### Harvard Medical School Curriculum Vitae

	Curriculum vitae
Date Prepared:	March 3, 2024
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Place of Birth:	Detroit, Michigan, USA

### Education

Year	Degree	Fields of Study	Institution
	(Honors)	(Thesis advisor for doctoral	
		research degrees)	
05/1982	BS	Atmospheric Science/Mathematics	Purdue University
12/1997	PhD	Biostatistics	Medical College of
		(Chris Gennings, PhD)	Virginia, Virginia
			Commonwealth University

# Faculty Academic Appointments

Year(s)	Academic Title	Department	Academic Institution
1/1998-	Research Assistant	Department of Statistics	University of Florida
4/2005	Professor/Biostatistician		College of Liberal Arts and
			Science
5/2005-	Research Assistant	Dept of Epidemiology and Health	University of Florida
8/2006	Professor/Biostatistician	Policy Research	College of Medicine
8/2006-	Research Associate	Dept of Epidemiology and Health	University of Florida
10/2009	Professor/Biostatistician	Policy Research	College of Medicine
12/2010-	Associate Professor of	Division of	Boston Children's Hospital
1/2024	Pediatrics	Hematology/Oncology	(BCH), Harvard Medical
			School, Harvard University
1/2024-	Professor of Pediatrics	Division of	Boston Children's Hospital
present		Hematology/Oncology	(BCH), Harvard Medical
			School, Harvard University

Year(s)	Academic Title	Department	Academic Institution
5/2008-	Affiliate Research	Dept of Biostatistics	University of Florida
6/2014; and,	Associate Professor		Colleges of Medicine and
12/2019-			of Public Health &Health
12/2023			Professions (non-voting)
7/2012-	Affiliate faculty member	Dept of Data Science	Dana-Farber Cancer
present			Institute (DFCI), HMS,
			Harvard University (non-
			voting)
7/2012-	Affiliate Associate	Dept of Biostatistics	Medical College of
12/2023	Professor		Virginia, Virginia
			Commonwealth University
			(non-voting)
1/2024-	Affiliate Research	Dept of Biostatistics	University of Florida
present	Professor		Colleges of Medicine and
			of Public Health &Health
			Professions (non-voting)
1/2024-	Affiliate Professor	Dept of Biostatistics	Medical College of
present			Virginia, Virginia
			Commonwealth University
			(non-voting)

### Faculty Academic Affiliate Appointments

### **Other Professional Positions**

Year(s)	Position Title	Institution
1982-1983	Meteorologist	Climatological Consulting Corp., Asheville,
		NC
1983	Meteorologist/Programmer	National Climatic Data Center, Asheville, NC
1983-1987	Programmer/Meteorologist	Simpson Weather Associates, Inc.,
		Charlottesville, VA
1987-1988	Senior Programmer/Analyst	Pharmaceutical Research Associates, Inc.
		(PRA), Charlottesville
1988-1992	Supervisor of Analysis Programming	Pharmaceutical Research Associates, Inc.
		(PRA), Charlottesville, VA
1992-1997	Graduate Assistant	Dept. of Biostatistics, Medical College of
		Virginia, Virginia Commonwealth University
1992-1997	Biostatistician	United Network for Organ Sharing (UNOS),
		Richmond, VA
2014-2021	Consultant	United Therapeutics Corporation, Silver
		Spring, MD
2018-	Consultant	Jubilant Draximage Inc, Kirkland, Quebec
present		
2018-2020	Consultant	ArQule, Inc. Burlington, MA
2020-2023	Consultant	Merck Sharp & Dohme Corp, Kenilworth, NJ
2022	Consultant	Healthcasts, New York, NY
2022-2023	Scientific Advisory Board Member	Y-mAbs Therapeutics, Inc, New York, NY

#### **Major Administrative Leadership Positions**

#### Local

Year(s)	Position Title	Institution (note if specific department)
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 <sup>1</sup> (COG) Statistics and Data Center,
		Univ of Florida
2009-	Director of Biostatistics	Division of Hematology/Oncology, Boston
present		Children's Hospital, Dana-Farber/Boston
		Children's Cancer and Blood Disorders
		Center, Harvard Medical School
2009-2019	Director, Clinical and Translational	Division of Hematology/Oncology, Boston
	Investigation Program (CTIP)	Children's Hospital, Dana-Farber/Boston
		Children's Cancer and Blood Disorders
		Center, Harvard Medical School
2012-	Faculty Director, Survey and Qualitative	Dana-Farber / Harvard Cancer Center
present	Methods Core	
2012-	Co-Director, Research and Data Analysis	Partnership of the University of
present	Core	Massachusetts/Boston and Dana-Farber
		Cancer Institute
2022-	Director, Biostatistics Core	Dana-Farber/Harvard Cancer Center Glioma
present		SPORE

### National and International

(Each COG<sup>1</sup> disease committee is a distinct, scientific working group with its own long term strategic plan. Dr. London was funded full-time by COG<sup>1</sup> grants for 12 years, and 30% effort for five years after moving to Boston Children's Hospital, thus her leadership on multiple COG<sup>1</sup> scientific and administrative committees.)

Year(s)	Position Title	Institution (note if specific department)
1998-	Scientific Steering Committee Member	Children's Oncology Group (COG <sup>1</sup> )
present		Neuroblastoma Committee
1998-2014	Executive Committee Member	COG <sup>1</sup> Neuroblastoma Committee
1998-2014	Lead Statistician	COG <sup>1</sup> Neuroblastoma Committee

<sup>&</sup>lt;sup>1</sup> 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 and basic science research; each competes separately for funding on the NIH U10 grant. COG leadership, including the statisticians, are nationally and internationally prominent members of the pediatric cancer research community.

Year(s)	Position Title	Institution (note if specific department)
1998-2003	Scientific Steering Committee Member	COG <sup>1</sup> Germ Cell Tumor Committee
1998-2003	Scientific Steering Committee Member	COG <sup>1</sup> Liver Tumor Committee
1999-2004	Scientific Steering Committee Member	COG <sup>1</sup> Hodgkin Disease Committee
2002-2003	Executive Committee Member	Children's Oncology Group <sup>1</sup>
2004-2009	Coordinating Statistician	COG <sup>1</sup> Statistics and Data Center, University of
		Florida site
2004-	Chair	Statistics Committee of the International
present		Neuroblastoma Risk Groups (INRG) Project
2024-2026	Co-Chair	American Society of Clinical Oncology
		/American Association for Cancer Research
		Methods in Clinical Cancer Research
		Workshop; La Jolla, CA

### **Committee Service**

### Local

Year(s) of	Name of Committee	Institution/Organization
Membership	Dates of Role(s)	Title of Role(s)
1999, 2001,	Dept. of Statistics Search Committee	University of Florida
2002	1999, 2001, 2002	Member
1999	Graduate Student Forum paper	University of Florida
	competition of the Graduate Student	Judge
	Council	
	1999	
2000	University of Florida Graduation	University of Florida
	Ceremony	Commencement Marshall
	2000	
2000-2003	Environmental Health and Safety	University of Florida
	Committee	Member
	2000-2003	
2002-2009	Pediatric Oncology Working Group	University of Florida Shands Cancer Center
	2002-2009	Member
2003	Challis Lecture Committee, Dept of	University of Florida
	Statistics	Dept of Statistics
	2003	Chair
2005	Division of Biostatistics Search	University of Florida
	Committee	Member of 3 committees
	2005	
2005	Search Committee for Human Resources	University of Florida, Dept of Epi & Health
	Staff	Policy Research, Div of Biostatistics
	2005	Member
2005-2007	CTSI Community Outreach: Subject	University of Florida
	Recruitment and Retention Core	Member
	Committee	
	2005	

Year(s) of	Name of Committee	Institution/Organization
Membership	Dates of Role(s)	Title of Role(s)
2005-2006	Search Committee for five tenure track	University of Florida, Dept of Epi & Health
	faculty members	Policy Research, Division of Biostatistics
	2005-2006	Member
2005-2006	Search Committee for Division Director	University of Florida, Dept of Epi & Health
	of Biostatistics	Policy Research, Division of Biostatistics
	2005-2006	Member
2005-2007	Epidemiology PhD Planning Committee	University of Florida, Department of
	2005-2007	Epidemiology and Health Policy Research
2007 2000		Member
2007-2008	Search Committee for Division Chief of	University of Florida, Department of
	Pediatric Hematology/Oncology	Pediatrics
2000 2010	2007-2008	Member
2009-2019	Search Committees for CTIP positions:	Division of Hematology/Oncology, Boston
	Associate Director trial monitor	Hogpital Cancer Care
	Associate Director, that monitor,	Chair
	Assoc Director: 2010	Chan Member
	Research Nurse: 2012 2015	Member
	Assoc Director: 2019	Chair
2010- present	Dana-Farber / Harvard Cancer Center	Division of Hematology/Oncology, Dana-
-oro prosent	Biostatistics Core	Farber/Boston Children's Cancer and Blood
	2010-present	Disorders Center
	1	Member
2011	Ad-hoc Promotion Committee for a	Harvard Medical School
	candidate for Associate Professor	Member
	2011	
2012	Strategic Planning: Clinical Studies	Dana-Farber Cancer Institute
	Committee	Member
	2012	
2012	OnCore Rollout: Biostatistics	Dana-Farber Cancer Institute
	Committee	Member
	2012	
2012	OnCore Rollout: Metrics and Reporting	Dana-Farber Cancer Institute
	Committee	Member
2012		
2012- present	Executive Committee of the Population	Dana-Farber Harvard Cancer Center
	Sciences Program	Member
2014 2015	2012-present	Distriction of Homestelland (O. 1. D. )
2014-2015	Search Committee for PhD faculty	Division of Hematology/Oncology, Boston
		Chair
1	2017-2013	Cilali

Year(s) of	Name of Committee	Institution/Organization
Membership	Dates of Role(s)	Title of Role(s)
2015-2019	Data and Safety Monitoring Board	Boston Children's Hospital protocol: A Phase
	2015-2019	I/II, double blinded, placebo controlled,
		single-center Study of Fecal Microbiota
		Transplant (FMT) for the Treatment of Active
		Pediatric Ulcerative Colitis
		Member
2016 & 2024	Search Committee for PhD Survey	Dana-Farber/Harvard Cancer Center's Survey
	Methodologist	and Qualitative Methods Core
	2016	Chair
	2024	Chair
2016-2019	Data and Safety Monitoring Board	Boston Children's Hospital protocol: A Phase
	2016-2019	I/II, double blinded, placebo controlled,
		single-center Study of Fecal Microbiota
		Transplant for the Treatment of Active
		Pediatric Crohn's Colitis
		Member
2016- present	Pediatric Hematology-Oncology	Dana-Farber / Boston Children's Cancer and
_	Informatics Steering Committee	Blood Disorders Center
	(Big Data Initiative)	Member
	2016- present	
2016-2019	Clinical Research Initiative	Dana-Farber / Boston Children's Cancer and
	2016-2019	Blood Disorders Center
		Member
2018-2019	Ad-hoc Promotion Committee for a	Boston Children's Hospital & Harvard
	candidate for Associate Professor	Medical School
	2018-2019	Member
2021- present	Diversity, Equity, and Inclusion	Dana-Farber / Boston Children's Cancer and
	Committee	Blood Disorders Center
	2021-	Member
2021-present	Wellesley College Internship Selection	Dana-Farber / Boston Children's Cancer and
	Committee	Blood Disorders Center
	2021-	Member

### National and International

Year(s) of Membership	Name of Committee Dates of Role(s)	Institution/Organization Title of Role(s)
1998- present	NIH/NCI Children's Oncology Group	Member
rijio present	1998 – present	Neuroblastoma Committee
	1999-2004	Member
	1999-2012	Informatics Advisory Committee
	2000-2006	Member
	2001-2014	Biological and Translational Research
	1998-2014	Committee
	2002-2003	Member
	2002 2003	Biological and Translational Research
	2006-2012	Committee
	2011-2013	Member
	2011-2015	Scientific Review Panel of the
		Neuroblastoma Biology Committee
		Member
		Statistics Discipline Committee
		Chair
		Neuroblastoma Common Data Elements
		Committee
		Member
		Search Committee for Group Statistician
		Executive Committee Member
		Phase II/III Data Safety Monitoring
		Committee
		Member
		Nominating Committee
2008-2009	Data Safety Monitoring Board	Neurofibromatosis Consortium
2000-2007	2008-2009	Member
2000 2015	Data Safety Monitoring Board	Division of Microbiology and Infectious
2009-2015	2000 2015	Division of Microbiology and Infectious Discoses (DMID) Protocol 07 0012:
	2009-2015	Diseases (DivinD) Flotocol 07-0012.
		Randonnized Inal of Aziunoniyem versus
		infaction in families in youth correctional
		facilities
		Mombor
2011 2019	International Neuroplasterna Degrange	National Cancer Institute
2011-2018	Criteria Working Crease	Free entires Committee Member
	2011-2018	Executive Committee Member
2019-2022	Data Safety Monitoring Board	"RQ 092 (Miransertib) in Subjects with
	2019-2022	PIK3CA-related Overgrowth Spectrum and
		Proteus Syndrome". Sponsor: Merck
		(originally ArQule, Inc.)
		Member

Year(s) of	Name of Committee	Institution/Organization
Membership	Dates of Role(s)	Title of Role(s)
2019- present	Data Safety Monitoring Board	Jubilant Draximage trial of
	2019- present	metaiodobenzylguanidine (MIGB) in
		neuroblastoma
		Member
2020-present	The INRG Version 2 Task Force	The International Neuroblastoma Risk
	2020- present	Groups Project
		Co-Chair
2022-present	Data Safety Monitoring Board	An international multicenter phase II
	2022-present	randomised trial comparing two
		intensification treatment strategies for
		metastatic neuroblastoma patients with a
		poor response to induction chemotherapy:
		A SIOPEN Study ("Veritas")
		Member
2022-present	Data Safety Monitoring Board	Memorial Sloan-Kettering pediatric cancer
	2022-present	trials
		Member
2023-present	FDA Advisory Committee	Cellular, Tissue, and Gene Therapies
	2023-2027	Advisory Committee of the Food and Drug
		Administration
		Member

# **Professional Societies**

Year(s) of	Society Name	Title of Role(s)	
Membership	Dates of Role(s)		
1987-1992	SAS Users' Groups International	Member	
	1987-1992	Session Coordinator	
	1990, 1991, 1992	Section Chair, Northeast SAS Users' Group	
	1991, 1992	Pharmaceutical Section	
1990- present	American Statistical Association	Member	
	1990-	Member, Local Arrangements Committee	
	1996	for Eastern North American Region	
	1999	(ENAR) of American Statistical	
		Association (ASA)	
		Session Chair, Joint Statistical Meetings	
2005- present	American Society of Clinical Oncology	Member, Scientific Program Committee	
	(ASCO)		
	2013-2016		
1999, 2004,	Societe Internationale d'Oncologie	Member	
2009-2019,	Pediatrique (SIOP)		
2022-present			

Year(s) of	Society Name	Title of Role(s)
Membership	Dates of Role(s)	
2008- present	Advances in Neuroblastoma Research	Abstract Selection Reviewer
	(ANR) Association	Elected Member, Advisory Board
	2006, 2010, 2014, 2016, 2018, 2020, 2022,	
	2023	
	2008-2023	
2010- present	American Association for Cancer Research	Member
	(AACR)	Annual Meeting Clinical Trials Committee
	2010- present	Plenary Session Chair of "Early Clinical
	2020-2022	Trials with New Anticancer Agents"
	2021	Invited Co-Chair, Clinical Trials Design
	2023	Workshop at the AACR annual meeting
	2024	Member, Selection Committee for the
	2024	Daniel Van Hoff award
		Plenary Session Chair of "Biostatistics in
		Clinical Trials Workshop: Out of the Rut
		and Beyond the Traditional – Parts 1 & 2"
		at the AACR annual meeting
2011-2014,	Society for Clinical Trials (SCT)	Member
2020-present	2020-2021	Chair, Communications Committee
	2022-	Member, Outreach Committee
2011- present	Society for Pediatric Research (SPR)	Elected Member
2014-2018	American Society of Hematology (ASH)	Member
2017- present	American Pediatric Society (APS)	Elected Member

### **Grant Review Activities**

Year(s) of	Name of CommitteeInstitution/Organization	
Membership	Dates of Role(s)	Title of Role(s)
2005-2010	Clinical Oncology (CONC) Study Section	National Institutes of Health (NIH)
	for R01 & R21 grant review	Ad hoc Member
	2005	Permanent Member
	2006-2010	
2005-2009	Grant Productivity Committee	STOP! Children's Cancer Inc., Gainesville,
	2005-2009	Florida
		Chair
2010	Subcommittee H Study Section for review	National Institutes of Health (NIH)
	of the NIH/NCI cancer cooperative groups	
	2010	Ad-hoc Member
2011-2012	Neuroblastoma Innovation Panel	Department of Defense (DoD)
	2011-2012	Congressionally Directed Medical Research
		Programs, American Institute of Biological
		Sciences
		Member
2012	Cancer Biomarkers Study Section (CBSS)	National Institutes of Health (NIH)
	for R01 and R21 grant review	Ad hoc Member
	2012	

Year(s) of Membership	Name of Committee Dates of Role(s)	Institution/Organization Title of Role(s)	
2016	Neuroblastoma (NB) peer review panel of Department of Defense (DoD)		
2021	the Peer Reviewed Cancer Research Congressionally Directed		
	Program (PRCRP)	Programs (CDMRP)	
	2016, 2021	Member	
2018-2019	Clinical Trial Support Award Committee	Dana-Farber Cancer Institute	
	2018, 2019	Member	
2018	Scientific peer review panel of grant	Neuroblastoma UK	
	applications	Member	
	2018		
2019	Scientific peer review panel of grant	Children's Cancer and Leukaemia Group	
	applications	UK	
	2019	Member	
2020	International Neuroblastoma Research	Solving Kids' Cancer UK	
	Initiative - Scientific peer review of grant	Member	
	applications for \$1.4M pilot trial		
	2020		
2021	Emerging Scientist Award (\$100,000)	Children's Cancer Research Fund	
	Review Committee	Member	
	2021		
2022	Cancer Immunopathology and	National Institutes of Health (NIH)	
	Immunotherapy (CII) Study Section	Ad-hoc member	
	for R01 and R21 grant review		
	2022		
2022-present	Therapeutic Immune Regulation (TIR)	National Institutes of Health (NIH)	
	Study Section for R01 and R21 grant	Permanent Member	
	review		
	2022-present		
2024	Consortia Project - neuroblastoma grant	KWF Dutch Cancer Society	
	review (€2,200,000)	External reviewer	
	2024		

### **Editorial Activities**

#### **Ad Hoc Reviewer**

- New England Journal of Medicine
- Journal of Clinical Oncology
- Journal of the American Medical Association Oncology
- Annals of Oncology
- Pediatric Blood and Cancer
- Statistics in Medicine
- Journal of Pediatric Hematology/Oncology
- Pediatrics
- Clinical Cancer Research
- Oncology
- Future Oncology

- Journal of the National Cancer Institute
- Journal of the National Cancer Institute Cancer Spectrum
- International Journal of Environmental Research and Public Health
- Expert Opinion on Drug Safety
- Targeted Oncology
- British Journal of Cancer
- Controlled Clinical Trials
- Cancer
- Cancers
- Cancer Medicine
- Translational Pediatrics
- *eBioMedicine (A Lancet family journal)*
- *Nature Medicine*
- *Nature Communications*

#### **Other Editorial Roles**

Year(s)	Role	Journal Name
2000-2003	Assistant Editor	Medical and Pediatric Oncology
2013-2020	Editorial Board	Journal of Clinical Oncology
	Member	
2020-	Editorial Board	Journal of the National Cancer Institute
present	Member	

Year	Name of Honor/Prize	Awarding Organization	Achievement for which awarded (if unclear from award title)
1989	Honorable Mention Paper	SAS User's Group International Section on Education, Consulting, and Technical Support	
1990	Best Contributed Paper	SAS User's Group International, Section on Education, Consulting, and Technical Support	
2005	International Educator of the Year	University of Florida College of Medicine	Junior Faculty Nominee
2006	Audrey Evans Prize	Advances in Neuroblastoma Research Association, Los Angeles, CA	Outstanding Paper in Clinical Research
2006	International Society of Pediatric Oncology (SIOP) Award	38 <sup>th</sup> Congress of the International Society of Paediatric Oncology, Geneva, Switzerland	Best Clinical Trials Abstract (as a co-author and lead statistician)
2006	Best Clinical Science Poster	University of Florida College of Medicine Research Day	
2007	Best of SIOP Award lecture	American Society of Pediatric Hem/Oncology, Toronto, Ontario	
2008	Audrey Evans Prize	Advances in Neuroblastoma Research Association, Chiba, Japan	Outstanding Paper in Clinical Research (as a co- author and lead statistician)
2010	Faculty 1000 selection	New England Journal of Medicine. 2010 Sep 30:363(14): 1324-34	Selected as being within the top 2% of published articles in biology and medicine (as co-author and lead statistician)
2015	Distinguished Clinical Research Achievement Award	The Clinical Research Forum – Top 10 Clinical Research Achievement Award winner	New England Journal of Medicine. 2014 371(15): 1407-1417 (as co-author and lead statistician)
2016	Audrey Evans Prize	Advances in Neuroblastoma Research Association, Cairns, Australia	Outstanding Paper in Clinical Research (as a co- author and statistician)
2018	Top 10 papers of 2018	Selected by the journal Blood	<i>Blood.</i> 2018 131:2183- 2192 (as co-author and lead statistician)
2021	Reviewer of the Month	Selected by the journal Translational Pediatrics	Reviewer of the Month for March 2021

### **Honors and Prizes**

# **Report of Funded and Unfunded Projects**

# **Funding Information**

### Past

Date	Grant Title	
	Grant Type and Number	
	Role on Project (if PI or site PI, total indirect costs)	
1000 0001	Description of the major goals	
1998-2001	Pediatric Oncology Group (POG) Statistical Office and Data Center (SDC) Grant	
	NIH/NCI: U10 CA29139 (5 <sup>th</sup> & 6 <sup>th</sup> competitive renewal)	
	Co-Investigator (PI: Jonathan Shuster)	
	Scientific oversight for design and conduct of national and international clinical and	
	of core for redictric concers at ~220 treating institutions. Determine new standard	
	Faculty (6) and staff (15) collaborate with POG investigators and perform study design	
	data collection safety monitoring statistical analyses and manuscript generation	
1999	Pediatric Oncology Group (POG) Statistical Office and Data Center Grant	
1777	Donor gifts from Dr. Sharon Murphy, Children's Memorial Hospital, Chicago, IL	
	Co-Investigator (PI: Ionathan Shuster)	
	Improve computer infrastructure of the POG Statistical Office	
1999-2002	Pediatric Oncology Group (POG) Statistical Office and Data Center grant – Phase I	
	Consortium	
	NIH/NCI: U10 CA57745 (5 <sup>th</sup> competitive renewal)	
	Co-Investigator (PI: Jonathan Shuster)	
	Design and conduct Phase I pediatric cancer clinical trials to determine safety and	
	maximum tolerated dose. Perform study design, data collection, safety monitoring,	
	statistical analyses, and manuscript generation.	
2001-2002	Supplemental Funding for The Pediatric Oncology Group Statistical Office and Data	
	Center Grant	
	NIH/NCI: UI0 CA3/3/9 Co. Investigator (DI. Janothan Shuator)	
	Co-investigator (P1: Jonathan Shuster)	
	trials in pediatric concers at 220 treating institutions. Determine new standard of care for	
	nediatric cancer. Trial/study design monitoring statistical analyses manuscripts	
2002	Pediatric Oncology Group Statistical Office and Data Center Grant	
2002	NIH/NCI: U10 CA29139 (7 <sup>th</sup> competitive renewal)	
	Co-Investigator and Site PI (PI: James Anderson): \$2.202.258 direct costs to site	
	Scientific oversight for design and conduct of national/international clinical and biological	
	trials in pediatric cancers at ~220 treating institutions. Determine new standard of care for	
	pediatric cancer. Trial/study design, monitoring, statistical analyses, manuscripts.	
2002	Supplemental Funding for the Children's Oncology Group Research Data Center	
	NIH/NCI: U10 CA37379 (1 <sup>st</sup> renewal)	
	Co-Investigator and Site PI (PI: James Anderson); \$329,925 total direct costs to site	
	Scientific oversight for design and conduct of national/international clinical and biological	
	trials in pediatric cancers at ~220 treating institutions. Determine new standard of care for	
	pediatric cancer. Trial/study design, monitoring, statistical analyses, manuscripts.	

Date	Grant Title	
	Grant Type and Number	
	Role on Project (if PI or site PI, total indirect costs)	
	Description of the major goals	
2002-2006	Community Clinical Oncology Program of the Children's Oncology Group	
	NIH/NCI: U10 CA95861 (3 <sup>rd</sup> competitive renewal)	
	Co-Investigator and Site PI (PI: Bradley Pollock); \$115,052 total direct costs to site	
	Scientific oversight for design and conduct of national/international epidemiologic trials in	
	pediatric cancers. Study design, monitoring, statistical analyses, and manuscripts.	
2003-2014	Children's Oncology Group Statistics and Data Center	
	NIH/NCI: U10 CA98413 (3 competitive renewals)	
	Co-Investigator	
	Site PI (PI: James Anderson); \$9,016,769 total direct costs to site	
	With the merger of the four pediatric cancer cooperative groups, the COG <sup>1</sup> became the	
	only NIH/NCI funded cooperative group for pediatric cancer. Scientific oversight for	
	design/conduct of national/international clinical/biological trials in pediatric cancer at ~230	
	treating institutions. Determine improved standard of care. Supervise faculty (3) and staff	
	(18) for study design, data collection, safety monitoring, statistical analyses, and	
	manuscripts. My scientific focus: neuroblastoma clinical research trials.	
2003	Supplemental Funding for the Children's Oncology Group (COG <sup>1</sup> ) Statistics and Data	
	Center (SDC)	
	NIH/NCI: U10 CA30969	
	Site PI (PI: James Anderson); \$323,320 total direct costs to site	
	See "COG <sup>1</sup> SDC goals" 2003-2004. My roles: Administrator for 18 staff and 4 faculty.	
	Led statistical/data teams for trials of neuroblastoma clinical, biologic, and translational	
2002 2000	research.	
2003-2008	Significance of Genetic Alterations in Neuroblastoma	
	Site PI (PI: John Maris); \$98,816 total direct costs to site	
	NIH/NCI: KUI CA8/84/	
	Create/maintain Neuroblastoma virtual lumor Bank (NVIB). Define inclusion criteria,	
	analysis of prognostic factors, and write manuscripts	
2007 2010	Neuroklastomo Virtual Turner Derly	
2007-2010	Neuroblastoma Children's Cancer Society	
	PL (\$100,000 total direct costs)	
	Maintain and expand the Neuroblastoma Virtual Tumor Bank (specimen type, amount	
	banking location and all associated clinical genetic biological and outcomes data)	
	Review scientific proposals select and distribute specimens to investigators worldwide	
2008 2012	The European and Individual in Human Neuroblastamas	
2008-2012	NIH/NCI: P01 CA004104 06	
	Site PL (PI: Garrett Brodeur): \$38,100 total direct costs to site	
	Design experiment define inclusion criteria, select specimens, link to clinical/outcomes	
	data and perform statistical analysis of prognostic significance of Trk expression	
	aata, and perform statistical analysis of prognostic significance of TTK expression.	

Date	Grant Title	
	Grant Type and Number	
	Role on Project (if PI or site PI, total indirect costs)	
	Description of the major goals	
2009-2011	Targeting Oncogenic ALK Signaling in Neuroblastoma	
	NIH/NCI: R01 CA140198-01	
	Site PI (PI: Yael Mosse); \$41,196 total direct costs to site	
	Design the experiment and perform statistical analyses to determine the clinical and	
	etiologic relevance of ALK aberrations (mutation, amplification, &/or regional allelic gain)	
	in patients with neuroblastoma.	
2008-2013	Genetic Susceptibility Factors in the Etiology of Neuroblastoma	
	NIH/NCI: R01 CA132887-01	
	Site PI (PI: Andrew Olshan); \$41,196 total direct costs to site	
	Design epidemiologic retrospective study of COG <sup>1</sup> neuroblastoma patients. Perform	
	statistical analysis of association of genetic and epidemiologic factors.	
2008-2014	Neuroblastomas Therapeutically Applicable Research to Generate Effective Treatments	
	(TARGET) initiative	
	NIH/NCI: 3U10 CA098543	
	Site PI (PI: John Maris); \$155,820 total direct costs to site	
	Using specimens and data from the Neuroblastoma Virtual Tumor Bank, identify	
	specimens for genomic analyses. Link genomic results to clinical and outcomes data and	
	upload data into public repository.	
2011-2013	Racial and Ethnic Disparities in Survival in Children with Neuroblastoma	
	Alex's Lemonade Stand Foundation	
	Site PI (PI: Susan L. Conn); \$13,092 total direct costs to site	
	Expand the INRG database to include race and ethnicity and perform statistical analyses of	
2011 2016	The Interactive International Neuroblestome Bigk Group (INDC) database	
2011-2010	St. Baldrick's	
	St. Daturick S Site PL (PI: Susan I., Cohn): \$65.140 total direct costs to site	
	Lead a team of international statisticians in data collection for neuroblastoma. Perform	
	database design and test website functionality. Collaborate with investigators worldwide to	
	analyze and interpret data.	
2012-2013	The Influence of KIR and FcR Genotype in the Efficacy of mAb and IL2 Immunotherapy	
	NIH: 5R01 CA166105-03	
	Site PI (PI: Paul Sondel); \$9,138 total direct costs to site	
	Responsible for provision of HIPAA de-identified clinical and laboratory data. Link these	
	data to study patients for whom DNA is received. Collaborate to write manuscripts.	
2014-2015	Molecular Diagnostics for Risk Stratification and Monitoring in Neuroblastoma	
	NIH: R01 CA182633-01	
	Site PI (PI: Robert Seeger); \$14,932 total direct costs to site	
	The major goals of this project are to perform study design and statistical analysis to	
	identify factor prognostic and/or predictive of outcome in patients with neuroblastoma.	

Date	Grant Title	
	Grant Type and Number	
	Role on Project (if PI or site PI, total indirect costs)	
	Description of the major goals	
2015-2016	Histologic-related genes for improved treatment assignment in neuroblastoma	
	Rally Foundation for Childhood Cancer	
	PI (\$25,000 total direct costs)	
	The major goals of this project are to perform statistical analyses to determine the	
	associations of histologic prognostic factors with genetic aberrations, to identify potential	
	new therapeutic targets.	
2011-2016	Dana-Farber/Harvard Cancer Center Support Grant – Biostatistics Core	
	NIH/NCI: 2P30 CA006516-49	
	Site PI (PI: Edward Benz); \$238,974 total direct costs to site	
	The major goals of this project are collaborative study design and statistical analyses for	
	therapeutic and non-therapeutic oncology trials at the Dana-Farber Cancer Institute. Lead	
	the Biostatistics Program of the Dana-Farber/Boston Children's Cancer and Blood	
	Disorders Center.	
2012-2016	Dana-Farber/Harvard Cancer Center Support Grant - Survey and Data Management Core	
	NIH/NCI: 2P30 CA006516-49	
	Site PI and Core Faculty Director (PI: Edward Benz); \$1,598,512 total direct costs to site	
	The major goals of this project are to provide vision and leadership for the Survey and	
	Data Management Core's work on survey design, data collection, data management, data	
	analyses, and report generation for DF/HCC investigators.	
2013-2016	The University of Massachusetts Boston-Dana-Farber/Harvard Cancer Center	
	Comprehensive Partnership for Cancer Disparities Research	
	NIH/NCI: 5U54 CA156732-04	
	Site PI and Core Director (PI: Kasisomayajula Viswanath); \$53,639 total direct costs to	
	site	
	The major goals of this project are to provide vision and leadership for the Research and	
	Data Analysis Core's collaboration with the Univ of Massachusetts Boston on research	
	into racial disparities in cancer treatment and outcomes.	
2010-2017	Gene Transfer for SCID-X1 using a self-inactivating gamma retroviral vector	
	NIH/DIS/NIAID- NIAD: 5U01 A108/628-05	
	Co-Investigator (PI: David A. Williams)	
	Provide statistical oversight in the study design, electronic data capture, data quality and	
	management, safety monitoring, and statistical analysis of the trial to determine the safety,	
	Teasibility and efficacy of the vector. NC101129544	
2014-2016	Exploratory Analysis of Ovarian Cancer Data Repository	
	Clearity Foundation	
	Co-Investigator and Site PI (PI: Laura Shawver)	
	Import data from the Clearity Foundation; perform statistical analyses to confirm	
	prognostic factors; determine the benefit of genomic profile-matched therapy.	

Date	Grant Title
	Grant Type and Number
	Role on Project (if PI or site PI, total indirect costs)
	Description of the major goals
2014-2017	Pilot and Feasibility Study of Hematopoietic Stem Cell Gene Therapy for the Wiskott-
	Aldrich Syndrome
	NIH/Social & Scientific Systems/NHLBI HHSN 268201200021
	Co-Investigator (PI: David A. Williams)
	The major goals of this project are to provide statistical support for a Phase 1 human gene
	therapy trial in Wiskott-Aldrich syndrome (WAS); to monitor the safety of the transplant
	and describe preliminary efficacy results. NCT01410825
2011-2018	Phase 1 Dose Escalation Study of Sorafenib and Irinotecan Combination Therapy in
	Pediatric Patients with Relapsed or Refractory Solid Tumors
	Bayer and Onyx Pharmaceuticals, Inc
	Co-Investigator (PI: Holly Meany) – Investigator initiated
	Perform study design, data collection, analysis to identify the maximum tolerated dose
	combination, and recommend a phase 2 dose for further study. NCT01518413
2015-2018	Serum Hepcidin Immunoassay: Laboratory to Marketplace
	NIH/NIDDK: 5 R44 DK083843-05
	Co-Investigator (PI: Mark Westerman)
	The major goals of this project are to perform a prospective clinical trial to validate a
	definitive differential diagnostic test, in the form of statistical model, for a rare genetic iron
	disorder, Iron Refractory Iron Deficiency Anemia (IRIDA). NCT03310736
2016	Phase 2 trial of therapy for atypical teratoid rhabdoid tumor (ATRT)
	Dana-Farber Cancer Institute
	Co-Investigator (PI: Susan Chi); \$27,400 total direct costs to site
	The major goals are to perform study design and collaborate on writing the protocol.
2016-2017	Extraorally delivered level light therapy for prevention of oropharyngeal mucositis in
	pediatric patients undergoing hematopoietic stem cell transplantation
	NIH: 1R34 DE025908-01
	Co-Investigator and Site PI (PI: Nathanial Treister); \$11,640 total direct costs to site
	Planning grant to design a phase 2 trial and write the protocol: to test feasibility of delivery
	of light therapy and estimate its efficacy in preventing mucositis.
2016-2019	Radiation and alkylator-free bone marrow transplant for patients with Dyskeratosis
	Congenita
	Mooney Family Initiative in Clinical and Translational Research in Rare Diseases, Boston
	Children's Hospital
	Co-investigator (PI: Suncei Agarwai) The major goals are to write the protocol perform study design and statistical evolvois to
	menitor sofety and estimate the sumiyel rate for national with Dyskeratesis Concentration who
	receive a hone morrow transplant. Publich a manuscript of the trial results. NCT01650606
2016 2010	Trial of CUDC 007 in in Children and Young Adults with Polonsod or Pofractory Solid
2010-2019	Tumors, CNS Tumors, or Lymphoma
	Dana-Farber Cancer Institute Friends for Life Grant Site PL and Co-Investigator (PI: Steven
	Dubois) \$40,000 total direct costs to site
	The major goals of this project are statistical design of the phase 1 trial and statistical
	analysis to identify a recommended phase 2 dose for CUDC-907 a dual PI3K/HDAC
	inhibitor. NCT02909777

Date	Grant Title
	Grant Type and Number
	Role on Project (if PI or site PI, total indirect costs)
	Description of the major goals
2017-2019	Melanoma and non-melanoma skin cancer in children and young adults
	Pediatric Dermatology Research Alliance
	Co-Investigator (PI: Jennifer Huang)
	The major goals of this retrospective study are to perform study design and statistical
	analysis, to describe the incidence and outcomes of children with melanoma and other skin
	cancers.
2018-2019	Dana-Farber Cancer Institute's Pediatric Global Health Program
	Co-Investigator (PI: Leslie Lehmann)
	The major goal is to provide teaching and training sessions on clinical research for
	physicians and observers from hospitals in low- and middle-income countries.
2013-2020	Registry of patients with pyruvate kinase deficiency (PKD)
	Agios Pharmaceuticals
	Director of Biostatistics (PI: Rachael Grace) – Investigator initiated
	The major goals of this project are to provide leadership for creating a data registry for
	PKD patients, to perform statistical analyses to mine the registry, and to collaborate on
	writing manuscripts.
2016-2020	Pilot and Feasibility Trial of Plerixafor for Hematopoietic Stem Cell (HSC) Mobilization in
	Patients with Sickle Cell Disease
	Bluebird Bio, Inc.
	Co-Investigator (PI: David A. Williams) – Investigator initiated
	The major goals are to lead the statistical efforts on the project: study design, data
	management, statistical analysis and interpretation; to describe the feasibility and safety of
	plerixafor adminstration. Collaborate to write the protocol and manuscripts. NCT02989701
2017-2020	Research on the Pyruvate Kinase Disease (PKD) Registry
	Rocket Pharmaceuticals
	Co-Investigator (PI: Rachael Grace) – Investigator initiated
	The major goal is to lead the statistical support for database design, descriptive statistical
	analyses of treatment and outcomes of PKD, and data export to Rocket Pharma.
2018-2020	Prognostic significance of STAG2 loss and TP53 mutations in Ewing sarcoma
	Dana-Farber Cancer Institute
	Co-Investigator, Site PI (PI: Brian Crompton); \$7,571 total direct costs to site
	The major goals are to perform study design, statistical analysis, and manuscript generation;
	to estimate the incidence of STAG2 and TP53 mutations and describe the outcome for
	patient with vs without these mutations.
2014-2021	Multicenter Cohort Study to Evaluate Outcomes after Receipt of Targeted Therapy
	Matched to an Individualized Cancer Therapy (iCat) Recommendations in Children and
	Young Adults with Solid Tumors: The iCat2, Genomic Assessment Informs Novel
	Therapy (GAIN) Consortium Study
	Medel Fund and C&S Grocers
	Co-Investigator and Site PI (PI: Katherine Janeway); \$143,009 total direct costs to site
	The main goals for this precision oncology project are to perform study design, provide
	oversight for data collection, perform statistical analysis to estimate the outcome of
	children who received matched targeted therapy, and collaborate to write manuscripts.

Date	Grant Title
	Grant Type and Number
	Role on Project (if PI or site PI, total indirect costs)
	Description of the major goals
2021	Integrating Longitudinal Clinical, Sociodemographic and Genomic Data into the National
	Childhood Cancer Registry (NCCR)
	NIH 3P30CA006516-55S7
	Site PI (PI: Katherine Janeway); \$16,149 total direct costs to site
	The goal of this informatics project is data integration from multiple sources, quality
	checking, and creating new derived variables, for data export/sharing to NCI's NCCR.
2021	Fragility index in pediatric phase 3 trials
	Dana-Farber Cancer Institute
	Co-Investigator (PI: Dubois); \$15,123 total direct costs to site
	The goal of this project is to determine the degree to which the results of phase 3 trials are
	unstable: We will perform a meta-analysis to quantify how small of a change in patient
	outcomes would be required before a different answer would have been reached by the
	trial.
2020-2021	DEsign and conDUCt of dose Escalation trials (DEDUCE)
	Northwestern Mutual Foundation
	PI; In-Kind contributions of \$96,750 of donated workforce – Investigator initiated
	The major goal of this project is to create an online, open-source application, DEDUCE,
	for clinical investigators and statisticians to design and conduct novel phase 1 adaptive
	design clinical trials. To conduct workshops to train clinicians and statisticians in the use
	of DEDUCE.
2019-2022	The Lymphatic Anomalies Registry
	The Lymphatic Malformation Institute
	Co-Investigator (PI: Denise Adams)
	The major goal is to provide study design, data management, and statistical analysis of a
	retrospective/prospective registry of patients with vascular anomalies. To mine the registry
	and perform descriptive statistical analyses of disease subgroups.
2020-2022	ctDNA as a biomarker in Ewing sarcoma and osteosarcoma
	1 million 4 Anna Foundation
	Co-Investigator and Site PI (PI: David Shulman); \$35,419 total direct costs to site
	The major goal of this project is to design the biologic study, coordinate data transfer from
	the Children's Oncology Group and linkage with data from Dr. Crompton's lab, perform
	statistical analyses of the level of ctDNA and outcome according to ctDNA level, and write
	a manuscript summarizing the results.
2019-2022	Phase 2 trial of palbociclib and ganitumab in patients with relapsed or refractory Ewing
	sarcoma
	Dana-Farber Cancer Institute
	Co-Investigator and Site PI (PI: David Shulman); \$36,030 total direct costs to site
	The major goal of this project is to design and conduct the trial, oversee the data collection,
	perform statistical analyses to estimate the response rate to palbociclib and ganitumab, and
	write manuscripts. NCT04129151

Date	Grant Title
	Grant Type and Number
	Role on Project (if PI or site PI, total indirect costs)
	Description of the major goals
2021-2022	A Randomized Phase 2 Study to Examine the Impact of Gut Decontamination on
	Intestinal Microbiome Composition in Pediatric Allogeneic Hematopoietic Stem Cell
	Transplant Patients
	Boston Children's Hospital
	Co-Investigator (PI: Whangbo)
	The goals are to design and conduct a randomized trial to determine if gut decontamination
	prior to transplant is beneficial. Statistical analysis for safety monitoring and manuscript
2010 2022	generation will be performed. NC102641236
2018-2022	Phase I Study of the Dual MDM2/MDMX Inhibitor ALRN-6924 in Pediatric Cancer
	Dana-Farber Cancer Institute
	Co-Investigator and Site PI (PI: David Shulman); \$32,222 total direct costs to site
	The major goals are to design a novel adaptive phase 2 trial, provide oversignt for dose
	escalation, perform statistical analysis to identify a maximum tolerated dose (MID) and
	recommended phase 2 dose (RP2D) of ALRN-0924, and conadorate for manuscript
2020 2022	Phase II Study of Clofershing in Deficients with Decurrent or Deficiency Longerhaus Coll
2020-2022	Histiocytosis and I CH related Disorders
	Dana-Farber Cancer Institute
	Co-Investigator and Site PI (PI: Degar): \$15,355 total direct costs to site
	The goals are to design and conduct a phase 2 trial to detect an efficacy signal of clofarabine
	for treatment of Langerhans cell histiocytosis (LCH) and LCH-related disorders. Statistical
	analyses for safety monitoring and manuscript generation will be performed. NCT02425904
2020	Phase 1 Trial of Marizomib Alone and in Combination with Panobinostat for Children
	with Diffuse Intrinsic Pontine Glioma
	Dana-Farber Cancer Institute
	Co-Investigator and Site PI (PI: Warren); \$33,900 total direct costs to site
	The goals are to design and conduct a phase 1 study of the safety and feasibility of
	administering marizomib in combination with Panobinostat using an adaptive design.
	Statistical analyses for dose recommendation, safety monitoring and manuscript generation
	will be performed. (Terminated early due to lack of drug.) NCT04341311
2020-2022	Therapeutic BCL11A enhancer gene editing to induce fetal hemoglobin in Beta-
	hemoglobinopathy
	NIH 10T2HL154984-01
	Co-Investigator (PI: Bauer)
	The goals are to perform study design and statistical analyses, and publish findings.
2021	Fragility
2021-2022	Genetic mutations prognostic of overall survival in Diffuse Intrinsic Pontine Glioma
	Boston Children's Hospital
	Co-Investigator (PI: Poussaint)
	The goals are to design and conduct a retrospective study that identifies genetic risk factors
	associated with worse survival in patients with Diffuse Intrinsic Pontine Glioma

Date	Grant Title
	Grant Type and Number
	Role on Project (if PI or site PI, total indirect costs)
	Description of the major goals
2022	Study of Autoimmune Hemolytic Anemia (AIHA) at Pediatric ITP Consortium of North
	America (ICON)
	Agios Pharmaceuticals, Inc.
	Co-Investigator (PI: Rachael Grace)
	The major goals of this project are to create a registry of patients with AIHA, perform
	descriptive analyses, and publish manuscripts.

### Current

Date	Grant Title
	Grant Type and Number
	Role on Project (if PI or site PI, total indirect costs)
	Description of the major goals
2006-2025	Statistical Support for International Landmark Research in Neuroblastoma
	Little Heroes Pediatric Cancer Research Foundation
	PI; \$179,566 (2006) + \$15,000 (2023)
	Assemble largest ever international database of clinical, biological, and outcomes data for
	neuroblastoma. Perform data mining on hypotheses not possible in smaller databases.
	Perform statistical analyses to identify unique pre-treatment groups and reach international
	consensus on the factors defining these groups. Identify new prognostic factors and create
	novel risk stratification for assignment of treatment intensity.
2013-2026	Dana-Farber/Children's Hospital Cancer Center Developmental Therapeutics Center of
	Excellence (COE)
	Alex's Lemonade Stand Foundation (3 <sup>rd</sup> competitive renewal)
	Multi-PI (additional PI: Steven Dubois); \$1,750,000 total direct costs for current funding
	cycle beginning in 2024
	The major goals of this project are to lead the clinical research infrastructure development
	and biostatistical science for the Experimental Therapeutics Unit. Develop software tool to
	connect patients with clinical trials. Create informal consortium of the four institutions
	who are COEs.
2015-2024	Late Effects After High-Risk Neuroblastoma (LEAHRN) Study
	St. Baldrick's Foundation
	Co-Investigator and Site PI (PI: Tara Henderson); \$271,554 total direct costs to site
	The major goals of this project are to lead efforts to create the case report forms, and
	collect and maintain data, interacting with the COG <sup>1</sup> Statistics and Data Center; and to
	write the protocol and statistical analysis plan, perform the statistical analysis, interpret the
	results and collaborate in manuscript preparation. NCT03057626

Date	Grant Title
	Grant Type and Number
	Role on Project (if PI or site PI, total indirect costs)
	Description of the major goals
2016-2027	Dana-Farber/Harvard Cancer Center Cancer Center Support Grant – Biostatistics Core
	NIH/NCI: 5P30 CA006516-56 (12 <sup>th</sup> competitive renewal)
	Site PI (PI: Laurie Glimcher); \$187,510 total direct costs to site for current funding cycle
	beginning in 2021
	The major goals of this project are collaborative study design and statistical analyses for
	therapeutic and non-therapeutic oncology trials at the Dana-Farber Cancer Institute. Lead
	the Biostatistics Program of the Dana-Farber/Boston Children's Cancer and Blood
	Disorders Center.
2016-2027	Dana-Farber/Harvard Cancer Center Support Grant - Survey and Qualitative Methods Core
	NIH/NCI: 5P30 CA006516-56 (12 <sup>th</sup> competitive renewal)
	Site PI and Core Faculty Director (PI: Laurie Glimcher); \$2,658,608 total direct costs to
	site for current funding cycle beginning in 2021
	The major goals of this project are to provide vision and leadership for the core's work on
	survey design, data collection, data management, data analyses, and report generation for
	DF/HCC investigators.
2016-2023	Phase I/II trial of lentiviral gene transfer for SCID-X1 with low dose targeted busulfan
	conditioning
	NIH/NIAID 5U01AI125051-05
	Co-Investigator (PI: David A. Williams)
	This project seeks to test the efficacy and safety of a new self-inactivating lentiviral (LV)
	vector to treat SCID-XI. The major goals are to design the study and perform statistical
2016 2026	analysis of safety and efficacy, and write a manuscript. NC103311503
2016-2026	The University of Massachusetts Boston-Dana-Farber/Harvard Cancer Center
	Comprehensive Partnership for Cancer Disparities Research
	NIH/NCI: 5054 CA156/32-10 (2 <sup>nd</sup> competitive renewal)
	Site PI and Core Director (PI: Kasisomayajula Viswanatn); 5000,155 total direct costs to
	Site for current funding cycle beginning in 2021 The major costs of this project on to provide vision and loadership for the Descent on d
	Data Analysis Care's calleboration with the Univ of Massachusette Destan on research
	Data Analysis Core's contaboration with the Univ of Massachuseus Boston on research
2017 2022	Cana thereasy terresting DCL 11A to induce fetal hermoglabin and reduce gights hermoglabin
2017-2023	in notion to with Sickle Cell Discose
	NILL / NILL DI 5D01LLI 127848 05
	Co. Investigator (PI: David A. Williams)
	Decreasing the expression of BCI 11A in sickle cell patients could increase the amount of
	fetal hemoglohin, while simultaneously reducing the amount of sickle hemoglohin, in their
	blood and therefore notentially cure the condition. Statistical analysis will test the ability of
	a virus vector to reduce the expression of BCI 11A in red blood cells NCT03282656
	a virus vector to reduce the expression of BCL11A in red blood cells. NCT03282656

Date	Grant Title
	Grant Type and Number
	Role on Project (if PI or site PI, total indirect costs)
	Description of the major goals
2018-2024	ICON3 Pines - A Phase 3 study of Eltrombopag vs. Standard First-Line Management for
	newly diagnosed immune thrombocytopenia (ITP) in children
	Novartis Pharmaceuticals Corporation
	Co-Investigator and Director of Biostatistics for the Data Coordinating Center (PI: Kristin
	Shimano); \$113,841 total direct costs to site – Investigator initiated
	The major goals of this project are to design and conduct the trial, lead the Data
	Coordinating and Statistical Center, perform statistical analyses to determine if
	eltrombopag is superior to standard first-line management in controlling ITP, and write a
	manuscript summarizing the results of the trial. NCT03939637
2018-2025	Liquid biopsy approaches to inform osteosarcoma prognosis and tumor evolution
	NIH/NCI 5R37 CA244355-03
	Co-Investigator and Site PI (PI: Brian Crompton); \$52,601 total direct costs to site
	The major goals are to perform study design, data integration, statistical analysis to describe
	the level of circulating tumor DNA (ctDNA) and outcome according to ctDNA level, and
2010 2020	manuscript generation.
2019-2020	Natural History and Biology of Long-Term Late Effects Following Hematopoietic Cell
	I ransplant for Childhood Hematologic Malignancies
	St. Baldrick's $(1, 2, 3, 4, 5)$ $(1, 2, 3, 4, 5)$ $(2, 2, 3, 4, 5)$ $(2, 2, 3, 4, 5)$
	Co-Investigator and Site PI (PI: Christine Duncan); \$32,216 total direct costs to site
	The goals of this study are to describe chronic kidney disease (CKD), metabolic syndrome
	and osteopenia after transplant, including study design, statistical analysis of the incidence
2010 2022	A Drage L Study of TAK 580 (MLN2480) for Children with Low Crede Clience and
2019-2023	A Phase I Study of TAK-380 (WLN2480) for Children with Low-Grade Ghomas and Other DAS/DAE/MEK/EDK Dethyway Activated Tymore
	Dana Farbar Canaar Institute
	Co. Investigator and Site DI (DI: Karon Wright): \$114,400 total direct costs to site
	The goals are to design and conduct a noval phase 1 adaptive design to identify the
	recommended phase 2 dose level within each of two weight subgroups. Statistical
	analyses for real-time dose recommendation safety monitoring and manuscript generation
	will be performed NCT03429803
2019-2023	A phase 1 study of combination nivolumab and inilimumab with irradiated GM-CSF
2017 2025	secreting autologous neuroblastoma cell vaccine (GVAX) for relansed or refractory
	neuroblastoma
	Dana-Farber Cancer Institute
	Co-Investigator and Site PI (PI: Natalie Collins): \$60.390 total direct costs to site
	The goals are to design and conduct a phase 1 study of the safety and feasibility of
	administering GVAX in combination with nivolumab and ipilimumab. Statistical analyses
	for safety monitoring and manuscript generation will be performed. NCT04239040

Date	Grant Title
	Grant Type and Number
	Role on Project (if PI or site PI, total indirect costs)
	Description of the major goals
2020-2025	International integrated analysis to identify markers of poor survival in high-risk
	neuroblastoma
	Solving Kids' Cancer United Kingdom
	Co-PI (PI: Lucas Moreno); \$262,051 total direct costs to site
	The major goals of this project are to identify biomarkers in a systematic review, integrate
	biomarker data from disparate sources, and perform statistical analysis using an optimal
	biomarker combination for risk stratification to identify an "ultra-high-risk" cohort.
2020-2023	Phase 1 Study of Cabozantinib in Combination with Topotecan-
	Cyclophosphamide for Patients with Relapsed Ewing Sarcoma or Osteosarcoma
	Dana-Farber Cancer Institute
	Co-Investigator and Site PI (PI: Dubois); \$27,480 total direct costs to site
	The goals are to design and conduct a phase 2 trial to detect an efficacy signal of
	cabozantinib for treatment of Ewing sarcoma. Statistical analyses for safety monitoring
	and manuscript generation will be performed. NCT04661852
2020-2023	Phase II trial of olaparib in combination with AZD6738 in patients with recurrent
	osteosarcoma
	Dana-Farber Cancer Institute
	Co-Investigator and Site PI (PI: Janeway); \$35,667 total direct costs to site
	The goals are to design and conduct a phase 2 trial to detect an efficacy signal of the
	combination of Olaparib and AZD0/38 for treatment of recurrent osteosarcoma. Statistical
	NCT03682289
2021_2023	Targeting enigenetic dysregulation in central nervous system tumors
2021-2023	Stand Up 2 Cancer (SU2C)
	Co-Investigator and Site PI (PI: Dubois) \$45,206 total direct costs to site
	The goals are to design and conduct a phase 2 trial of targeted therapy for central nervous
	system tumors, and publish the results. NCT03936465
2021-2024	Phase 2 Study of Hematopoietic Stem Cell Gene Transfer Inducing Fetal Hemoglobin in
	Sickle Cell Disease
	California Institute of Regenerative Medicine (CIRM) CLIN2SCD-12031
	Co-Investigator (PI: David A. Williams)
	The goal of this project is to conduct a clinical trial of therapeutic gene editing of the
	BCL11A erythroid enhancer in patients with sickle cell disease and beta-thalassemia to
	durably induce fetal hemoglobin. Perform study design and statistical analysis to test the
	safety and feasibility of gene editing. NCT05353647
2021-2024	Therapeutic BCL11A enhancer gene editing to induce fetal hemoglobin in Beta-
	hemoglobinopathy patients
	NIH / NHLBI 10T2HL154984-01
	Co-Investigator (PI: David A. Williams)
	The goal of this project is to conduct a clinical trial of therapeutic gene editing of the
	BCL11A erythroid enhancer in patients with sickle cell disease and beta-thalassemia to
	durably induce fetal hemoglobin. Perform study design and statistical analysis to test the
	safety and feasibility of gene editing. NCT# pending

Date	Grant Title
	Grant Type and Number
	Role on Project (if PI or site PI, total indirect costs)
	Description of the major goals
2021-2024	DEsign and conDUCt of dose Escalation trials (DEDUCE)
	Northwestern Mutual Foundation
	PI; \$86,000 – Investigator initiated
	The major goal of this project is to create an online, open-source application, DEDUCE,
	for clinical investigators and statisticians to design and conduct novel phase 1 adaptive
	design clinical trials. To conduct workshops to train clinicians and statisticians in the use
	of DEDUCE.
2021-2026	The Genetic Basis of Treatment Outcomes and Late Effects After High-Risk
	Neuroblastoma
	NIH X01-CA268005 (Gabriella Miller Kids First Pediatric Research Program)
	Co-Investigator and Site PI (PI: Sharon Diskin); \$0 total direct costs to site (Sequencing
	only)
	The major goals of this project are to identify genetic factors contributing to high-risk
	neuroblastoma treatment failure and adverse late effects through sequencing the
	germline of 1,100 high-risk neuroblastoma subjects and matched tumor DNA and
	RNA. Mechanism includes sequencing costs only.
2021-2023	A Phase 1/2 Trial of Uproleselan Combined with High Dose Busulfan Pre-Transplant
	Conditioning in Hematopoietic Stem Cell Transplantation for Patients with Chemotherapy
	Resistant Acute Myeloid Leukemia
	Co-Investigator and Site PI (PI: Horan) \$34,274 total direct costs to site
	The major goals of this project are to design and conduct a phase 1/2 trial to identify the
	dosage of uproleselan and test for an efficacy signal; to perform statistical analysis and
2021 2020	write a manuscript.
2021-2028	A Phase I/II Combination Trial of Tazemetostat with Nivolumab and Ipilimumab for
	Children with INII-Negative or SMARCA4-Deficient Tumor
	Co-Investigator and Site PI (PI: Chi) \$134,447 total direct costs to site
	The goals are to design and conduct a phase I study to identify the maximum tolerated
	dose of tazemetostat, followed by a phase 2 study to detect an efficacy signal of the
	combination. Statistical analyses for safety monitoring and manuscript generation will be
2022 2024	The Dame Factor / Harrison Constant Clinese SPOPE - Directoristics Constant
2022-2024	Ine Dana-Farber/Harvard Cancer Center Glioma SPORE - Biostatistics Core
	NIT / NCI P30-CA103902-09
	direct costs to site
	The major goals of this project are to provide statistical support to the investigators on the
	SPORE including the design and conduct clinical trials for patients with glioma
2022 2024	Association of enovangein with risk of thrombosis and hemorrhage
2022-2024	Co-Investigator (PI: Kumar) \$14,995 total direct costs to site
	The major goal is to perform a statistical analysis of a cohort of nationts with thrombosis
	from the PHIS database and to identify risk factors and describe the use of enovaparin
	Technical reports and a manuscript will be written
	Technical reports and a manuscript will be written.

Grant Title
Grant Type and Number
Role on Project (if PI or site PI, total indirect costs)
Description of the major goals
Venous thromboembolism and acute ischemic stroke in children with COVID-19
Co-Investigator (PI: Kumar) \$25,019 direct costs to site
The major goal is to perform a statistical analysis of a cohort of patients with COVID-19
from the PHIS database, and to describe and estimate the incidence of venous
thromboembolism and acute ischemic stroke. Technical reports and a manuscript will be
A Single Center Pilot Study of Intraoral Photobiomodulation Therapy for the
Prevention of Oral Mucositis in Patients Undergoing Myeloablative Allogeneic
Co. Investigator (DI: Traistor) \$24.578 direct costs to site
The major goal is to design and conduct a clinical trial to test the safety and feasibility of
intraoral photobiomodulation therapy. Statistical analysis will be performed, and technical
reports and a manuscript will be written
Venous thromboembolism and acute ischemic stroke in transgender children
Co-Investigator (PI: Kumar) \$10.603 direct costs to site
The major goal is to perform a statistical analysis of a cohort of transgender patients from
the PHIS database, and to describe and estimate the incidence of venous thromboembolism
and acute ischemic stroke. Technical reports and a manuscript will be written.
Immature platelet fraction (IPF) in children with immune thrombocytopenic purpura
Co-Investigator (PI: Grace) \$11,562 direct costs to site
The major goal is to perform a retrospective statistical analysis to identify an association
between the level of pre-treatment IPF and treatment response. Technical reports and a
manuscript will be written.
A Phase 2 randomized trial of intraoral, extraoral, and combined intraoral/extraoral
photobiomodulation for the prevention of oral mucositis in patients undergoing
myeloablative allogeneic hematopoietic cell transplantation.
Co-Investigator (PI: Treister) \$55,477 direct costs to site
The major goal is to design and conduct a three-arm selection design clinical trial to test
analysis will be nonformed, and technical reports and a manuscript will be written
analysis will be performed, and technical reports and a manuscript will be written.
Neuroblastoma
NIH/NCI/Children's Oncology Group - Star Act
Co-Investigator (PI: Diller) \$9 658 direct costs to site
The major goal is to perform a case-control study using data from COG study ALTE15N2
to identify late effects associated with MIBG treatment. Statistical analysis will be
performed, and technical reports and a manuscript will be written.

### **Training Grants and Mentored Trainee Grants**

Date	Grant Title
	Grant Type and Number
	Role on Project (if PI or site PI, total indirect costs)
	Description of the major goals
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.

### **Current Unfunded Projects**

Year(s)	Role on Project/ Title of Project
funded	Purpose of the Project
2010-	U.S. News and World Report – Best Children's Hospitals survey
present	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-	Datamart: The Pediatric Patient Informatics Platform (PPIP)
present	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**

Year(s)	Course Title	Location
	Type of student/audience	Level of Effort
2006-2008	Science of Clinical and Translational	University of Florida College of Medicine
	Research Course	Annual 1 hr lecture
	Medical students, residents, fellows, and	
	faculty members	
2007	Writing the statistical section of a grant	University of Florida, Division of
	Epidemiology graduate students	Epidemiology and Health Policy Research
		1 hr lecture

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

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

# **Research Supervisory and Training Responsibilities**

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

### Formally Mentored Harvard Medical, Dental, and Graduate Students

·	
Year(s)	Student
	Type of supervision/ Specific accomplishment
2016-2022	Derek Shyr, MS / Department of Biostatistics, Harvard School of Public Health Class of
	2022
	Conducting clinical research in neuroblastoma prognostic factors in my laboratory. Poster
	presentation at the Dana-Farber/Harvard Cancer Center (DF/HCC) Celebration of Early
	Career Investigators in Cancer Research. Submitted a neuroblastoma risk stratification
	manuscript.

Year(s)	Student
	Type of supervision/ Specific accomplishment
2020-2021	Alana McGovern, MS / Department of Biostatistics, Harvard School of Public Health
	Class of 2021
	Conducted an adaptive designed phase 1 trial for pediatric low-grade glioma. Poster
	presentation at the DF/HCC Celebration of Early Career Investigators in Cancer Research.
2021-	Hannah Bender / Medical Student, Harvard Medical School
present	Career stage: HMS student, Resident at BCH. Mentoring role: Clinical research mentor.
	Accomplishments: Poster presentation at the 2021 American Society of Clinical Oncology
	annual meeting and 2023 manuscript published in the Journal of Clinical Oncology on
	reduction of therapy in neuroblastoma due to age stratification change.

# Other Mentored Trainees and Faculty

Year(s)	Student	
	Type of supervision/ Specific accomplishment	
2000-2013	Patrick McGrady, MS / retired	
	Career stage: Statistician, University of Florida. Mentoring role: Research supervisor.	
	Accomplishments: Authorship on 17 scholarly publications on pediatric cancer as a result	
	of my supervision, including two in <i>Nature</i> and one in <i>New England Journal of Medicine</i> .	
2002-2005	Pavlina Rumcheva, PhD / Senior Risk Analyst, GE Capital, Sydney, Australia	
	Career stage: Statistics graduate student, University of Florida. Mentoring role: Research	
	advisor & graduate committee member. Accomplishments: Published two neuroblastoma	
	manuscripts, including one in Journal of Clinical Oncology. PhD at University of Florida.	
2002-2014	Allen Buxton, MS / Statistician, COG <sup>1</sup> , Monrovia, CA	
	Career stage: Statistician, Children's Oncology Group. Mentoring role: Research	
	supervisor. Accomplishments: Authorship on six scholarly publications on neuroblastoma	
	as a result of my supervision, including two in New England Journal of Medicine.	
2002-2009	Rani George, MD, PhD / Associate Professor of Pediatrics, Dana-Farber Cancer Institute,	
	Harvard Medical School	
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments:	
	Published three manuscripts, including one in <i>Nature</i> . Achieved a faculty appointment in	
	HMS and then promoted to Associate Professor.	
2003-2009	Robert Gerbing, MA / Statistician, COG <sup>1</sup> , Monrovia, CA	
	Career stage: Statistician, Children's Oncology Group. Mentoring role: Research	
	supervisor. Accomplishments: Authorship on five scholarly publications on	
	neuroblastoma as a result of my supervision, including two in the Journal of Clinical	
	Oncology.	
2004-2012	Suzanne Shusterman, MD / Assistant Professor of Pediatrics, Dana-Farber Cancer	
	Institute, Harvard Medical School	
	Career stage: Instructor. Mentoring role: Clinical research mentor, COG <sup>1</sup> mentor.	
	Accomplishments: Wrote two clinical trial protocols, conducted trials, presentations at the	
	American Society of Clinical Oncology, and published two manuscripts, including one in	
	the Journal of Clinical Oncology.	

Year(s)	Student	
	Type of supervision/ Specific accomplishment	
2003-2009	Rochelle Bagatell, MD / Professor of Pediatrics, Children's Hospital of Philadelphia;	
	Chair, Neuroblastoma Committee, Children's Oncology Group (COG <sup>1</sup> )	
	Career stage: Assistant Professor. Mentoring role: Clinical research mentor, COG <sup>1</sup> mentor.	
	Accomplishments: Design, protocol writing, and conduct of two practice-changing clinical	
	trials for neuroblastoma in COG <sup>1</sup> . Published two manuscripts in <i>Journal of Clinical</i>	
	Oncology.	
2006-2008	John Yap, PhD / Mathematical Statistician, Food and Drug Administration (FDA)	
	Career stage: Graduate student. Mentoring role: Clinical research and statistical methods	
	mentor. Accomplishments: Published one manuscript and collaborated on SIOP award-	
	winning abstract.	
2006-2009	Yang Zhang, MS / Statistician, COG <sup>1</sup> , University of Florida	
	Career stage: First year biostatistician. Mentoring role: Clinical research and statistical	
	methods mentor. Accomplishments: Authorship on three scholarly publications, including	
	one in Journal of Clinical Oncology.	
2007-2010	I-Chan Huang, PhD / Faculty member, St. Jude Children's Research Hospital	
	Career stage: Post-doctoral fellow. Mentoring role: Outcomes research mentor.	
	Accomplishments: K23 award from the NIH, "Using item response theory to improve	
2005	children's quality of life assessment".	
2007-	Arlene Naranjo, PhD / Research Associate Professor of Biostatistics, University of Florida	
present	Career stage: Graduate student. Mentoring role: Clinical research, statistical methods, and	
	COG <sup>4</sup> mentor. Accomplishments: Published 38 manuscripts, including one in <i>Lancet</i>	
2007 2000	Oncology. Lead Statistician for the COG <sup>2</sup> Neuroblastoma Committee.	
2007-2008	Steven Dubois, MD, MPH / Associate Professor of Pediatrics and Director of	
	Experimental Inerapeutics, Boston Children's Hospital and Dana-Farber Cancer Institute,	
	Harvard Medical School	
	A accomplishments: First paper in <i>Padiatria Blood and Cancer</i> (2008), plus 5 publications	
	Design and conduct of clinical trials including adaptive designs	
2008-2010	Tamekia Jones, PhD / Associate Professor of Pediatrics & Preventive Medicine	
2008-2010	University of Tennessee Health Science Center: Director, Children's Foundation Research	
	Institute Biostatistics Core, Le Bonheur Children's Hospital Memphis, TN	
	Career stage: First PhD faculty position Mentoring role: Clinical research statistical	
	methods and $COG^1$ mentor. Accomplishments: Design conduct and analysis of $COG^1$	
	trials	
2008-2010	Xiaomin Lu PhD / Assistant Professor of Biostatistics University of Florida	
2000 2010	Career stage: Research Assistant Professor Mentoring role: Clinical research statistical	
	methods, and $COG^1$ mentor. Accomplishments: Design, conduct, and analysis of $COG^1$	
	trials.	
2008-2009	Joanne Lagmay, MD / Associate Professor of Pediatrics, University of Florida	
	Career stage: Resident, Mentoring role: Clinical research mentor. Accomplishments:	
	Publication in <i>Clinical Cancer Research</i> . Now leads the Pediatric Solid Tumor program at	
	Shands Hospital, University of Florida.	

Year(s)	Student	
	Type of supervision/ Specific accomplishment	
2009-2010	Ning Li, PhD / Associate Professor, Division of General Internal Medicine and Health	
	Services Research, University of California-Los Angeles	
	Career stage: first-year Assistant Professor. Mentoring role: Clinical research, statistical	
	methods, and COG <sup>1</sup> mentor. Accomplishments: Design, conduct, and analysis of COG <sup>1</sup>	
	trials.	
2010-2020	Veronica Moroz, MS / Biostatistician, Cancer Research UK Clinical Trials Unit,	
	University of Birmingham, Birmingham, UK	
	Career stage: junior biostatistician. Mentoring role: Clinical research, statistical methods,	
	and INRG mentor. Accomplishments: Design, conduct, and publication of two INRG	
2010	projects.	
2010-	Paola Angelini, MD / Consultant in Pediatric Oncology, The Royal Marsden NHS	
present	Foundation Trust	
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments: One	
2010 2011	neuroblastoma publication, and another neuroblastoma manuscript in preparation.	
2010-2011	Kelly Strait, MS / Biostatistician, Center for Outcomes Research and Evaluation, Yale	
	School of Medicine	
	matheds montor Accomplishments: Authorship on four scholarly publications on	
	nethods mentor. Accomprisiments. Authorship on rour scholarry publications on pediatric cancer or hematology as a result of my supervision	
2010-	Madhumitha Sridharan BS / Database Administrator III Dana-Earber/Boston Children's	
nresent	Cancer and Blood Disorders Center, Harvard Medical School	
present	Career stage: Database Administrator I. Mentoring role: Clinical research, informatics, and	
	data management. Accomplishments: Authorship on six scholarly publications on	
	pediatric cancer or hematology as a result of my supervision. Major achievements on the	
	<i>PPIP</i> datamart. Two promotions: from Database Administrator (DBA) I, to DBA II, to	
	DBA III.	
2010-2011	Daniel Bauer, MD, PhD / Associate Professor of Pediatrics, Director of the Gene Therapy	
	Program, Dana-Farber/Boston Children's Cancer and Blood Disorders Center, Harvard	
	Medical School	
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments: Wrote	
	a protocol for a nut midline carcinoma registry; published a manuscript in the <i>Journal of</i>	
	Clinical Oncology.	
2010-2012	Paola Friedrich-Medina, MD, MPH / Assistant Member, St. Jude Faculty, St. Jude	
	Children's Research Hospital	
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments: Study	
	design, conduct, and manuscript publication.	
2010-2012	Nathan Robison, MD / Assistant Professor of Pediatrics at the University of Southern	
	California Keck School of Medicine	
	Career stage: Clinical Instructor. Mentoring role: Clinical research mentor.	
	Accomplishments: At DFCI, design, analysis, and publication of a retrospective study	

Year(s)	Student	
	Type of supervision/ Specific accomplishment	
2010-2020	Inga Hofmann, MD, PhD / Assistant Professor, Director - Pediatric Bone Marrow	
	Transplant Program, Medical Director – University of Wisconsin Program for	
	Advanced Cellular Therapy, Division of Pediatric Hematology, Oncology and Bone	
	Marrow Transplant, University of Wisconsin School of Medicine and Public Health	
	Career stage: Instructor. Mentoring role: Clinical research mentor. Accomplishments: At	
	BCH, protocol writing, design and creation of two rare disease registries, resulting in two	
	abstracts and two publications.	
2010-2018	Allison O'Neill, MD / Assistant Professor of Pediatrics, Clinical Director – Solid Tumor	
	Center, Boston Children's Hospital and Dana-Farber Cancer Institute, Harvard Medical	
	School	
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments: design	
	and conduct of three clinical research protocols, two retrospective studies, and one	
2010 2015	publication.	
2010-2013	Cameron Trenor, MD/ Senior TME 1, Novarus Institutes for BioMedical Research	
	Designed four clinical trials and created a rare disease registry.	
2011 2017	Christing Duncan MD / Assistant Professor of Pediatrics Medical Director of Clinical	
2011-2017	Research and Clinical Development, Gene Therapy Program, Boston Children's Hospital	
	and Dana-Farber Cancer Institute. Harvard Medical School	
	Career stage: Clinical Instructor, Mentoring role: Clinical research mentor	
	Accomplishments: Obtained a 5-year grant from St Baldrick's to study late effects after	
	transplant.	
2012-2105	Phillip Poorvu, MD / Instructor in Medicine, Dana-Farber Cancer Institute, Harvard	
	Medical School	
	Career stage: Medical student. Mentoring role: Clinical research mentor.	
	Accomplishments: publication of a retrospective analysis on the effectiveness of GnRH	
	agonists.	
2012-2021	Dongjing Guo, MPH / Senior Biostatistician, Intuitive Surgical Inc, Los Altos, CA	
	Career stage: Biostatistician I (new graduate). Mentoring role: Clinical research and	
	statistical methods mentor. Accomplishments: Authorship on 16 scholarly publications on	
	pediatric cancer or hematology as a result of my supervision. Two promotion at HMS:	
	from Biostatistician I to II, and II to III.	
2012-2016	Venee Tubman, MD, MMSc / Assistant Professor of Pediatrics-Hematology, Co-Director,	
	Hemoglobinopathies Program, Texas Children's Hospital, Baylor College of Medicine	
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments:	
2012 2015	Design, conduct, and publication of a sickle cell disease infant screening study in Liberia.	
2012-2015	Natasha Archer, MD / Assistant Professor of Pediatrics, Boston Children's Hospital and	
	Dana-Farber Cancer Institute, Harvard Medical School	
	Career stage: renow. Wentoring role: Clinical research mentor. Accomplishments:	
2012 2021	Design and conduct a screening/education study of sickle cell disease in Haiti.	
2012-2021	Natalie Bezier, ND/ Assistant Professor of Pediatrics, Connecticut Unildren's Medical	
	Center, University of Connecticut	
	Career stage: reliow. Mentoring role: Clinical research mentor. Accomplishments: Study	
	design and conduct, and a publication on nearth interacy (project funding obtained).	

Year(s)	Student	
	Type of supervision/ Specific accomplishment	
2012-2018	Kira Bona, MD/ Assistant Professor of Pediatrics, Boston Children's Hospital and Dana-	
	Farber Cancer Institute, Harvard Medical School	
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments: Wrote	
	a protocol, obtained grant funding, and published three manuscripts on financial	
	hardship/disparity in families of children with cancer.	
2012-	Daniel Morgenstern, MD / Assistant Professor of Paediatrics, Hospital for Sick Kids,	
present	University of Toronto	
	Career stage: Fellow, Royal Marsden Hospital. Mentoring role: Clinical research mentor,	
	INRG mentor. Accomplishments: Conducted and published four manuscripts on	
	neuroblastoma prognostic factors. Wrote and submitted a 5-year grant to Canadian	
	Institutes of Health Research for an international randomized cancer prevention trial for	
	patients with Li-Fraumeni syndrome.	
2012-2017	Pratiti Bandopadhayay, MBBS, PhD / Assistant Professor of Pediatrics, Boston Children's	
	Hospital and Dana-Farber Cancer Institute, Harvard Medical School	
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments: Wrote	
	a protocol and published two retrospective studies on low-grade glioma and ependymoma.	
2013-2017	Richard Li, MD / Internist, Brookline, MA	
	Career stage: Resident. Mentoring role: Clinical research mentor. Accomplishments:	
	Designed, conducted, and published a retrospective study on patterns of relapse in high-	
	risk neuroblastoma in International Journal of Radiation Oncology Biology Physics.	
2013-	Erica Esrick, MD/ Instructor, Boston Children's Hospital and Dana-Farber Cancer	
present	Institute, Harvard Medical School	
-	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments: Wrote	
	three clinical trial protocols; one activated so far. Two publications, including one in New	
	England Journal of Medicine.	
2013-2017	Suneet Agarwal, MD, PhD / Associate Professor of Pediatrics, Boston Children's Hospital	
	and Dana-Farber Cancer Institute, Harvard Medical School	
	Career stage: Instructor. Mentoring role: Clinical research mentor. Accomplishments:	
	Design and conduct of clinical trial for dyskeratosis congenita; presentation at the	
	American Society of Hematology. Manuscript underway.	
2013-	David Shulman, MD / Instructor, Boston Children's Hospital and Dana-Farber Cancer	
present	Institute, Harvard Medical School	
	Career stage: Resident. Mentoring role: Clinical research mentor. Accomplishments:	
	Design, conduct, and publication of two retrospective studies. Design, protocol writing,	
	and conduct of two ongoing adaptive clinical trials. Mentor on his K08 grant application.	
2013-2023	Junne Kamihara, MD / Instructor, Boston Children's Hospital and Dana-Farber Cancer	
	Institute, Harvard Medical School.	
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments:	
	Design and conduct of two ongoing genetic predisposition protocols.	
2013-2018	Robert Grant Rowe, MD / Assistant Professor of Pediatrics, Boston Children's Hospital	
	and Dana-Farber Cancer Institute, Harvard Medical School	
	Career stage: Resident. Mentoring role: Clinical research mentor. Accomplishments:	
	Design, conduct, and publication of a retrospective study on risk factors for infection in	
	stem cell transplant.	

Year(s)	Student	
-	Type of supervision/ Specific accomplishment	
2013-2023	Jennifer Huang, MD / Associate Professor, Boston Children's Hospital, Harvard Medical	
	School	
	Career stage: Instructor. Mentoring role: Clinical research mentor. Accomplishments:	
	Design, conduct, and publication of six retrospective research studies on risk factors for	
	skin cancer in children. Designed and wrote protocol for therapeutic trial for skin cancer	
2012 2018	Johanna Sheu Sang MD / Interniet, Dermetology Clinic at Mount Zion, University of	
2013-2018	California-San Francisco	
	Career stage: HMS student. Mentoring role: Clinical research mentor. Accomplishments:	
	Design, conduct, and publication of three retrospective research studies on risk factors for	
	skin cancer in children.	
2013-2016	Collin Van Ryn, MS / Researcher, Biostatistics, University of Minnesota	
	Career stage: first-year statistician. Mentoring role: Clinical research and statistical	
	methods mentor, COG <sup>1</sup> mentor. Accomplishments: Authorship on seven scholarly	
	publications on pediatric cancer as a result of my supervision.	
2014-2015	Craig Forester, MD / Assistant Professor, Pediatrics-Heme/Oncology and Bone Marrow	
	Transplantation, University of Colorado	
	Design conduct and publication of a retrospective research study on outcome and	
	predictors of pediatric aplastic anemia	
2014-2018	Christina Ullrich MD / Assistant Professor of Pediatrics Boston Children's Hospital and	
2011 2010	Dana-Farber Cancer Institute. Harvard Medical School	
	Career stage: Clinical Instructor. Mentoring role: Clinical research mentor.	
	Accomplishments: Design of two prospective quality of life studies. Publication of two	
	retrospective studies, including one evaluating end-of-life care patterns.	
2014-2017	Michelle Lee, MD, PhD / Assistant Professor of Pediatrics, Director of the Transplantation	
	and Cellular Therapy Program, The Children's Hospital at Montefiore. Albert Einstein	
	College of Medicine	
	Career stage: Clinical Instructor. Mentoring role: Clinical research mentor.	
2014 2019	Accomplishments: Designed and wrote a clinical research transplant protocol.	
2014-2018	Brian Crompton, MD / Assistant Professor of Pediatrics, Boston Children's Hospital and Dana Farbar Canaar Institute, Harward Madical School	
	Career stage: Clinical Instructor, Mentoring role: Clinical research mentor	
	Accomplishments: Design conduct and publication of research on the association of	
	circulating tumour DNA with inferior outcomes in sarcoma. Obtained R37 grant funding.	
2014-2018	Prasanna Ananth, MD / Assistant Professor of Pediatrics (Hematology/Oncology), Yale	
	School of Medicine	
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments:	
	Design, conduct, and publication of a retrospective research study of medical marijuana in	
	children with cancer.	
2014-2018	Jonathan Marron, MD / Instructor in Pediatrics, Boston Children's Hospital and Dana-	
	Farber Cancer Institute, Harvard Medical School	
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments: Wrote	
	Written and funded. Won an American Society of Clinical Oncology young investigator	
	award	
	written and funded. Won an American Society of Clinical Oncology young investigator award.	

Year(s)	Student	
	Type of supervision/ Specific accomplishment	
2014-2016	Sonia Rubens, PhD / Assistant Professor, Department of Counseling Psychology, Santa	
	Clara University, Santa Clara, CA	
	Career stage: post-doctoral fellow. Mentoring role: Clinical research mentor.	
	Accomplishments: Design, conduct, and publication of a prospective study of a pediatric	
	cancer school consultation program.	
2014-2017	Lisa Northman, PhD / Instructor in Psychology, Clinical Director of Psychosocial Services	
	for Pediatric Stem Cell Transplant, Boston Children's Hospital and Dana-Farber Cancer	
	Institute, Harvard Medical School	
	Career stage: Instructor. Mentoring role: Clinical research mentor. Accomplishments:	
	besign, conduct, and publication of a two prospective studies of a nospital-based school	
2014	Joanna Vi MD / Assistant Professor, Dent of Pediatrics, Section of	
201 <del>4</del> -	Hematology/Oncology Baylor College of Medicine	
present	Career stage: Fellow Mentoring role: Clinical research mentor Accomplishments: Design	
	and write two phase 1/2 clinical trial protocols (ongoing).	
2014-	Rachael Grace. MD / Associate Professor of Pediatrics. Boston Children's Hospital.	
present	Harvard Medical School	
1	Career stage: Instructor. Mentoring role: Clinical research mentor. Accomplishments:	
	Built prospective registry of rare patients with pyruvate kinase deficiency (PKD). Award	
	for Top 10 papers of 2018 from <i>Blood</i> . Four abstracts and five manuscripts published.	
	Design, protocol writing, and conduct of phase 3 clinical trial for immune	
	thrombocytopenia (ITP) (ICON3 - ongoing).	
2014-2018	Susanne Baumeister, MD / Assistant Professor of Pediatrics, Boston Children's Hospital	
	and Dana-Farber Cancer Institute, Harvard Medical School	
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments: Wrote	
	a phase 2 protocol for a neuroblastoma vaccine trial. Funded by my Alex's Lemonade	
2014	Stand Foundation grant.	
2014-	d'Habran Hagnital Paraolona, Spain	
present	Career stage: Post-doctoral Investigator Mentoring role: Clinical research mentor INRG	
	mentor Accomplishments: Design and publication of a retrospective international	
	neuroblastoma study. Three neuroblastoma manuscripts in preparation. Obtained 3-year	
	\$420,000 grant from Solving Kids Cancer, on prognostic factors in high-risk	
	neuroblastoma.	
2015-2023	Daniel Gundersen, PhD / Lead Scientist, Dana-Farber Cancer Institute	
	Career stage: Senior Scientist. Mentoring role: Clinical research mentor, INRG mentor.	
	Accomplishments: Promoted to Lead Scientist. Synergistic for substantial growth in the	
	DF/HCC Survey and Qualitative Methods Core in terms of quantity and quality of grants	
	and funding.	
2015-	Anna Revette, PhD / Senior Scientist, Dana-Farber Cancer Institute	
present	Career stage: Scientist II. Mentoring role: Clinical research mentor. Accomplishments:	
	Promoted to Senior Scientist. Submitted a NIH R50 grant. Synergistic for substantial	
	growth in the DF/HCC Survey and Qualitative Methods Core.	

Year(s)	Student
	Type of supervision/ Specific accomplishment
2015-2018	Amanda Marinoff, MD / Fellow, Pediatric Hematology/Oncology, University of
	California San Francisco Medical Center
	Career stage: HMS student. Mentoring role: Clinical research mentor. Accomplishments:
	Published a manuscript in on a retrospective study.
2015-2019	Mark Applebaum, MD / Assistant Professor of Pediatrics, University of Chicago
	Career stage: Fellow. Mentoring role: Clinical research mentor, INRG mentor.
	Accomplishments: Published 4 manuscripts in high-impact factor journals. Audrey Evans
	Prize in Clinical Research at the 2016 Advances in Neuroblastoma Research meeting.
	Brigid Leventhal Special Merit Award from the Conquer Cancer Foundation.
2015-2019	Lillian Guenther, MD / Instructor of Pediatrics, Boston Children's Hospital and Dana-
	Farber Cancer Institute, Harvard Medical School
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments:
2015	Published a retrospective analysis of sarcoma patients in <i>Pediatric Blood and Cancer</i> .
2015-	Clement Ma, PhD/ Assistant Professor of Biostatistics, Centre for Addition and Mental
present	Health, Dalla Lana School of Public Health, University of Toronto
	Career stage: Instructor (first-year faculty). Mentoring role: Clinical research and
	statistical methods mentor. Accomplishments: Published four manuscripts to date; two
	additional papers underway. Lead biostatistician on >50 projects while at HMS.
	DEDUCE adaptive place 1 trial design website. Dremated to Assistant Defeases of
	Dedictrice while at UMS
2015 2020	Hesen Al Savagh MS/ Senier Passarahar, Axias International Dubai United Arab
2013-2020	Emirates
	Career stage: Biostatistician I. Mentoring role: Clinical research and statistical methods
	mentor Accomplishments: Authorship on 12 scholarly publications on pediatric cancer or
	hematology as a result of my supervision. Promoted to Biostatistician II while at HMS.
2015-2020	Ami Desai, MD / Assistant Professor of Pediatrics. Division of Pediatric
2010 2020	Oncology/Hematology/Transplant, University of Chicago
	Career stage: Fellow. Mentoring role: Clinical research mentor. INRG mentor.
	Accomplishments: Wrote a clinical trial protocol at the AACR/ASCO Methods in Clinical
	Cancer Research Workshop; trial is underway. Presentation at the 2018 Advances in
	Neuroblastoma Research meeting. Two publications in the Journal of Clinical Oncology.
2016-2023	Kevin Campbell, MD / Fellow, Boston Children's Hospital and Dana-Farber Cancer
	Institute, Harvard Medical School
	Career stage: HMS student. Mentoring role: Clinical research mentor. Accomplishments:
	Four publications on retrospective analyses. Design and conduct of a clinical trial.
	Accepted to the fellowship program in our division.
2017-	Pei-Chi (Paige) Kao, MPH / Biostatistician II, Dana-Farber/Boston Children's Cancer and
present	Blood Disorders Center, Harvard Medical School
	Career stage: Biostatistician I (new graduate). Mentoring role: Clinical research and
	statistical methods mentor. Accomplishments: Authorship on six scholarly publications on
	pediatric cancer or hematology as a result of my supervision. Promotion to Biostatistician
	II.
Year(s)	Student
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	Type of supervision/ Specific accomplishment
2017-2020	Anran (Annie) Li, BS / Medical student, University of Michigan
	Career stage: undergraduate; Wellesley intern. Mentoring role: Clinical research and
	statistical methods mentor. Accomplishments: Learned SAS programming, database
	design, statistical methods, and diagnostic coding systems. Authorship on two scholarly
	publications on pediatric cancer or hematology as a result of my supervision. Major
	achievements on the PPIP datamart. Acceptance to medical school.
2017-2020	Elizabeth Sokol, MD / Assistant Professor of Pediatrics, Hematology, Oncology, and Stem
	Cell Transplantation, Northwestern University Feinberg School of Medicine
	Career stage: Fellow. Mentoring role: Clinical research mentor, INRG mentor.
	Accomplishments: Two publications in the <i>Journal of Clinical Oncology</i> . Presentation at
	the 2018 Advances in Neuroblastoma Research meeting.
2018-2020	Connie Zhong, MD / Resident, Brigham and Women's Hospital, Harvard Medical School
	Career stage: HMS student. Mentoring role: Clinical research mentor. Accomplishments:
	Publication on non-melanoma skin cancer.
2018-2021	Maya Ilowite, MD / Instructor in Pediatrics, Boston Children's Hospital and Dana-Farber
	Cancer Institute, Harvard Medical School
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments:
	Submitted manuscript on our prospective study of health literacy in patients and parents of
	children with cancer.
2018-	Natalie Collins, MD, PhD / Instructor in Pediatrics, Boston Children's Hospital and Dana-
present	Farber Cancer Institute, Harvard Medical School
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments:
	Design and conduct (underway) of two phase 2 clinical trials of novel targeted therapy for
	cancer.
2019-2023	Adam Durbin, MD, PhD / Assistant Member, St. Jude Faculty, St. Jude Children's
	Research Hospital
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments:
	Published a study of pAK1 in neuroblastoma/ganglioneuroblastoma vs ganlioneuroma.
2010 2020	New translational neuroblastoma research project underway. K08 grant application.
2019-2020	Danielle Bitterman, MD / Instructor of Radiation Oncology, Brigham and Women's
	Hospital/Dana-Farber Cancer Institute, Harvard Medical School
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments:
2010	Published a study of racial disparities in proton radiotherapy in <i>JAMA Oncology</i> .
2019	Alexandra Nieuwesteeg / Medical Student, Koyal Conege of Surgeons, Dublin, Ireland
	A accomplishments: Data surgion Catagorization and improved acding of toxicity in
	Accomptisinents. Data cutation - Categorization and improved coding of toxicity in neuroblastoma patients receiving diputuyimab
2019	Vaa Obeng / Undergraduate, Amberst College, Amberst MA
2017	Career stage: Undergraduate and DE/HCC CURE program summer intern Mentoring role:
	Clinical research and statistical mentor Accomplishments: - Publication on prognostic
	factors LDH and ferritin in neuroblastoma.
2019-	Suzanne Forrest, MD / Instructor in Pediatrics, Boston Children's Hospital and Dana-
present	Farber Cancer Institute. Harvard Medical School
r'esent	Career stage: Fellow, Mentoring role: Clinical research mentor. Accomplishments:
	Design and conduct (underway) of two phase 2 clinical trials of novel targeted therapy for
	cancer.

Year(s)	Student
	Type of supervision/ Specific accomplishment
2021-	Emma Anghel / Undergraduate, Wellesley College
present	Career stage: Undergraduate, Wellesley summer intern. Mentoring role: Clinical research
	and biostatistical methods mentor, INRG mentor. Accomplishments: Analysis of sex as a
	neuroblastoma prognostic factor. Manuscript draft in progress.
2021-2023	Whitney Eng, MD / Instructor in Pediatrics, Boston Children's Hospital, Harvard Medical
	School
	Career stage: Instructor. Mentoring role: Clinical research mentor. Accomplishments:
	Manuscript in progress on vascular anomalies.
2021-2024	Michelle Schoettler, MD / Acting Assistant Professor of Pediatrics, Children's Heathcare
	of Atlanta, Emory University School of Medicine
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments: Several
	retrospective research projects in progress.
2021-	Nan Chen, MS / Biostatistician I, Dana-Farber/Boston Children's Cancer and Blood
present	Disorders Center, Harvard Medical School
	Career stage: Biostatistician I. Mentoring role: Clinical research and statistical methods
	mentor. Accomplishments: Authorship on scholarly publications on pediatric cancer or
	hematology as a result of my supervision.
2021-	Kee Kiat (Aaron) Yeo, MD / Instructor in Pediatrics, Boston Children's Hospital and
present	Dana-Farber Cancer Institute, Harvard Medical School
	Career stage: Instructor. Mentoring role: Clinical research mentor. Accomplishments:
	Manuscript in development on a retrospective study of IDH mutant glioma.
2021-	Mary Jane Lim Fat, MD / Fellow, Boston Children's Hospital and Dana-Farber Cancer
present	Institute, Harvard Medical School
	Career stage: Fellow. Mentoring role: Clinical research mentor. Accomplishments:
	Manuscript in development on a retrospective study of IDH mutant glioma.
2022-	Riten Kumar, MD, MSc / Associate Professor of Pediatrics, Boston Children's Hospital,
present	Harvard Medical School
	Career stage: Assoc Professor. Mentoring role: Clinical research mentor.
	Accomplishments: Manuscripts in development on VTE during COVID and VTE in
	transgender children.
2022-	Boris Decarolis, MD / University of Cologne, UOC Children's Hospital
present	Career stage: junior faculty. Mentoring role: Clinical research mentor. Accomplishments:
	Manuscript in development on changes in therapy-associated outcome over time in
	neuroblastoma
2023-	Jung Joo Kim / undergraduate student, Wellesley College
present	Career stage: student. Mentoring role: Clinical research mentor. Accomplishments:
	Manuscript in development on changes in therapy-associated outcome over time in
	neuroblastoma

## Formal Teaching of Peers (e.g., CME and other continuing education courses)

Year(s)	Title(s) or topic(s) or talk(s) Course Name (Sponsor, if you)	Number of talks in a single course Location(s) (city or country)
2012	Clinical trials in small patient cohorts: Designs to detect efficacy or monitor adverse effects Translational Research Program, Boston Children's Hospital	Single presentation Boston, MA
2020	The evolution of prognostic factors in neuroblastoma (NB), and their changing roles in risk stratification to assign intensity of therapy Pediatric Oncology Conference, Dana-Farber / Boston Children's Cancer and Blood Disorders Center, Harvard Medical School CME	Single presentation Boston, MA
2021	De-mystifying adaptive designs: Four examples from phase 1 trials in our division Pediatric Oncology Conference, Dana-Farber / Boston Children's Cancer and Blood Disorders Center, Harvard Medical School CME	Single presentation Boston, MA
2023	Clinical Trials Design Workshop (Invited Organizer and Co-Chair) American Association of Cancer Research Annual Meeting CME	One-day workshop Orlando, FL
2024	Phase 1 Clinical Trial Development Workshop, featuring the DEDUCE app (Organizer)	4-day workshop Tucson, AZ
2024	Biostatistics in Clinical Trials Workshop: Out of the Rut and Beyond the Traditional – Parts 1 & 2 (Invited Organizer and Chair) American Association of Cancer Research Annual Meeting CME	One-day workshop San Diego, CA

No presentations below were sponsored by 3<sup>rd</sup> parties/outside entities.

## **Local Invited Presentations**

No presentations below were sponsored by 3<sup>rd</sup> parties/outside entities.

Year(s)	Title of presentation
	Department and Institution where presented (if any)
1996	A survival analysis of a prospective study comparing a new procedure to the standard
	procedure for variceal bleeding / Seminar
	Department of Biostatistics, Medical College of Virginia, Virginia Commonwealth
	University
1999	Simulation of multivariate gamma data with exponential marginals for independent
	clusters / Seminar
	Department of Statistics, University of Florida

Year(s)	Title of presentation
	Department and Institution where presented (if any)
2001	The role of statistics in clinical trials research: Basic statistical concepts that clinical
	researchers need to know / Grand Rounds
	Department of Hematology/Oncology, Shands Hospital, University of Florida
2005	Evidence for an age cutoff higher than 365 days for neuroblastoma risk group stratification
	in the Children's Oncology Group (COG <sup>1</sup> ) / Seminar
	Topics in Cancer Cell Biology Seminar Series, University of Florida Shands Cancer
	Center
2006	Study designs for clinical trials in humans / Seminar
	Department of Epidemiology and Health Policy Research, University of Florida
2008	The use of biologic, genetic and clinical risk factors for treatment determination of patients
	with neuroblastoma / Seminar
	Topics in Cancer Cell Biology Seminar Series, University of Florida
2009	The use of biologic, genetic, clinical, and morbidity factors to determine treatment for
	children with cancer / Seminar
	Division of Biostatistics, University of Florida
2010	The use of biologic, genetic, clinical, and morbidity factors to determine treatment for
	children with cancer / Seminar
	Department of Biostatistics and Computational Biology, Dana-Farber Cancer Institute,
	Harvard Medical School
2011	Factors predictive of survival in newly diagnosed and relapsed neuroblastoma patients /
	Seminar
	Division of Pediatric Hematology/Oncology, Boston Children's Hospital and Dana-Farber
	Cancer Institute, Harvard Medical School
2012	Success of chimeric anti-GD2 antibody + GM-CSF + IL2 immunotherapy in high-risk
	neuroblastoma (NB) in first response: A critical appraisal / Seminar
	Division of Pediatric Hematology/Oncology, Boston Children's Hospital and Dana-Farber
	Cancer Institute, Harvard Medical School
2013	What makes for a good endpoint? / Seminar
	Gamma Globin Induction Mini-retreat, Division of Pediatric Hematology/Oncology,
	Boston Children's Hospital, Harvard Medical School
2014	Snapshots from Pediatric Oncology / Seminar
	Biostatistics Briefing, Department of Biostatistics and Computational Biology, Dana-
	Farber Cancer Institute
2016	Leadership update: <i>PPIP</i> , our Data Resource and <i>PPIP</i> 360, our Query Tool / Invited
	Seminar
	Dana-Farber / Boston Children's Cancer and Blood Disorders Center
2017-	The <i>PPIP</i> and the <i>PPIP</i> 360 / Invited Training Course (>5 sessions)
present	Dana-Farber / Boston Children's Cancer and Blood Disorders Center
2017-	PPIP Data Governance / Invited Training Course (>5 sessions)
present	Dana-Farber / Boston Children's Cancer and Blood Disorders Center
2017	Infrastructure and Biostatistics for the Conduct of Clinical Research – Session 1 / Invited
	Seminar for our physician visitors from Beijing
	Dana-Farber / Boston Children's Cancer and Blood Disorders Center

Year(s)	Title of presentation
	Department and Institution where presented (if any)
2017	Infrastructure and Biostatistics for the Conduct of Clinical Research – Session 2 / Invited
	Seminar for our physician visitors from Beijing
	Dana-Farber / Boston Children's Cancer and Blood Disorders Center
2017	Infrastructure and Biostatistics for the Conduct of Clinical Research / Invited Seminar for
	our physician visitors from Egypt
	Dana-Farber / Boston Children's Cancer and Blood Disorders Center
2018	Infrastructure and Biostatistics for the Conduct of Clinical Research / Invited Seminar for
	our physician visitors from Beijing
	Dana-Farber / Boston Children's Cancer and Blood Disorders Center
2018	Statistical Aspects of Correlative Studies / Invited Seminar
	DF/HCC-UMass-Boston U54 Research and Data Analysis Core Seminar Series
	Dana-Farber/Harvard Cancer Center
2019	Infrastructure and Biostatistics for the Conduct of Clinical Research / Invited Seminar for
	our physician visitors from China
	Dana-Farber / Boston Children's Cancer and Blood Disorders Center
2022	The Research Design and Analysis Core / Invited virtual presentation
	DF/HCC-UMass-Boston U54 Scientific Advisory Committee meeting
2022	Validation of the change in age cut-off, from 12-months to 18-months, for assignment to
	reduction of therapy in COG neuroblastoma risk stratification / Invited Seminar
	Endicott Retreat, Dana-Farber/Boston Children's Cancer and Blood Disorders Center
2022	Design of adaptive phase 1 clinical trials for dose escalation using the DEDUCE
	application / Invited Seminar
	Seminar series of the Univ. of Mass Boston-DF/HCC Comprehensive Partnership for
	Cancer Disparities Research
2022	Design and implementation of Bayesian adaptive phase 1 trials in oncology using the
	DEDUCE application / Invited Seminar
	Dana-Farber Cancer Institute Frontiers in Biostatistics Seminar series
2023	Biostatisticians: What we do on investigator-initiated trials / Invited Seminar for the
	Clinical and Translational Investigation Program (CTIP) Staff Development Workshop
	Dana-Farber / Boston Children's Cancer and Blood Disorders Center
2023	The Biostatistics Program of the Dana-Farber/Boston Children's Cancer and Blood
	Disorders Center / Invited meeting

# **Report of Regional, National and International Invited Teaching and Presentations**

One presentation below\* was sponsored by an outside entity, a health education company, Healthcasts.

# **Invited Presentations and Courses**

National	
Year(s)	Title of presentation or name of course/Type of presentation/role(s) (note if
	presentation the result of a selected abstract)
	Location (Sponsor, if any)
1989	Standard operating procedure in the creation, maintenance, and quality assurance of SAS
	programs / Platform presentation (abstract)
	SAS Users Group International 14 <sup>th</sup> Annual Conference, San Francisco, CA
1990	Teaching the SAS programming language to programmers and non-programmers /
	Platform presentation (abstract)
	SAS Users Group International 15 <sup>th</sup> Annual Conference, Nashville, TN
1992	How to gain a working knowledge of the FREQ procedure without freaking out / Platform
	presentation (abstract)
	SAS Users Group International 17 <sup>th</sup> Annual Conference, Honolulu, HI
1997	Characteristics of patients placed on the transplant waiting list before requiring dialysis /
	Platform presentation (abstract)
	American Society of Nephrology 30 <sup>th</sup> Annual Meeting, Orlando, FL
1997	A survival analysis of dependent waiting times to transplant with censoring using a
	generalized estimating equations approach / Platform presentation (abstract)
	Joint Statistical Meetings of the American Statistical Association, Anaheim, CA
1998	A survival analysis of clusters of dependent times to event with censoring using a
	generalized estimating equations (GEE) approach / Platform presentation (abstract)
	Joint Statistical Meetings of the American Statistical Association, Dallas, TX
1999	Simulation of multivariate gamma data with exponential marginals for independent
	clusters / Platform presentation (abstract)
1000	Joint Statistical Meetings of the American Statistical Association, Baltimore, MD
1999	The role of statistics in clinical trials research / Invited platform presentation
	Joint Meeting of the Pediatric Oncology Group/Children's Cancer Group, St. Petersburg,
• • • • •	FL A REAL REAL AND A R
2000	Criteria for validating ordinal surrogates for time-related endpoints in randomized
	experiments / Platform presentation (abstract)
2001	Joint Statistical Meetings of the American Statistical Association, Indianapolis, IN
2001	Designs for stratified phase II clinical trials / Platform presentation (abstract)
2002	Joint Statistical Meetings of the American Statistical Association, Atlanta, GA
2003	One- and two-stage designs for stratified phase II clinical trials / Platform presentation
	(abstract)
2004	Joint Statistical Meetings of the American Statistical Association, San Francisco, CA
2004	Evidence for an age cutoff higher than 365 days for neuroblastoma risk group stratification
	in the Children's Oncology Group (COG <sup>1</sup> ) / Platform presentation (invited)
2005	Children's Oncology Group meeting, Tuscon, AZ
2005	Evidence for an age cutoff higher than 365 days for neuroblastoma risk group stratification
	in the Children's Oncology Group (COG <sup>+</sup> ) / Platform presentation (abstract)
	American Society for Clinical Oncology, Orlando, FL

Year(s)	Title of presentation or name of course/Type of presentation/role(s) (note if
	presentation the result of a selected abstract)
	Location (Sponsor, if any)
2005	Contrasting roles of the hazard ratio and the p-value in identifying a continuous variable's
	cut-off for prognostic stratification / Platform presentation (abstract)
	Joint Statistical Meetings of the American Statistical Association, Minneapolis, MN
2006	Prognostic factors and risk stratification in neuroblastoma: From specimens to treatment
	groups / Invited Seminar
	Pediatric Oncology Branch of the National Cancer Institute, Bethesda, MD
2006	Interim monitoring against a fixed standard: A3961 and D9602 / Invited Seminar
	Statistics Symposium, Children's Oncology Group meeting, Dallas, TX
2006	Proposed risk groups for neuroblastoma / Invited Seminar
	Statistics Symposium, Children's Oncology Group meeting, Dallas, TX
2007	Preliminary efficacy results of COG <sup>1</sup> study A3973: purged versus unpurged peripheral
	blood stem cell transplant / Invited platform presentation
	Children's Oncology Group meeting, Dallas, TX
2007	Utilization of the Neuroblastoma Virtual Tumor Bank (NVTB) for microarray analyses /
	Invited platform presentation
	Translational Genomics in Neuroblastoma, Rockville, MD
2008	Prognostic stratification of children with neuroblastoma: Statistical methods and
	collaborative application for clinical consensus / Invited seminar
2000	University of Alabama–Birmingham Comprehensive Cancer Center Seminar
2008	The use of biologic, genetic, and clinical risk factors to determine treatment for patients
	with neuroblastoma / Invited seminar
2000	Division of Pediatric Hematology/Oncology, University of Chicago
2008	The use of biologic, genetic, clinical, and morbidity risk factors to determine treatment for
	Children's Hospital of Dhiladalphia. University of Danneylyania
2008	The use of hielegie, genetic, elinical, and merhidity right factors to determine treatment for
2008	children with concer / Invited sominer
	Dana-Farber Cancer Institute, Harvard Medical School
2009	One- and two-stage designs for stratified Phase 2 clinical trials / Invited seminar
2007	Children's Hospital of Philadelphia. University of Pennsylvania
2010	Factors predictive of survival after relanse in patients with neuroblastoma / Invited
2010	Platform presentation
	American Society for Clinical Oncology (ASCO) Annual Meeting Chicago II
2010-	Methods in Clinical Cancer Research Workshon / Invited Course
present	American Society of Clinical Oncology /American Association for Cancer Research
present	Workshop: Vail. Colorado
	~60 hours of non-HMS teaching each year
2012	Electronic data capture of central laboratory results to direct (in real time) risk-based
-	therapy for COG <sup>1</sup> neuroblastoma patients / Invited platform presentation (abstract)
	Society of Clinical Trials meeting, Miami, Florida
2012	Success of chimeric anti-GD2 antibody + GM-CSF + IL2 immunotherapy in high-risk
	neuroblastoma in first response: A critical appraisal / Invited seminar
	Dept of Biostatistics, Virginia Commonwealth University, Richmond, VA

Year(s)	Title of presentation or name of course/Type of presentation/role(s) (note if
	presentation the result of a selected abstract)
	Location (Sponsor, if any)
2016	Statistical Aspects of Correlative Studies / Invited Plenary Lecture
	American Society of Clinical Oncology /American Association for Cancer Research
	Methods in Clinical Cancer Research Workshop; Vail, Colorado
2017	Integration and user-accessibility of diverse, cross-institutional systems of clinical,
	outcome, and genomic data via a common datamart technology: The Dana-Farber/Boston
	Children's "Pediatric Patient Informatics Platform" (PPIP) / Invited Seminar
	St. Jude Children's Research Hospital; Memphis, Tennessee
2017	Statistical Aspects of Correlative Studies / Invited Plenary Lecture
	American Society of Clinical Oncology /American Association for Cancer Research
	Methods in Clinical Cancer Research Workshop; Vail, Colorado
2018	The evolution of prognostic factors in neuroblastoma, and their changing roles in risk
	stratification to assign intensity of therapy / Invited Seminar
	Biostatistics Seminar Series, Memorial Sloan Kettering Cancer Center, New York, New
2010	York
2018	The evolution of prognostic factors in neuroblastoma, and their expanding role in study
	design / Invited Seminar
2019	Division of Pediatric Hematology/Oncology, Columbia University, New York, New York
2018	The evolution of prognostic factors in neuroblastoma, and their changing roles in risk
	Stratification to assign intensity of therapy / invited Seminar
	Chicago, Illinois
2018	The evolution of prognostic factors in neuroblastoma, and their changing roles in risk
2010	stratification to assign intensity of therapy / Invited Seminar
	Division of Pediatric Hematology/Oncology Stanford University Palo Alto California
2018	Statistical Aspects of Correlative Studies / Invited Plenary Lecture
2010	American Society of Clinical Oncology /American Association for Cancer Research
	Methods in Clinical Cancer Research Workshop: Vail. Colorado
2019	The evolution of prognostic factors in neuroblastoma, and their changing roles in risk
	stratification to assign intensity of therapy / Invited Pediatric Grand Rounds
	Pediatric Hematology/Oncology, Oklahoma University Health Science Center, Oklahoma
	City, Oklahoma
2019	Statistical Aspects of Correlative Studies / Invited Plenary Lecture
	American Society of Clinical Oncology /American Association for Cancer Research
	Methods in Clinical Cancer Research Workshop; Vail, Colorado
2021	Statistical Aspects of Correlative Studies / Invited Plenary Lecture
	American Society of Clinical Oncology /American Association for Cancer Research
	Methods in Clinical Cancer Research Workshop (virtual)
2021	Adaptive Clinical Trials Initiative: Translating from bench to bedside / Invited Seminar
	Northwestern Mututal Foundation
2022	Statistical Aspects of Correlative Studies / Invited Plenary Lecture
	American Society of Clinical Oncology /American Association for Cancer Research
	Methods in Clinical Cancer Research Workshop; Vail, Colorado

Year(s)	Title of presentation or name of course/Type of presentation/role(s) (note if	
	presentation the result of a selected abstract)	
	Location (Sponsor, if any)	
2023	Statistical and Practical Aspects of Correlative Studies / Invited Plenary Lecture	
	American Society of Clinical Oncology /American Association for Cancer Research	
	Methods in Clinical Cancer Research Workshop; La Jolla, CA	
2023	Statistical and Practical Guidance for Biomarker Studies / Invited Plenary Lecture	
	American Association for Cancer Research Annual Meeting; Orlando, FL	
2024	Introduction to design of phase 1 trials / Invited Platform presentation	
	Phase 1 clinical trial development workshop, featuring the DEDUCE app	
	Tucson, AZ	
2024	Practical considerations for the conduct of phase 1 trials / Invited Platform presentation	
	Phase 1 clinical trial development workshop, featuring the DEDUCE app	
	Tucson, AZ	
2024	Design and implementation of Bayesian adaptive designs	
	for pediatric Phase 1 clinical trials / Invited Seminar	
	Texas Children's Hospital, Department of Pediatrics, Section of Hematology/Oncology,	
	Baylor College of Medicine	
2024	Implementation of Phase 1 Trials that Use Adaptive Designs / Invited Plenary Lecture	
	American Association for Cancer Research Annual Meeting; San Diego, CA	
2024	Bayesian adaptive design of phase 1 dose-finding trials / Invited Roundtable Discussion	
	Society for Clinical Trials annual meeting; Boston, MA	

## International

Year(s)	Title of presentation or name of course/Type of presentation/role(s) (note if
	Location (Sponsor, if any)
2006	Age, tumor grade, and MKI are independently predictive of outcome in neuroblastoma /
	Platform presentation (prize-winning abstract)
	Advances in Neuroblastoma Research (ANR <sup>2</sup> ) Meeting, Los Angeles, CA
2006	The International Neuroblastoma Risk Group project: Report of the Statistics Committee /
	Invited platform presentation
	International Neuroblastoma Risk Group meeting in Los Angeles, CA
2006	Univariate versus multivariable analyses of histologic features / Invited platform
	presentation
	International Meeting of Neuroblastoma Pathologists, Children's Hospital of Los Angeles,
	Los Angeles, CA
2007	Evidence for an age cut-off >365 days: INRG results / Invited platform presentation
	International Society for Pediatric Oncology – Neuroblastoma, Tel Aviv, Israel
2007	Surgery and restricted use of chemotherapy as treatment of low-risk neuroblastoma:
	Preliminary results of Children's Oncology Group protocol P9641 / Invited platform
	presentation
	"Best of SIOP" Award Lecture, American Society of Pediatric Hematology/Oncology,
	Toronto, Ontario

<sup>&</sup>lt;sup>2</sup> ANR is an international, and the primary, organization of scientists who perform research on neuroblastoma. Meetings are held bi-annually in locations around the world. See www.anrmeeting.org.

Year(s)	Title of presentation or name of course/Type of presentation/role(s) (note if
	presentation the result of a selected abstract)
	Location (Sponsor, if any)
2007	An optimality criterion for prognostic risk groups in pediatric cancer: Analysis of data
	from the Children's Oncology Group / Platform presentation (abstract)
	28 <sup>th</sup> Annual Conference of the International Society for Clinical Biostatistics (ISCB),
	Alexandroupolis, Greece
2007	A proposal for two versions of the International Neuroblastoma Pathologic Classification
	(INPC): with and without age / Invited platform presentation
	International Neuroblastoma Pathology Meeting, Los Angeles, CA
2008	Use of intravenous gammaglobulin therapy for patients with neuroblastoma associated
	opsoclonus-myoclonus-ataxia syndrome treated with chemotherapy and prednisone: COG <sup>1</sup>
	Protocol ANBL00P3 / Invited platform presentation
	Fourth Dancing Eye Syndrome Workshop, Oxford, United Kingdom
2009	Success of chimeric anti-GD2 antibody + GM-CSF + IL2 immunotherapy in high-risk
	neuroblastoma (NB) in first response: A critical appraisal. / Invited platform presentation
	Societe Internationale D'Oncologie Pediatrique (SIOP), Sao Paulo, Brazil
2009	Success of chimeric anti-GD2 antibody + GM-CSF + IL2 immunotherapy in high-risk
	neuroblastoma (NB): COG <sup>1</sup> Study ANBL0032 / Invited seminar
	Royal Marsden, Sutton, United Kingdom
2009	Success of chimeric anti-GD2 antibody + GM-CSF + IL2 immunotherapy in high-risk
	neuroblastoma (NB): COG <sup>1</sup> Study ANBL0032 / Invited seminar
	University of Cologne, Cologne, Germany
2010	Changes over three decades in the prognostic influence of age in patients with
	neuroblastoma: A report from the International Neuroblastoma Risk Group Project /
	Platform presentation (abstract)
	Advances in Neuroblastoma Research (ANR <sup>2</sup> ) Meeting, Stockholm, Sweden
2010	Clinical and biological features predictive of survival after relapse of neuroblastoma /
	Invited seminar
	Neuroblastoma Update Course, Advances in Neuroblastoma Research (ANR <sup>2</sup> ) meeting,
	Stockholm, Sweden
2012	Ultra-high-risk neuroblastoma: Phenotype according to outcome versus definition
	according to risk factors. / Invited platform presentation
	NCI Clinical Trials Planning Meeting (CTPM) for Neuroblastoma, Washington, DC
2012	Using a selection design ('Pick the Winner') in a COG <sup>1</sup> Phase II study
	of relapsed neuroblastoma. / Invited platform presentation
	Joint Meeting of the Royal Statistical Society Medical Section, the Medical Research
	Council Hubs for Trials and Methodology Research, the European Network for Cancer
	Research in Children and Adolescents, and the International Rare Cancers Initiative.
2012	London, United Kingdom
2012	Factors that contribute to inferior survival of low-risk stage 2B neuroblastoma patients: A
	Children's Oncology Group study / Platform presentation (abstract)
2012	Advances in Neuroblastoma Research (ANR <sup>2</sup> ) Meeting, Toronto, Ontario
2012	Neuroblastoma in Older Children, Adolescents and Young Adults: A Report from the
	International Neuroblastoma Risk Group Project / Platform presentation (abstract)
	Advances in Neuroblastoma Research (ANR <sup>2</sup> ) Meeting, Toronto, Ontario

Year(s)	Title of presentation or name of course/Type of presentation/role(s) (note if		
	presentation the result of a selected abstract)		
	Location (Sponsor, if any)		
2014	A neuroblastoma risk classification model for developing countries: A study from the		
	International Neuroblastoma Risk Group (INRG) database / Platform presentation		
	(abstract)		
	Societe Internationale D'Oncologie Pediatrique (SIOP), Toronto, Ontario		
2014	Historical gold standard for time-to-progression (TTP) and progression-free survival (PFS)		
	from relapsed/refractory neuroblastoma modern era (2002-14) patients / Platform		
	presentation (abstract)		
2021	Societe Internationale D'Oncologie Pediatrique (SIOP), Toronto, Ontario		
2021	Data Quality of the International Neuroblastoma Risk Groups (INRG) Data Commons /		
	Virtual platform presentation		
	Neuroblastoma Risk Groups (INRG) Task Force meeting, Advances in		
2021	Development Plans for the INPG Pisk Classification Version 2.0 / Virtual platform		
2021	presentation		
	International Neuroblastoma Risk Groups (INRG) Task Force meeting Advances in		
	Neuroblastoma Research ( $ANR^2$ ) Meeting		
2021	The London Clinical Neuroblastoma Risk Groups (LCNRG) / Virtual platform		
2021	presentation		
	International Neuroblastoma Risk Groups (INRG) Task Force meeting, Advances in		
	Neuroblastoma Research (ANR <sup>2</sup> ) Meeting		
2022	The International Neuroblastom Risk Groups Data Commons – Statistical and Data		
	Quality Update / Virtual platform presentation		
	International Neuroblastoma Risk Groups (INRG) Task Force meeting, Advances in		
	Neuroblastoma Research (ANR <sup>2</sup> ) Meeting		
2022	The International Neuroblastom Risk Groups Classification, Version 2 / Virtual platform		
	presentation		
	International Neuroblastoma Risk Groups (INRG) Task Force meeting, Advances in		
	Neuroblastoma Research (ANR <sup>2</sup> ) Meeting		
2022	Survival of patients with neuroblastoma before vs after reduction of therapy due to the		
	change in age cut-off from 12 to 18 months in COG risk stratification		
	Healthcasts website, <u>https://app.healthcasts.com/asset/id/10095/?view_type=primary</u>		
2023	Design and implementation of Bayesian adaptive designs for pediatric Phase I clinical		
	trials / Invited Plenary Presentation		
	International Society of Pediatric Oncology (SIOP) annual meeting; Ottawa, Ontario,		
2022	Canada The DODNEO ansiest DiOmedians in high Disk NExaOhlastanse / Distform Dresentation		
2025	Advances in Neuroblastoma Research Meeting: Amsterdam, The Netherlands		
2023	The BORNEO project: BiOmarkers in high Rick NEurOblastoma / Invited Virtual		
2023	Platform Presentation		
	Neuroblastoma Parent Global Symposium, Sponsored by Solving Kids Cancer UK		
2023	Beyond 3+3 Phase 1 clinical trials: Design and implementation of Bayesian adaptive		
2025	designs – Session 1 / Invited Virtual Platform Presentation		
	First Affiliated Hospital of Sun Yat Sen Medical Center: Guangzhou, China		
	Guuigenou, China		

Year(s)	Title of presentation or name of course/Type of presentation/role(s) (note if presentation the result of a selected abstract)	
	Location (Sponsor, if any)	
2023	Beyond 3+3 Phase 1 clinical trials: Design and implementation of Bayesian adaptive	
	designs – Session 2 / Invited Virtual Platform Presentation	
	First Affiliated Hospital of Sun Yat Sen Medical Center; Guangzhou, China	

# **Report of Clinical Activities and Innovations**

# **Report of Technological and Other Scientific Innovations**

Innovation (date if applicable)	Patent (if any, pending, or awarded)	
	Describe the influence or potential influence of the innovation	
	on research or clinical care	
1998-2014	In this cutting-edge informatics project, I designed and built a	
The COG <sup>1</sup> Neuroblastoma Virtual	database, integrating and harmonizing biology, clinical, and	
Tumor Bank (NVTB)	outcome data from POG, COG <sup>1</sup> , and CCG, and specimen data	
	from a multi-center national laboratory system, to create the	
	Neuroblastoma Virtual Tumor Bank (NVTB) database. I had the	
	vision to recognize the critical added value that linking the	
	clinical/outcome data with specimen data would provide. I	
	initiated efforts to obtain data from POG institutions and labs.	
	This resource includes $>10,000$ COG <sup>1</sup> neuroblastoma patients	
	enrolled nationally 1990-present, and has been invaluable for	
	identification of neuroblastoma prognostics factors and mapping	
	the genomic landscape of neuroblastoma. Investigators nationally	
	and internationally rely on the NVTB for specimens and data for	
	basic science and clinical research.	
2004- present	The INRG Data Commons is a shared repository of data from	
The International Neuroblastoma	neuroblastoma patients at all major pediatric cancer treatment	
Risk Group (INRG) Data Commons	centers in the world. In 2004, I developed the data dictionary of	
	standardized data items, gathered data on 8,800 patients from 12	
	countries or cooperative groups, and harmonized the data on a	
	central platform. As the largest database of neuroblastoma	
	patients of its kind, it has supported over 30 published analyses of	
	prognostic factors to date, including the landmark analysis to	
	create the INRG risk stratification, which I performed [Cohn et al,	
	Journal of Clinical Oncology 2009]. In 2014, the University of	
	Chicago assumed responsibility for the technical oversight of the	
	INRG Data Commons. This database has set the standard; the	
	Pediatric Cancer Data Commons, a national federally-funded	
	organization, is using the INRG Data Commons as a model for	
	other national disease-specific data commons.	

Innovation (date if applicable)	Patent (if any, pending, or awarded)	
``````````````````````````````````````	Describe the influence or potential influence of the innovation	
	on research or clinical care	
2012- present	I provide vision and lead the efforts to develop and implement a	
Datamart: The Pediatric Patient	database, the PPIP, that integrates patient data (clinical, outcome,	
Informatics Platform (PPIP)	genomics, specimens) and protocol data (PI, accrual goal,	
	activation date) from disparate sources at BCH and DFCI [Ma et	
	al, J Clin Oncol Clinical Cancer Informatics 2021]. The PPIP	
	facilitates research, operations and safety reporting, and strategic	
	planning. This innovative resource of data on >30,000 patients	
	may be queried by faculty and staff, and allows biostatisticians to	
	perform analyses using data previously inaccessible. The PPIP	
	will contribute data to DFCI's multicenter Pragmatic	
	Implementation of Phenomic Data Standards for Curating	
	Outcomes of Cancer Treatment (PRISSMM) project, to the	
	Massachusetts Cancer Registry and the NCI's National Childhood	
	Cancer Registry, and internationally through the American	
	Association for Cancer Research's Project Genomics Evidence	
	Neoplasia Information Exchange (GENIE).	
2015- present	I provide vision, leadership, and technical oversight for the	
MicroStrategy <i>PPIP360</i> query tool	development of the <i>PPIP360</i> query tool in MicroStrategy. A series	
	of customizable reports are accessible to independent local users,	
0.10	to generate aggregate counts from the <i>PPIP</i> database.	
2019- present	The DEDUCE application is a tool to create, simulate, and	
DEDUCE application	compare cutting-edge adaptive designs for phase 1 clinical trials.	
	Dr. Clement Ma (mentee) and Dr. London partnered with	
	Northwestern Mutual Foundation (NMF) (who donated their 15/11	
	ongoing work to add new designs to DEDUCE. A statistician	
	clinical investigator team use the DEDUCE's point-and-click	
	interface to design and conduct their adaptive trial according to	
	their specific requirements for safety accrual rate and available	
	resources Funded by NMF a nationwide DEDUCE program will	
	provide training and access to statisticians and clinicians, thereby	
	increasing the use of phase 1 adaptive designs, for more accurate	
	identification of the optimal dose of an experimental drug. A	
	workshop for adaptive phase 1 trial design using DEDUCE was	
	conducted in February 2024.	
	https://deduce.shinyapps.io/DEDUCE/	
2019-present	Building on a foundation of two decades of my experience in	
Nomogram of clinical/biologic	identification of NB prognostic factors and NB risk stratification,	
factors to predict survival in high-	my mentee Lucas Moreno and I developed a user-friendly online	
risk NB	nomogram to calculate the estimated 3-year OS of high-risk NB	
	patients based on optimally-selected particular risk factors: MYCN	
	status, bone marrow metastases, and LDH (lactate dehydrogenase).	
	PMID: 33205902. <u>https://neuroblastoma.shinyapps.io/High-Risk-</u>	
	<u>Neuroblastoma-Nomogram/</u>	

### **Report of Education of Patients and Service to the Community**

### Activities

Year(s)	Organization or institution/Role (Sponsor, if any)			
	Description			
2004-2009	009 "Big Sister", Big Brothers Big Sisters of Mid-Florida, Gainesville, Florida			
	Served as a Big Sister to child whose parents were in prison.			
2005-2009	9 Board of Directors of STOP! Children's Cancer Inc., Gainesville, Florida			
	Performed strategic planning for fundraising.			
2005-2009	9 Chair, Grant Productivity Committee of STOP! Children's Cancer Inc., Gainesville, Florida			
	Reviewed/scored research grants; instituted accountability for use of funding.			
2008-2009	09 Board of Directors, Big Brothers Big Sisters of Mid Florida, Gainesville, Florida			
	Performed strategic planning for programming and fundraising.			
2008-2009	Board of Directors, Pace Center for Girls, Gainesville, Florida			
	Strategic planning for fundraising; chaired the golf tournament committee.			
2015-2017	17 Member/Fundraiser/Runner, Dana-Farber Marathon Challenge Team			
	Dana-Farber/Harvard Cancer Center, Boston, MA			
	Ran three marathons; raised over \$25,000 for Dana-Farber/Harvard Cancer Center.			
2018	Member/Fundraiser/Runner, Boston Marathon "Team Eye and Ear", Massachusetts Eye and			
	Ear Institute, Boston, MA			
	Ran one marathon; raised over \$13,000 for Massachusetts Eye and Ear Institute.			

### Recognition

Year(s)	Name of award/recognition	Organization conferring recognition
2008	STOP! Children's Cancer Board	
	Member of the Quarter, 4 <sup>th</sup> quarter 2008	

### **Report of Scholarship**

ORCiD: 0000-0003-3571-6538; Web of Science Researcher ID: ABA-8948-2021 \*co-first or co-senior authorship \*\*denotes a mentee

#### Peer-reviewed scholarship in print or other media Research Investigations

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# Non-peer reviewed scholarship in print or other media

### **Book chapters**

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- 2. Lau L, London WB. "Recurrent Neuroblastoma" in *Neuroblastoma Present and Future*. H. Shimada (ed.) InTech, 2012. 29-52. Web.
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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

1. London, Wendy Beth. Application of within-cluster correlations in a generalized estimating equations (GEE) approach: Implications for inference in survival analysis. Virginia Commonwealth University, Tompkins-McCaw Library Special Collections and Archives R111.M489 1997 .L66

Year(s)	Abstracts published/Exhibits presented
2022	COVID-19 Is Associated with an Increased Risk of Venous Thromboembolism, but Not
	Arterial Ischemic Stroke in Hospitalized Children: A Multicenter Observational Study
	American Society of Hematology Annual Meeting
2022	Long-Term Outcome of Gene Therapy for X-Linked Severe Combined Immunodeficiency
	(SCID-X1) Using an Enhancer-Deleted Self-Inactivating Gammaretroviral Vector
	American Society of Hematology Annual Meeting
2022	Induction of Fetal Hemoglobin and Reduction of Clinical Manifestations in Patients with
	Severe Sickle Cell Disease Treated with Shmir-Based Lentiviral Gene Therapy for Post-
	Transcriptional Gene Editing of BCL11A: Updated Results from Pilot and Feasibility Trial
	American Society of Hematology Annual Meeting
2022	Lentiviral Gene Therapy with Low Dose Conditioning for X-Linked SCID Results in
	Complete Immune Reconstitution and No Evidence of Clonal Expansion
	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	A Phase 3 Study of Eltrombopag vs. Standard First-Line Management for Newly
	Diagnosed Immune Thrombocytopenia in Children (selected poster)
	American Society of Hematology Annual Meeting
2019	Outcome of Hematopoietic Stem Cell Gene Therapy for Wiskott-Aldrich Syndrome
	(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

Abstracts, Poster Presentations and Exhibits Presented at Professional Meetings

2019	Prognostic Influence of Lactate Dehydrogenase & Serum Ferritin in Neuroblastoma
	Continuing Umbrella of Research Experiences Symposium, Dana-Farber/Harvard Cancer
2010	Center
2019	Evaluation of the Intrinsic Hepcidin Idx <sup>IM</sup> Test to Detect Iron Deficiency in
	Adolescents/ Young Adults (selected poster)
2010	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 Hencidin IdvIM Test to Detect Iron Deficiency in
2017	Adolescents/Voung Adults (selected poster)
	Pediatric Academic Society Annual Meeting
2016	Second malignancies in patients with neuroblastoma: a report from the International
2010	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)
2006	38 <sup>th</sup> 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)
2006	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 Poscarch (ANP) 2006 Macting
1000	Advances in Neurobiastonia Research (ANR) 2000 Meeting
1990	Contributed Paper" in the section Education Consulting and Technical Support)
	SAS Users Group International 15 <sup>th</sup> Annual Conference
1989	Standard operating procedure in the creation maintenance and quality assurance of SAS
1707	programs ("Honorable Mention" in the section on in Education. Consulting, and Technical
	Support)
	SAS Users Group International 14 <sup>th</sup> Annual Conference

## Narrative Report

I am a biostatistician, a teacher, a mentor, a leader, an administrator, a scientist. Team science: I am a recognized expert for design and analysis of pivotal clinical trials, improving cure rates for neuroblastoma (NB) and other pediatric cancers and blood disorders. 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 PRA Health Sciences. 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 [COG<sup>1</sup>], 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 and validated an optimal 547-day (18-month) age cut-off to differentiate younger (better outcome) from older (worse outcome) patients [34,244]. We reached international consensus to change the age cut-off from 12 months to 18 months. COG<sup>1</sup> 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 Staging System (INRGSS) [56]. As the Chair of 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] <u>https://neuroblastoma.shinyapps.io/High-Risk-Neuroblastoma-Nomogram/</u>, 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 COG<sup>1</sup> 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, COG<sup>1</sup> committees are scientific working groups that design and conduct clinical trials, with a separate 'committee' for each disease. Appointment to a COG<sup>1</sup> 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 COG<sup>1</sup> trials from 1998-2009, decreasing to 30% (2009-2014) when I moved to DFCI/BCH. During my tenure as a COG<sup>1</sup> 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] (ANR<sup>2</sup> 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 (crizotanib) [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 Paolo, 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 ANR<sup>2</sup> (Advances in Neuroblastoma Research) network: A study of the contributions 1975-2015". Of 7,787 authors /investigators worldwide, I ranked 11<sup>th</sup> in the number of ANR<sup>2</sup> abstracts. My H-indices are 92 (Google Scholar) and 73 (Web of Science), my i10-index is 228, and my publications have been cited 33,339 times (Google Scholar) or 20,372 (Web of Science), large numbers given the rarity of NB.

*COG<sup>1</sup> NB Virtual Tumor Bank development* - I conceived and designed the COG<sup>1</sup>'s NB Virtual Tumor Bank (NVTB) database, linking clinical, biological, outcomes, and specimen data for COG<sup>1</sup> and international contributors. My foresight to require submission of outcome data on COG<sup>1</sup> 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 COG<sup>1</sup> and international INRG risk stratifications; one approach used a novel finite mixture survival model [63]. I collaborated with Dr. Arlene Naranjo to create the new COG<sup>1</sup> 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 in development). 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 application is open-source, available to scientists worldwide. https://deduce.shinyapps.io/DEDUCE/

*Mentoring and teaching* - I have mentored >100 fellows and junior faculty in COG<sup>1</sup>, 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 graduated in 2023 from 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 (Vail, CO & La Jolla, CA) (plenary lecture on correlative studies), and will Co-Chair the workshop in 2024-26. I lecture on clinical trials and statistics to hem/onc fellows, clinicians and COG<sup>1</sup> 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 serve on the Therapeutic Immune Regulation (TIR) Study Section, the Cellular, Tissue, and Gene Therapies Advisory Committee of the Food and Drug Administration, and the editorial board of the *Journal of the National Cancer Institute* (impact factor: 12.6). I have served as a permanent member on the NIH's Clinical Oncology (CONC) Study Section, ad-hoc on Subcommittee H (peer review of NIH/NCI Cancer Cooperative Groups), NIH's Cancer Biomarker Study Section, the Department of Defense Congressionally Directed Medical Research Neuroblastoma Peer Reviewed Cancer Research Program, the International Neuroblastoma Research Initiative for pilot trials for Solving Kids' Cancer UK, 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 COG<sup>1</sup> Statistics and Data Center while transitioning to electronic data capture, managing five PhD statisticians and 20 staff (~\$2M annual budget). At DFCI/BHC, 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 PRISSMM project, the National Childhood Cancer Registry, Massachusetts Cancer Registry, locally to the oncology "clinical database", 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.