

Major Administrative Leadership Positions

Local

1995-1996	Biostatistical Consulting Lab Co-Director	Dept. of Biostatistics, Medical College of Virginia, Virginia Commonwealth University
2002-2009	Associate Program Director / Co-Director	National Institutes of Health (NIH)/National Cancer Institute (NCI) Children's Oncology Group ¹ (COG) Statistics and Data Center, Univ of Florida
2009-present	Director of Biostatistics	Division of Hematology/Oncology, Boston Children's Hospital, Dana-Farber/Boston Children's Cancer and Blood Disorders Center, Harvard Medical School
2009-2019	Director, Clinical and Translational Investigation Program (CTIP)	Division of Hematology/Oncology, Boston Children's Hospital, Dana-Farber/Boston Children's Cancer and Blood Disorders Center, Harvard Medical School
2012-present	Faculty Director, Survey and Qualitative Methods Core	Dana-Farber / Harvard Cancer Center
2012-present	Co-Director, Research and Data Analysis Core	Partnership of the University of Massachusetts/Boston and Dana-Farber Cancer Institute
2022-present	Director, Biostatistics Core	Dana-Farber/Harvard Cancer Center Glioma SPORE

National and International

(Each COG¹ disease committee is a distinct, scientific working group with its own long term strategic plan. Dr. London was funded full-time by COG¹ grants for 12 years, and 30% effort for five years after moving to Boston Children's Hospital, thus her leadership on multiple COG¹ scientific and administrative committees.)

1998-present	Scientific Steering Committee Member	Children's Oncology Group (COG ¹) Neuroblastoma Committee
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¹ The Children's Oncology Group is not a professional society, it is the only pediatric cancer cooperative group in the country, funded by the NIH / NCI via U10 grants (since ~1975). >220 treating institutions in North America, Australia, New Zealand, and Switzerland comprise the COG, with >5,000 members (oncologists, surgeons, pathologists, nurses, CRAs, statisticians). Half of all children with cancer in North America will enroll on at least one COG study. At any given time, COG is conducting over 100 clinical or biological trials, trials that set the standard of care. The COG Statistics and Data Center provides the infrastructure, including study design, data collection, interim monitoring, statistical analysis, and manuscripts. COG is organized by permanent scientific working 'committees' (led by an Executive committee) to conduct national clinical

2008-2009	Data Safety Monitoring Board 2008-2009	Neurofibromatosis Consortium Member
2009-2015	Data Safety Monitoring Board 2009-2015	Division of Microbiology and Infectious Diseases (DMID) Protocol 07-0012: Randomized Trial of Azithromycin versus Doxycycline for genital Chlamydial infection in females in youth correctional facilities Member
2011-2018	International Neuroblastoma Response Criteria Working Group 2011-2018	National Cancer Institute Executive Committee Member
2019- present	Data Safety Monitoring Board 2019- present	“RQ 092 (Miransertib) in Subjects with PIK3CA-related Overgrowth Spectrum and Proteus Syndrome”. Sponsor: Merck (originally ArQule, Inc.) Member
2019- present	Data Safety Monitoring Board 2019- present	Jubilant Draximage trial of metaiodobenzylguanidine (MIGB) in neuroblastoma Member
2020- present	The INRG Version 2 Task Force 2020- present	The International Neuroblastoma Risk Groups Project Co-Chair

Professional Societies

1987-1992	SAS Users’ Groups International 1987-1992 1990, 1991, 1992 1991, 1992	Member Session Coordinator Section Chair, Northeast SAS Users’ Group Pharmaceutical Section
1990- present	American Statistical Association 1990- 1996 1999	Member Member, Local Arrangements Committee for Eastern North American Region (ENAR) of American Statistical Association (ASA) Session Chair, Joint Statistical Meetings

Training Grants and Mentored Trainee Grants

- 2009-2010 Using item response theory to improve children’s quality of life assessment
NIH 1K23HD057146-01A2
Mentor of I-Chan Huang
The major goal is to train Dr. Huang to become an independent researcher in the area of children's health-related quality of life (HRQOL) assessment, which measures physical and psychosocial functioning, and its clinical application.
- 2014-2019 Research Training in Pediatric Oncology
NIH 2T32CA136432-06A1
Faculty
The major goal is to train physicians who will be the future academic leaders in basic and/or clinical pediatric oncology research and who will work to reduce the burden of cancer in the pediatric population.
- Submitted
11/2021 Characterization and validation of circulating tumor DNA (ctDNA) as a clinical biomarker
in Ewing sarcoma
NIH / K08
Mentor of David Shulman
The major goal is to provide mentorship to Dr. Shulman as he develops statistical skills. Dr. London’s mentorship for this grant focuses on survival analysis and regression modeling for ctDNA biomarker validation.
SRG Action: Impact/Priority Score: 27 (not funded)

Current Unfunded Projects

- 2010-
present U.S. News and World Report – Best Children’s Hospitals survey
Role: Statistician
The major goal of this project was to accurately and reproducibly answer questions on the survey on an annual basis, including the 5-year pediatric cancer survival rates and number of oncology patients on clinical trials.
- 2012-
present Datamart: The Pediatric Patient Informatics Platform (*PPIP*)
Role: PI
The major goal of this project is to create and maintain a datamart to serve as a local and national resource. The *PPIP* datamart integrates patient data (clinical, outcome, genomics, specimens) and protocol data (PI, accrual goal, activation date) from disparate sources at BCH and DFCI, to facilitate research, operations and safety reporting, and strategic planning.

Report of Local Teaching and Training

Teaching of Students in Courses

2006-2008	Science of Clinical and Translational Research Course Medical students, residents, fellows, and faculty members	University of Florida College of Medicine Annual 1 hr lecture
2007	Writing the statistical section of a grant Epidemiology graduate students	University of Florida, Division of Epidemiology and Health Policy Research 1 hr lecture

Formal Teaching of Residents, Clinical Fellows and Research Fellows (post-docs)

2005-2009	Evaluating experimental design and statistics of research publications 2 nd and 3 rd year surgery residents	University of Florida, Dept of Surgery Annual 1-hour lecture
2009-2017	Data Blitz Fellows and faculty	Dana-Farber Cancer Institute/ Boston Children’s Hospital, Division of Hematology/Oncology Annual 5-min lecture, 5 min Q&A
2010-present	Consolidation course Fellows and faculty	Dana-Farber Cancer Institute/Boston Children’s Hospital, Division of Pediatric Hematology/Oncology Annually: two 1-hour lectures
2017	Innovative Phase 1 Study Designs Fellows, faculty, and staff of the Experimental Therapeutics Program	Dana-Farber Cancer Institute/Boston Children’s Hospital, Division of Pediatric Hematology/Oncology 1-hour lecture

Research Supervisory and Training Responsibilities

2001-2008	Advised/instructed a statistics department graduate assistant in the design and statistical analysis of the Children’s Oncology Group clinical trials	Mentorship 3 days a week for 1 year
2009-present	Train and educate statisticians of the Biostatistics Program: authorship on scholarly works for peer-reviewed publication	Mentorship 4-5 hours per week
2009-present	Train and educate residents, fellows, and junior faculty regarding the design and conduct of clinical research	Mentorship 2-4 hours per week

Formally Mentored Harvard Medical, Dental, and Graduate Students

deAlarcon P, Chauvenet A. Risk-adapted, response-based approach using ABVE-PC for children and adolescents with intermediate and high risk Hodgkin lymphoma: The results of P9425. *Blood* 2009 Sep 3;114(10):2051-9. PMID: 19584400 PMCID: PMC2744567.

71. Lagmay J**, **London WB**, Gross T, Termuhlen A, Sullivan N, Axel A, Mundy B, Ranalli M, Canner J, McGrady P**, Hall B. Prognostic significance of interleukin-6 single nucleotide polymorphism genotypes in neuroblastoma: *rs1800795* (promoter) and *rs8192284* (receptor). *Clinical Cancer Research* 2009 Aug 15;15(16):5235-9. PMIC: 19671870 PMCID: PMC2740837.
72. Combaret V, Hogarty MD, **London WB**, McGrady P**, Iacono I, Brejon S, Swerts K, Noguera R, Gross N, Rousseau R, Puisieux A. Influence of neuroblastoma stage on serum-based detection of *MYCN* amplification. *Pediatric Blood and Cancer* 2009 Sep;53(3):329-31. PMID: 19301388 PMCID: PMC2857568.
73. Okamatsu C, **London WB**, Naranjo A**, Hogarty MD, Gastier-Foster JM, Look AT, LaQuaglia M, Maris JM, Cohn SL, Matthay KK, Seeger RC, Saji T, and Shimada H. Clinicopathological characteristics of ganglioneuroma and ganglioneuroblastoma: A report from the CCG and COG¹. *Pediatric Blood and Cancer*. 2009 Oct;53(4):563-9. PMID: 19530234 PMCID: PMC2730988.
74. Bray I, Bryan K, Prenter S, Buckley PG, Foley NH, Murphy DM, Alcock L, Mestdagh P, Vandesompele J, Speleman F, **London WB**, McGrady PW**, Higgins DG, O'Meara A, O'Sullivan M, Stallings RL. Widespread dysregulation of MiRNAs by *MYCN* amplification and chromosomal imbalances in neuroblastoma: association of miRNA expression with survival. *PloS One*. 2009 Nov 16;4(11):e7850.PMID: 19924232. PMCID: PMC2773120
75. **London WB**, Sondel P, Gilman AL, Ozkaynak F, Kreissman S, Buxton A**, Chen H, Matthay KK, Cohn SL, Maris JM, Yu AL. Success of chimeric anti-GD2 antibody+GM-CSF+IL2 immunotherapy in high-risk neuroblastoma (NB) in first response: a critical appraisal. *Pediatr. Blood Cancer*. 2009 Sept; 53(5):708-708. [_____](#)
76. Katzenstein HM, Chang KW, Krailo M, Chen Z, Bowman LC, Finegold MJ, Rowland J, Greffe B, Reynolds M, Newman K, Womer R, Castleberry RP, Pappo A, **London WB**, Malogolowkin M. Amifostine does not prevent platinum-induced hearing loss associated with the treatment of children with hepatoblastoma. A report of the Intergroup hepatoblastoma study P9645 as part of the Children's Oncology Group. 2009. *Cancer* 2009 Dec 15;115(24):5828-5835. PMID: 19813275 PMCID: PMC2795100
77. Devidas M, **London WB**, Anderson JR. The use of central laboratories and remote electronic data capture to risk-adjust therapy for pediatric acute lymphoblastic leukemia and neuroblastoma. *Seminars in Oncology*. 2010 Feb 37(1):53-59. PMID: 20172365 PMCID: PMC2843557
78. Bensimhon P, Villablanca JG, Sender LS, Matthay KK, Park JR, Seeger R, **London WB**, Yap JS**, Kreissman SG. Peripheral blood stem cell support for multiple cycles of dose intensive induction therapy is feasible with little risk of tumor contamination in advanced stage neuroblastoma: A report from the Children's Oncology Group. *Pediatric Blood and Cancer*. 2010 Apr;54(4):596-602. PMID: 20049927 PMCID: PMC2905158.
79. **London WB**, Frantz FN, Campbell LA, Seeger RC, Brumback BA, Cohn SL, Matthay KK,

96. Villablanca JG, **London WB**, Naranjo A**, McGrady P**, Ames MM, Reid JM, McGovern RM, Buhrow SA, Jackson H, Stranzinger E, Kitchen BJ, Sondel PM, Parisi MT, Shulkin B, Yanik GA, Cohn SL, Reynolds CP. Phase II study of oral capsular 4-hydroxyphenylretinamide (4-HPR/fenretinide) in pediatric patients with refractory or recurrent neuroblastoma: A report from the Children's Oncology Group. *Clinical Cancer Research*. 2011 Nov. 1;17(21):6858-66. Epub 2011 Sept. 9. Doi:10.1158/1078-0432.CCR-11-0995 PMID: 21908574 PMCID: PMC3207022.
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98. Light JE**, Koyama H, Minturn JE, Ho R, Simpson AM, Iyer R, Mangino JL, Kolla V, **London WB**, Brodeur GM. Clinical significance of NTRK family gene expression in neuroblastomas. *Pediatr Blood Cancer*. 2012 Aug;59(2):226-32. Doi: 10.1002/pbc.23343. Epub 2011 Oct 11. PMID: 2199026
99. Park JR, Scott JR, Stewart CF, **London WB**, Naranjo A**, Santana VM, Shaw PJ, Cohn SL, Matthay KK. A pilot induction regimen incorporating pharmacokinetically guided topotecan for treatment of newly diagnosed high-risk neuroblastoma: a Children's Oncology Group study. *J Clin Oncol*. 2011 Nov 20;29(33):4351-7. Epub 2011 Oct 17. PMID: 22010014 PMCID: PMC3221519.
100. De Preter K*, Mestdagh P*, Vermeulen J*, Zeka F, Naranjo A**, Bray I, Castel V, Chen C, Drozynska E, Eggert A, Hogarty MD, Izycka E, **London WB**, Noguera R, Piqueras M, Bryan K, Schowe B, van Sluis P, Molenaar JJ, Schramm A, Schulte JH, Stallings RL, Versteeg R, Laureys G, Van Roy N, Speleman F, Vandesompele J. miRNA expression profiling enables risk stratification in archived and fresh neuroblastoma tumor samples. *Clinical Cancer Research*. 2011 Dec. 15;17(24):7684-92. Epub 2011 Oct. 26. Doi:10.1158/1078-0432.CCR-11-0610. [* = share first authorship] PMID: 22031065 PMCID: PMC4008338
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 - Audrey Evans Prize for the Outstanding Paper in Clinical Research, Advances in Neuroblastoma Research (ANR) 2008 meeting
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Children's Oncology Group (ANBL0621). *Pediatr Blood Cancer*. 2013 Jun;61(6):990-6. Doi: 10.1002/pbc.24900. Epub 2013 Dec 18. PMID: 24347462*

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- Invited commentary

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Non-peer reviewed scholarship in print or other media

Book chapters

1. Kasiske BL, **London W**, Ellison MD. "Factors influencing early placement on the kidney transplant waiting list in the United States" in *Organ Allocation*. J.L Touraine (ed.) Kluwer Academic Publishers, Great Britain, 1998. 135-137.
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Technical reports:

1. **London WB**, Gennings C, Edward E. (1999). A survival analysis of clusters of dependent times to event with censoring using a generalized estimating equations (GEE) approach. Technical Report Number 610, Department of Statistics, University of Florida.

Thesis

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Abstracts, Poster Presentations and Exhibits Presented at Professional Meetings

2022

American Society of Hematology Annual Meeting

2022

American Society of Hematology Annual Meeting

2022

American Society of Hematology Annual Meeting

2022

American Society of Hematology Annual Meeting

2022

Survival of patients with neuroblastoma before versus after reduction of therapy due to the change in age cut-off from 12 to 18 months in Children's Oncology Group (COG) risk stratification (selected for oral poster discussion)
American Society of Clinical Oncology Annual Meeting

2022

Patterns of Relapse after Immunotherapy in Patients with High-Risk Neuroblastoma (selected poster)
American Society of Clinical Oncology Annual Meeting

2021

Integrating Longitudinal Clinical, Sociodemographic and Genomic Data into the National Childhood Cancer Registry (NCCR) (selected poster)
Childhood Cancer Data Initiative National Childhood Cancer Registry Data Summit

2021

Phase II Study of Nivolumab and Ipilimumab in Children and Young Adults with INI1-

- Negative Cancers (selected poster)
American Society of Clinical Oncology Annual Meeting
- 2019 TARGET-CRM: a novel adaptive dose-escalation design for targeted therapies with applications in pediatric oncology (selected oral presentation)
Society of Clinical Trials Annual Meeting, New Orleans, LA
- 2019 Pyruvate Kinase (PK) Protein and Enzyme Levels in the Diagnosis and Clinical Phenotype of PK Deficiency (selected poster)
American Society of Hematology Annual Meeting
- 2019 (selected poster)
American Society of Hematology Annual Meeting
- 2019 (selected poster)
American Society of Hematology Annual Meeting
- 2019 Targeted sequencing in 386 patients with high-risk or recurrent / refractory pediatric extra-cranial solid malignancies: An interim report from the GAIN Consortium / iCat2 Study (selected poster)
Pediatric Cancer Working Group of the American Association for Cancer Research
- 2019 Prognostic Influence of Lactate Dehydrogenase & Serum Ferritin in Neuroblastoma
- 2019 Evaluation of the Intrinsic Hepcidin Idx™ Test to Detect Iron Deficiency in Adolescents/Young Adults (selected poster)
American Society of Pediatric Hematology and Oncology Annual Meeting
- 2019 Health Literacy and Patient Outcomes following Bone Marrow Transplantation (selected poster)
American Society of Pediatric Hematology and Oncology Annual Meeting
- 2019 Evaluation of the Intrinsic Hepcidin Idx™ Test to Detect Iron Deficiency in Adolescents/Young Adults (selected poster)
Pediatric Academic Society Annual Meeting
- 2016 Second malignancies in patients with neuroblastoma: a report from the International Neuroblastoma Risk Group project (Audrey Evans Prize for the Outstanding Paper in Clinical Research)
Advances in Neuroblastoma Research (ANR) 2016 Meeting
- 2008 A Randomized Phase 3 Trial of Myeloablative Autologous Peripheral Blood Stem Cell (PBSC) Transplant (ASCT) for High-Risk Neuroblastoma (HR-NB) Employing Immunomagnetic Purged versus Unpurged PBSC: A Children's Oncology Group (COG)

Study (Audrey Evans Prize for the Outstanding Paper in Clinical Research)
Advances in Neuroblastoma Research (ANR) 2008 Meeting

- 2007 Surgery and restricted use of chemotherapy as treatment of low-risk neuroblastoma: Preliminary results of Children's Oncology Group protocol 9641 ("Best of SIOP" Award Lecture)
American Society of Pediatric Hematology/Oncology (ASPHO)
- 2006 Surgery and restricted use of chemotherapy as treatment of low-risk neuroblastoma: Preliminary results of Children's Oncology Group protocol 9641 (Winner of "Best Clinical Trials" presentation)
38th Congress of the International Society of Paediatric Oncology
- 2006 Age, Tumor Grade, and Mitosis-Karyorrhexis Index are Independently Predictive of Outcome in Neuroblastoma (Best Clinical Science Poster)
University of Florida College of Medicine Research Day
- 2006 Age, Tumor Grade, and MKI Are Independently Predictive of Outcome in Neuroblastoma (Audrey Evans Prize for the Outstanding Paper in Clinical Research)
Advances in Neuroblastoma Research (ANR) 2006 Meeting
- 1990 Teaching the SAS programming language to programmers and non-programmers ("Best Contributed Paper" in the section Education, Consulting, and Technical Support)
SAS Users Group International 15th Annual Conference
- 1989 Standard operating procedure in the creation, maintenance, and quality assurance of SAS programs ("Honorable Mention" in the section on in Education, Consulting, and Technical Support)
SAS Users Group International 14th Annual Conference

Narrative Report

I am a biostatistician, a teacher, a mentor, a leader, an administrator, a scientist. Team science:

Above and beyond team science, I lead independent research as a NB scientist; I am the world's leading expert in the identification and application of NB prognostic factors to determine treatment intensity. My NB research program has been conducted in my dry lab; I have mentored dozens of clinical investigators in successful publication of research and career development. My unique combination of expertise in NB and in biostatistics is synergistic; few others, if any, could develop the innovations in NB risk/treatment stratification that I have. My area of excellence is Investigation, with interdisciplinary expertise in biostatistics, pediatric solid tumors and blood disorders, leadership in clinical trials, and advancements in NB.

Early career - I played an instrumental role (1987-92) in the success of CRO start-up I trained at Virginia Commonwealth University's Medical College of Virginia while working at the United Network for Organ Sharing (UNOS). My interests in survival analysis and cancer led to a faculty position as a biostatistician in the Children's Oncology Group [COG¹], an NIH/NCI cancer cooperative group, at the University of Florida's COG Statistics and Data Center. Thereafter, my research career evolved to a focus in NB.

NB Risk stratification research and impact - I am the world's leading statistical expert in NB risk stratification. My dry lab research has accurately identified which children need more/different therapy to survive, and who can survive/thrive with less/no therapy [33,34,37,38,43,51,53,56,59,60,66,68,71,80,86,92,94,97,100,114,127,133,136,137,138,153,160,174,194,200,207,210,216,220]. I identified an optimal 547-day (18-month) age cut-off to differentiate younger (better outcome) from older (worse outcome) patients [34,243]. We reached international consensus to change the age cut-off from 12 months to 18 months. COG¹ instituted a new standard of care for two subgroups of toddlers 12-18 months old at diagnosis: (INSS stage 4, favorable *MYCN*, INPC, and ploidy) and (INSS stage 3, *MYCN* not amplified, unfavorable INPC). Due to the age cut-off change, these patients received a reduction of therapy from intensive multi-modality including stem cell transplant, to response-adaptive chemotherapy, resulting in less treatment-related toxicity. The 18-month age cut-off was used in the new International Neuroblastoma Risk Group Staging System (INRGSS) [56]. As the Chair of the International Neuroblastoma Risk Group (INRG) Statistics Committee, I have scientific oversight for the INRG Data Commons (>24,000 patients), and review/approve national and international proposals for data analyses.

I have a unique perspective and skill set, a hybridization of expertise in NB and statistical methodology. Dr. Lucas Moreno and I developed a nomogram to identify an “ultra-high-risk” cohort [220] <https://neuroblastoma.shinyapps.io/High-Risk-Neuroblastoma-Nomogram/>, utilized by the Global Neuroblastoma Network (coordinated by St. Jude Children's Research Hospital). Next, my dry lab research seeks improvement in high-risk NB stratification. My mentee, Dr. Moreno (PI), and I (Co-PI) were awarded a 3-year grant from Solving Kids' Cancer to identify children with the highest chance of dying from their NB, to offer experimental therapy instead of standard of care at diagnosis. (Without a government funding system, preeminent European foundations like Solving Kids' Cancer use a rigorous NIH-like peer-review process to award funding.)

Clinical trials: design, conduct, and impact - The COG¹ is an NIH/NCI funded infrastructure for the conduct of trials that set the standard of care for children with cancer; COG is not a professional society. Unlike committees for societies, COG¹ committees are scientific working groups that design and conduct clinical trials, with a separate ‘committee’ for each disease. Appointment to a COG¹ committee as the biostatistician carries a greater level of national prominence than election to a national society. I was 95-100% funded by the NIH/NCI to perform research on COG¹ trials from 1998-2009, decreasing to 30% (2009-2014) when I moved to DFCI/BCH. During my tenure as a COG¹ statistician, our NB clinical trials resulted in dramatic improvements in outcome: 3-year overall survival for high-risk NB increased from ~30% in 1998 to >60% in 2019. Over two decades, I designed and conducted phase 2 and 3 trials that set new standards of care: FDA approval of dinutuximab after transplant in high-risk NB [75,82] (ANR² plenary 2010); tandem transplant for high-risk NB [204] (American Society of Clinical Oncology [ASCO] plenary 2016); expectant observation for infants <6 months old [116]; reduction of chemotherapy in intermediate-risk NB [81,202]; emergent therapy for symptomatic intermediate-risk NB [193]; topotecan plus cyclophosphamide for relapsed/refractory [79] and newly diagnosed NB [99]; and, intravenous immunoglobulin for opsoclonus myoclonus ataxia syndrome [179]. I have been the statistician for key NB biomarkers, including ALK for targeted therapy (crizotinib) [53,92,142], 1p and 11q LOH [39], ODC1 [57], *MYCN* expression [11], and the genetic landscape of high-risk NB [120]. In addition, I led the efforts to describe progression-free survival in a large historical cohort of relapsed/refractory NB [176], providing a historical basis to which experimental therapies can be compared in future national/international phase 2 trials. I served as statistician on landmark trials for gene therapy for X-Linked Severe Combined Immunodeficiency [139], secondary malignancies in pediatric Hodgkin disease [49], outcome/staging/treatment of malignant germ cell tumors [19,20,22], NUT midline carcinoma [110], the kidney transplant waiting list [5], and response-based treatment for intermediate/high-risk Hodgkin disease [70].

International reputation in NB clinical research - I received invitations to present the landmark results of our randomized trial of dinutuximab at the University of Cologne (2009), Royal Marsden (2009) and the International Society of Pediatric Oncology (Sao Paulo, Brazil, 2009). Drs. Frank Berthold (University of Cologne) and Lothar Krempel (Max Planck Institute for the Study of Societies) conducted an analysis entitled, “The development of the ANR² (Advances in Neuroblastoma Research) network: A study of the contributions 1975-2015”. Of 7,787 authors/investigators worldwide, I ranked 11th in the number of ANR² abstracts. My H-indices are 88 (Google Scholar) and

66 (Web of Science), my i10-index is 214, and my publications have been cited 29,429 times (Google Scholar) or 17,610 (Web of Science), a large number given the rarity of NB.

COG¹ NB Virtual Tumor Bank development - I conceived and designed the COG¹'s NB Virtual Tumor Bank (NVTB) database, linking clinical, biological, outcomes, and specimen data for COG¹ and international contributors. My foresight to require submission of outcome data on COG¹ NB biology studies laid the groundwork for two decades of fruitful genetic biomarker research that would otherwise have not been possible. Scientists use the NVTB for national and international basic science projects, including Dr. John Maris' [38,46,64,69,88,118,120], and Dr. Michelle Haber's labs [11,28,42,57,95,103,135,157,162,165,196,226].

Impact of statistical methodology development - I developed new methods for stratified Phase 2 designs [35], utilized for design and conduct of at least eight national multi-center NIH/NCI oncology phase 2 clinical trials of small, heterogeneous cohorts. I developed the statistical framework for the national COG¹ and international INRG risk stratifications; one approach used a novel finite mixture survival model [63]. I am mentoring Dr. Arlene Naranjo in creating the new COG¹ NB risk stratification [195]. Under my mentorship, Dr. Clement Ma and I have developed new methods for novel adaptive phase 1 trial designs to favor accrual within rare genomic subgroups (manuscript submitted). I am the statistician for four adaptive-design phase 1 trials currently underway at DFCI/BCH; adaptive phase 1 designs are a groundbreaking approach in pediatric oncology. Dr. Ma and I have developed the DEDUCE application for design and conduct of adaptive trials by a statistician-clinician duo; this soon-to-be-released application will be open-source, available to scientists worldwide.

Mentoring and teaching - I have mentored >100 fellows and junior faculty in COG¹, BCH, DFCI, and elsewhere; many have advanced to leadership roles or published landmark papers (see "Other Mentored Trainees and Faculty"). I have mentored five biostatistics graduate students, including two at Harvard School of Public Health. I mentored junior faculty on K awards (including Dr. David Shulman), and my first Wellesley College intern attends the University of Michigan medical school. I am an invited faculty member at the annual American Association for Cancer Research (AACR)/ASCO Methods in Clinical Cancer Research workshop in Vail, Colorado (plenary lecture on correlative studies). I lecture on clinical trials and statistics to hem/onc fellows, clinicians and COG¹ members, some for CME credit. I have taught >20 oncologists in our Global Health Initiative. In my dry lab, I have mentored dozens of clinicians on NB clinical research projects, with successful manuscript publications. An integral component of my teaching occurs daily, in one-on-one sessions with clinician-scientists for specific trials.

National service - I have served as a permanent member on the NIH's Clinical Oncology (CONC) Study Section and Therapeutic Immune Regulation (TIR) Study Section (R01/R21), ad-hoc on Subcommittee H (peer review of NIH/NCI Cancer Cooperative Groups) and NIH's Cancer Biomarker Study Section. I am on the editorial board of the *Journal of the National Cancer Institute* (impact factor: 12.6) and the AACR Clinical Trials Committee. I served on the editorial board of the *Journal of Clinical Oncology* (impact factor: 44.54), ASCO Program Committee, and as an assistant editor for Medical and Pediatric Oncology.

Local administrative and informatics accomplishments - My Significant Supporting Activity is Administrative and Institutional Service. I led the University of Florida's COG¹ Statistics and Data Center while transitioning to electronic data capture, managing five PhD statisticians and 20 staff (~\$2M annual budget). At DFCI/BCH, I built two new programs: the Biostatistics Program, and the Clinical and Translational Investigation Program (CTIP) to provide infrastructure for clinical research. CTIP is a model for clinical research infrastructure at BCH, growing from 15 to >60 staff and supporting seven disease programs during my 10-year tenure. The Biostatistics Program has a self-sustaining funding model. My infrastructure and training grant from Alex's Lemonade Stand Foundation (Multi-PI: London and Dubois) supports clinical research staff and protected time for junior faculty. To address a critical need to integrate and harmonize data between BCH and DFCI for efficient and reproducible analyses, I created the Pediatric Patient Informatics Platform (PPIP) [223], a datamart harmonizing 14 source databases: 2,622 data items/33,674 patients/3.6 million visits. PPIP contributes data to DFCI's PRISMM project, the National Childhood Cancer Registry, Massachusetts Cancer Registry, and internationally via NIH/AACR's Project GENIE. I

am the Director for the DF/HCC Survey and Qualitative Methods Core (2014-present) and I have served on multiple institutional committees.

I take great pleasure and pride in the complimentary/interdisciplinary aspects of my research and teaching. It is a privilege to contribute to world class team science for pediatric cancers and blood disorders. Using my biostatistical and neuroblastoma expertise, I will continue work in my dry lab to advance my research program to improve treatment and outcome for children with neuroblastoma.