philadelphia, PA. Jun 2006.
197. Bayesian Designs in Oncology. Drug Information Association. Philadelphia, PA. Jun 2006.
198. Utilizing Bayesian Methods to Create Optimal Trial Designs. ExLpharma Workshop on Trial Design Innovation: Administering Safer Drugs Faster with Adaptive Trials. Washington, DC. Jul 2006.
199. Bayesian Minefields: Multiplicities. Workshop of the Statistical and Applied Mathematical Sciences Institute. Durham, NC. Jul 2006.
200. Decision Analysis and Clinical Trial Design. Joint Statistical Meetings. Seattle, WA. Aug 2006.
201. Novel Clinical Trial Designs in Cancer Research. American Society of Clinical Oncology Breast Cancer Retreat. Aspen, CO. Aug 2006.
202. Just How Flexible Can a Prospective Clinical Trial Be? FDA/Industry Statistics Workshop. Washington DC. Sep 2006.
203. Bayesian Clinical Trials. International Workshop on Statistical Methodology in Clinical R&D. Drug Information Association. Heidelberg, Germany. Oct 2006.
204. Efficient Designs for Lupus Clinical Trials. Lupus Clinical Trials Consortium. Princeton, NJ. Oct 2006.
205. Adaptive Designs in Drug Development. PhRMA/FDA Workshop on Adaptive Design. Washington, DC. Nov 2006.
206. Lumpectomy Plus Tamoxifen with or without Irradiation in Women 70 Years of Age or Older with Early Breast Cancer: A Report of Further Follow-up. (Presented by Hughes KS.) San Antonio Breast Cancer Symposium. San Antonio, TX. Dec 2006.
207. A Sharp Decrease in Breast Cancer Incidence in the United States in 2003. (Presented by PM Ravdin) San Antonio Breast Cancer Symposium. San Antonio, TX. Dec 2006.
208. Bayesian Adaptive Designs: How can a Bayesian statistical approach enhance efficiency and interpretability? Conference on the Design, Analysis, & Interpretation of RCT's in Obesity. Newark, NJ. Dec 2006.
209. Statistical Considerations in Preoperative Clinical Trials. National Cancer Institute Meeting on Preoperative Therapy in Invasive Breast Cancer: Reviewing the State of the Science and Exploring New Research Directions. Washington, DC. Mar 2007.
210. Adaptive trial designs: Bayesian approaches. Global HIV Enterprise Clinical Trials Workshop: Approaches to Expediting HIV Vaccine Efficacy Evaluation. New York, NY. Apr 2007.
211. Recent Innovations in Oncology Clinical Trials. American Association of Cancer Research. Los Angeles, CA. Apr 2007.
212. Breast Cancer News: What's Behind the Headlines. Annual Conference of National Breast Cancer Coalition. Apr 2007.
213. Adaptive Design: What's All the Talk About? Annual Conference of National Breast Cancer Coalition. Apr 2007.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

214. Innovative Approaches for Early Drug Development: Disease Models and Novel Trial Design. Frontiers Symposium of American College of Clinical Pharmacology. Baltimore, MD. May 2007.
215. Overview of Meta-analysis Methods: Advantages and Limitations. The Workshop, Council for Responsible Nutrition's Day of Science: Dietary Supplements and the Evidence-based Medicine Paradigm. Washington, DC. May 2007.
216. Dealing with Heterogeneity and Subpopulations in Clinical Trials. HIV Vaccine Trials Network. May 2007.
217. What Are Adaptive Trial Designs and How Can They Greatly Improve Drug Development? American Society of Clinical Oncology. Chicago, IL. Jun 2007.
218. Bayesian Approaches. Alliance for Microbicide Development Alternative Trials Meeting. Arlington, VA. Jul 2007.
219. Progress in Using Adaptive Designs for Clinical Trials. Joint Statistical Meetings. Salt Lake City, UT. Aug 2007.
220. Applications of Adaptive Designs, Including Seamless Phase 2b/3 Trials. Drug Development Science: A Critical Path Update. American College of Clinical Pharmacology Annual Meeting. San Francisco, CA. Sep 2007.
221. Drug and Device Safety Issues: A Bayesian Perspective. FDA/Industry Statistics Workshop. Arlington, VA. Sep 2007.
222. Bayesian Designs. NIH/NIA Methodological Issues in Randomized Clinical Trials in the Elderly 2007. Bethesda, MD. Sep 2007.
223. Adaptive Clinical Trials. Institute of Medicine Workshop on Improving the Quality of Cancer Clinical Trials. Washington, DC. Oct 2007.
224. High-Dose Chemotherapy with Autologous Stem-Cell Support Versus Standard-Dose Chemotherapy: Meta-Analysis of Individual Patient Data from 15 Randomized Adjuvant Breast Cancer Trials. San Antonio Breast Cancer Symposium. San Antonio, TX. Dec 2007.
225. Adaptive Design of Trials involving Cancer Stem Cells as Markers. Cancer Stem Cell Workshop of the National Cancer Institute. Bethesda, MD. Jan 2008.
226. Bayesian Biostatistics. Opening address at Bayesian Biostatistics 2008. Houston, TX. Jan 2008.
227. Biostatistics, Science, and the Public Eye. Presidential Invited Address, Eastern North American Region of the International Biometric Society. Arlington, VA. Mar 2008.
228. Noninferiority Clinical Trials. Eastern North American Region of the International Biometric Society. Arlington, VA. Mar 2008.
229. Ethics and Clinical Trials. Ethics and Compliance in Oncology Research (ECOR). Houston, TX. Apr 2008.
230. Data Safety Monitoring Boards. Ethics and Compliance in Oncology Research (ECOR). Houston, TX. Apr 2008.
231. So What's New in Breast Cancer? Annual Conference of the National Breast Cancer Coalition. Washington, DC. Apr 2008.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

232. Statistical Science & Decision-making. University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials: From Bench to Bedside to Community. Philadelphia, PA. Apr 2008.
233. Adaptive Trial Designs: Past, Present, and Future. Third Annual Developmental Therapeutics Symposium. New York Cancer Consortium. New York NY. May 2008.
234. Combining Lung Cancer Screening Trials. Harvard/Schering-Plough Workshop in Biostatistics. Cambridge MA. May 2008.
235. Discussion of "Prediction of Survival Benefits from Progression-free Survival in Patients with Advanced Non-small Cell Lung Cancer: Evidence from a Pooled Analysis of 2,838 Patients Randomized in 7 trials," by Marc E Buyse. American Society of Clinical Oncology Meeting. Chicago IL. Jun 2008.
236. Adaptive Clinical Trial Design. Era of Hope, sponsored by the U.S. Department of Defense. Baltimore MD. Jun 2008.
237. Building Cancer Risk Models Using Multifarious Complex Data Sources: Exploiting the Elegance of Bayes. Joint Statistical Meetings. Denver CO. Aug 2008.
238. SLC Consensus on Research Priorities in Genomics Stakeholder. Scientific Leadership Council in Breast Cancer. Dallas TX. Sep 2008.
239. Molecular Marker Driven Trial Design. Third Annual AACR International Conference on Molecular Diagnostics in Cancer Therapeutic Development. Philadelphia PA. Sep 2008.
240. Modeling Outcomes of Cancer Therapy. Brookings Conference on Clinical Cancer Research. Washington DC. Sep 2008.
241. Adaptive Phase II Trials. EORTC-NCI-AACR symposium on Molecular Targets and Cancer Therapeutics, Geneva, Switzerland. Oct 2008.
242. Adaptive Trials for Phase II and III Studies in Oncology. Phacilitate Oncology Leaders' Forum. San Diego CA. Oct 2008.
243. Keynote Address: New Developments in Bayesian Clinical Trials. Biopharmaceutical Applied Statistics Symposium (BASS) XV. Savannah GA. Nov 2008.
244. High-dose chemotherapy with autologous stem-cell support versus standard-dose chemotherapy: meta-analysis of individual patient data from 6 randomized metastatic breast cancer trials. (Joint with NT Ueno, MM Johnson, X Lei, D Smith, J Caputo, L Yancey, M Bregni, T Demirer) San Antonio Breast Cancer Symposium. San Antonio, TX. Dec 2008.
245. Bayesian Biostatistics. Opening address at Bayesian Biostatistics 2009. Houston, TX. Jan 2009.
246. Adaptive Trial Designs to Facilitate Identifying Effective Therapies and Their Associated Predictive Markers. The Breast Cancer Intergroup of North America Correlative Science Summit. Washington, DC. Feb 2009.
247. Clinical Research Using Biomarkers. NCI Latin American Breast Cancer Pilot Project. Washington, DC. Mar 2009.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

248. Keynote Address: Clinical Trials and Biomarkers in Improving Outcomes: Focus on Breast Cancer. Joint Workshop of Cancer Intervention and Surveillance Modeling Network and Integrative Cancer Biology Program. Washington, DC. Mar 2009.
249. High- vs Standard-Dose Chemotherapy with Stem Cell Support in Breast Cancer: Metaanalyses of 15 Adjuvant Trials and 6 Metastatic Trials. Annual Meeting of The European Group for Blood and Marrow Transplantation. Goteborg, Sweden. Mar 2009.
250. Bayesian Statistics in Medical Device Clinical Trials. AdvaMed/FDA Conference on Statistical Issues for Medical Devices and Diagnostics. Washington, DC. Apr 2009.
251. Discussion of Developmental Therapeutics: Cytotoxic Chemotherapy. American Society of Clinical Oncology. Orlando, FL. Jun 2009.
252. Use and Interpretation of Bayesian Methods in Design and Analysis of Clinical Trials. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) at the Centers for Medicare & Medicaid Services (CMS): Bayesian vs. frequentist statistics: Applying these approaches to coverage decisions. Baltimore, MD. Jun 2009.
253. Statistics and The New York Times. (Joint with Gina Kolata.) Joint Statistical Meetings. Washington, DC. Aug 2009.
254. Bayesian Approaches to Missing Data. National Academy of Sciences Workshop in Missing Data. Sep 2009.
255. Adaptive Designs in Clinical Trials. International Society for CNS Drug Trials and Methodology (ISCTM). San Diego, CA. Oct 2009.
256. Population Breast Cancer Mortality Reductions: Screening or Treatment? Canadian Breast Cancer Research Foundation: It's About Time! Toronto, Canada. Oct 2009.
257. Innovative Clinical Trial Designs. 60th Anniversary Celebration of Department of Biostatistics at the University of North Carolina, Chapel Hill. Oct 2009.
258. Small Trials for Small Patients. FDA Workshop on Pediatric Clinical Trials. Washington, DC. Oct 2009.
259. Cancer Vaccine Clinical Trial Design Issues. FDA-NCI Workshop on Therapeutic Cancer Vaccines. Washington, DC. Oct 2009.
260. Adjuvant Tamoxifen Treatment Outcome According to Cytochrome P450 2D6 (CYP2D6) Phenotype in Early Stage Breast Cancer. San Antonio Breast Cancer Symposium. (Joint with M. Goetz and T. Klein, presented by M. Goetz.) San Antonio, TX. Dec 2009.
261. Benefits of Adding Paclitaxel to Adjuvant Doxorubicin/Cyclophosphamide in Node-Positive Breast Cancer Depending on HER2 & ER Status: Analysis of Tumor Tissue Microarrays and Immunohistochemistry in CALGB 9344 (Intergroup 0148). San Antonio Breast Cancer Symposium. (Joint with AD Thor, SD Jewell, G Broadwater, SM Edgerton, DF Hayes, CA Hudis, EP Winer, TO Nielsen, MJ Ellis.) San Antonio, TX. Dec 2009.
262. I-SPY 2: A Biomarker-Driven, Adaptive Bayesian Phase II Drug-Screening Clinical Trial. Bayesian Biostatistics 3. Houston, TX. Jan 2010

263. Bayesian Clinical Trials for Orphan Products. FDA Workshop on Orphan Drugs. Feb 2010.
264. Decision Analysis in Clinical Research. Berger Conference in Statistics. San Antonio, TX. Mar 2010.
265. (1) The Screening Mammography Brouhahas and (2) Adaptive Clinical Trials. Dana-Farber Cancer Institute/Frontier Science and Technology Research Foundation Annual Lecture on Biostatistics in Cancer. Sponsored by the Friends of DFCI, Cambridge, MA. Mar 2010.
266. Statistics in 2025. Eastern North American Region of the International Biometric Society. New Orleans, LA. Mar 2010.
267. Statistical Issues in Breast Cancer Research. Donna J. Brogan Annual Lecture at Emory University, Atlanta, Georgia. Apr 2010.
268. Adaptive Clinical Trials in Cancer Research: Focus on the I-SPY2 Trial. American Association for Cancer Research. Washington, DC. Apr 2010.
269. Bayesian Approaches to Comparative Effectiveness Research. Workshop on Statistical Issues in Comparative Effectiveness Research. University of Pennsylvania. Philadelphia PA. Apr 2010.
270. Innovative Clinical Trial Design in Early Drug Development. 23d International Symposium on Cancer. Tokyo, Japan. Apr 2010.
271. Adaptive Designs and Personalized Medicine in Clinical Trials. Biomedical Research Centres (BRC) of UK National Institute of Health Research, London, England. May 2010.
272. How to Design Innovative Trials for Targeted Agents. IMPAKT IMProving CAre and Knowledge through Translational Research 2010 Breast Cancer Conference. Brussels, Belgium. May 2010.
273. Neoadjuvant statistical designs. 2010 Annual Meeting of BIG-NABCG (Breast International Group and North American Breast Cancer Group). Brussels, Belgium. May 2010.
274. Innovative Clinical Trials in Neurological Oncology. American Society of Clinical Oncology (ASCO). Jun 2010.
275. Adaptive Biomarker-driven Clinical Trials. The Twenty-fifth Aspen Cancer Conference: Mechanisms of Toxicity, Carcinogenesis, Cancer Prevention and Cancer Therapy 2010. Aspen CO. Jul 2010.
276. Adaptive Factorial Designs for Combination Therapy in Oncology. Joint Statistical Meetings. Vancouver, BC, Canada. Aug 2010.
277. Statistical Perspective on Clinical Trial Design: Small ‘n’ Trials. FDA, NIH, AAP, & ACC Workshop on Optimizing Clinical Trial Design for Pediatric Cardiovascular Devices. San Francisco, CA. Sep 2010.
278. Statistical Evidence Regarding the Benefits and Limits of Screening Mammography. American College of Surgeons' 96th Annual Clinical Congress. Washington, DC. Oct 2010.
279. Bayesian Adaptive Approaches to Proof of Concept. Cambridge Healthtech Institute’s Accelerating Proof-of-Concept meeting. Philadelphia, PA. Oct 2010.
280. Building Efficient, Informative, Biomarker-Based Clinical Trials. Policy Roundtable of the National Coalition for Cancer Survivorship. Washington, DC. Oct 2010.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

281. Adaptive Clinical Trials: A New Paradigm in Drug Development. Interesting Times: The Academic Contribution to Drug Development in an Era of Reform. Institute for Translational Medicine and Therapeutics. University of Pennsylvania, Philadelphia, PA. Oct 2010.
282. I-SPY2 Overview and Creative Clinical Trial Design. Ruesch Scientific Symposium on Personalized Medicine and the Cure for Cancer. Georgetown University, Washington, DC. Nov 2010.
283. Keynote Address. Innovative and Efficient Drug Development: Endpoints, Examining Different Statistics-based Approaches to Clinical Trial Design Pre-phase III: Which Are Best in Oncology and How to Choose? Phacilitate Oncology Forum. Boston, MA. Nov 2010.Statistical Methods for Trials of Orphan Products and Rare Diseases. Bayesian Biostatistics 4. Houston, TX. Jan 2011.
284. Biomarkers, Imaging, and Adaptive Designs. Strategies for Clinical Oncology Drug Development, Cambridge Health Institute. San Francisco, CA. Feb 2011.
285. Designing Informative Clinical Trials for Personalized Medicine. Personalized Medicine: Principles to Practice. A Symposium of Nature Reviews Drug Discovery, Nature Medicine and the Association of Clinical Pharmacology and Therapeutics. Dallas, TX. Mar 2011.
286. Adaptive Designs for Time-to-event Clinical Trials. 9th Annual ASA Connecticut Chapter Conference on Analysis of Time-to-event Data. Danbury, CT. Mar 2011.
287. Adaptive Clinical Trials in Oncology: A Necessary Step. Twenty-Second Annual Cancer Progress Conference. Communitech. New York City, NY. Mar 2011.
288. I-SPY 2 and Personalized Medicine. Alexandria Forum. New York City, NY. Apr 2011
289. Adaptive Designs in Drug Development. SAS Health Leader Symposium. May 2011.
290. Development of Drugs for Personalized Medicine. FDA, AACR, ASCO, NCI, Duke Workshop on Accelerating Anticancer Agent Development and Validation. Washington, DC. May 2011.
291. Personalized Medicine in Clinical Trials. Case Comprehensive Cancer Center. Cleveland, OH. May 2011.
292. Lung Cancer Clinical Trial Design: Targeted Agents & Enriched Patient Subgroups. National Lung Cancer Partnership. Chicago IL. Jun 2011
293. Adaptive Clinical Trials in Cancer Research. Sarcoma Alliance for Research through Collaboration. Chicago, IL. Jun 2011
294. Workshop on Facilitating Collaborations to Develop Combination Investigational Cancer Therapies. Institute of Medicine. Washington, DC. Jun 2011
295. Adaptive Clinical Trials. Grand Rounds, University of Cincinnati, College of Medicine. Cincinnati OH. Jun 2011.
296. Are there better ways to analyze clinical trial data? Alzheimer's Association Research Roundtable. Washington, DC. Jun 2011.
297. Adaptive Study Designs in Emergency Pandemic Research. Colloquium on Pandemic Research Preparedness. Toronto, Canada. Jun 2011.
298. Adaptive Clinical Trials. Grand Rounds, Medical Oncology and Hematology Grand Rounds, Columbia University. New York, NY. Jun 2011.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

299. Using biomarkers prospectively in adaptive trials. Worldwide Innovative Network in Personalized Therapy. Paris, France. Jul 2011
300. Contributions of Joseph B. Kadane. Joint Statistical Meetings. Miami, FL. Aug 2011.
301. A Reality Check: Early Detection. Sixth Era of Hope Conference. Orlando, FL. Aug 2011.
302. There's Adaptive, but then there's Really Adaptive! The Past, Present, and Future of Innovative Designs in Clinical Trials. Design of Experiments in Healthcare. Isaac Newton Institute for Mathematical Sciences. Cambridge University. Cambridge, England. Aug 2011.
303. Considerations for Trials of Combination Therapy. International Melanoma Working Group. New York City. Sep 2011.
304. Using Biomarkers Prospectively in Adaptive Clinical Trials. Clinical Trials Methodology Conference of the Medical Research Council. Bristol, England. Oct 2011.
305. The Target, the Drug, the Patient, the Dose: Adaptive Clinical Trial Designs. Targets, Tissues and Trials. Molecular Therapeutics for Cancer Ireland. Dublin, Ireland, Oct 2011.
306. Clashes among Randomized Trials, Modeling, Politics and Common Sense: The Case of Screening Mammography. The Mater 14th International Breast Cancer Meeting. Dublin, Ireland, Oct 2011.
307. Adaptive Clinical Trial Design in the Molecular Era. The Mater 14th International Breast Cancer Meeting. Dublin, Ireland, Oct 2011.
308. Using Genomic Signatures in Adaptive Clinical Trials. Statistical and Quantitative Issues in Genomic Medicine. Harvard School of Public Health Program in Quantitative Genomics. Cambridge, MA. Nov 2011.
309. Innovative Methodologies for Expedited Evidence Development. Expert Workshop: An Expedited Drug Development Pathway for Promising Therapies. Engelberg Center for Health Care Reform, Brookings Institution. Washington, DC. Dec 2011.
310. Increasing Clinical Program Success with Modeling and Simulation. Drug Information Association. Miami, FL. May 2012.
311. Overdiagnosis of Cancer. NCI Workshop on Natural History of Disease. Washington, DC. Mar 2012.
312. I-SPY2: A Change in the Landscape of Targeted Drug-biomarker Development. American Association of Cancer Research, Annual Meeting. Chicago, IL. Apr 2012.
313. Highly Adaptive Trials in Drug Development. American Association of Cancer Research, Annual Meeting. Chicago, IL. Apr 2012.
314. Sixth Annual Distinguished Professor S. James Press Endowed Lecture. University of California at Riverside. Apr 2012.
315. Innovative Designs for Clinical Trials in Neurology. Alexandria Summit. New York City, NY. May 2012.
316. How to Assess the Efficacy of Screening Methods. Columbia University Epidemiology Scientific Symposium: Modern controversies in screening. New York City, NY. May 2012.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

317. Genetics, Biomarkers, and Designing Clinical Trials in Cancer: Application to I-SPY 2. The GARNET Consortium. Rockville, MD. May 2012.
318. Prediction and Simulation in Clinical Trials. Society for Clinical Trials. Miami, FL. May 2012.
319. State-of-the-Art Clinical Trials. National Cancer Institute Workshop on Evolutionary Dynamics in Cancer Therapy. Bethesda, MD. May 2012.
320. The Revised Common Rule: IRB And DSMB Logistics. Session on Possible Impact of the Proposed Changes to the Common Rule on Clinical Trial Practice. American Society of Clinical Oncology, Annual Meeting. Chicago IL. Jun 2012.
321. ISBA Lecture on Bayesian Foundations. Slowly but Surely, Bayesian Ideas Revolutionize Medical Research. International Society for Bayesian Analysis. Kyoto, Japan. Jun 2012.
322. Prediction and Simulation in Clinical Trials. Drug Information Association. Philadelphia PA. Jun 2012.
323. "Innovative, Biomarker-driven Designs for Lymphoma Clinical Trials" Pan Pacific Lymphoma Conference. Maui HI. Jul 2012.
324. Introductory Overview Lecture. Adaptive Design and Personalized Medicine: The Future Is Now. Joint Statistical Meetings. San Diego, CA. July 2012.
325. Biomarkers and Adaptive Designs. FDA/Industry Statistics Workshop. Washington, DC. Sep 2012.
326. Adaptive Biomarker Trial Designs: I-SPY 2 and Beyond. Fourth Annual ADAPT Congress. Washington, DC, Sep 2012.
327. An Overview of the Adverse Effects of Screening. 4th PNOC International Breast Cancer Conference. Jeddah, Saudi Arabia. Oct 2012.
328. Breast Cancer Screening: Controversy of Impact. 4th PNOC International Breast Cancer Conference. Jeddah, Saudi Arabia. Oct 2012.
329. Adaptive Biomarker Trial Designs: I-SPY 2 and Beyond. American Society for Radiation Oncology. Boston, MA. Oct 2012.
330. Trial Sample Size and Decision Analysis. FDA Workshop on The Science of Small Clinical Trials. Washington, DC. Nov 2012.
331. I-SPY 2: An Adaptive Trial Too Complicated for IRBs? PRIM&R's 2012 Advancing Ethical Research Conference: Guided by Principles in an Era of Change. San Diego, CA. Dec 2012.
332. What Would You Do with the FDA? Forbes Healthcare Summit. New York City, NY. Dec 2012
333. "Mind-Bending Presentation:" Designing and Implementing Biomarker Driven Clinical Trial: Reflections on the ISPY-2 and other Experiences – Can this be Generalized? Conference for Designing, Constructing and Implementing a Standards-based End-to-End System for Biomarker Development. National Biomarker Development Alliance Workshop. Phoenix AR. Dec 2012.
334. Adaptive Design and Personalized Medicine: The Future is Now. Barcelona Bayesian Biostatistics Conference. Barcelona, Spain. Dec 2012.
335. Adaptive Phase II Study Designs. Gynecologic Oncology Group Educational Symposium "Ovarian Cancer—The Front Line." San Diego, CA. Jan 2013.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

336. Informative, Efficient Clinical Trials for Personalized Medicine: I-SPY 2 and BATTLE and Beyond. Molecular Med Tri-CON 2013. San Francisco, CA. Feb 2013.
337. Adaptive Trial Design Using Surrogate Outcomes. 17th Annual International Congress on Hematologic Malignancies – Focus on Leukemias, Lymphomas, and Myeloma. New York City, NY. Feb 2013.
338. Adaptive Clinical Trials, with Focus on Biomarkers. American Society of Clinical Pharmacology and Therapeutics. Indianapolis, IN. Mar 2013.
339. Breast cancer screening: Controversy of impact. 13th International St. Gallen Breast Cancer Conference. St. Gallen, Switzerland. Mar 2013.
340. Adaptive Designs for Biomarker-Driven Trials: The Future of Cancer Clinical Research. Grand Rounds, University of Texas Medicine, Health Science Center San Antonio. San Antonio, TX. Mar 2013.
341. Using Surrogate Endpoints in Adaptive Clinical Trials. Hematology/Oncology Grand Rounds. Memorial Sloan-Kettering Cancer Center. New York City, NY. Apr 2013.
342. Adaptive Designs in Clinical Trials. Therapy Development for Neuromuscular Diseases: Translating Hope Into Promise, a Muscular Dystrophy Association Scientific Conference. Washington, DC. Apr 2013.
343. Poolability Issues in Clinical Trials. 6th Annual FDA/MTLI Medical Device and IVD Statistical Issues Meeting. Washington DC. Apr 2013.
344. Adaptive Biomarker-driven Designs with Longitudinal Modeling, Cancer Immunotherapy Consortium. Washington, DC. Apr 2013.
345. Adaptive Trials – Is It Time to Change How We Conduct Clinical Trials? Society of Gynecologic Oncologists of Canada. Toronto, Canada. Apr 2013.
346. How Bayes Is Changing the World of Medicine. Celebrating 50 Years: Yale Statistics. New Haven, CT. Apr 2013.
347. Personalized Medicine and Revolutions in Cancer Clinical Trial Designs. 6th Mildred Scheel Cancer Conference. Bonn, Germany. Jun 2013.
348. Combination Trials: Time to Open a New Front in AD? Washington, DC. May 2013.
349. Keynote Speaker: Adaptive Designs and IRBs. Harvard Catalyst Adaptive Clinical Trial Design. The Harvard Clinical and Translational Science Center's Regulatory Program and Research Ethics. Boston, MA. May 2013.
350. Adaptive Clinical Trial Design. International Chinese Statistical Association. Bethesda, MD. June 2013.
351. Applying Lessons from I-SPY 2 to Alzheimer's Clinical Trials New York Academy of Sciences. New York City, NY. June 2013.
352. Adaptive Clinical Trial Design, Using Biomarkers, and Personalized Medicine in Research. American Association of Colleges of Pharmacy. Chicago, IL. July 2013.
353. Media and Statistics: Of Excellence and Otherwise. Joint Statistical Meetings. Montreal, Canada. Aug 2013.
354. Statisticians, Statistics, and Doping Science: The Case of Andrus Veerpalu. (Session organizer and joint presentation with Krista Fischer.) Late-breaking session. Joint Statistical Meetings. Montreal, Canada. Aug 2013.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

355. "Goldilocks" Phase 3 Trials Evaluating Pathologic Complete Response (pathCR) and Event-free Survival (EFS) in High-risk Primary Breast Cancer. Opportunities and challenges: The new FDA draft guidance for accelerated approval using pCR in breast cancer. FDA-Industry Statistics Workshop. Washington, DC. Sep 2013.
356. Novel Adaptive Trial Designs: Experience with BATTLE and I-Spy 2. The NCI-ABC^2 Scientific Meeting: Improving the Treatment of Glioblastoma. Chantilly, VA. Sep 2013.
357. Innovative Clinical Trial Design. American Society for Radiation Oncology (ASTRO). Atlanta, GA. Sep 2013.
358. Revamping the RCT, Including Integrating Observational Studies. The Second David Sackett Symposium. Niagara Falls, Canada. Sep 2013.
359. Adaptive Designs: Pros and Cons. International Consensus Meeting on Neoadjuvant Treatment of Breast Cancer: Upcoming Challenges. Biedenkopf, Germany. Oct-Nov 2013.
360. The Core of Statistics: Does It Exist. Future of the Statistical Sciences Workshop, The International Year of Statistics: The Statistics2013 Capstone Event. London, UK. Nov 2013.
361. Clinical Trial Design in the Era of Genomic Medicine. Research Advocacy Network. Dallas, TX. Nov 2013.
362. Declines in Breast Cancer Mortality in the Industrialized Countries: What Is Behind it? San Antonio Breast Cancer Symposium. San Antonio, TX. Dec 2013.
363. Robust Experimental Design is Critical for Effective Biomarker Discovery and Development. NBDA Forum: Overview of Biomarkers, Barriers to their Development – and Strategies for Change. National Press Club. Washington, DC. Jan 2014.
364. Scientific Irreproducibility and Irresponsibility. Panel Presentation. President's Council of Advisors on Science and Technology (PCAST). Washington, DC. Jan 2014.
365. Efficient and Adaptive Clinical Trials for Personalized Medicine. Personalised Genomic Medicine and Therapeutic Innovation: The Case of Cancer. SIRIC. Paris, France. Feb 2014.
366. Bayesian Adaptive Clinical Trials: Past, Present, & Future Bayesian Biostatistics and Bioinformatics 2014. Houston, TX. Feb 2014.
367. A Vision for Clinical Trial Designs in the XXI Century: Clinical Perspective – Innovation in the Design of Clinical Studies. International Conference on Drug Development. Austin, TX. Feb 2014.
368. RCT with Sample-Size Re-Estimation Based on pCR Results. Pioneering Statistical Approaches to Accelerate Drug Development through Adaptive Trial Designs. Engelberg Center for Health Care Reform, Brookings Institution. Washington, DC. Mar 2014.
369. Biomarkers and Longitudinal Modelling in I-SPY 2 and I-SPY 3. DIA/FDA Statistics Forum. Washington, DC. Apr 2014.
370. Clinical Trials in the Brave New World of Cancer Research. Major Symposium. American Association for Cancer Research. San Diego, CA. Apr 2014.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

371. Keynote Address: Bayesian Ideas Are (Slowly) Revolutionizing Medical Research—A Personal Perspective. The Ohio State-Cleveland Clinic Foundation-Case Western Reserve Biostatistics Symposium. Columbus, OH. Apr 2014.
372. Optimizing Clinical Trial Results through Novel Design. MPM Capital's 13th Annual Healthcare Leaders Summit. Bal Harbour, FL. May 2014.
373. Guidelines for Biomarker Assays Used in CTEP-Sponsored, Early Phase Clinical Trials. American Society of Clinical Oncology. Chicago, IL. May 2014.
374. Adaptive Multi-arm, Multi-biomarker Clinical Trials: a Bayesian perspective. International Biometric Society. Florence, Italy. Jul 2014.
375. Designing Platform Trials for Antibacterial Agents. NIH/FDA Workshop: The Development of New Antibacterial products. Jul 2014.
376. How and Why the Media Gets It Wrong. Joint Statistical Meetings. Boston, MA. Aug 2014.
377. Longitudinal Modeling and Adaptive Trials. Centre for Innovation in Regulatory Science. Medicines adaptive pathways: A practical strategy to improve patient access to medicines. London, UK. Oct 2014.
378. Adaptive Platform Clinical Trials in Oncology: Focus on I-SPY 2. Keynote Address. 17th Annual Research Retreat. University of Alabama. Birmingham, AL. Oct 2014.
379. Statistical Innovations for Single Agent and Combination Clinical Trials Relevant for Clinical Decision Making. CNS Anticancer Symposium of Society for Neuro-Oncology. Miami, FL. Nov 2014.
380. Let's Revisit and Perhaps Reinvent the Surrogate Endpoint. The Ever-promising but Elusive Surrogate Endpoint: What Will It Take? Workshop of the National Biomarker Development Alliance. Dec 2014.
381. Platform Trials. DIA/FDA Conference on Adaptive Design and Bayesian Statistics. Washington, DC. Feb 2015.
382. Platform Clinical Trials in Oncology and Neurology. Treatment, Clinical Trials, Resistance. Mathematical Biosciences Institute. The Ohio State University. Columbus, OH. Feb 2015.
383. Blurring the Lines: Using Observational Studies to Improve Recruitment in RCTs. Symposium on Health Outcomes Research in an Era of Cost Containment: Improving Efficiency of Interventional Research, Decreasing Costs, Increasing Quality. Centre de Recherche INSERM Epidemiologies et Biostatistique, PRES Sorbonne Paris Cité, France. Mar 2015.
384. Using Microsimulation to Assess the Relative Contributions of Screening and Treatment in Observed Reductions in Breast Cancer Mortality in the United States. Eastern North American Region of the International Biometric Society. Miami, FL. Mar 2015.
385. Innovation in Clinical Trial Design. President's Symposium, Annual Meeting of American Society of Pediatric Hematology/Oncology (ASPHO). Phoenix, AR. May 2015.
386. Project Management of Adaptive Trials. Annual Meeting Drug Information Association. Jun 2015.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

387. Adaptive Study Designs in Phase 1/2 Clinical Trials of Biologics. American Association of Pharmaceutical Scientists National Biotechnology Conference. San Francisco, CA. Jun 2015.
388. Bayesian Adaptive Clinical Trials. International Society of Biopharmaceutical Statistics. Beijing, China. Jun 2015.
389. Exploiting the Media's Obsession with Controversy to Promote Good Science. Joint Statistical Meetings. Seattle, WA. Aug 2015.
390. Clinical trial dose selection through adaptive designs. Joint meeting of American Society for Microbiology (Interscience Conference on Antimicrobial Agents and Chemotherapy, ICAAC) and International Society of Chemotherapy for Infection and Cancer (International Congress of Chemotherapy, ICC). San Diego, CA. Sep 2015.
391. Adaptive Design: Longitudinal Modeling, Clinical Utility Indices, Subgroup Analysis, Evaluating Interactions, Indication Finding. ACTA2015 International Clinical Trial Symposium. Sydney, Australia. Oct 2015.
392. I-SPY 2: Prototype Platform Trial. ACTA2015 International Clinical Trial Symposium. Sydney, Australia. Oct 2015.
393. New Ways to Embed Clinical Trials into Routine Care. ACTA2015 International Clinical Trial Symposium. Sydney, Australia. Oct 2015.
394. Personalised Medicine and the Clinical Trial—Where to Next? ACTA2015 International Clinical Trial Symposium. Sydney, Australia. Oct 2015.
395. Reinventing Clinical Trials: Application to GBM AGILE. Keynote address at Society of Neuro-Oncology Scientific Meeting. San Antonio, TX. Nov 2015.
396. Multi-armed Bandits and Clinical Trials: Present and Future. Multi-armed Bandit Workshop 2016 at STOR-i, Lancaster University, UK. Jan 2016.
397. Adaptive Platform Trials: The Future of Clinical Research. Eastern North American Region of the International Biometric Society. Austin, TX. Mar 2016.
398. The Brave New World of Cancer Clinical Trials: Learning Who Benefits from What? Eastern North American Region of the International Biometric Society. Austin, TX. Mar 2016.
399. Bayes, Modeling, Clinical Trials, and Delivering Good Medicine to Patients. International Society of Bayesian Analysis. Sardinia, Italy. Jun 2016.
400. Contributions of Kathryn Chaloner. International Society of Bayesian Analysis. Sardinia, Italy. Jun 2016.
401. Meta-analyses and Innovative Clinical trials: The Present and Future of Breast Cancer Research. Symposium on Computational Biology—Developing Therapy for the Next Generation of Patients. Mayo Clinic, Rochester, MN. Jul 2016.
402. Can Statisticians Enlist the Media to Successfully Change Policy? Joint Statistical Meetings. Chicago, IL. Jul 2016.
403. Adaptive Biomarker-driven Platform Clinical Trials Using Longitudinal Models and Time Trend Models of Control Therapy. Symposium on Statistical and Computational Methods for Pharmacogenetic Epidemiology of Cancer. Memorial Sloan Kettering Cancer Center. New York, NY. Aug 2016.
404. Minimal Residual Disease as a Surrogate Endpoint in Hematologic Cancer Trials. Washington, DC. Duke-Margolis Center for Health Policy. Sep 2016.
405. The Future of Cancer Clinical Trials. ASNO-COGNO. Sydney, Australia. Sep 2016.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

406. The Role of Novel Trial Designs and Adaptive Designs in Community-Based Research. American Society of Clinical Oncology, 2016 Research Community Forum Annual Meeting. Alexandria, VA. Sep 2016.
407. Introducing Decision-Making Under Uncertainty to Medical Research: Designing More Efficient and More Accurate Clinical Trials. Optimization and Decision-Making Under Uncertainty. University of California. Berkeley, CA. Sep 2016.
408. Reinventing the Clinical Trial. Fortune Brainstorm HEALTH. San Diego, CA. Nov 2016.
409. Adaptive Trials, Platform Trials, Master Protocols and Beyond: Pathways to Transformation – or Not? Partnering for Cures. FasterCures: A Center of the Milken Institute. New York City, NY. Nov 2016.
410. Biomarkers and Innovations in Clinical Trial Designs: The Future of Clinical Research. Radboud New Frontiers in Cancer Research: Bridging the Gap between Biology and Daily Practice. Nijmegen, The Netherlands. Nov 2016.
411. Adaptively randomized multi-arm platform clinical trial: GBM AGILE. American Association of Cancer Research. Washington DC, Apr 2017.
412. Understanding Clinical Trials in Oncology. American Association of Cancer Research. Washington DC, Apr 2017.
413. I-SPY 2 and Its Clones in Cancer Research. Platform Trial Coalition and Workshop. Boston MA. May 2017.
414. ASCO poster. Jun 2017.
415. Dose Escalations and Designs for Chronically Administered Agents. How to Capture Late Toxicity? Should We Dose-escalate Based on Cycle 1 Safety? Longitudinal modeling in drug development?14th International Conference on Malignant Lymphoma. Lugano, Switzerland. Jun 2017.
416. Innovations in Phase 3 Platform Clinical Trials in Cancer. Biomedical Statistical Modeling. University of Michigan, Ann Arbor, MI. Jun 2017.
417. DIA Annual Meeting. Chicago, IL. Jun 2017.
418. The Need to Accelerate Therapeutic Development—Must Randomized Controlled Trials Give Way? NYU School of Medicine and New York Academy of Sciences. New York City, NY. Mar 2017.
419. Shifting the Clinical Trial Paradigm to Keep Pace with Rapidly Changing Cancer Biology. The 7th WIN Symposium. Paris, France. Jun 2017.
420. Adaptive Platform Trials in Drug Development. Innovative Medicines Initiative (IMI) Workshop on Platform Trials. Brussels, Belgium. Jun 2017.
421. Keynote Address: Precision Medicine. Annual Meeting of the American Neurological Association (ANA). San Diego, CA. Oct 2017.
422. Role of pCR in HER2-positive Breast Cancer. Oct 2017. Stockholm, Sweden.
423. Innovations in Clinical Trials. 2017 AACR Translational Cancer Research for Basic Scientists Workshop. Boston, MA. Oct 2017.
424. MRD as a surrogate end point in acute lymphoblastic lymphoma. Foundation for the National Institutes of Health Cancer Biomarker Consortium. Washington, DC. Nov 2017.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

425. Novel Adaptive Designs for Immunotherapy Trials. ESMO Immuno Oncology Congress. Geneva, Switzerland. Dec 2017.
426. Design Innovations in Precision Promise: Adaptive Platform Clinical Trial in Pancreatic Cancer. The 2nd International Congress on Clinical Trials in Oncology & Hemato-Oncology (ICTO). Berlin, Germany. Feb 2018.
427. Benchmarks of Surrogacy. FDA-IASLC Workshop on Neoadjuvant Therapy in Lung Cancers. Washington, DC. Mar 2018.
428. Innovations in Precision Clinical Trials. Advances in Neuroblastoma Research Precision Medicine Workshop. San Francisco, CA. May 2018.
429. Bayesian Bandit Designs for Clinical Trials. Keynote presentation at the Workshop on Multi-armed Bandits and Learning Algorithms. Erasmus University. Rotterdam, Netherlands. May 2018.
430. Bayesian Baskets and Platforms in Precision Oncology. OncoStat2018. Univ of Chicago. Chicago IL. May 2018.
431. What's New and Transformative in a Phase III Clinical Trial? International Society of Bayesian Analysis. Edinburgh, Scotland. Jun 2018.
432. I-SPY 2. Drug Information Association Conference on Platform Clinical Trials. Washington, DC. Nov 2018.
433. New Classes of Clinical Trial Design. Symposium on Biomarkers from Specimen to Clinical Impact. University of Arizona College of Medicine. Phoenix, AR. Dec 2018.
434. The Science of Doping … or Lack Thereof. The Statistics of Drug Testing in Sport. Royal Statistical Society, Joint Conference of Sections of Statistics & Law and Statistics in Sport. London, UK. April 2019.
435. The Bayesian Revolution in Clinical Trials. The Robert W. Makuch Distinguished Lecture in Biostatistics. Univ of Connecticut. Storrs, CT. May 2019.
436. Innovative Approaches to Clinical Trial Design. Frontiers in Cancer Immunotherapy. New York Academy of Sciences. New York City, NY. May 2019.
437. The Science of Doping, or Lack Thereof. Royal Statistical Society. London, UK. June 2019.
438. PET-CR as a Surrogate Endpoint in DLBCL (poster). 15th International Conference on Malignant Lymphoma. Lugano, SW. June 2019.
439. Re-Imagining Clinical Trials: Platforms and Baskets. Biotechnology Innovation Organization (BIO), I would like to invite you to participate as a speaker on a special program at the 2019 BIO (Biotechnology Innovation Organization) International Convention. Philadelphia, PA. June 2019.
440. MRD as a Surrogate Endpoint in ALL. Cancer Biomarkers Consortium. Foundation for the National Institutes of Health. Washington, DC. July 2019.
441. The Role of Pathologic Complete Response in Breast Cancer. Paradigm Shifts in Early Stage Breast Cancer. Rush University Medical Center. Chicago, IL. Aug 2019.
442. RCTs Are Not the Only Way to Change Practice. 5th World Congress on Controversies in Breast Cancer (CoBrCa). San Francisco, CA. Sept 2019.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

443. Statistical Considerations Regarding the Role of MRD in Hematological Malignancies. National Meeting of the Foundation for the National Institutes of Health. Washington, DC. Nov 2019.
444. Approaches to Neoadjuvant Treatment in Melanoma. Public Workshop, Food and Drug Administration and Melanoma Research Alliance. Washington, DC. Nov 2019.
445. Adaptive Trial Designs for Rare Diseases: Merging Clinical Practice with Clinical Research. Annual meeting of American Society of Hematology. Orlando, FL. Dec 2019.
446. Patient-level Meta-analysis of End-of-Therapy PET-CR as a Surrogate Endpoint for PFS and OS in Patients with Previously Untreated DLBCL: Implications for Clinical Trial Design (poster). Annual meeting of American Society of Hematology. Orlando, FL. Dec 2019.
447. Fundamental Dilemmas of Detecting Cancer Early. Public Workshop on ctDNA in Cancer Screening. Food and Drug Administration. Silver Spring, MD. Mar 2020.
448. Multi-Armed Bandit Problems and the Merger of Medical Research and Practice. 2020 Conference of Texas Statisticians. Texas A&M University–Corpus Christi. Corpus Christi, TX (Virtual). Sep 2020.
449. Efficiently validating surrogate endpoints: Is randomization necessary? FDA/Industry Statistics Workshop. Washington, DC (Virtual). Sep 2020.
450. DIA1 (Virtual) Oct 2020.
451. DIA2 (Virtual) Oct 2020.
452. EU PEARL (Virtual) Oct 2020.
453. Keynote Presentation: Novel trial designs. 22nd Annual John Goldman Conference on Chronic Myeloid Leukemia: Biology and Therapy. International Chronic Myeloid Leukemia Foundation. Mandelieu, France (Virtual). Oct 2020.
454. Modeling. Preventing Overdiagnosis Conference Series. Centre for Evidence-Based Medicine, University of Oxford, UK (Virtual). Oct 2020.
455. Bayesian Statistics Enables a Revolution in Medical Research: Patient-focused Clinical Trials for the 21st Century. Keynote address. Second Annual Biopharmaceutical Symposium, Orange County Long Beach Chapter of the ASA (OCLBASA). Irvine, CA (Virtual). Dec 2020.
456. Multi-armed Bandit Problems in Clinical Research and Practice: Their Time Has Come. Decision Making in Health and Medical Care: Modeling and Optimization. Conference of the Institute for Mathematical and Statistical Innovation, National Science Foundation. Chicago, IL (Virtual). May 2021.

VI. INVITED PRESENTATIONS AT PROFESSIONAL CONFERENCES (CONT'D)

457. Bayesian Methods at FDA: Development of Guidances. 2021 Nonclinical Biostatistics Conference. American Statistical Association. (Virtual). June 2021.
458. Regulatory Feedback and Pharmaceutical Partner's Perspective on Precision Promise Phase II/III Platform Study Design. Joint presentation with Alexandra Vaury of Novartis. 6th Regulatory Statistics Workshop of the European Federation of Statisticians of the Pharmaceutical Industry (EFSPI), Complex innovative designs: Where is their place in drug development? (Virtual) Sep 2021.
459. ~~Drug Testing in Sport. 11th International Conference on Forensic Inference and Statistics (ICFIS 2020). Faculty of Law, Lund University, Sweden. 2021.~~
460. Bayesian Platform Trials. New England Research Development (NERD). Boston MA (Virtual) Nov 2021.