

Curriculum Vitae

Daniel Paul Normolle

**Associate Professor
Department of Biostatistics
University of Pittsburgh Graduate School of Public Health
Director, UPMC Hillman Cancer Center Biostatistics Facility**

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Education

Ph.D. in Mathematics (Statistics), State University of New York at Binghamton, 1988.

M.A. in Mathematics, State University of New York at Binghamton, 1979.

B.S. in Mathematics, Wilkes College, Wilkes-Barre, Pennsylvania, 1977.

Employment History

Director UPMC Hillman Cancer Center Biostatistics Facility, since August, 2009.

Associate Professor with Tenure Department of Biostatistics, University of Pittsburgh, since August, 2009.

Associate Professor Department of Radiation Oncology, University of Michigan, September, 2006 to August, 2009.

Visiting Scholar Department of Health Research Sciences, University of Virginia, June, 2004 to August, 2004.

Assistant Professor Department of Radiation Oncology, University of Michigan, September, 1999 to August, 2006.

Adjunct Assistant Professor Department of Biostatistics, School of Public Health, University of Michigan, September, 1998-August, 2004.

Senior Research Associate University of Michigan Comprehensive Cancer Center, September, 1995 to August, 1999.

Assistant Professor Department of Biostatistics, School of Public Health, University of Michigan, September, 1989 to August, 1995.

Clinical Biostatistician The Procter & Gamble Company, September, 1988 to August, 1989.

Senior Research Associate Department of Biostatistics, School of Public Health, University of Michigan, September, 1986 to August, 1988.

Research Assistant and Lecturer School of Management, SUNY, September, 1983 to August, 1986.

Teaching Assistant Department of Mathematical Sciences and School of General Studies Program in Applied Technology, SUNY, September, 1977 to August, 1984.

Intern Statistician Mine Safety and Health Administration, Department of Labor, May through August, 1979 and May through August, 1980.

Detailed Employment History

Director, University of Pittsburgh Cancer Institute Biostatistics Facility

Associate Professor, Department of Biostatistics, Graduate School of Public Health, University of Pittsburgh

Overview: The Biostatistics Facility of the UPMC Hillman Cancer Center (BF) currently comprises six PhD FTEs (staff and faculty in the Department of Biostatistics), two Master FTEs and two staff FTEs. The BF is involved with all of the Hillman research programs, and the GI, Brain and Hematology centers, and collaborates closely with Hillman Clinical Research Services, Medical Informatics, Bioinformatics, and several University departments. The BF supports the design, monitoring and analysis of bench, clinical and translational research. Each research area has a portfolio statistician, responsible for understanding the activities of the research area, who works with the Director to allocate BF resources as required. Statisticians acquire expertise in research platforms (e.g., Illumina, Ion Torrent, Flow Cytometry, Mass Spectrometry, NanoString) so that the BF has available in-house expertise for bench and translational experiments using these platforms. Statisticians regularly attend DSMB, dry lab and wet lab meetings to enhance the exchange of ideas between the BF and researchers. The BF is currently working with investigators on over 50 NCI-funded projects.

Administration: Management of budget presentation of facility to Hillman programs; allocation of effort to ongoing projects; oversight of statistical activities in committees in which the facility is involved; hiring and review of staff and faculty; advancing the careers of faculty and staff; membership on cancer center committees for protocol review, clinical oversight, clinical informatics and the data safety and monitoring for individual programs and the cancer center as a whole.

Project Leadership: Biostatistics Core Leader for Head & Neck SPORE. Lead statistician for GI, lung, hematology and brain groups.

Sponsored Research: Co-PI, with Thomas Braun of University of Michigan on R01, Statistical Methods and Issues for Implementing Adaptive Phase I Trials, 2010-2014. Responsibilities include development, validation, documentation and dissemination of software for the simulation and conduct of Phase I dose-escalation trials. Submitted proposals for coordinating center and program project grants in immunotherapy, cancer energetics and cancer therapy. Multiple R01, R03 and R21 proposals for cancer biology, dietary research, chemoprevention, imaging, GI, virology, lung and other programs.

Teaching: Introduction to Statistics for Bench Scientists and Clinical Trial Design of GSPH students. Service on Master and PhD thesis committees and GSPH core curriculum committee.

Active Research Interests: Integration of statistics into bench science. Design and implementation of innovative trials designs for Phase I and II studies. General, robust, useful workflows for analysis of high-dimensional data.

Service: Member, NCI Subcommittee F (Training Grants), 2013-2016. Member of SRG for NCI National Clinical Trials Network review. *Ad hoc* reviewer on over 50 review subcommittees since 1999.

Detailed Employment History

Assistant and Associate Professor, University of Michigan Department of Radiation Oncology

Design of clinical trials: Design of Phase I and Phase II trials for treatment of head and neck, hepatic, pancreatic and other cancers using Bayesian paradigms. Design of pilot trials to determine variability of positioning in radiation treatment of pancreatic and hepatic cancer.

Analysis: Multivariate repeated measures experiment comparing planning methods for radiation therapy for breast cancer. Relate RT dose-volume histograms to toxicity in patients treated for hepatic cancer. Analysis of relapse as a function of dose in prostate cancer. Analysis of retrospective data. Analysis of pharmacokinetic data.

Sponsored Research: Support of R01, R03, R21, K07, K23, P01, P50 and U54 mechanism grants, including refinement of research hypotheses, authorship of analysis plans and justification of experiment designs. Participated in successful competing renewals for Head & Neck SPORE. Director of Statistics for successful new GI SPORE application.

Service: Parent review panel for NCI SPOREs, and various NCI *ad hoc* review panels. Data safety and monitoring boards for clinical trials in pancreas and liver cancer. Consulting Editor for *Journal of Clinical Oncology*.

Instruction: Statistical analysis for clinical investigators, and for Radiation Oncology residents. Design of translational research for Program in Biomedical Sciences.

Senior Research Associate, University of Michigan Comprehensive Cancer Center

UMCCC Biostatistics Core: Collaboration with preclinical and clinical investigators; design of preclinical, Phase I clinical and Phase II clinical experiments, analysis of data; review of proposals and oversight of ongoing clinical trials; authorship of statistical sections of grant proposals and co-authorship of Biostatistics Core section of the competing renewal application.

Chemoprevention programs: Supervising statistician for ongoing Phase I and multi-center Phase II clinical trials in chemoprevention of cervical cancer, colon cancer and Barrett's esophagus. Design of protocols, supervision of data management and analysis of data, including innovative models for radioimmunoassay calibration and assays of stained biopsy specimens.

Immunotherapy Program Project: Design of Phase I clinical trials and analysis of laboratory results, including applications of generalized estimating equations and the EM algorithm to sets of limiting dilution assays.

Prostate Cancer SPORE: Director of biostatistics core of program project, including authorship of the statistical section of the competing application; consultation and collaboration on projects involving multiple modality imaging for vascularity, assessment of chromosomal abnormalities via FISH and preclinical projects.

Detailed Employment History

Assistant Professor, University of Michigan Department of Biostatistics

National Cooperative Center for Infertility Research at Michigan: Collaborative investigation using pulse-and cycle-detection programs; integration of robust nonlinear regression program in automated bioassay system; design and supervision of construction of automated data management system for bioassays.

Michigan Diabetes Research and Training Center: Publications and computer program on robust nonlinear regression for radioimmunoassay applications; design and implementation of an automated data management system for light microscopy images collected from multi-center Phase II trials; supervision of data management.

Center for Reproductive Sciences: Associate director of biostatistics core; publications and computer program on detection of seasonality in non-stationary non-Gaussian time series; collaborative investigation using these programs; collaborative research using integration of robust nonlinear regression program in automated bioassay system.

Antimetabolite Selectivity: Regional Rx Modulation: Director of biostatistics core of program project; collaborative research resulting in publications; development of statistical methodology, supervision of statisticians and data base programmers; authorship of statistical sections of clinical protocols and core material for successful competing renewal application.

Other Projects: Authorship of statistical sections of clinical protocols, competing applications and papers for publication with various investigators in the Departments of Epidemiology (School of Public Health), Internal Medicine, Urology, Pathology, Obstetrics and Gynecology, Plastic and Reconstructive Surgery and Radiation Oncology (Medical Center).

Clinical Biostatistician, The Procter & Gamble Company

DeNol: Supervised PK study for Phase I of FDA New Drug Application; wrote statistical section of large-sample dose-ranging protocols for Phase II studies of NDA; interacted with FDA and outside consultants in support of protocol development.

Pepto-Bismol: Performed analysis of new indication study.

Senior Research Associate, School of Public Health, University of Michigan

Medical, Epidemiological and Social Aspects of Aging: Collaborative research, data base management and programming, supervision of research assistants.

Small Area Resource Allocation: Collaborative research, data base management and programming.

Research Assistant, School of Management, SUNY

R&D Accounting Rule and DOD Contracts: Longitudinal comparative study of 10-year history of DOD R&D contracts of high-technology firms under different accounting rules.

Grant Support

Current

Biostatistics Core Director

UPMC Hillman Cancer Center Support Grant, 2015-2019, P30, PI: Robert Ferris. Total cost for core: \$1.2M/year.

SPORE in Head and Neck Cancer, 2015-2019, P50, PIs: Robert Ferris and Jennifer Grandis. Total cost for project, \$1.65M/year.

Co-Investigator

Peptide Vaccine-based Immunology for Children with Recurrent Ependymomas, 2013-2018, R01, PI: Ian Pollack. Total cost for project, 1.05M/year.

Role of Neurogenic Inflammation in Pancreatic Cancer, 2013-2018, R01, PI: Brian Davis. Total cost for project, 1.05M/year.

Pancreatic Ductal Adenocarcinoma is a Disease of Constitutive Autophagy, 2014-2019, R01, PI: Herbert Zeh. Total cost for project, 1.05M/year.

Chinese Herbal Medicine as a Novel Paradigm for Cancer Chemotherapy, 2014-2019, P01, PI: Edward Chu. Total cost for project, 1.05M/year.

Role and Regulation of Beta-catenin in Cholestatic Liver Disease, 2015-2020, R01, PI: Kari Nejak-Bowen. Total cost for project, 1.05M/year.

Synergies Among Inhibitory Receptors in Tolerance, Cancer and Antiviral Immunity, 2015-2020, P01, PI: Dario Vignali. Total cost for project, 1.05M/year.

Grant Support

Significant Completed Grants

Biostatistics Core Director

Prostate Cancer SPORE 1995-2000, Core Director. PI: Kenneth Pienta; total cost \$5M over five years.

Optimization of High Dose Conformal Therapy P01 2000-2010 PI: Benedick A. Fraass, total cost \$25.3M over ten years.

UPMC Hillman Cancer Center P30 2009-2017, Core Director. PIs: Nancy Davidson and Robert Ferris; total cost \$26M over five years.

Lung Cancer SPORE 2010-2012, Core Director. PI: Jill Siegfried; total cost \$5M over five years.

Head & Neck Cancer SPORE 2009-2017, Core Director. PIs: Jennifer Grandis and Robert Ferris; total cost \$5M over five years.

Co-PI

Statistical Methods and Issues for Implementing Adaptive Phase I Trials R01 2010-2014, PIs: Thomas Braun and Daniel Normolle, total cost \$1.7M over four years.

Co-Investigator

Phase I Vaccine Study using Brain Tumor Initiating Cells in WHO Grade II Gliomas, 2014-2016, R21, PI: Frank Lieberman. Total cost for project, 1.05M/year.

MCC Tumor-Specific Biomarkers: Basis for Rational Therapy of Merkel Cell Carcinoma, 2012-2017, R01, PI: Patrick Moore. Total cost for project, 1.25M/year.

Cell-specific Transcription in Cancer Microenvironment in vitro and in vivo, 2012-2017, R01, PI: Richard Steinman. Total cost for project, 1.05M/year.

Directing Tumor-specific T cells to Tumors, 2009-2014, PI: Pawel Kalinski. Total cost: \$5.6M over five years.

The Molecular Basis for Head and Neck Cancer Therapy (SPORE) 2002-2012, PI: Gregory Wolf; total cost \$9.4M over five years.

Great Lakes/New England Epidemiology Center 2000-2010, PI: Dean Brenner; total cost: \$14.0M over ten years.

University of Michigan Cancer Center Biostatistics Unit 2001-2011, PI: Max Wicha; total cost (core) \$1.7M over five years.

University of Michigan Comprehensive Cancer Center CCOP Research Base 1998-2007, PI: Dean Brenner; total cost \$3.1M over nine years.

Service

National Cancer Institute Review Panels

Special Emphasis Panel (SEP) on Prostate Cancer Clinical Trials, 1999-2000
SEP, Hyperthermia for Prostate Cancer P01, 2000
SEP on Shared Resources for Scientists outside NCI Cancer Centers, 2000
SEP, Molecular Pathways of Bladder Cancer Progression P01, 2000
SEP for SPORE Applications in Lung and Prostate Cancer, 2000
SEP for SPORE Applications in Skin Cancer, 2001
SEP for SPORE Applications in GI Cancer, 2001
SEP, Molecular Mechanisms of Human Bladder Cancer Carcinogenesis, 2001-2002
SEP, Hyperthermia for Radiosensitization in Cancer Treatment P01, 2002
SEP for Inter-SPORE Proposals, 2002
SEP for SPORE Applications in Lung Cancer, 2002
SEP for Early Clinical Trials on New Anti-Cancer Agents with Phase I Emphasis, 2002
SEP for SPORE Applications in Pancreatic Cancer, 2003
SEP for SPORE Applications in Ovarian Cancer, 2003
SEP for SPORE Applications in Brain Cancer, 2004
SEP for SPORE Applications in Myeloma and GU Cancer, 2004
SEP for SPORE Applications in Breast Cancer, 2005
SPORE Parent Standing SEP, 2005-2008, 2010 (13 meetings)
Ad Hoc Reviewer, Subcommittee C, Molecular Oncology, 2007-2008
Ad Hoc Reviewer, Cancer Biomarkers Study Section, 2009
Ad Hoc Reviewer, Subcommittee H (Gynecological Oncology Group Review), 2009
SEP, Barrett's Esophagus Translational Research Network, 2011
Ad Hoc Reviewer, SBIR Applications, 2011
SEP, CCOP Applications, 2011
Ad Hoc Reviewer, Subcommittee F (Training Grants), 2012
Standing Member, Subcommittee F, 2013-2016
SEP, National Clinical Trials Network, 2013
SEP, Adult and Pediatric Brain Tumor Consortia, 2013

Service

National Cancer Institute Review Panels (continued)

SEP for PROSPR U54 Centers for Cervical Cancer, 2014

SEP for NCI Community Oncology Research Program Research Bases, 2014

SEP for U01 Centers for Molecular and Cellular Characterization of Screen-Detected Lesions, 2015

R03 and R21 Omnibus SEP, 2015-2017

R01 Prevention SEP, 2016

R50 SEP, 2016-2018

Ad Hoc Reviewer, Subcommittee A (Cancer Center Support Grants), 2016

SEP, U24 and U54 for Barrett's Esophagus, 2016

SEP, R01 and U01 for Clinical Trials (Chair), 2016, 2017

SEP, U01 and U24 for Small Cell Lung Cancer, 2017

SEP, Developmental R03 and R21, 2017

SEP, U24 and U54 for PDX Development and Trial Center and PDX Data Commons and Coordinating Center, 2017

SEP, SEER N01, 2017

SEP, P01 for Biobehavioral Research in Cancer (Chair), 2018

SEP, R21 and U01 for Development of Informatics Technologies for Cancer Research and Management, 2018

SEP, U54 for Minority PDX Development and Trial Center, 2018

National Cancer Institute Advisory Board

Head & Neck Cancer Steering Committee, 2017-2020

National Institute of Environmental Health Sciences Review Panel

SEP, Dietary Influence on Health Effects of Environmental Exposures, 2011

National Institute of Dental and Craniofacial Research Review Panel

SEP, Basic and Pre-Clinical Studies in Cancer Immunotherapy, 2017

Service

National Aeronautics and Space Administration

Review Panel on Translational Research Institute Grants for Surgical Instruments, 2017

Review Panel on Clinical Research, 2018

Cancer Research UK

Panel on Biomarker Research and Drug Discovery, Standing Reviewer, 2013-2016

Medical Research Council (UK)

Grant Reviewer, 2017

Canada Foundation for Innovation, Ad hoc Reviewer, 2013

Conquer Cancer Foundation (ASCO)

Grant Review Panel, Standing Reviewer, 2014-2017

Grant Selection Executive Committee, 2016-2017

Protocol Review and Data Safety and Monitoring Committees

Therapeutic Protocol Review University of Michigan Comprehensive Cancer Center, 1994-1999, 2008-2009, (Associate Chair, 2008-2009)

Prevention and Control Protocol Review University of Michigan Comprehensive Cancer Center, 2002-2004

Head and Neck Cancer University of Michigan Department of Radiation Oncology, 1999-2009

Liver Cancer University of Michigan Department of Radiation Oncology, 1999-2009

Lung Cancer University of Michigan Department of Radiation Oncology, 1999-2009

Pancreatic Cancer University of Michigan Department of Radiation Oncology, 1999-2009

Brain Cancer University of Michigan Department of Radiation Oncology, 2003-2009

Breast Cancer University of Michigan Department of Radiation Oncology, 2003-2009

Chemoprevention University of Michigan Comprehensive Cancer Center, 2004-2009 (Chair)

GI Cancer University of Pittsburgh Cancer Institute, 2009-2018

Lung Cancer University of Pittsburgh Cancer Institute, 2009-2013

Hematology University of Pittsburgh Cancer Institute, 2011-2018

Brain Cancer University of Pittsburgh Cancer Institute, 2013-2018

Aging Successfully with Pain University of Pittsburgh (chair), 2011-2014

Institutional Oversight DSMC University of Pittsburgh Cancer Institute, 2013-2018

Protocol Review Committee C University of Pittsburgh Cancer Institute, 2013

Protocol Review Committee E University of Pittsburgh Cancer Institute, 2014-2016

Service

External Advisory Boards

Program Project, *Signals That Regulate Therapeutic Resistance In Breast Cancer*, University of Virginia 2005.

University of Chicago Lung SPORE, 2005-2006

UAB-UMN Pancreatic Cancer SPORE 2008-2009

University of Michigan GI SPORE 2011-2016

Moffitt Skin Cancer SPORE 2012-2018

University of Michigan Prostate Cancer SPORE 2012

Industrial DSMCs

NewLink Genetics NLG2104, 2016-2018

Other Committees

Faculty Search Department of Biostatistics, University of Michigan, 1992

Computing Department of Biostatistics, University of Michigan, 1989-1995 (Chair, 1993-1994)

Seminar Department of Biostatistics, University of Michigan, 1991-1993

Computing School of Public Health, University of Michigan, 1992-1995, Chair 1992-1993

Intramural Research Award Review University of Toledo, 2003, 2006, 2007

K07 Scientific Advisory Committee Michelle Anderson, PI 2008-2009

Faculty Search Departments of Biostatistics and Epidemiology, University of Pittsburgh, 2009-2013

Clinical Research Oversight Committee University of Pittsburgh Cancer Institute, 2009-2018

Clinical Trial Management Application Oversight Committee University of Pittsburgh Cancer Institute, 2009-2017

Cancer Epidemiology Associate Director Search Committee University of Pittsburgh Cancer Institute, 2011

Core Curriculum Committee University of Pittsburgh Graduate School of Public Health, 2011-2013

Program Leaders Research Executive Advisory Committee, University of Pittsburgh Cancer Institute, 2014-2018

Chair Search, Department of Biostatistics, University of Pittsburgh, 2016-2017

Service

Editorial Board

Cancer Research, 2013-2017

International Journal of Radiation Oncology Biology Physics, 2015-2018

Consulting Editor

Journal of Clinical Oncology, 2006-2008

Reviewer

Annals of Surgical Oncology, 2007

Biometrics, 1994

BMC Cancer, 2012, 2016, 2017

Breast Cancer Research and Treatment, 2004

Cancer, 2004-2006

Cancer Biomarkers, 2007

Cancer Epidemiology, Biomarkers and Prevention, 2005, 2008, 2012

Cancer Investigation, 2005

Cancer Research, 2010-2017

Clinical Cancer Research, 2011, 2012, 2014-2018

Clinical Colorectal Cancer, 2017-2018

Clinical Investigation, 2010

Clinical Trials, 2005, 2016

Communications in Statistics—Simulation and Computation, 2012

Computational Statistics and Data Analysis, 1996

Cytometry A, 2014, 2015

Gastroenterology, 2005

International Journal of Radiation Oncology Biology Physics, 2008, 2015-2018

JAMA Oncology, 2014-2018

Journal of Clinical Oncology, 2002-2011

Journal of Gastrointestinal Oncology, 2011

Journal for ImmunoTherapy of Cancer, 2016-2017

Service

Reviewer (continued)

Neoplasia, 2004, 2007

Science, 2015

Statistical Methods in Medical Research, 2018

Statistics in Medicine, 2011

Teaching

Courses

School of General Studies Program in Applied Technology, SUNY (undergraduate):

Applied Mathematics (two-semester, junior-level, post-Calculus)

Department of Mathematical Sciences, SUNY (undergraduate):

Ordinary Differential Equations (undergraduate)

Introduction to Statistics (undergraduate)

FORTRAN (undergraduate)

School of Management, SUNY (undergraduate and graduate):

Introduction to Statistics (graduate and undergraduate)

Mathematical Models for Management (graduate)

Production Management (graduate and undergraduate).

Department of Biostatistics, University of Michigan (graduate):

Design and Analysis of Biostatistical Investigations

Biostatistical Modeling in Clinical Research

Analysis of Variance and Mixed Models

Introduction to Statistics

Department of Radiation Oncology, University of Michigan Medical Center:

Statistical Analysis for Clinical Investigators

Clinical Trials: Methods and Practice

Department of Biostatistics, University of Pittsburgh (graduate):

Introduction to Statistics for Laboratory Scientists

Introduction to Biostatistics

Design and Analysis of Clinical Trials

Teaching

Dissertation and Thesis Committees

Department of Pharmacy Sciences, College of Pharmacy, University of Michigan

Zheng Lu, 2005-2007, Doctorate.

Department of Biostatistics, Graduate School of Public Health, University of Pittsburgh

Yuanyuan Wang, 2010, Doctorate; Kidane Gebreharwariat, 2015, Doctorate.

Human Genetics, Graduate School of Public Health, University of Pittsburgh

Rebecca Sullenberger, 2012, Master's; Lauren Brown, 2014, Master's.

Primary Thesis Advisor

Department of Biostatistics, Graduate School of Public Health, University of Pittsburgh

Xinxin Sun, 2017-2018, Master's.

Workshops

AACR/ASCO Methods in Clinical Cancer Research Workshop, Vail, 2008-2010, 2016.

Consulting

Fujisawa Pharmaceuticals: design of Phase II protocol with neuropathological endpoints; generation of randomization codes; LIMS design and construction; interim and final analyses, 1990-1993.

Wyeth-Ayerst: randomization; laboratory data management; data analysis, 1990-1993.

Hoffman-La Roche: randomization; laboratory data management; data analysis, 1992-1994.

Hematronix: implementation of assay calibration algorithms, 1998-1999.

La Jolla Pharmaceuticals: Phase III protocol design including sample resizing; fertility analysis, 2000-2001.

Santarus: design and interim analysis of Phase II trials, 2001-2004.

Pfizer: Bayesian designs of Phase I trials, 2003; design of early stage studies, 2016; analysis and design of biosimilarity studies, 2017.

Alliance Pharmaceuticals: clinical trial data analysis, 2003-2005.

AmberGen: design of validation experiments for proteomics assays in support of SBIR, 2005.

Adventrx Pharmaceuticals: database design for pharmacokinetics, 2010.

Genzyme Corporation: database design for pharmacokinetics, 2010.

Eisai Pharmaceuticals: database design for pharmacokinetics, 2011.

Johnson & Johnson: support of FDA response, 2011-2012.

Jennerex: analysis of *in vivo* data, 2012.

Takeda: database design for pharmacokinetics, 2012; analysis of pharmacokinetic studies, 2016-2017

Shire Pharmaceuticals: analysis of bioequivalence study data, 2012.

Mayne Pharmaceuticals: support for FDA submission, 2011-2013.

Dermira: analysis of PK studies, 2016.

SteadyMed Therapeutics: clinical trial design for FDA submission, 2016.

Prothena: analysis of data from bioequivalence trial for FDA submission, 2016.

Galera Therapeutics: design of bioequivalence trial, 2017.

Strongbridge Biopharma: design of bioequivalence trial, 2018.

Karyopharm Therapeutics: exposure-response analysis of data from pooled clinical trials, 2018.

Celltrion: analysis of patient dropout in clinical trials, 2018.

Computer Languages, Packages, and Operating Systems

Statistical Packages: R, JAGS, SAS.

Programming Languages: C++, Python, FORTRAN.

Operating Systems: Mac OS, Linux, Windows.

Other Applications: L_AT_EX, Sublime Text 3, Microsoft Office.

Publications in Peer-Reviewed Journals

1. Diokno AC, Brown MB, Brock BM, Herzog AR, **Normolle DP**. (1988) Clinical and Cystometric Characteristics of Continent and Incontinent Noninstitutionalized Elderly. *Journal of Urology* 140(3): 567-571. PMID: 3411676.
2. Horwitz B, and **Normolle, D**. (1988) Federal Agency R&D Contract Awards and the FASB Rule For Privately-Funded R&D. *The Accounting Review* 63: 414-435. PMID: N/A.
3. Diokno AC, Brown MB, Brock BM, Herzog AR, **Normolle DP**. (1989) Prevalence and Outcome of Surgery for Female Incontinence. *Urology* 33(4): 285-290. PMID: 2929058.
4. Herzog AR, Fultz NH, **Normolle DP**, Brock BM, Diokno AC. (1989) Methods Used to Manage Urinary Incontinence by Older Adults in the Community. *Journal of the American Geriatric Society* 37(4): 339-347. PMID: 2921456.
5. McLaughlin CG, **Normolle DP**, Wolfe RA, McMahan LF Jr, Griffith JR. (1989) Small-Area Variation in Hospital Discharge Rates. Do Socioeconomic Variables Matter? *Medical Care* 27(5): 507-521. PMID: 2725083.
6. Diokno AC, **Normolle DP**, Brown MB, Herzog AR. (1990) Urodynamic Tests for Female Geriatric Incontinence. *Urology* 36(5): 431-439. PMID: 2238302.
7. Herzog AR, Diokno AC, Brown MB, **Normolle DP**, Brock BM. (1990) Two-Year Incidence, Remission, and Change Patterns of Urinary Incontinence in Noninstitutionalized Older Adults. *Journal of Gerontology: Medical Sciences* 45(2): M67-74. PMID: 2313045.
8. Sisson JC, Hutchinson RJ, Shapiro B, Zasadny KR, **Normolle D**, Wieland DM, Wahl RL, Singer DA, Mallett SA, Mudgett EE. (1990) Iodine-125-MIBG to Treat Neuroblastoma: Preliminary Report. *Journal of Nuclear Medicine* 31(9): 1479-1485. PMID: 2395016.
9. Sisson JC, Wieland DM, Koeppe RA, **Normolle D**, Frey KA, Bolgos G, Johnson J, Van Dort ME, Gildersleeve DL. (1990) Scintigraphic Portrayal of Beta Receptors in the Heart. *Journal of Nuclear Medicine* 32(7): 1399-1407. PMID: 1648608.
10. Hutchinson RJ, Sisson JC, Miser JS, Zasadny KR, **Normolle DP**, Shulkin BL, Francis IR, Wieland DM, Shapiro B. (1991) Long-term Results of I-131 Metaiodobenzylguanidine Treatment of Refractory Advanced Neuroblastoma. *Journal of Nuclear Biology and Medicine* 35(4): 237-240. PMID: 1823826.
11. Lawrence TS, Davis MA, McKeever PE, Maybaum J, Stetson PL, **Normolle DP**, Ensminger WD. (1991) Fluorodeoxyuridine-Mediated Modulation of Iododeoxyuridine Incorporation and Radiosensitization in Human Colon Cancer Cells in vitro and in vivo. *Cancer Research* 51(15): 3900-3905. PMID: 1830239.
12. Stetson PL, **Normolle DP**, Knol JA, Johnson NJ, Yang ZM, Sakmar E, Prieskorn D, Terrio P, Knutsen CA, Ensminger WD. (1991) Biochemical Modulation of 5-Bromo-2'-deoxyuridine and 5-Iodo-2'-deoxyuridine Incorporation Into DNA in VX2 Tumor-Bearing Rabbits. *Journal of the National Cancer Institute* 83(22): 1659-1667. PMID: 1836238.
13. Buchsbaum DJ, Wahl RL, Glenn SD, **Normolle DP**, Kaminski MS. (1992) Improved Delivery of Radiolabeled Anti-B1 Monoclonal Antibody to Raji Lymphoma Xenografts by Predosing with Unlabeled Anti-B1 Monoclonal Antibody. *Cancer Research* 52(3): 637-642. PMID: 1732052.

Publications in Peer-Reviewed Journals

14. Canman CE, Tang HY, **Normolle DP**, Lawrence TS, Maybaum J. (1992) Variations in Patterns of DNA Damage Induced in Human Colorectal Tumor Cells by 5-Fluorodeoxyuridine--Implications for Mechanisms of Resistance and Cytotoxicity. *Proceedings of the National Academy of Science* 89(21): 10474-10478. PMID: 1438236.
15. Hutchinson RJ, Sisson JC, Shapiro B, Miser JS, **Normolle D**, Shulkin BL, Francis IR, Zasadny K, Carey JE, Johnson JW, Mallette B. (1992) 131-I Metaiodobenzylguanidine Treatment in Patients with Refractory Advanced Neuroblastoma. *American Journal of Clinical Oncology* 15(3): 226-232. PMID: 1590275.
16. Lawrence TS, Davis MA, Maybaum J, Mukhopadhyay SK, Stetson PL, **Normolle DP**, McKeever PE, Ensminger WD. (1992) The Potential Superiority of Bromodeoxyuridine to Iododeoxyuridine as a Radiation Sensitizer in the Treatment of Colorectal Cancer. *Cancer Research* 52(13): 3698-3704. PMID: 1617642.
17. Kaminski MS, Fig LM, Zasadny KR, Koral KF, DelRosario RB, Francis IR, Hanson CA, **Normolle DP**, Mudgett E, Liu CP, Moon S, Scott P, Miller R, Wahl R. (1992) Imaging, Dosimetry, and Radioimmunotherapy With Iodine-131-Labeled Anti-CD37 Antibody in B-Cell Lymphoma. *Journal of Clinical Oncology* 10(11): 1696-1711. PMID: 1403053.
18. Henley K, Normolle DP (1992) Statistics and clinical trials: The case of prednisolone in alcoholic hepatitis. *Hepatology* 16(4): 1098-1099. PMID: N/A.
19. Turgeon DK, **Normolle DP**, Leichtman AB, Annesley TM, Smith DE, Watkins PB. (1992) Erythromycin Breath Test Predicts Oral Clearance of Cyclosporine in Kidney Transplant Patients. *Clinical Pharmacology and Therapeutics* 52(5): 471-478. PMID: 1424421.
20. Sisson JC, **Normolle D**, Zasadny K, Brown R, Fisher S, Moon S, Gutowski T, Wahl R. (1992) Biodistribution and Therapeutic Effects of Radiolabeled Metaiodobenzylguanidine in a Human Neuroblastoma Xenograft. *Antibody, Immunoconjugates, and Radiopharmaceuticals* 5: 23-36. PMID: N/A.
21. Buchsbaum DJ, Wahl RL, **Normolle DP**, Kaminski MS. (1992) Therapy with Unlabeled and 131-I-labeled Pan B-Cell Monoclonal Antibodies in Nude Mice Bearing Raji Burkitt Lymphoma Xenografts. *Cancer Research* 52(23): 6476-6481. PMID: 1423295.
22. Rodriguez JL, Miller CG, Garner WL, Till GO, Guerrero P, Moore NP, Corridore M, **Normolle DP**, Smith DJ, Remick DG. (1993) Correlation of the Local and Systemic Cytokine Response with Clinical Outcome Following Thermal Injury. *Journal of Trauma* 34(5): 684-94; discussion 694-5. PMID: 8497003.
23. **Normolle DP**. (1993) An Algorithm for Robust Nonlinear Analysis of Bioassays. *Statistics in Medicine* 12(21): 2025-2042. PMID: 8296112.
24. Lawrence TS, **Normolle DP**, Davis MA, Maybaum J. (1993) The Use of Biphasic Linear Ramped Pulsed Field Gel Electrophoresis to Quantify DNA Damage Based on Fragment Size Distribution. *International Journal of Radiation Oncology Biology and Physics* 27(3): 659-663. PMID: 8226161.
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Invited Talks

1. **Normolle D.** Design of Early Validation Trials of Biomarkers, *Early Detection and Research Network SELDI/MALDI Statistical Workshop*, Seattle, March, 2004.
2. **Normolle D.** Dose-Escalation Trials for Treatments with Late Toxicities: Using and Extending TITE-CRM, *University of Wisconsin Cancer Center Grand Rounds*, September, 2004.
3. **Normolle D.** Dose-Escalation Trials for Treatments with Late Toxicities: Using and Extending TITE-CRM, *Radiation Therapy Oncology Group*, Philadelphia, October, 2004.
4. **Normolle D.** Clinical Approaches to Validate Biomarkers: Proteomics as an Example, *Third International Kidney Cancer Symposium*, November, 2004.
5. **Normolle D.** Detecting Colon Cancer from Serum Using SELDI-TOF: Analyses from GLNE 001, *University of Michigan Department of Biostatistics Seminar*, January 2005.
6. **Normolle D.** Designing Dose-Escalation Trials in Radiation Oncology, *ASTRO Annual Meeting*, Philadelphia, November, 2006.
7. **Normolle D.** Improving Dose Selection and Assessing Data Sooner With Seamless Phase I/II Trials, *ASTRO Translational Research in Radiation Oncology and Radiology Symposium*, San Francisco, September, 2007.
8. **Normolle D.** Design of a Biomarker-Adaptive Phase II Trial, *IBC International Conference on Adaptive Designs for Clinical Trials*, April, 2008.
9. **Normolle D.** Adaptive Trial Designs in Translational Research, a Fish (Oil) Story, *University of Alabama Birmingham Comprehensive Cancer Center*, May, 2008.
10. **Normolle D.** An Adaptive Early-Phase Trial For Treatment of Intrahepatic Cancer, *ADAPT Congress 2009*, September, 2009.
11. **Normolle D.** Truth and Consequences in Early Phase Dose Escalation Trials, *University of Pittsburgh CTSI*, June, 2010.
12. **Normolle D.** Biostatistical Considerations: Biologics and Biomarkers in Oncology, *Immuno-Oncology Biomarkers 2010 and Beyond: Perspectives from the iSBTc Biomarker Task Force and Collaborating Organizations*, September, 2010.
13. **Normolle D.** New Experimental Designs and Data Analysis Methods for Tumor Xenograft Studies, *University of Pittsburgh Cancer Institute Basic & Translational Research Seminar Series*, June, 2011.
14. **Normolle D.** Challenges and Promises of New Clinical Experimental Designs in Oncology, *ASTRO Annual Meeting*, September, 2013.
15. **Normolle D.** Deriving information from high-dimensional data, *Great Lakes International Imaging and Flow Cytometry Association Annual Meeting*, September, 2014.
16. **Normolle D.**, Diergaard B, Bauman J. Beyond the MTD: Precision Medicine and Clinical Trial Design, *ENAR Annual Meeting*, March, 2015.