

Curriculum Vitae

Daniel Paul Normolle

**Director, Biostatistics Facility
University of Pittsburgh Cancer Institute**

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

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 University of Pittsburgh Cancer Institute Biostatistics Facility, since August, 2009.

Associate Professor 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 Research Scientist 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.

Research Interests

Design of Dose-Escalation Trials The traditional "cohorts-of-three" dose-escalation trial design is not appropriate for the multi-modality therapies employed in contemporary clinical oncology. The design has poor statistical qualities, due to the small number of patients enrolled per dose, and is insufficiently flexible to deal with trial objectives and tolerable levels of toxicity that vary by clinical context. The Department of Radiation Oncology was the first in the world to implement the Time-to-Event Continual Reassessment Method (TITE-CRM) paradigm for dose escalation trials (in UMCC 9976), and is a leader in novel early-phase trial design. Along with clinical collaborators in Radiation Oncology, and statistical collaborators in the Department of Biostatistics and the Biostatistics Unit of the Comprehensive Cancer Center, I have extended the TITE-CRM paradigm in a number of ways, including the use of flexible objective functions, re-estimation on multi-parameter objective functions, integration of Phase II endpoints, use of sub-clinical toxicities in modeling and the use of constrained estimation in modeling. This has led to the concept of the early phase trial as a Seamless Phase I/II study.

Statistical Classification I have been analyzing proteomic assays (SELDI-TOF) and (MALDI-TOF) of serum samples from normal subjects and subjects with colon cancer as part of the GLNE EDRN Colon Cancer Proteomics Bakeoff. Mass spectrometry data of this type are characterized by having high dimensionality and significant noise. We believe that valid estimates of sensitivity and specificity of such assays must be estimated from blinded samples not used to train the discriminators. While there are any number of statistical classification and machine learning methods in the literature (e.g., Fisher's Discriminant Analysis, logistic regression, neural networks, support vector machines, penalized discriminant analysis, elastic net, random forests), there is very limited general guidance as to which method is better for any particular type of data, how to choose a method given a data set in hand (when there is only one chance to classify a blinded validation set), and how to allocate a fixed number of samples between a training and testing set. I am developing working expertise in all these machine learning methods, and addressing the questions of method selection and sample allocation.

Organ Motion The targets of radiological treatment move during treatment. This movement is constrained by adjacent structures, and has both periodic and aperiodic components, so that the resulting motion is irregular. I am working with physicists and clinicians in the Department of Radiation Oncology to characterize this motion, and to use those characterizations to produce treatment plans that increase the delivery of radiation to the targets, while controlling toxicity caused by irradiation of adjacent normal organs.

Assay Calibration and Biomarker Modeling via Multiply Hierarchical Bayes Models Values of biomarkers assessed on biological samples are commonly determined in batched assays that require calibration, and may be clustered, especially when multiple samples are collected from subjects at each of a number of times, in, for example, geographical surveys. Hierarchical Bayes models have the potential to represent these relationships in the presence of nonlinear calibration functions and dose-response relationships. However, these models pose computational challenges for off-the-shelf packages (e.g., WinBUGS). I am implementing these models in the context of a number of different assays, including Ki-67 for Barrett's Esophagus, and curcumin conjugates for colon cancer prevention.

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.

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 biostatistical 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 (Continued)

Assistant Research Scientist, 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 biostatistical core; publications and computer program on detection of seasonality in nonstationary 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 biostatistical 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 construction.

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.

Clinical Protocols

Statistician of record of the following clinical protocols. The principal investigator is listed after the title. Protocol documents are online at <http://www-personal.umich.edu/~monk/protocols.html>

- UMCC 9555** Phase IIb Chemoprevention Trial of Difluoromethylornithine (DFMO) in Human Subjects with Intestinal-type Barrett's Esophagus (Brenner)
- UMCC 9609** Retinoids and Intermediate Biomarkers for CIN II and III (Ruffin)
- UMCC 9644** Radiotherapy and Gemcitabine for Chest Wall Recurrences in the Treatment of Breast Cancer (Pierce)
- UMCC 9727** Hearing loss in Patients Undergoing Irradiation (RT) to the Auditory Pathways (Eisbruch)
- UMCC 9759** Assessment of the Quality of Life of Patients with Head and Neck Cancer Irradiated with Parotid Sparing or Standard Techniques (Eisbruch)
- UMCC 9961** Hyperfractionated Radiation and Gemcitabine for Advanced Head and Neck Tumors (Eisbruch)
- UMCC 9974** Pilot Study of On-Line Imaging During Radiotherapy (Eisbruch)
- UMCC 9976** A Phase I Trial of Cisplatin plus Gemcitabine and Radiation Therapy in Pancreatic Cancer (McGinn)
- GCRC 1633** Radioiodine Treatment & Graves' Eye Disease (Sisson)
- UMCC 2000-004** The Tolerance and Reproducibility of Lung Tumor Immobilization Using Active Breathing Control (Hayman)
- UMCC 2000-008** A Study of Early Tumor Response Assessment and Modification of Head and Neck Cancer Irradiation Plans Using Diffusion MRI (Eisbruch)
- UMCC 2000-046** Phase II Trial of Preoperative Radiation Therapy with Capecitabine in Rectal Cancer (Zalupski)
- UMCC 2000-088** A Phase I Study of High Dose Conformal Three-Dimensional Irradiation in a Shortened Time Interval for Medically Inoperable Stage I Lung Cancer (Henning)
- UMCC 2000-147** GLNE 001: Preliminary Clinical Characterization of Serum, Plasma and Urine Biomarkers for Colorectal Neoplasms (Brenner)
- UMCC 2001-008** A Phase II Study of High Dose Radiation (Combined with Hepatic Arterial Floxuridine) for Patients with Unresectable Intrahepatic Malignancies (Lawrence)
- UMCC 2001-046** Pilot Trial of Capecitabine and Radiation Therapy with Pre and Post Combination Chemotherapy in Advanced Pancreatic Cancer (Zalupski)
- UMCC 2001-054** Phase I Clinical Trial of Black Raspberries for Prevention of Colorectal Cancer (Brenner)
- UMCC 2002-008** Phase I Trial of Dose Escalated Whole Liver Irradiation with Hepatic Arterial Floxuridine / Leucovorin / Streptozotocin Chemotherapy Followed Subsequently by Chemoembolization with Mitomycin-C for Patients with Neuroendocrine Hepatic Metastases (Ensminger)

Clinical Protocols (continued)

- UMCC 2002-014** A Phase I Whole Liver Radiation Dose Escalation Trial Using Amifostine as a Radioprotective Agent (Lawrence)
- UMCC 2002-021** Optimized Intensity Modulated Irradiation for Head and Neck Cancer (Eisbruch)
- UMCC 2002-054** A Pilot Study to Quantify and Compare the Volume of Target and Normal Tissue Irradiated Using Sequential MRI-CT Fusion, Video Fluoroscopy, and Daily Portal Imaging in Radiation Therapy Treatment Planning for Cervical Cancer (Pan)
- UMCC 2002-066** Phase I Study of Concurrent Temozolomide and 3D Conformal Radiotherapy Dose Escalation for Treatment of High Grade Gliomas (Tsien)
- UMCCOP 02-01** Phase II Trial of Encapsulized Ginger as a Treatment for Chemotherapy-Induced Nausea and Vomiting (Zick)
- UMCC 2003-008** GLNE 003: Preliminary Validation of Biomarkers Predictive of Barrett's Esophagus Progression to Dysplasia and Adenocarcinoma (Brenner)
- UMCC 2003-023** Phase I Study of Concurrent Gemcitabine and Radiotherapy for Malignant High Grade Gliomas (Tsien)
- UMCC 2003-032** PET in Whole Brain Radiation (Meirovitz)
- UMCC 2003-039** Quantification of Set-Up Uncertainty and Organ Motion Due to Breathing in Breast Cancer Patients (Pierce)
- UMCC 2003-042** GLNE 005: Preliminary Characterization of Colorectal Flat Adenomas (Brenner)
- UMCC 2003-043** GLNE 006: Preliminary Characterization of Colorectal Flat Polyps Identified by Chromoendoscopy in Subjects with Hereditary Nonpolyposis Colorectal Cancer (Brenner)
- UMCC 2003-050** Assessing Cognitive Function in Women with Breast Cancer Using Functional Magnetic Resonance Imaging: A Feasibility Study (Cimprich)
- UMCC 2003-064** Phase I Single-Dose Safety and Pharmacokinetics Clinical Study of Resveratrol (Abrams)
- UMCC 2003-067** A Randomized, Phase II Trial of Urethral Sparing Intensity-Modulated Radiation Therapy (US-IMRT) compared to Standard 3D Conformal Radiation Therapy (3D-CRT) for Low-risk Prostate Cancer Patients to improve Quality of Life (QOL) within the Urinary Domain as measured by the Expanded Prostate Cancer Index Composite (EPIC) (Sandler)
- UMCC 2003-072** A Pilot Study of Radiation-Induced Liver Disease Onset Using CT-based Perfusion (Ben-Josef)
- UMCC 2003-073** A Phase I/II Randomized Trial in Radiation Dose Escalation and Timing of Concurrent Chemotherapy for Patients with Stage III Unresectable/Inoperable Non-Small Cell Lung Cancer (Kong)
- UMCC 2003-076** A Pilot Study to Evaluate the Impact of Multiple Functional Images on Radiation Treatment Planning and Radiation Lung Toxicity Prediction (Kong)
- UMCC 2003-081** Assessment of Liver Function in Patients Undergoing Hepatic Irradiation (Ben-Josef)

Clinical Protocols (continued)

- UMCC 2003-082** Gemcitabine, Oxaliplatin and Radiation Therapy in Pancreatic Cancer (Zalupski)
- UMCC 2003-083** MRI Study of Radiation-Induced Damage to White Matter and Blood-Brain-Barrier (Cao)
- UMCC 2004-024** A Pilot Study of [F-18]FLT-PET in Patients with Head and Neck Cancer Undergoing Chemo-Irradiation (Eisbruch)
- UMCC 2004-029** Pilot Study of ZD1839 (Iressa) and Intensity Modulated Radiotherapy (IMRT) in Recurrent Gliomas (Tsien)
- UMCC 2004-032** Pilot study to evaluate the feasibility of MR colonography with oral fecal tagging in the detection of colorectal lesions (Adusumilli)
- UMCC 2004-038** A Randomized Comparison of Radiation Therapy Techniques in the Management of Node Positive Breast Cancer (Pierce)
- GCRC 1916** HPV Infection and High Fruit and Vegetable Diet (HIgh FiVeD): Pilot (Ruffin)
- UMCC 2005-003** MRI Study of Changes in Blood-Brain/Tumor-Barrier Permeability in Patients with Brain Metastases During and After Radiotherapy (Cao)
- UMCC 2005-008** GLNE 007: Evaluation of Stool Based Markers for the Early Detection of Colorectal Cancers and Adenomas (Brenner)
- UMCC 2005-013** A Pilot Study of Pancreatic Motion in Patients Undergoing Radiation Therapy for Pancreatic Cancer (Ben-Josef)
- UMCC 2005-015** A Pilot Trial To Determine The Effect Of Intratreatment Organ Motion On The Minimum Dose To The Prostate During External Beam Prostate Radiotherapy (Sandler)
- UMCC 2005-065** Pilot study to assess EGFR inhibition by erlotinib in tumors as compared with normal mucosa in patients with locally advanced squamous cell carcinoma of the head and neck (Tsien)
- UMCC 2005-084** A Pilot Study of Tumor and Critical Normal Tissue Motion in Head and Neck Cancer Using Cone Beam CT (Eisbruch)
- UMCC 2006-018** A Phase I Radiation Dose-Escalation Study Of Intensity-Modulated Radiotherapy (IMRT) With Concurrent Gemcitabine In Patients With Unresectable Pancreatic Cancer (Ben-Josef)
- UMCC 2006-025** A Multi-Institutional Phase II Study of Neoadjuvant Gemcitabine and Oxaliplatin with Radiation Therapy in Patients with Pancreatic Cancer (Zalupski)
- UMCC 2006-040** Using Functional Image and Circulating Molecular Markers to Predict Tumor Response and Lung Toxicity in Treatment of Non-Small Cell Lung Cancer (Kong)
- UMCC 2006-047** A Phase I Study Evaluating VELCADE as a Radiosensitizer in Patients with Metastatic Melanoma to the Brain who Require Whole Brain Radiation (Redman)
- UMCC 2006-067** A Pilot Study of Radiation Toxicity Using MRI-based Perfusion (Pan)
- UMCC 2006-075** Altered Brain Function in Chemotherapy for Breast Cancer (Cimprich)

Clinical Protocols (continued)

- UMCCOP 02-01** Phase II Trial of Encapsulized Ginger as a Treatment for Chemotherapy-Induced Nausea and Vomiting (Zick)
- GCRC 2018** Single Dose Pharmacokinetic Trial of an Encapsulated Ginger Standardized to 5%-6-Gingerols (Zick)
- Resveratrol Task 1** Phase I Single-Dose Safety and Pharmacokinetics Clinical Study of Resveratrol (Boocock, Brenner)
- Resveratrol Task 2A** Phase I Repeat-Dose Clinical Study of Safety, Pharmacokinetics and Pharmacodynamics of Resveratrol (Boocock, Brenner)
- Resveratrol Task 2B** Phase I Repeat-Dose Study of Resveratrol in Colorectal Cancer Patients: Tolerability, Target Tissue Levels and Pharmacodynamics (Boocock, Brenner)
- UMCC 2006-098** A Phase I/II Study of Enzastaurin, Gemcitabine and Radiotherapy for Locally Advanced Unresectable Pancreatic Cancer (Ben-Josef)
- GCRC 2246** A Phase II Study of the Effect of Ginger Root on Markers of Inflammation in Gut Mucosa (Zick)
- UMCC 2007-017** A Pilot Study of [18F] FLT-PET in Patients With Resectable Pancreatic Cancer Undergoing Neoadjuvant Chemoradiotherapy (Ben-Josef)
- UMCC 2007-025** GLNE 008: Preliminary Longitudinal Validation of Biomarkers Predictive of Barrett's Esophagus Progression to Dysplasia and Adenocarcinoma (Brenner)
- UMCC 2007-029** A Phase II Organ Preservation Trial Using Cetuximab and Radiation Therapy in Advanced Laryngeal Cancer Patients Who Have Responded to One Cycle of Induction Chemotherapy with Taxotere, Cisplatin, 5-Fluorouracil (TPF), and Cetuximab (Worden)
- UMCC 2007-037** Women's Healthy Lifestyle Study (Djuric Longworth)
- UMCC 2007-047** Assessment of Neuronal Synaptic CNS Markers by Neurotransmitter PET in Patients with Neuro-Cognitive Decline after Radiation Treatment (Tsien)
- UMCC 2007-123** Using FDG-PET Acquired During the Course of Radiation Therapy to Individualize Adaptive Radiation Dose Escalation in Patients with Non-Small Cell Lung Cancer (Kong)
- UMCC 2008-034** A Pilot Study of Diffusion MRI in the Assessment of Pancreatic Tumor Response (Cao)
- UMCC 2009-029** A Phase II Study of RT Concurrent with Cetuximab in Patients with Locally Advanced Head and Neck Squamous Cell Carcinoma Who Do Not Qualify For Standard Chemotherapy Due To Age>70 Or Co-Morbidities (Jolly)

Grant Support

Recent

Biostatistics Core Director

Antimetabolite Selectivity: Regional Rx Modulation 1993-1998, Core Director. PI: William Ensminger; total cost \$2.8M over three years.

Prostate Cancer SPORE 1995-2000, Core Director. PI: Kenneth Pienta; total cost \$5M over five years (extended; still current. Dr. Jeremy Taylor is now Core Director).

Gene Therapy in Cancer 1996-1998, Core Director. PI: Alfred Chang; total cost \$4M over five years.

Co-Investigator

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

Brain Tumor Therapeutic Efficacy by Quantitative MR 2001-2006, PI: Brian Ross; total cost \$3.6M over five years.

Socioeconomic diversity of CAM Integration in Oncology 2002-2004, PI: June Chan; total cost \$125K over two years

The Combination of Radiotherapy with the Anti-angiogenic Agent Tetrathiomolybdate (TM) in the Treatment of Non-Small Cell Lung Cancer (NSCLC): A Phase I Study 2003-2008, PI: Mohamed Khan; total cost: \$250K over two years.

IMRT in the Treatment of Node-Positive Breast Cancer 2003-2007, PI: Lori Pierce; total cost \$1.8M over three years.

Ginger Control of Chemotherapy Induced Nausea and Emesis 2003-2006, PI: Suzie Zick; total cost \$1.7M over two years.

Gemcitabine-Radiation for Advanced Head and Neck Cancer 2002-2005, PI: Theodore Lawrence; total cost \$1.3M over four years.

Radiation Dose Escalation of Focal Liver Cancer 2001. PI: Theodore Lawrence; total cost \$2.1M over four years.

A Mediterranean Diet in for Colon Cancer Prevention 2006-2011, PI: Zora Djuric Longworth; total cost \$2.4M over five years.

Improving Gene Therapy Mediated Radiosensitization 2003-2007, PI: Theodore Lawrence; total cost \$1.1M over four years.

Grant Support (continued)

Current

Biostatistics Core Director

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

Co-Investigator

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

Phase 1 Single and Multiple-Dose Safety and Pharmacokinetic Clinical Study of Resveratrol 2002-2009, PI: Dean Brenner; total cost \$1.1M over two years (extended).

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

Gemcitabine-Radiation for Advanced Pancreatic Cancer 2007-2011, PI: Theodore Lawrence; total cost \$1.3M over five years.

Altered Brain Function in Chemotherapy for Breast Cancer 2008-2012, PI: Bernadine Cimprich; total cost \$1.8M over five years.

Phase II Neoadjuvant Gemcitabine & Oxaliplatin with Radiation Therapy for Pancreatic Cancer 2007-2010, PI: Mark Zalupski, total cost \$41K over four years.

Functional Imaging as a Biomarker for Neurotoxicity After Brain Irradiation Assessment of BBB Disruption During RT Using DCE MRI 2009-2014, PI: Cao; total cost \$675K over five years.

Advisory

Validation Study of Select Biomarkers for the Diagnosis of Pancreatic Cancer K07 2008-2013, PI: Michelle Anderson, total cost: \$690K over five years.

Grant Support (continued)

Pending

Biostatistics Core Director

GI SPORE submitted 2007, 2008, 2009, PI: Dean Brenner; total cost \$13M over five years.

Co-PI

Statistical Methods and Issues for Implementing Adaptive Phase I Trials submitted 2009, PI: Thomas Braun and Daniel Normolle, total cost \$225K over five years.

Co-Investigator

Radiobiology P01 submitted 2007, 2008, 2009, PI: Theodore Lawrence, total cost \$7M over five years.

A Phase I/II study of Hypofractionated Prostate Stereotactic Body Radiotherapy (SBRT) Using Continuous Re-time Evaluation of Prostate Motion submitted 2009, PI: Daniel Hamstra, total cost \$500K over five years.

Individualizing Radiation Therapy R01 submitted 2009, PI: Theodore Lawrence, total cost \$95K over five years.

Functional Image and Molecular Marker to Individualize Adaptive Radiation Dose Escalation in Patients with Non-Small Cell Lung Cancer submitted 2009, PI: Feng-Ming Kong, total cost \$600K over five years.

Early Assessment Radiotherapy Outcome and Toxicity Using DCE MRI submitted 2009, PI: Yue Cao, total cost 500K over five years.

Tenofovir DF and Lamivudine to Treat HERV-K HML-2 Virus in Refractory Lymphoma submitted 2009, PI: Marc Kaplan, total cost \$250K over three years.

Effect of Dietary Fat on Fish Oil Supplementation submitted 2009, PI: Zora Djuric, total cost \$250K over two years.

Effect of Dietary Omega-6 fats on Omega-3 supplementation submitted 2009, PI: Zora Djuric, total cost \$350K over two years.

Physiologic Magnetic Response (MR) and Metabolic Positron Emission Tomography (PET) Imaging to Predict Response to Anti-Angiogenic Therapy and Overall Survival (OS) in Newly Diagnosed Glioblastoma Multiforme (GBM) submitted 2009, PI: Christina Tsien, total cost \$140K over three years.

Advisory

Curcumin and Piperine in Breast Cancer Prevention K07 submitted 2007, 2008, 2009; PI: Madhuri Kakarula; total cost: \$675K over five years.

Service

National Cancer Institute Review Panels

Special Emphasis Panel on Prostate Cancer Clinical Trials 1999-2000

Site Visit Team, Hyperthermia for Prostate Cancer 2000

Special Emphasis Panel on Shared Resources for Scientists outside NCI Cancer Centers 2000

Site Visit Team, Molecular Pathways of Bladder Cancer Progression 2000

Special Emphasis Panel for SPORE Applications in Lung and Prostate Cancer 2000

Special Emphasis Panel for SPORE Applications in Skin Cancer 2001

Special Emphasis Panel for SPORE Applications in GI Cancer 2001

Special Emphasis Panel, Molecular Mechanisms of Human Bladder Cancer carcinogenesis 2001-2002

Special Emphasis Panel, Hyperthermia for Radiosensitization in Cancer Treatment 2002

Special Emphasis Panel for Inter-SPORE Proposals 2002

Special Emphasis Panel for SPORE Applications in Lung Cancer 2002

Special Emphasis Panel for Early Clinical Trials on New Anti-Cancer Agents with Phase I Emphasis 2002.

Special Emphasis Panel for SPORE Applications in Pancreatic Cancer 2003

Special Emphasis Panel for SPORE Applications in Ovarian Cancer 2003

Special Emphasis Panel for SPORE Applications in Brain Cancer 2004

Special Emphasis Panel for SPORE Applications in Myeloma and Genitourinary Cancer 2004

Special Emphasis Panel for SPORE Applications in Breast Cancer 2005

SPORE Parent Standing Special Emphasis Panel 2005-2008

Ad Hoc Reviewer, Subcommittee C, Molecular Oncology 2007-2008

Protocol Review Committees

Protocol Review University of Michigan Comprehensive Cancer Center, 1994-1999, associate chair, 2008-2009.

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

Data Safety and Monitoring Boards

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

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

Service (Continued)

Data Safety and Monitoring Boards (continued)

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

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

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

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

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

Other Committees

Faculty Search Department of Biostatistics, 1992.

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

Seminar Department of Biostatistics, 1991-1993.

Computing School of Public Health, 1992-1995, Chair 1992-1993.

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

External Advisory Committee University of Chicago SPORE in Lung Cancer, 2005-2008.

External Advisory Committee Program Project, *Signals that regulate therapeutic resistance in breast cancer*, University of Virginia, 2005.

External Advisory Committee UAB-UMN Pancreatic Cancer SPORE, 2008-2009.

K07 Scientific Advisory Committee Michelle Anderson, PI 2008-2009.

Referee

Biometrics 1994

Computational Statistics and Data Analysis 1996

Journal of Clinical Oncology 2002-2009; Consulting Editor, 2006-2008

Breast Cancer Research and Treatment 2004

Cancer 2004-2006

Neoplasia 2004, 2007

Cancer Epidemiology, Biomarkers and Prevention 2005, 2008

Cancer Investigation 2005

Clinical Trials 2005

Gastroenterology 2005

Annals of Surgical Oncology 2007

Cancer Biomarkers 2007

International Journal of Radiation Oncology, Biology, Physics 2008

Teaching

Courses

Department of Radiation Oncology, University of Michigan Medical Center:

Statistical analysis for clinical investigators;
Design of clinical trials.

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.

School of Management, SUNY:

Introduction to Statistics(graduate and undergraduate);
Mathematical Models for Management (graduate);
Production Management (graduate and undergraduate).

Department of Mathematical Sciences, SUNY:

Ordinary Differential Equations (undergraduate);
Introduction to Statistics (undergraduate);
FORTRAN (undergraduate).

School of General Studies Program in Applied Technology, SUNY:

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

Dissertation Committees

Pharmacy Sciences, College of Pharmacy

Zheng Lu, 2005-2007.

Workshops

AACR/ASCO Methods in Clinical Cancer Research Workshop, Vail, 2008-2009.

Consulting

Fujisawa Pharmaceuticals: design of Phase II protocol with neuropathological endpoint; 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; futility analysis, 2000-2001.

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

Pfizer: Bayesian designs of Phase I trials, 2003.

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

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

Computer Languages, Packages, and Operating Systems

Programming Languages: C++, FORTRAN.

Statistical Packages: SAS (including GRAPH, ETS, AF, FSP, and OR), R, WinBUGS, JAGS, Matlab.

Operating Systems: LINUX, Mac OS X, Windows.

Other Applications: LaTeX, Microsoft Office.

Publications in Peer-Reviewed Journals

1. Diokno, A., Brown, M., Brock, B., Herzog, A., Normolle, D. (1988) Clinical and Cystometric Characteristics of Continent and Incontinent Noninstitutionalized Elderly, *Journal of Urology* **140(3)**: 567-571.
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.
3. Diokno, A., Brown, M., Brock, B., Herzog, A., Normolle, D. (1989) Prevalence and Outcome of Surgery for Female Incontinence, *Urology* **33(4)**: 285-290.
4. Herzog, A., Fultz, N., Normolle, D., Brock, B., Diokno, A. (1989) Methods Used to Manage Urinary Incontinence by Older Adults in the Community, *Journal of the American Geriatric Society* **37(4)**: 339-347.
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Publications Submitted to Peer-Reviewed Journals

97. Zick, S., Ruffin, M., Djuric, Z., Normolle, D., Brenner, D. (2009) Quantitation of 6-, 8- and 10-Gingerols and 6-Shogaol in Plasma by High-Performance Liquid Chromatography, submitted to *Journal of Chromotography B*.
98. Morgan, M., Parsels, L., Parsels, J., Davis, M., Hassan, M., Arumugarajah, S., Hylander-Gans, L., Morosini, D., Zhao, L., Simeone, D., Normolle, D., Zabludoff, D., Maybaum, J., Lawrence, T. (2009) Radiosensitization by the Chk1/2 inhibitor, AZD7762 involves abrogation of the G2 checkpoint and inhibition of homologous recombination repair, submitted to *Clinical Cancer Research*.
99. Pan, C., Ensminger, W., Walker, S., Olson, L., Ben-Josef, E., Normolle, D., Lawrence, T. (2009) Final Results of a Phase I Whole Liver Radiation Dose Escalation Trial using Amifostine as a Radioprotector, submitted to *Journal of Clinical Oncology*.

Publications in Peer-Reviewed Journals in Preparation

100. Lu, Z., Normolle, D., Chen, L., Lawrence, T., Smith, D. (2009) Relationship between Amifostine Dose, Administration Route, and Sampling Time on WR-1065 Exposure in the Liver of Tumor-Bearing Rats, to be submitted to *Drug Metabolism and Disposition*.
101. Normolle, D., Ruffin, M., Brenner, D. (2009) Making Decisions About the Development of a Biomarker, to be submitted to *Cancer Epidemiology, Biomarkers and Prevention*.

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.

Contributed Talks

1. Normolle, D., Comparison of Five Linear Discrimination Functions, presented at the 1988 Joint Statistical Meetings.
2. Normolle, D. (1989) Comparison of 'Local Model' Classification Methods, *Computing Science and Statistics: Proceedings of the 20th Symposium on the Interface*.
3. Normolle, D., A Nonparametric Stopping Rule for a Time-Dependent Clustering Algorithm, presented at the 1990 Joint Statistical Meetings.
4. Normolle, D., Brown, M. (1990) A Computer Program for a Time-Dependent Clustering Algorithm, presented at the XVth International Biometric Conference.
5. Normolle, D., St. Laurent, R., Brown, M. Robustness and Efficiency of Estimators for Bioassays with Continuous Sigmoidal Responses, presented at the 1994 Joint Statistical Meetings.
6. Normolle, D. (1996) Maximum Likelihood Estimation of Chromosomal Damage and Processing Artifacts in FISH Data, *Fourth Annual SPORE Conference*, Bethesda, MD.
7. Normolle D., Padmanabhan, V. (1996) Using Smooth Curves to Analyze Hormone Suppression Experiments, presented at the 1996 Joint Statistical Meetings.
8. Normolle, D., Elliott, M., Bishop, K., Mule, J., Chang, A. (2000) Serial dilution assays when the outcome variable is continuous, presented at the 2000 Eastern North American Regional Meeting of the International Biometrics Society.