Janice E. Sullivan, MD; FAAP, FCCM, CPI

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Research

Pediatric Clinical Research Unit University of Louisville 231 East Chestnut Street, N-97 Louisville, Kentucky 40202

Academic University of Louisville Health Sciences Center 571 South Flord State 1

571 South Floyd Street, STE 332 Louisville, Kentucky 40202

EDUCATION		
1966 – 1977	B.S. in Bible, Nursing, Pillsbury Baptist Bible College, Owatonna, Minnesota	
1967 – 1970	Diploma in Nursing, Swedish Hospital School of Nursing, Minneapolis, Minnesota	
1976 – 1984	B.S. in Biochemistry (magna cum laude), Mankato State University, Mankato, Minnesota	
1978	Nursing, University of Dubuque, Dubuque, Iowa	
1979 - 1982	Certificate in Adult Nurse Practitioner University of Adv	
1984 - 1988	Certificate in Adult Nurse Practitioner, University of Minnesota, Minneapolis, Minnesota M.D., University of Minnesota School of Medicine, Minneapolis, Minnesota	
1988 - 1991	Residency (Pediatrics) University of Arbanya for Arban	
	Residency (Pediatrics), University of Arkansas for Medical Sciences/Arkansas Children's Hospital, Little Rock, Arkansas	
1991 - 1995		
	Fellowship (Pediatric Pharmacology & Critical Care), Case Western Reserve University School of Medicine/Rainbow Babies & Children's Hospital, Cleveland, Ohio	
ACADEMIC APPOINT	TMENTS	
2021 Descent		

ACAD	<u>EMI</u>	<u>C AP</u>	POIN	ITM	ENT	S

2021 - Present	Assistant Research Director (0.25 FTF)

Norton Children's Research Institute (NCRI)

Louisville, Kentucky

2016 - Present	Vice Chair for Research (7/1/2021 changed to 0.75 FTF)
	1000 Cir (7/1/2021 Ciraligeu (0 0/5 FTF

Department of Pediatrics University Louisville Louisville, Kentucky

2006 – Present	Profess

2001 - 2006Associate Professor 1995 - 2001Assistant Professor Department of Pediatrics University Louisville Louisville, Kentucky

2014 – Present	Associate
2006 – 2014	Professor

2001 - 2006 Associate Professor 1998 - 2001Assistant Professor

1995 - 1998Associate Department of Pharmacology and Toxicology

University of Louisville Louisville, Kentucky

2018 - 2019Division Chief

Division of Clinical and Translational Research

Department of Pediatrics University of Louisville Louisville, Kentucky

2019 - 2020Medical Director

Kosair Charities Pediatric Clinical Research Unit

Department of Pediatrics University of Louisville

Louisville, Kentucky

2001 – 2019 Chief and Medical Director

Kosair Charities Pediatric Clinical Research Unit

Department of Pediatrics University of Louisville Louisville, Kentucky

2003 – Present Member of the Graduate Faculty

University of Louisville Louisville, Kentucky

2001 – Present Consultant

Kentucky Regional Poison Center of Norton Children's Hospital

University of Louisville Louisville, Kentucky

1995 – 2001 Associate Director

Kentucky Regional Poison Center of Kosair Children's Hospital

University of Louisville Louisville, Kentucky

1998 – 2001 Associate Director

Pediatric Clinical Trials Unit Department of Pediatrics University of Louisville Louisville, Kentucky

1997 – 1998 Acting Medical Director

Pediatric Intensive Care Unit Kosair Children's Hospital Louisville, Kentucky

1994 – 1995 Instructor

Division of Pediatric Pharmacology & Critical Care

Department of Pediatrics

Case Western Reserve University School of Medicine

Cleveland, Ohio

OTHER POSITIONS AND EMPLOYMENT

1993 – 1995 Resident Physician

Health Hill Hospital for Children

Cleveland, Ohio

1993 – 1995 Resident Physician

Mt. Sinai Hospital Cleveland, Ohio

1991 – 1995 Resident Physician

Pediatric Urgent Care Center

Lorain, Ohio

1989 – 1991 Resident Physician

Transport Team, Non-urgent ER Arkansas Children's Hospital Little Rock, Arkansas

CERTIFICATION AND LICENSURE

03/1989 National Board of Medical Examiners (#357749)

11/1991– Current American Board of Pediatrics (#47948)

Recertified 04/1998

Recertified 12/2005 Recertified 05/2015

08/1996 – Current American Board of Pediatrics Subspecialty Board of Pediatric Critical Care Medicine (#000688)

Recertified 05/2002 Recertified 09/2013

05/1999 – Current American Board of Clinical Pharmacology (#99101) **03/2010 – 5/31/2022** Certified Physician Investigator (CPI)—Expires 05/2022

Academy of Pharmaceutical Physicians & Investigators (APPI)

09/2008 – 12/2022 Council for Certification of IRB Professionals (CIP) (#2081423)

09/1995 – Current Kentucky (#31607)

09/1991 – 09/1996 Ohio (#062441) – Expired 09/30/1996

10/1992 – Current DEA (#BS3372529)

PROFESSIONAL MEMBERSHIPS AND ACTIVITIES

2017 – Present American Pediatric Society (APS)

2012 – 2018 Academy of Physicians in Clinical Research (APCR)
 2012 – Present Association of Clinical Research Professionals (ACRP)

2020 - Present

2004 – 2010 American College of Clinical Pharmacology
 1997 – 2018 American Academy of Clinical Toxicology
 1996 – 2012 Southern Society for Pediatric Research

1996 – Present Kentucky Pediatric Society

1995 – Present American Society for Clinical Pharmacology and Therapeutics

1995 – 2007 Jefferson County Medical Society 1995 – 2007 Kentucky Medical Association

1994 – Present Society of Critical Care Medicine (Fellow)
 1994 – 1996 Society of Critical Care Medicine; Ohio Chapter
 1993 – Present American Academy of Pediatrics (Fellow)
 1986 – 1988 Hennepin County Medical Society

1986 – 1988 Minnesota Medical Society

1986 – 1988 American Student Medical Association

1984 – 1988 Christian Medical Society1984 – 1985 Humanistic Health Organization

Organized Spring Symposium "Breaking Cycles of Abuse"

HONORS AND AWARDS

2019 Top Two Teaching Divisions of the Year, Division of Pediatric Critical Care, Department of Pediatrics,

University of Louisville

Outstanding Peer Mentor Award, Department of Pediatrics, University of Louisville
 Outstanding Peer Mentor Award, Department of Pediatrics, University of Louisville
 Outstanding Peer Mentor Award, Department of Pediatrics, University of Louisville
 Outstanding Peer Mentor Award, Department of Pediatrics, University of Louisville
 Outstanding Peer Mentor Award, Department of Pediatrics, University of Louisville
 Commonwealth Scholar, Awarded by Commonwealth Institute of Kentucky (CIK)

2016 Clinical Research Site Award by INC Research to the KCPCRU/University of Louisville Research Foundation,

Inc.

2015 Outstanding Peer Mentor Award, Department of Pediatrics, University of Louisville
 2014 Outstanding Peer Mentor Award, Department of Pediatrics, University of Louisville

2013 Top Three Peer Mentor Award of the Year, Department of Pediatrics, University of Louisville.

2013 Top Two Teaching Divisions of the Year, Division of Pediatric Critical Care, Department of Pediatrics,

University of Louisville.

2012 Top Two Teaching Divisions of the Year, Division of Pediatric Critical Care, Department of Pediatrics,

University of Louisville.

2011 HHS Organ Donation Medal of Honor to Kosair Children's Hospital (Bronze Medal) KODA

2011 Top Three Peer Mentor Award, Department of Pediatrics, University of Louisville.

2011 Top Two Teaching Divisions of the Year, Division of Pediatric Critical Care, Department of Pediatrics,

University of Louisville.

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2010 – 2011 Outstanding Division Award, Division of Pediatric Critical Care, Department of Pediatrics, University of

Louisville. For consistent excellence in patient care and resident teaching.

2010 HHS Organ Donation Medal of Honor to Kosair Children's Hospital (Silver Medal)

KODA

2005 Fellow (FCCM)

American College of Critical Care Medicine

2002 Professional Achievement Award

Montgomery VL, Sullivan JE, Orman K, Davis JC, Hardin A, Kentucky Organ Donor Affiliates

1998 Outstanding Clinical Professor of the Year

Pediatric House Staff
Department of Pediatrics
University of Louisville

1991 Resident Award for Excellence in Primary Care

Department of Pediatrics

University of Arkansas for Medical Sciences

1991 Service Appreciation Award

Arkansas Easter Seal Society

1984 Phi Kappa Phi, Mankato State University

COMMITTEE ASSIGNMENTS AND ADMINISTRATIVE SERVICES

International

2010 EMEA Invited Grant Reviewer

Brussels, Belgium

2009 – 2012 Planning Committee

Brazilian Medical Student Exchange Program

2007 – 2009 Planning Committee for April 23-26, 2009

International Pediatric Pharmacology Meeting

Orlando, Florida

1999 Romanian-American Assistance Project

BLS, PALS and PALS Instructor Courses

Team Leader

Iasi and Timisora, Romania

1998 Romanian-American Assistance Project

BLS, PALS and PALS Instructor Courses

Team Member

Bucharest and Cluj-Napoca, Romania

National

2020 NIH/NICHD T32 Postdoctoral Research in Pediatric Clinical Pharmacology Special Emphasis Panel

2020 NIH NIAID HIV Grant Reviewer, Special Emphasis Panel

2019 DSMB, HEAL GRANT (Tuft's University)

2019 DSMB, Respiridone Grant (DCRI—Duke University) **05/06/2018** Moderator, Platform Pediatric Critical Care II,

PAS Annual Meeting

Toronto, Canada.

2017 – Present Nominations Committee Member

Section on Clinical Pharmacology and Therapeutics

Executive Committee

American Academy of Pediatrics

2016 NIH U54 Grant Reviewer

Eunice Kennedy Shriver NICHD

2015 Special Emphasis Panel/Scientific Review Group

Pediatric Pharmacogenetics: PAR14-274

2014 Stakeholders Planning Committee for Pediatric Clinical Research

American Academy of Pediatrics

2014 – 2017 Pediatrics On-line Module Development Committee

Society of Critical Care Medicine

2014 Special Emphasis Panel/Scientific Review Group

NIH Small Business PAR Panel (March and July)

2014, 2015 NIH T32 Grant Reviewer; Eunice Kennedy Shriver NICHD

2013 – Present Member, Committee on Drugs

American Academy of Pediatrics

2013 Chair, NIH Section Review

NIAID Networks

2011 NIH Grant Reviewer

Eunice Kennedy Shriver NICHD

2011 Reference Committee, Academy Leadership Forum

American Academy of Pediatrics

2009 – 2010 Coordinating Committee on Scientific Sections

American Society for Clinical Pharmacology and Therapeutics

2009 Bylaws Committee

American Society for Clinical Pharmacology and Therapeutics

2007 – 2017 Member

Section of Pediatric Resident Education Committee

Society of Critical Care Medicine

2007 – Present Member

ACCM Task Force for Sedation & Analgesia during Pediatric Mechanical Ventilation Guidelines

Society of Critical Care Medicine

2008 – 2010 Chair **2006 – 2008** Vice Chair

Pediatric and Maternal Pharmacology Section Coordinating Committee on Scientific Sections

American Society for Clinical Pharmacology and Therapeutics

2005 – 2010 Invited Author

APP Policy on Antipyretics

Section on Clinical Pharmacology and Therapeutics

American Academy of Pediatrics

2009 – 2013 Chair

2003 – 2013 Committee Member

Section on Clinical Pharmacology and Therapeutics

Executive Committee

American Academy of Pediatrics

2003 – 2005 Drug Management Review Advisory Board

Cabinet for Human Resources Commonwealth of Kentucky

2000 – 2001 National Association of Children's Hospitals and Related Institutions (NACHRI)

Pharmacy Focus Group Physician Representative

Kosair Children's Hospital, Louisville, Kentucky

1997 – 2001 Drug Utilization Review Subcommittee

Alternate representative

Cabinet for Human Resources, Commonwealth of Kentucky

1996 – 2001 Committee on Hospital Care

Kentucky Pediatric Society

University of Louisville

2021 – JPROC representative to , Joint Pediatric Advisory Committee (JPAC): joint committee UofL and NCRI
 2021 - Member, Joint Pediatric Research Oversight Committee (JPROC): joint committee UofL and NCRI

2017 – 2020 Committee of Inclusive Excellence

2016 – 2018 ULP ad hoc Research Practices Committee

2015 – 2017 ULP Clinical & Outcomes Research Interface Committee

2013 Member, Promotion, Appointment and Tenure Committee, Department of Pediatrics

2012 - 2013Member, Search Committee for Dean of the School of Medicine

2012 - Present Member, Faculty Research Advisory Council (FRAC)

Member, Industry Relations Work Group 2012

2012 - 2013Chair, Search Committee, Chair of Family Medicine, University of Louisville 2011 - 2012Search Committee Senior Associate Dean for Clinical Research (SADCR)

2009 **Neurology Pediatric Residency Committee**

2007 - 2014CTSA Advisory Committee

Chair, Pediatric Section for CTSA

2007 - 2013Louisville Institute for Clinical and Translational Sciences (LICTS)

Medical Director, PCIR Core

Annual Pediatric Pharmacology Conference Organizer 2004 - Present

2003 - 2006**GCRC Advisory Committee**

1999 - Present **Human Studies Committee (HSPPO)**

1999 - 2000**ENT Oversight Committee** 2004 - 2010Judge, Research! Louisville 1996 - 2004Judge, Study Research Day

Norton Children's Hospital

2013 – 2018	Chemotherapy Safety Committee

2012 - 2018Neonatal and Pediatric Medication Oversight Committee (Advisor & member)

2011 - 2017 **Daily Patient Safety Reviews** 2011 - 2013 **EPIC Order Set Committee** 2010 - 2018**Sedation Committee**

2007 - 2009NHORA Medical Research Advisory Committee 2003 - 2005Norton Healthcare Research Office Advisory Board

2001 - 2018System Pharmacy Therapeutics Committee

Norton Healthcare

2000 - 2018Norwood Congenital Heart Team 1998 - 2018Medical Executive Committee 1996 - 1998 **Financial Oversight Committee** 1996 **Patient Care Committee**

1996 Surgical Case Review Committee

1995 - Present Pharmacology and Therapeutics Committee

> 1997 - 2018Chair

2005 - 2010Sedation Subcommittee, Chair

2000 - 2004Pain Subcommittee

1995 - 2018Critical Care Committee

Review Board for Reviews and Updates in Toxicology 1995 - Present

Kentucky Regional Poison Center (KCH)

Department of Pediatrics

2018 - 2019Member, Executive Director of Finance and Accounting Search Committee, Department of Pediatrics,

University of Louisville

2018 - Present Chair, Pediatric Innovation and Research Advisory Team (PIRATs)

2018 Member, Executive Director of Finance Search Committee, Department of Pediatrics, University of

Louisville

2015 - Present Member, Pediatric Endocrinology Endowed Chair Search Committee

2012 Member, KACHRI Chair Search Committee, Department of Pediatrics, University of Louisville

2011 - 2018Member, Pediatric Research Advisory Committee

2010 - 2018Chair, Endowed Chair Search Committee for Clinical Pharmacology (KCPCRU)

2010 - 2018Pediatric Research Committee

2007 - 2013Promotion, Appointment, and Tenure Committee 2007 Member of Research Endowed Chair Search Committee 2005 - 2006Member of Department of Pediatrics Chair Search Committee **2001** Director of Pediatric Critical Care Fellowship

1997 – 2002 Editor, *Intensive Thoughts*

Division of Pediatric Critical Care

1996 – 1999 Director of Resident Education in the PICU

Other

2009 – 2012 Contributing Author, *Pediatric Update*

1994 – 1995 Coordinator Bi-Monthly Critical Care Patient Management Conference

Rainbow Babies and Children's Hospital, Cleveland, Ohio

1992 – 1995 PICU Task Force Committee

Rainbow Babies and Children's Hospital, Cleveland, Ohio

1990 Committee on Ethical Issues of HIV

University of Arkansas for Medical Sciences, Little Rock, Arkansas

1989 – 1991 Critical Care Medicine Committee

University of Arkansas for Medical Sciences, Little Rock, Arkansas

EDUCATIONAL ACTIVITIES

Teaching / Students

03/16/18 - 3/24/18 PALS (CMDA Conference)

04/04/16 Marathon, Greece

01/16/2016 Medical Pharmacology/Toxicology Course

01/06/2015 Neonatal Pharmacology

University of Louisville School of Medicine, Louisville, Kentucky

2014 – Present PALS Provider Course

Norton Children's Hospital (Kosair Children's Hospital until 12/31/16)

01/29/2014 Management of Respiratory Emergencies Skill Station (Lecturer)

PALS Provider Course Kosair Children's Hospital

04/09/2013 Competency Testing (Cardiac/Resp/Shock) (Lecturer)

PALS Provider Course Kosair Children's Hospital

01/10/2012 Pediatric Clinical Research, University of Louisville (Lecturer)

Pediatrics Club

University of Louisville School of Medicine, Louisville, Kentucky

09/19/2011 Avoiding "Orange": Principles of Research Conduct (Lecturer)

Department of Pediatrics Research Luncheon

University of Louisville School of Medicine, Louisville, Kentucky

09/20/2010 "Hypertension, A New Roadmap?" (Lecturer)

Department of Pediatrics Research Luncheon

University of Louisville School of Medicine, Louisville, Kentucky

08/06/2010 "Antipyresis-Yes, No or Maybe?" (Lecturer)

Pediatric Grand Rounds

University of Louisville School of Medicine, Louisville, Kentucky

2009 – 2016 Medical Pharmacology/Toxicology Course (Annual Lecturer)

Prescription Writing

University of Louisville School of Medicine, Louisville, Kentucky

2007 Pediatric Drug Administration and Medication Errors (Lecturer)

Pediatric Dental Research Core Lecture Series

2007 Sedation Practices and ASA Classifications in Pediatrics (Lecturer)

Pediatric Denta	l Research	Core	Lecture	Series
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05/01/2006 "BIG" Step Forward for Infantile Botulism and Vasopressin for Shock in Pediatric Patients (Lecturer)

Department of Pediatrics Research Luncheon

University of Louisville School of Medicine, Louisville, Kentucky

10/10/2001 "Pediatric Clinic Pharmacology Research-What's New?" (Lecturer)

Education Conference

Division of Neonatal Medicine, Department of Pediatrics, University of Louisville School of Medicine,

Louisville, Kentucky

08/13/2001 "Pediatric Clinic Pharmacology Research-What's New?" (Lecturer)

Research Seminar

Department of Pediatrics, University of Louisville School of Medicine, Louisville, Kentucky

06/28/2001 "Pediatric Clinic Pharmacology Research-What's New?" (Lecturer)

Research Seminar

Department of Pharmacology and Toxicology, University of Louisville School of Medicine,

Louisville, Kentucky

01/27/2001 "Sedation: For Pleasure, Not Pain" (Lecturer)

Pediatric Grand Rounds

University of Louisville School of Medicine, Louisville, Kentucky

12/18/1998 "Therapeutic Drug Monitoring" (Lecturer)

Pediatric Grand Rounds

University of Louisville School of Medicine, Louisville, Kentucky

04/19/1996 "Hi-Tech Update: Partial Liquid Ventilations" (Lecturer)

Pediatric Grand Rounds

University of Louisville School of Medicine, Louisville, Kentucky

1996 – 2015 Medical Pharmacology/Toxicology Course (Annual Lecturer)

Poisonings

University of Louisville School of Medicine, Louisville, Kentucky

1996 – 2011 Medical Pharmacology/Toxicology Course (Annual Lecturer)

Common Pediatric Poisonings

University of Louisville School of Medicine, Louisville, Kentucky

1996 – 2012 Medical Pharmacology Course and Problem Solving Groups

Group Leader (2-4 topics/year)

University of Louisville School of Medicine, Louisville, Kentucky

1996 – 1998 Nursing Pharmacology Course (Nursing 395) (Annual Lecturer)

Common Pediatric Poisonings

University of Louisville, Louisville, Kentucky

11/30/1995 "PK and PD Dose-Ranging Study of Bumetanide in Infants" (Lecturer)

Department of Pharmacology Seminar

University of Louisville School of Medicine, Louisville, Kentucky

Teaching / Residents

7/11/19 Clinical Research: Shooting the Hoops

Pediatric Critical Care Fellow Conference University of Louisville, Louisville, KY

1/21/18 Perinatal & Neonatal Pharmacology: Past, Present, and Future

Neonatal Fellow Conference

University of Louisville, Louisville, Kentucky

2008 Resident Lecturer on Pharmacology

University of Louisville School of Medicine, Louisville, Kentucky

2008 "Bench to Bedside: Introduction to Clinical Research"

Clinical and Translational Research in Pediatrics

Resident Lecturer

University of Louisville School of Medicine, Louisville, Kentucky

2001 – Present "Medication Use and Pharmacy Processes" (Lecturer)

Annual Intern Orientation

Department of Pediatrics, University of Louisville School of Medicine, Louisville, Kentucky

1996 – 2000 Resident Lectures

Intern Orientation – "Pediatric Pharmacology"

Annual Lecturer

Norton Children's Hospital, Louisville, Kentucky (Kosair Children's Hospital until 12/31/16)

1996 – 2018 Resident Lectures

Pediatric Critical Care Core Lectures

Lecturer (4-6 times/year)

Norton Children's Hospital, Louisville, Kentucky (Kosair Children's Hospital until 12/31/16)

1991 – 1995 Monthly Resident Lecturers: "CV Physiology "

Lecturer

Rainbow Babies & Children's Hospital, Cleveland, Ohio

Teaching / Professionals

02/18/2021 Writing in Response to an RFA

Jr. Faculty development Symposia

ISPCTN DCOC, University of Arkansas, Little Rock, Arkansas

10/12/2018; 2019 Challenges & Opportunities in Pediatric Clinical Research

Department of Pediatrics New Faculty Orientation

University of Louisville School of Medicine, Louisville, Kentucky

8/30/2016 "Study Design"

Department of Pediatrics Faculty Development

University of Louisville School of Medicine, Louisville, Kentucky

2012 "Glucose Control", PICU Nurses Skills Day (quarterly)

2011 – 2016 "Putting it All Together", PALS

Norton Children's Hospital, Louisville, Kentucky (Kosair Children's Hospital until 12/31/16)

2009 - 2015 "Anticoagulation", Pediatric Critical Care Unit Nurses Hi-Tech Course

Kosair Children's Hospital, Louisville, Kentucky

2006 – 2009 "Clinical Pharmacology in the PICU. Beyond the Basics"

Kosair Children's Hospital, Louisville, Kentucky

2002 – Present Pharmacokinetics and Pharmacodynamics Teaching Slides

Developed Lecture in collaboration with Brian Yarberry, PharmD., Norton Children's Hospital, Louisville,

Kentucky (Kosair Children's Hospital until 12/31/16) Society of Critical Care Medicine PICU Educational Website

2002 – 2009 Science Update, PALS

Kosair Children's Hospital, Louisville, Kentucky

2002 "Paralytics, Sedatives and Narcotics. Beyond the Basics"

Course, JFKCCC

Kosair Children's Hospital, Louisville, Kentucky

2001 – 2014 "Norwood Physiology and Patient Management", Hi-Tech Team Orientation

Pediatric Critical Care Unit Nurses

	Kosair Children's Hospital, Louisville, Kentucky
1999 – 2010	Case Studies in Respiratory Failure and Shock, PALS Kosair Children's Hospital, Louisville, Kentucky
1998 – 2010	Respiratory Failure Teaching Station, PALS Kosair Children's Hospital, Louisville, Kentucky
1994 – 2004	Cardiovascular Drugs, Hi-Tech Team Orientation Pediatric Critical Care Unit Nurses Kosair Children's Hospital, Louisville, Kentucky
1999	Newborn Resuscitation, PALS Kosair Children's Hospital, Louisville, Kentucky
1997 – 2001	Lung Protection Strategies, Hi-Tech Team Orientation Pediatric Critical Care Unit Nurses Kosair Children's Hospital, Louisville, Kentucky
1997 – 2004	"Transport of O _{2"} , Hi-Tech Team Orientation Pediatric Critical Care Unit Nurses Kosair Children's Hospital, Louisville, Kentucky
1997 – 2004	"Hemodynamic Calculations", Hi-Tech Team Orientation Pediatric Critical Care Unit Nurses Kosair Children's Hospital, Louisville, Kentucky
1997 – 2004	"Sedatives, Analgesics and Paralytics", Hi-Tech Team Orientation Pediatric Critical Care Unit Nurses Kosair Children's Hospital, Louisville, Kentucky
04/14-17/1997	"Pharmacology Research—What? When? How?" Pediatric Critical Care Unit Nurses Kosair Children's Hospital, Louisville, Kentucky
1997	Infant/Child Case Presentations, PALS Kosair Children's Hospital, Louisville, Kentucky
1997	"Dysrhythmia's", Hi-Tech Team Orientation Pediatric Critical Care Unit Nurses Kosair Children's Hospital, Louisville, Kentucky
1997 – 1998	"Fluid Therapy and Medications", PALS Kosair Children's Hospital, Louisville, Kentucky
1995 – Present	Toxicology Case Review (Monthly) Kentucky Regional Position Center and Norton Children's Hospital, Louisville, Kentucky (Kosair Children's Hospital until 12/31/16)
1995 – 1998	"Partial Liquid Ventilation" Pediatric Critical Care Nurses Kosair Children's Hospital, Louisville, Kentucky
1993 – Present	Pediatric Advanced Life Support Instructor (2-4 times/year) Norton Children's Hospital, Louisville, Kentucky (Kosair Children's Hospital until 12/31/16)
Mentorship 2018 – Present	Resident Scholarship Oversight Committee Marie Trace, M.D. Fellow, Developmental Pediatrics University of Louisville School of Medicine, Louisville, KY

Resident Scholarship Oversight Committee

2018 - 2020

Jennie Greene, M.D. Fellow, Forensic Medicine

University of Louisville School of Medicine, Louisville, KY

2016 – Present Faculty Mentor

Lori Devlin, D.O.

Division of Pediatric Critical Care Department of Pediatrics

University of Louisville School of Medicine, Louisville, Kentucky

2016 – Present Faculty Mentor

Scott G. Bickel, M.D., M.S. Division of Pediatric Pulmonology Department of Pediatrics

University of Louisville School of Medicine, Louisville, Kentucky

2016 – 2018 Resident Scholarship Oversight Committee

Brittany Woodall, M.D.

Fellow, Developmental Pediatrics

University of Louisville School of Medicine, Louisville, Kentucky

2019 – Faculty Mentor

Kevin Havlin, M.D.

Assistant Professor, Pediatric Critical Care Medicine

University of Louisville School of Medicine, Louisville, Kentucky

2016 – 2019 Resident Scholarship Oversight Committee

Kevin Havlin, M.D.

Fellow, Pediatric Critical Care Medicine

University of Louisville School of Medicine, Louisville, Kentucky

2015 – 2018 Faculty Mentor

Lindsey Rasmussen, M.D.
Division of Pediatric Critical Care
Department of Pediatrics

University of Louisville School of Medicine, Louisville, Kentucky

2015 – Present Faculty Mentor

Sara E. Watson, M.D., MSc Division of Endocrinology Department of Pediatrics

University of Louisville School of Medicine, Louisville, Kentucky

2014 – 2018 Medical Student Mentor

Samuel Williams

University of Louisville School of Medicine, Louisville, Kentucky

2014 – 2018 Faculty Mentor

David Lohr, M.D.
Division of Psychiatry
Department of Pediatrics

University of Louisville School of Medicine, Louisville, Kentucky

2014 – 2017 Resident Scholarship Oversight Committee

Brooke Jones, M.D. Fellow, Living Forensics

University of Louisville School of Medicine, Louisville, Kentucky

2013 – 2016 Resident Scholarship Oversight Committee

Michelle Curtin, M.D.

Fellow, Developmental Pediatrics

University of Louisville School of Medicine, Louisville, Kentucky

2013 – 2015 Resident Scholarship Oversight Committee

Christy Howard, M.D. Fellow, Living Forensics

University of Louisville School of Medicine, Louisville, Kentucky

2013 - 2016 Faculty Mentor

Bethany Hodge, M.D., MPH

Assistant Professor, Pediatric Hospitalist

University of Louisville School of Medicine, Louisville, Kentucky

2013 – 2014 Medical Student Mentor

Sarah Hawkins DIR Program

University of Louisville School of Medicine, Louisville, Kentucky

2013 – 2014 Medical Student Mentor

Hasaan Siddiqui DIR Program

University of Louisville School of Medicine, Louisville, Kentucky

2012 – Present Faculty Mentor

Kyle Brothers, M.D.

Assistant Professor, Research and General Pediatrics

University of Louisville School of Medicine, Louisville, Kentucky

2010 – 2019 Medical Student Mentor

Andrew O'Brien DIR Program

University of Louisville School of Medicine, Louisville, Kentucky

2010 Faculty Mentor

Christina Sotiropoulos, M.D.

Assistant Professor, General Pediatrics

University of Louisville School of Medicine, Louisville, Kentucky

2009 – 2012 NIH R01 Mentor

Michael Stroud, M.D.

Assistant Professor, Pediatric Critical Care

University of Arkansas for Medical Sciences, Little Rock, Arkansas

2009 – 2013 Faculty Mentor

Keith Cross, M.D.

Assistant Professor, Pediatric Emergency Medicine

University of Louisville School of Medicine, Louisville, Kentucky

2008 – 2010 Faculty Mentor

Elaine Stauble, M.D.

Assistant Professor, Obstetrics and Gynecology

University of Louisville School of Medicine, Louisville, Kentucky

2006 – 2009 CREST Student Advisor

Angela Peters Jeffries, M.D.

Fellow, Pediatric Gastroenterology

University of Louisville School of Medicine, Louisville, Kentucky

2005 – 2008 Resident Scholarship Oversight Committee

Travis Anschutz, M.D. Fellow, Neonatology

University of Louisville School of Medicine, Louisville, Kentucky

2004 – 2007 Resident Scholarship Oversight Committee

Katherine Potter, M.D. Fellow, Pediatric Critical Care

University of Louisville School of Medicine, Louisville, Kentucky

2004 – 2007 Resident Scholarship Oversight Committee

Nagendra Polvarapu, M.D. Fellow, Pediatric Critical Care

University of Louisville School of Medicine, Louisville, Kentucky

2004 – 2007 Resident Scholarship Oversight Committee

Robyn Livingston

Fellow, Infectious Disease

University of Louisville School of Medicine, Louisville, Kentucky

2003 – 2005 CREST Student Advisor

Miriam Louthan, M.D.

Fellow, Pediatric Gastroenterology

University of Louisville School of Medicine, Louisville, Kentucky

2003 – 2004 CREST Student Advisor

Amanda Myers, M.D.

Fellow, Pediatric Emergency Medicine

University of Louisville School of Medicine, Louisville, Kentucky

2003 – 2004 Medical Pharmacology Course

Masters Student Project Advisor and Thesis Committee

Jennifer Loehle

University of Louisville School of Medicine, Louisville, Kentucky

CLINICAL ACTIVITIES

My primary clinical responsibilities are in pediatric clinical research and administration in the Department of Pediatrics, Division of Clinical and Translational Research, and the Norton Children's Research Institute. My clinical service time in the Pediatric Intensive Care Unit continued through June 2019 when I retired from PICU clinical duties.

The Pediatric Clinical Research Program was developed in the Department of Pediatrics to conduct pharmacologic and non-pharmacologic clinical and translational research. A portion of my clinical responsibilities involved clinical research processes from study feasibility through study closure. These responsibilities require about 50 hours of work/week. I currently am mentoring Dr. Sara Watson, the new Medical Director of this program. I remain involved in budget negotiation and am actively involved in getting the studies initiated at our site as well as seeing both inpatients and outpatients for their study visits. Particularly for Phase I studies, I usually conduct the informed consent and assent process with the patient and their family. A portion of my time is exerted on developing clinical protocols and securing funding to conduct the trial. I work with faculty members from all subspecialties in pediatrics to help train them in the conduct of clinical trials emphasizing their responsibilities in this capacity. During the past year over 75 faculty members have been involved in pediatric clinical trials through the KCPCRU. I serve as the Principal Investigator on some of these trials however an increasing number of subspecialists are now serving as a Principal Investigator in clinical trials in their area of expertise. As part of my workload, I travel to investigator meetings for training for upcoming trials. Because we are an academic institution, part of my responsibilities are directed to providing educational opportunities for the pediatric residents, pharmacy students, medical students, and nursing staff. Most importantly, it is my responsibility to ensure that all clinical trials and research activities are conducted within the confines of all regulatory requirements.

GRANTS AND CONTRACTS

Grants and Awards

2021 – Sullivan JE, Watson SE, Brother KB. Pediatric Improvement Collaborative for Clinical Trials & Research (Trailblazer). PICTR: Improving the Picture of Research for Children. \$7,500.

2020 – 2025 Watson SE (M-PI), Devlin LA (M-PI), <u>Sullivan JE</u>, Bickel SG, Brothers KB, Barnes GN, Morton RL, Davis DW. The Kentucky ECHO Pediatric IDeA Research Center (Goal: To provide medically underserved and rural populations access to state-of-the-art clinical trials, applying findings from relevant pediatric cohort studies to children in IDeA state locations, and

- building pediatric research capacity at a national level) (Grant #: 2 UG1 OD024954; IDeA Grant); NIH Office of Director; \$1,673,259; 9/1/2020-8/31/2025.
- **2020 2021** States CJ (PI), <u>Sullivan JE</u>, etc. (ADMIN CORE) Environmental Health Sciences Core Centers (EHSCC). NIH 1P30ES030283-01A1, \$1,170,401. 7/1/2020-6/30/2021.
- **2020 2021** Devlin LA (PI), <u>Sullivan JE</u>, Quantitation of opioids in neonates with neonatal opioid withdrawal syndrome (NOWS). INBRE Subaward UAMS, \$10,000.
- 2019 2022 Sullivan JE. Pediatric Trial Network Steering Committee Member. NIH/Duke University. HHSN275201800003I, \$51,891.
- **2018 2022** Morton R, O'Hagan A, <u>Sullivan JE</u>. Therapeutic Development Center. Cystic Fibrosis Foundation. Award# MORTON18Y0, \$66,733.
- 2018 2022 Raj A, Sullivan JE. Education and Mentoring to Bring Access to Care for SCD (EMBRACE-SCD). Health Resources and Services Administration (HRSA). Grant# A17-0142-S004, \$28,035 (salary support)
- 2018 2023 Raj A, Glisson S, <u>Sullivan JE</u>. PCORI ST3P-UP: Management of Care Transitions in Emerging Adults with SCD. PCORI funded through Carolinas Medical Center. Grant# A18-0056-S004, \$212,144
- 2017 2018 Sullivan JE (PI), Rabalais GP. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. Grant #712H. \$100,000. (N/A).
- 2016 2020 Sullivan JE, Watson SE (Co-Pl's), Smith MJ, Brothers KB, Barnes GN, Lohr WD, Morton RL, Bickel SG, Radmacher P, Espinosa CM, Devlin LA, Davis DW, Liu GC. The Kentucky Pediatric Clinical Trials Rural/Urban Partnership (Goal: To provide medically underserved and rural populations access to state-of-the-art clinical trials, applying findings from relevant pediatric cohort studies to children in IDeA state locations, and building pediatric research capacity at a national level) (Grant #: 1UG1HD090904-01; IDeA Grant); NICHD/NIGMS; \$1,673,259; 9/21/2016-8/31/2020.
- 2016 2017 Sullivan JE (PI), Rabalais GP. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. Grant #712H. \$140,000. (N/A).
- **2015 2016** Sullivan JE (PI), Rabalais GP. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. Grant #712H. \$135,000. (N/A).
- 2014 2015 Stevenson M, Sullivan JE. "Infant Specific-IgE, Rhinovirus-C Bronchiolitis and Incident Asthma in MARC-35." Massachusetts General Hospital. Grant # 1R01A114552-01. \$11,338.
- 2014 2015 Sullivan JE (PI), Rabalais GP. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. Grant #712H. \$110,000. (N/A).
- **2013 2014** Sullivan JE (PI), Rabalais GP. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. Grant #712H. \$125,000. (N/A).
- 2012 2014 Smith MJ, Condurache CT, Sullivan JE. "Safety and Pharmacokinetics of Multiple Dose Intravenous and Oral Clindamycin in Pediatric Subjects with BMI > 85th Percentile", The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), Protocol NICHD-2012-CLIN01. HSPPO #13.0182, \$36,500 (clinical trial support).
- 2012 2014 Smith MJ, Condurache CT, Sullivan JE. "Safety and Pharmacokinetics of Multiple Dose Intravenous and Oral Clindamycin in Pediatric Subjects with BMI > 85th Percentile", The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), Protocol NICHD-2012-CLIN01. HSPPO #13.0182, \$88,861 (Salary Support).
- 2012 2013 Sullivan JE (PI), Rabalais GP. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. Grant #712H. \$75,000. (N/A).
- **2011 2012** Sullivan JE (PI), Rabalais GP. "Goal-directed Resuscitative Interventions during Pediatric Inter-facility Transport." NIH. Subcontract Arkansas Children's Hospital Research Institute. #1R21HD060171-01A2. \$17,515.
- 2011 2012 Sullivan JE (PI), Rabalais GP. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. Grant #712H. \$175,000. (N/A).
- **2010 2011** Sullivan JE (PI), Rabalais GP. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. Grant #712H. \$100,000. (N/A).
- 2009 2010 Sullivan JE (PI). "Recovery Act Administrative Supplement." National Institute of Child Health and Human Development

- (NICHD), Pediatric Pharmacology Research Network, (PPRU). #NOT-OD-09-056. \$262,578. (10%).
- **2009 2010** Sullivan JE (PI), Rabalais GP. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. Grant #712H. \$100,000. (N/A).
- 2009 Sullivan JE. "Glady's Doll Fund." University of Louisville School of Medicine. \$30,000.
- Asamoah A, <u>Sullivan JE</u>, Goodin KM, Gowans GC, Hersh JH, Condurache CT. "An Open-Label Treatment Protocol to Evaluate the Safety of Replagal Treatment in Patients with Fabry Disease," Shire Human Genetic Therapies, Inc. (Shire HGT). Protocol HGT-REP-059. HSPPO N/A. \$7,560.
- 2008 2010 Aranda J, Ward R, Gaedigk A, Capparelli E, <u>Sullivan JE</u>, Stewart DL, Blumer JL. "A Multi-Center, Single-Dose, Open-Label Clinical Trial to Determine the Absorption and Metabolism of Oral Codeine in Mechanically Ventilated Term and Preterm Neonates Already Receiving Opioid Analgesia." NIH R03 (PPRU). \$3,019. (1%).
- 2008 2009 Sullivan JE (PI), Kennedy MJ, Rabalais GP. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. Grant #712H. \$150,000. (N/A).
- Berkenbosch JW, <u>Sullivan JE</u>, Campbell DR. "Near Infrared Spectroscopy Cerebral/Somatic Oximetry Monitors." WHAS Crusade. \$92,246.
- Williams PG, <u>Sullivan JE</u>, Yarberry B, Wright S. Double-Blind, Placebo-Controlled, Crossover Study of Glutathione, Vitamin C and Cysteine in Children with Autism and Severe Behavior Problems. Children's Foundation of Kosair Children's Hospital, HSPPO # 08.0220. \$284,999. (2%).
- 2008 2018 Jeffries A, Stewart DL, Stutts J, Condurache CT, Sullivan JE. A Multi-Center, Open-Label, Single-Dose Pharmacokinetic Study of Intravenous Pantoprazole in Preterm Infants and Infants 0-11 Months with a Clinical Diagnosis of Gastroesophageal Reflux Disease (GERD) or the need for Acid Suppression. Wyeth Investigator Grant Award, Protocol # UL Panto 01. HSPPO #08.0372. \$306,000 (2%).
- 2008 <u>Sullivan JE</u> (PI), Kennedy MJ, Rabalais GP. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. Grant #712H; \$136,431. (N/A).
- 2007 <u>Sullivan JE, Bomgaars L, Blumer JL. (Multiple Pl's). "Pharmacologic Determinants of CNS Opioid Distribution and Response in Children." NIH 1 R21 HD058255-01; PPRU. Submitted June 2007. Not funded. HSPPO #08.0015.</u>
- 2007 Kennedy MJ, Sullivan JE, Klein J. "Urinary Proteomics in Aminoglycoside Treated Newborns." NIH. R21 Submission November 1, 2004. Resubmitted March 2006. (1 R21 HD050564-01A1). Awarded April 2007. \$346,500. (1%).
- 2007 Sullivan JE (PI), Montgomery VL. "Pediatric Glidescope for use in the PICU." G2008186; \$5,000. (N/A).
- 2006 2007 <u>Sullivan JE (PI)</u>, Kennedy MJ, Rabalais GP. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. \$150,000. (N/A).
- 2005 2007 <u>Sullivan JE (PI)</u>, Kennedy MJ. 2006 Center for Excellence in Clinical Pharmacology. Pharmaceutical Research and Manufacturers of America (PhRMA) Foundation. Unfunded. (N/A).
- **2005 2006** Sullivan JE (PI), Kennedy MJ, Rabalais GP. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. \$198,993. (N/A).
- 2004 2009 Sullivan JE (PI), Kennedy MJ, Stewart D, Yarberry B. "Dose-Ranging, Safety and Efficacy of Cathflo™ Activase® (Alteplase) for the Treatment of Central Catheter Occlusion in Neonates and Infants." Genetech; PPRU #10742. \$6,000. (1%).
- 2004 2009 <u>Sullivan JE (PI)</u>, Kennedy MJ. "Center for Pediatric Pharmacology Research." National Institute of Child Health and Human Development (NICHD), Pediatric Pharmacology Research Network, (PPRU) RFA #HD-003-01. Funding awarded October 2003. \$1,862,408. (10%).
- 2004 2007 Klein JB, Kennedy MJ, <u>Sullivan JE</u>. Further Development for the University of Louisville Pediatrics Proteomics Laboratory to Support Research on Proteomics Technology that Focuses on the Products of Genes and How Changes in Specific Patterns or Alignment of Proteins Affect Functions in the Body. One of the Goals is to Investigate Changes in Proteins Specifically as Children Develop from Infants Through Childhood to Adolescence. Department of Energy. \$3,000,000. (N/A).

- 2004 2005 <u>Sullivan JE (PI)</u>, Kennedy MJ, Cook LC. "Kosair Charities Pediatric Clinical Research Unit". Kosair Charities. \$198,993. (N/A).
- Paul R, Montgomery VL, <u>Sullivan JE</u>. Emergency Airway Equipment. WHAS Crusade for Children #04-082. \$27,057. (N/A).
- **2003 2008** Kennedy MJ, <u>Sullivan JE</u>, Hein D, Sublett J, Badgett JT. "Histamine Pharmacogenetics in Caucasian Children with A-topic Dermatitis." American College of Clinical Pharmacy Research Institute. PPRU #10744. \$12,313. (N/A).
- **2003 2005** Sullivan JE (PI), Kennedy MJ. 2004 Center for Excellence in Pediatric Clinical Pharmacology. Pharmaceutical Research and Manufacturers of America (PhRMA) Foundation. Unfunded. (N/A).
- 2003 2004 <u>Sullivan JE (PI)</u>, Kennedy MJ, Cook, LN. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. \$218,668. (N/A).
- **2003 2004** Myers A, Koller D, Godambe S, Kennedy MJ, <u>Sullivan JE</u>. "Efficacy or Oral Oxycodone for the Management of Acute Pain in Children with Orthopedic Injuries: a Pilot Study." Funded by University Pediatric Foundation. \$4,000. (N/A).
- **2002 2005** Montgomery VL, <u>Sullivan JE</u>, Yarberry B, Davis JC. "Nalbuphine Versus Fentanyl for Control of Post-Operative Pain in Pediatric Patients." University Pediatrics Foundation Research Grant. \$8,000. (N/A).
- 2002 2005 Kennedy MJ, <u>Sullivan JE</u>, Gozal D, Ivanenko A. "Effect of Chronic Intermittent Nocturnal Hypoxia on Hepatic Drug Biotransformation in Children with Obstructive Sleep Apnea." University Pediatrics Foundation Research Grant #003-03. \$8,000. (N/A).
- 2002 2003 Sullivan JE (PI), Cook LN. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. \$227,029. (N/A).
- 2001 Sullivan JE (PI), Cook LN. "Kosair Charities Pediatric Clinical Research Unit." Kosair Charities. \$357,188 (N/A).
- **O3/1998** Sullivan JE, Rabalais GP, Hurst HE, Matyunas NJ, Rodgers, GC, Hein DW, Stewart D, Myers SR, Ross MP. NICHD Pediatric Pharmacology Research Unit Grant. Submitted March 1998 but not funded. (N/A).
- Buchino JJ, Montgomery VL, <u>Sullivan JE</u>, Stewart D. Alliant Community Trust Fund. "Troponin I as a Prognostic Indicator Following Open Heart Surgery". \$12,250. (N/A).
- Montgomery VL, Ross MP, Rodgers GC, <u>Sullivan JE</u>. WHAS Crusade for Children. "Renovation of the Pediatric Intensive Care, Transitional Care and Burn Units of Kosair Children's Hospital". \$216,620. (N/A).
- Montgomery VL, Ross MP, Rodgers GC, <u>Sullivan JE</u>. WHAS Crusade for Children. "Meeting the Needs of Critically and Seriously III Children: Improvements in the Pediatric Intensive Care Unit of Kosair Children's Hospital". \$228,115. (N/A).
- 1996 <u>Sullivan JE (PI)</u>, Rodgers GC, Windmill I, Hurst H. "Bumetanide Induced Ototoxicity in Critically III Children". Alliant Community Trust Fund. \$33,836. (N/A).
- Meyers S, Ross MP, Rodgers GC, <u>Sullivan JE</u>. WHAS Crusade for Children. "Chromatographic Equipment for the Pediatric Critical Care Pharmacology Laboratory". \$55,150. (N/A).
- 1995 <u>Sullivan JE (PI)</u>, Rodgers GC. "Otoacoustic Emissions Monitor to Reduce Incidence of Drug Induced Hearing Loss in Critically III Children." WHAS Crusade for Children Grant. \$15,800. (N/A).

Contracts / Ongoing Research

- 2021- Present Marshall GS, Bryant K, Blatt D, Statler V, Greene J, Brothers K, Watson SE, Sullivan JE. A Phase 1, Open-label Dose-finding Study to Evaluate Safety, Tolerability, and Immunogenicity and Phase 2/3 Placebo-controlled, Observer-blinded Safety, Tolerability, and Immunogenicity Study of a SARS-COV-2 RNA Vaccine Candidate Against COVID-19 in Healthy Children <12 Years of age. Protocol # C4591007. Pfizer. HSPPO 21.0313.
- **2021 Present** Bryant K, Blatt D, Grill J, Morris M, <u>Sullivan JE</u>. A Phase 2, Randomized, Double-blind, Placebo-controlled, 2-Part Study to Evaluate EDP-938 Regimens in Subjects Aged 28 Days to 24 Months Infected with Respiratory Syncytial Virus (RSV). Protocol #: EDP 938-201. Enanta Pharmaceuticals, Inc, HSPPO 21.0199.
- **2021 Present** Morton R, O'Hagan A, Bickel S, Sullivan JE. A master protocol to test the impact of discontinuing chronic therapies in people with cystic fibrosis on highly effective CFTR modulator therapy (SIMPLIFY). Protocol SIMPLIFY-IP-19. Cystic Fibrosis Foundation. HSPPO 20.0501. \$.

- 2021- Present Bryant K, Bichir N, Brothers KB, Kinney MD, Marshall GS, Morris ME, Pendleton AL, Porter J, Sayat JG, Statler VA, Thompson JE. A Phase 3, Randomized, Double-blind Trial to Evaluate the Safety and Immunogenicity of a 20-valent Pneumococcal Conjugate Vaccine in Healthy Infants. Protocol # B7471011. Pfizer. HSPPO 20.0542. \$.
- 2020 Present Marshall GS, <u>Sullivan JE</u>, Bichir N, Brothers KB, Kinney MD, Morris ME, Pendleton AL, Porter J, Sayat JG, Thompson JE. A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety of MEDI8897, a Monoclonal Antibody with an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Preterm and Term Infants (MELODY); Protocol #: D5290C00004. MedImmune, HSPPO 19.1055. \$.
- **2020 Present** Sullivan JE, Berkenbosch JW. Pharmacokinetics, Pharmacodynamics, and Safety Profile of Understudied Drugs Administered to Children per Standard of Care / (POPS): NICHD-2019-POP02. HSPPO # 20.0525. \$.
- **2020 Present** Telang S, Devlin LA, Schumacher EA, Singh T, Sullivan JE, Watson SE. Eating, Sleeping, Consoling for Neonatal Opioid Withdrawal (ESC-NOW): a Function-Based Assessment and Management Approach. Protocol # 239729. HSPPO # 20.0068.
- **2020 Present** Bickel S, Morton RL, O'Hagan AR, Orangias MS, Sullivan JE, Watson SE, Evaluating the Respiratory Effect of Green Environmental Enhancement in Children with Asthma (The Green Lung Study). Protocol # GL1.3. HSPPO # 20.0029. \$25,000 (American Lung Association).
- **2020 Present** Singh T, Stewart D, Duncan S, Sullivan JE. The NICU Antibiotics and Outcomes Trial (NANO). University of Pittsburg (NIH Subaward). HSPPO# 20.0490. \$.
- **2020 Present** Devlin LA, Sullivan JE. Quantitation of opioids in neonates with neonatal opioid withdrawal syndrome (NOWS). HSPPO @ 20.1118. \$.
- 1010 Present Robinson T, Duncan S, Sullivan JE. A Partially-Blind, Randomized, Controlled, Parallel-Group Dose Ranging Study to Determine the Efficacy, Safety and Tolerability of AeroFactTM (SF-RI 1 surfactant for inhalation combined with a dedicated drug delivery system) in Preterm Infants at Risk of Worsening Respiratory Distress Syndrome. Protocol # APC-AF-CLN-002. HSPPO# 19.0748
- **2019 Present** Puri V, Barnes G, Karia S, Sullivan JE. A Phase 2 Study to Assess the Safety, Tolerability, Exploratory Efficacy, and Pharmacokinetics of Orally Administered JBPOS0101 for Refractory Infantile Spasms Patients. Protocol # CL-0101-WS01. Bio-Pharm Solutions Co. HSPPO# 19.0708. \$.
- 2019 Present O'Hagan A, Morton RL, Bickel S, Sullivan JE. A Phase 3, OpenOlabel Study Evaluating the Long-term Safety of VX-445 Combination Therapy in Subjects with Cystic Fibrosis. Protocol # VX18-445-113. Vertex Pharmaceuticals, Inc. HSPPO 19.0830. \$
- **2019 Present** Robinson T, <u>Sullivan JE</u>, Berkenbosch JW. A Phase 2/3 Randomized, Double-blind, Palivizumab-controlled Study to Evaluate the Safety of MEDI8897, a Monoclonal Antibody with an Extended Half-life Against Respiratory Syncytial Virus, in High-risk Children (MEDLEY); MedImmune, HSPPO 18.1053.
- **2019 Present** Johnsrude C, <u>Sullivan JE.</u> Intravenous Sotalol in Pediatric and Congenital Patients: A Multicenter Registry Study. PACES. Protocol# N/A, HSPPO#19.0616, \$5,000.
- **2019 Present** Johnsrude C, <u>Sullivan JE</u>. Atrial Tachycardia Pacing Therapy in Congenital Heart. University of Iowa Stead Family Children's Hospital. Protocol# AT-PATCH, HSPPO# 18.1187, \$1,600.
- 2019 Present Espinosa C, Sullivan JE. A Phase 1, Non-comparative, Open-Label Study of Pharmacokinetics and Safety of a Single-Dose of ZTI-01 (Fosfomycin for Injection) in Pediatric Subjects (Less than 12 Years of Age) Receiving Standard of Care Antibiotic Therapy for Proven or Suspected Infection or for Peri-operative Prophylaxis. Nabriva Therapeutics Ireland DAC. Protocol# ZTI-01-00, HSPPO# 18.0796, \$74,578.
- 2019 Present Espinosa C, Marshall GS, Statler VA, Green JV, Sullivan JE. A Phase II, Single-Stage, Single-Arm Investigation of Oral Valganciclovir Therapy in Infants with Asymptomatic Congenital Cytomegalovirus Infection. National Institutes of Allergy and Infectious Disease and Genetech, Inc. (subaward through University of Alabama) Protocol# DMID 16-0095, HSPPO# 18.0591, \$187,027.
- **2019 Present** Shah S, Gupta S, Smith C, <u>Sullivan JE</u>. The Chronic Kidney Disease in Children (CKiD) Study. The National Institute of Health (NIH). (subaward through CHOP) Protocol# N/A, HSPPO# 18.0585, \$88,882.

- **2018 Present** Bickel S, Morton RL, O'Hagan AR, Sullivan JE, Watson SE. Vitamin D Oral Replacement in Asthma (VDORA1). Protocol # 228446. HSPPO # 18.1301. S.
- **2018 Present** Lakhotia A, Evanczyk, Puri V, <u>Sullivan JE</u>. A Prospective Long-Term Registry of Patients with a Diagnosis of Spinal Muscular Atrophy (SMA). AveXis, Inc. Protocol# AVXS-101-RG-001, HSPPO# 18.0774, \$218,292.
- 2018 Present Espinosa C, Statler V, <u>Sullivan JE</u>. A Phase 1, Open-Label, Two-Part Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of a Single Dose of Intravenous Lefamulin in Hospitalized Pediatric Subjects Receiving Standard of Care Antibiotic Therapy for Confirmed or Suspected Infection. Nabriva Therapeutics, DAC. Protocol# NAB-BC-3781-1202, HSPPO#18.0510, \$78,018.
- 2017 Present Barnes GN, Puri V, Farber D, Hersh J, Asamoah A, Brothers KB, <u>Sullivan JE.</u> Sequence to Savings: A University of Louisville Health Economics Pilot Study. Commonwealth of KY, Protocol# UL-TGen 2017-001, HSPPO# 17.0806, \$2,000,000.
- **2016 Present** Stevenson MD, <u>Sullivan JE</u>. Airway Microbiome and age 6-year asthma in healthy infant cohort. DHHS, NIH, National Institute of Allergy and Infectious Diseases. Protocol: MARC 43 ECHO, HSPPO# 16.1216, \$130,980.
- **2016 Present** Johnsrude C, <u>Sullivan JE</u>, Sobczyk W. Improving Diagnosis and Treatment in CPVT. Heart and Stroke Foundation of Canada, Canadian Institute of Health Research, Genome Canada. Protocol# N/A, HSPPO# 14.1114, \$4,000.
- **2016 Present** Tzanetos D, <u>Sullivan JE</u>. Registry of ECMO Anticoagulation in Pediatrics (PEDECOR). Baylor, Protocol# H-34120, HSPPO#16.0592, unfunded.
- **2016 Present** Sparks J, <u>Sullivan JE</u>. The International Pediatric Heart Failure Registry (iPHFR). International Society for Heart and Lung Transplantation (ISHLT). Protocol# N/A, HSPPO# 16.0759, unfunded.
- **2016 Present** Johnsrude C, <u>Sullivan JE</u>. Defibrillation Testing at the Time of Cardioverter Defibrillator Implantation in Pediatric and Congenital Heart Disease Patients. HSPPO# 16.0801. Unfunded.
- **2016 Present** Johnsrude C, Lau K, <u>Sullivan JE</u>. SOLAR Infant SVT Registry. University of British Columbia and BC Children's Hospital, Protocol# N/A, HSPPO# 16.0804, unfunded.
- 2016 Present Johnsrude C, Sullivan JE, Condurache CT. Exercise in Genetic Cardiovascular Conditions: Lifestyle and Exercise in Hypertonic Cardiomyopathy: "LIVE-HCM", Lifestyle and Exercise in Long QT Syndrome: "LIVE-LQTS. National Institutes of Health/National Heart, Lung, and Blood Institute (NIH 1 R01 HL125918-01), Protocol# EXERCISE IN GENETIC, HSPPO# 16.0089, \$12,000.
- **2015 Present** Johnsrude C, <u>Sullivan JE</u>, Lau K. Catheter Ablation with Reduction or Elimination of Fluoroscopy (CAREFL)—A Multicenter Registry. Providence Medical Research Center, Protocol# N/A, HSPPO# 15.0348, Unfunded.
- 2015 Present Barnes GN, Sullivan JE, Williams PG, Lohr WD, Sears L, Puri V, Farber D. "Safety and Tolerability of GWP42006 in Subjects with Drug Resistant Epilepsy and Autism. EAP Extension" GW Pharmaceuticals, Protocol# GWP42006, HSPPO# 20.0748., \$.
- 2015 Present

 Barnes GN, Sullivan JE, Williams PG, Lohr WD, Sears L, Puri V, Farber D. "Safety and Tolerability of GWP42006 in Subjects with Drug Resistant Epilepsy and Autism." GW Pharmaceuticals, Protocol# GWP42006, HSPPO# 16.0505, \$350,000.
- 2015 Present Statler VA, Woods C, Stephen T, Condurache TC, <u>Sullivan JE</u>. "A Long Term Follow-up Registry for Adolescent and Pediatric Subjects Who Received a Gilead Hepatitis C Virus Direct Acting Antiviral (DAA) in Gilead-Sponsored Chronic Hepatitis C Infection Trials." Gilead Sciences, Inc., Protocol# GS-US-334-1113, HSPPO# 15.1142, \$105,092.
- 2014 Present Espinosa CM, Smith M, Sullivan JE, Condurache CT, Berkenbosch J. An Open label, Dose-finding, Pharmacokinetics, Safety, and Tolerability Study of Oritavancin Single Dose Infusion in Pediatric Subjects Less Than 18 Years of Age with Suspected or Confirmed Bacterial Infections. Melinta Therapeutics, Inc., Protocol# TMC-ORI-11-01, HSPPO# 14.0587, \$75,124.
- 2014 Present Sparks J, Sullivan JE. "Pediatric Heart Transplant Study (PHTS)" HSPPO #14.0339, Unfunded.
- **2013 Present** Watson SE, Baba S, Bhatnagar A, Shaffer L, Rai S, Keith R, Sweeney B, <u>Sullivan JE</u>, Brothers KB, Conklin D. Evaluating Effect of Carnosine Supplement on Childhood Obesity (STUDY 1). Protocol# N/A, HSPPO# 13.0334, Unfunded.

- **2013 Present** Montgomery VL, <u>Sullivan JE</u>. "Influenza and Other Emerging Respiratory Pathogens Surveillance Registry", PALISI, Protocol N/A. HSPPO#13.0547, \$3,750.
- 2011 Present Stevenson MD, Sullivan JE. "Prospective Cohort Study of Severe Bronchiolitis and Risk of Recurrent Wheezing." Massachusetts General Hospital. Protocol MARC-35. Phase N/A. MARC 35. HSPPO 11.0521. \$10,708 (Yr 1), \$26,731 (Yr 2), \$24,821 (Yr 3).
- 2010 Present Owen, E, Montgomery VL, Sullivan JE, Orman K, Calhoun A, McDonald M, Berkenbosch J, Porter M. "Observation of Multi-center Quality Improvement Project: Improving Safety and Quality of Tracheal Intubation Practice in Pediatric ICUs." (NEAR4KIDS) National Institute of Health. Subcontract with Children's Hospital of Philadelphia. Protocol 09-007253. Phase N/A. HSPPO #10.0238. \$2,090.
- 2009 Present Montgomery VL, <u>Sullivan JE</u>, Condurache CT. "Genetic Epidemiology and Immune Response to Life-threatening Influenza Infection in Children and Young Adults." PALISI Network/NIH. Protocol X08-11-0534. Phase N/A. HSPPO #09.0641. Award # 1RO1AI08401101A1. \$12,150.
- **2009 Present** Montgomery VL, <u>Sullivan JE</u>, Condurache CT. "Epidemiology and Immune Response to Life-Threatening Influenza in Children and Young Adults." NIH (subcontract with Children's Hospital Boston). Protocol X08-110534. Phase N/A. HSPPO# 09.0641. \$6,000.
- **2009 Present** Montgomery VL, Calhoun A, <u>Sullivan JE</u>, Berkenbosch JW, Porter M, Potter K, Gupta M, Hardin A. "Genetic Epidemiology of Life-Threatening Influenza Infection in Children and young adults." PALISI Network. Protocol N/A. Phase N/A. HSPPO# 08.0642. \$30,000.

Contracts / Completed Research

- 2019 2021 Porter M, Sullivan JE, Prolonged Mechanical Ventilation in Paediatric Intensive Care : An International Cross-Sectional Prevalence Study (LongVentKids Study (for Prolonged Ventilation in Kids in Intensive Care)), PALISI, HSPPO#19.0786, Unfunded.
- 2019 2021 Morton R, Bickel S, O'Hagan A, <u>Sullivan JE</u>. Human Tissue Repository to Support Personalized Models of the Airway for Predicting Effectiveness of Therapeutic Compounds. Precision Care Network, LLC (PCN). Protocol# SAIRB-18-0024, HSPPO# 19.0308, \$38,327.
- 2019 2020 Marshall GS, Brother K, Bryant K, Espinosa C, Kinney M, Kurbasic M, Martin E, Meiman S, Morris M, Pendleton A, Porter J, Purcell K, Sayat J, Statler VA, Sullivan JE, Singh T, Theriot J, Thompson J. A Phase 3, Multicenter, Randomized, Double-blind, Active Comparator-controlled Study to Evaluate the Safety and Tolerability of V114 in Healthy Infants (PNEU-LINK). Merck Sharp & Dohme Corp., (a subsidiary of Merck & Co. Inc.). Protocol# V114-031, HSPPO# 18.1178, \$236,074.
- 2018 2020 Graff D, Spurlin B, Berkenbosch JW, McDonald MJ, Sullivan JE, Stevenson M. Open label clinical study to evaluate the safety and efficacy of ProvayBlueTM (methylene blue) for the treatment of acquired methemoglobinemia. Provepharm SAS. Protocol# PVP-2016003, HSPPO# 17.0837, \$70,573.
- 2018 2021 Sowell M, Doll E, <u>Sullivan JE</u>. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Crossover Study to Evaluate the Efficacy and Safety of Zolmitripan Nasal Spray for the Treatment of Acute Migraine in Subjects Ages 6 to 11 Years, with an Open-Label Extension. Impax Laboratories, Inc. Protocol# IPX229-B16-01, HSPPO# 18.0374, \$148,073.
- 2018 2020 Ehret A, Puri V, Sullivan JE, Bishop A. An Open-Label, Long-Term Safety Study Including a Double-Blind, Placebo-Controlled, Randomized Withdrawal Period of TEV-50717 (deutetrabenazine) for the Treatment of Tourette Syndrome in Children and Adolescents. Teva Branded Pharmaceutical Products R&D, Inc. Protocol# TV50717-CNS-30047, HSPPO# 18.0513, \$99,447.
- 2018 2020 Ehret A, Puri V, <u>Sullivan JE</u>, Bishop A. A Well-Controlled, Fixed-Dose Study of TEV 50717 (Deutetrabenazine) for the Treatment of Tics Associated with Tourette Syndrome. Teva Branded Pharmaceutical Products R&D, Inc. Protocol# TV50717-CNS-30060, HSPPO# 18.0512, \$84,900.
- 2018 2020 Espinosa C, Statler V, <u>Sullivan JE</u>. A Phase 2, Open-Label, Multicenter, Multi cohort Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir in Adolescents and Children with Chronic HCV Infection. Gilead Sciences, Inc., Protocol# GS US 342-1143, HSPPO# 18.0498, \$74,085.

- 2018 2019 Sullivan JE. A Nationally Representative Drug Utilization Study of OxyContin in Children Aged 17 Years and Younger. PMR 2923-2; HSPPO#18.0743, \$\$\$\$
- 2018 2019 Marshall G, Statler V, Bryant K, Espinosa C, Brothers KB, Kinney M, Kurbasic M, Martin E, Meiman S, Morris M, Pendleton A, Porter J, Purcell K, Sayat J, Sullivan JE, Theriot J, Thompson J. Safety and Immunogenicity of GSK Meningococcal Group B Vaccine and 13-valent Pneumococcal Vaccine administered Concomitantly with Routine Infant Vaccines to Healthy Infants. GlaxoSmithKline (GSK) Biologicals S.A., Protocol# 20539 (MENB REC 2ND GEN-023 [V72 57]), HSPPO# 18.0651, \$319,224.
- 2018 2019 O'Hagan A, Morton R, Bickel S, <u>Sullivan JE</u>. A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability, Pharmacokinetics, and Effect of PTI-428 in Subjects with Cystic Fibrosis. Proteostasis Therapeutics, Inc., Protocol# PTI-428-06, HSPPO# 18.0611, \$125,630.
- 2018 2019 Schikler K, Schmidt K, <u>Sullivan JE</u>. Randomized Clinical Trial of Fibromyalgia Integrative Training (FIT Teens) for adolescents with Juvenile Fibromyalgia FIT Teens Study (Umbrella) R01AR070474. National Institutes of Health-NIAMS, Protocol# 2015-6338, HSPPO# 17.0377, \$65,494.
- 2018 2019 Devlin L, <u>Sullivan JE</u>. ACT NOW Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT NOW)

 Current Experience: Infant Exposure and Treatment. University of Arkansas/National Institutes of Health, Protocol# N/A, HSPPO# 18.0284, \$84,546.
- 2018 2020 Morton R, Bickel S, O'Hagan A, <u>Sullivan JE</u>. A Phase III, randomized, double-blind, placebo-controlled study of AeroVanc for the treatment of persistent methicillin-resistant Staphylococcus aureus lung infection in cystic fibrosis patients. Savara, Inc., Protocol# SAV005-04, HSPPO# 17.0888, \$103,912.
- 2018 2019 Statler V, Sullivan JE, Brothers K, Espinosa C, Caperell K. A Phase IV Double-Blind, Placebo-Controlled, Randomized Trial to Evaluate Short Course vs. Standard Course Outpatient Therapy of Community Acquired Pneumonia in Children (SCOUTCAP). National Institute of Health (NIH)/Division of Microbiology and Infectious Diseases (DMID), Protocol# 14-0079, HSPPO# 17.1282, \$73,304.
- Statler V, Marshall G, Morris M, Bryant K, Pendleton A, Espinosa C, Porter J, Brothers K, Purcell K, Kinney M, Sayat J, Kurbasic M, Theriot J, Martin E, Thompson J, Meiman S, <u>Sullivan JE</u>. A Phase 3, Double-Blind, Randomized, Multicenter, Controlled Study to Evaluate the Immunogenicity, Safety, and Tolerability of VARIVAX™ Passage Extension 34 (PE34) Process Administered Concomitantly with M-M-R™ II. Merck Sharp & Dohme Corp., Protocol#V210-A03, HSPPO#17.0939, \$292,604.
- 2018 2020 Morton R, Bickel S, O'Hagan A, Sullivan JE. Randomized, Double-Blind, Phase 3b Trial to Evaluate the Safety & Efficacy of 2 Treatment Regimens of Aztreonam 75mg Powder & Solvent for Nebulizer Solution/Aztreonam for Inhalation Solution (AZLI) in Pediatric Subjects with Cystic Fibrosis (CF) & New Onset Respiratory Tract Pseudomonas aeruginosa (PA) Infection/Colonization. Protocol# GS-US-2015-1850, HSPPO# 17.0889, \$106,848.
- 2018 2019 O'Hagan A, Morton R, <u>Sullivan JE</u>, Bickel S. A Phase 3, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-659 Combination Therapy in Subjects with Cystic Fibrosis Who Are Heterozygous for the F508del Mutation and a Minimal Function Mutation (F/MF). Vertex Pharmaceuticals Incorporated, Protocol# VX17-659-102, HSPPO# 18.0493, \$55,813.50.
- 2018 2020 O'Hagan A, Morton R, <u>Sullivan JE</u>, Bickel S. A Phase 3, Open-label Study Evaluating the Long-term Safety and Efficacy of VX-659 Combination Therapy in Subjects with Cystic Fibrosis Who Are Homozygous or Heterozygous for the F508del Mutation. Vertex Pharmaceuticals Incorporated, Protocol# VX17-659-105, HSPPO# 18.0495, \$132,769.
- 2018 2019 Holland B, Kozik DJ, Dydynski, PB, Austin E, <u>Sullivan JE.</u> Clinical Impact of Rapid Prototyping 3D Models of Congenital Heart Disease on Surgical Management. Children's National Medical Center, Protocol# 15-090, HSPPO# 17.1283, unfunded.
- O'Hagan A, Morton R, <u>Sullivan JE.</u> A Multi-Center, Randomized, Placebo-Controlled, Phase 1, Two-Part Study Designed to Assess the Safety, Tolerability, Pharmacokinetics, Food Effect, and Drug-Drug Interactions of PTI-801 in Healthy Volunteers, and Safety, Tolerability, and Pharmacokinetics of PTI-801 in Subjects with Cystic Fibrosis (Part 2). Proteostasis Therapeutics, Inc., Protocol# PTI-801-01, HSPPO#17.0882.\$\$\$
- 2018 2020 Stewart D, <u>Sullivan JE.</u> Multicenter, Prospectively Defined Observational Registry with Retrospective Data Collection, Evaluating Premature and Term-Near-Term Neonates with Pulmonary Hypertension Receiving Inhaled

Nitric Oxide via Invasive or Noninvasive Ventilator Support at US Centers. Mallinckrodt Inc., Protocol# MKN19050056, HSPPO# 17.0696, \$462,846.

- 2017 2019 Schikler K, Sullivan JE, Condurache TC, Schmidt K. A randomized, double-blind, placebo-controlled, multicenter, phase 3 efficacy and safety study of 2 dose levels of subcutaneous anakinra (Kineret®) in patients with Still's Disease (SJIA and AOSD) (The anaSTILLs Study). Swedish Orphan Biovitrum AB (Sobi), Protocol# Sobi ANAKIN-301, HSPPO# 17.1149. \$78.441.
- 2017 2019 Puri V, Sullivan JE, Skjei K, Barnes GN, O'Donnell D. An Open-Label Study to Determine Safety, Tolerability, and Efficacy of Long-term Oral Lacosamide (LCM) as Adjunctive Therapy in Children with Epilepsy. UCB Sciences Inc., Protocol# SP848, HSPPO#17.0891, \$100,272.
- 2017 2020 Statler V, Espinosa C, <u>Sullivan JE</u>. A Phase 1, Open-Label, Multicenter, Non-comparative Pharmacokinetics and Safety Study of Intravenous Isavuconazonium Sulfate in Pediatric Patients. Astellas Pharma Global Development, Inc, Protocol# 9766-CL-0046, HSPPO# 17.0837, \$123,470.
- 2017 2019 Hanofee C, Sullivan JE. The PARK-PICU Study: Prevalence of Acute Rehab for Kids in the PICU. HSPPO#17.0895, unfunded.
- 2017 2019 Berkenbosch JW, Gravari E, Hanofee CR, Sandquist MK, <u>Sullivan JE</u>. A Multi-Center, Open-Label Pharmacokinetic and Safety Study for Reduction in Fever or Management of Pain in Pediatric Subjects Aged Birth to Six Months. Cumberland Pharmaceuticals Inc., Protocol# CPI-CL-022, HSPPO# 17.0097, \$81,533.
- 2017 2020 Espinosa CM, <u>Sullivan JE</u>, Condurache CT. Pharmacokinetics of a Single-Dose of Dalbavancin in Preterm Neonates to Infants Ages 3 Months with Suspected or Confirmed Bacterial Infection. Durata Therapeutics International, Inc, and Allergan Affiliate, Protocol# DAL-PK-02, HSPPO#16.1072, \$107,940.
- 2017 2020 Sparks J, Sullivan JE, Keller BB. Multicenter, open-label, study to evaluate safety, tolerability, pharmacokinetics and, pharmacodynamics of LCZ696 followed by a 52-week randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared with enalapril in pediatric patients from 1 month to < 18 years of age with heart failure due to systemic left ventricle systolic dysfunction. Novartis, Protocol# CLCZ696B2319—Part 1, HSPPO# 16.1153, \$557,406.
- 2017 2020 Sparks J, <u>Sullivan JE</u>, Keller BB. Multicenter, open-label, study to evaluate safety, tolerability, pharmacokinetics and, pharmacodynamics of LCZ696 followed by a 52-week randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared with enalapril in pediatric patients from 1 month to < 18 years of age with heart failure due to systemic left ventricle systolic dysfunction. Novartis, Protocol# CLCZ696B2319—Part 2, HSPPO# 16.1153, \$557,406.
- 2017 2018 McGowan KK, Berkenbosch JW, <u>Sullivan JE</u>, Raj A. A Phase 3, open-label, randomized, multi-center, controlled trial to evaluate the pharmacokinetics and pharmacodynamics of edoxaban and to compare the efficacy and safety of edoxaban with standard of care anticoagulant therapy in pediatric subjects from birth to less than 18 years of age with confirmed venous thromboembolism (VTE). Daiichi Sankyo, Inc., Protocol# DU176b-D-U312, HSPPO# 16.1070, \$210,080.
- 2016 2018 Devlin L, <u>Sullivan JE</u>, Radmacher P, Duncan S. Aim 2: Prevention of Neonatal Abstinence Syndrome (NAS2). NIH and Stanford University, Protocol# N/A, HSPPO# 16.0684, \$82,452.
- 2016 2020 Lakhotia A, <u>Sullivan JE</u>, Puri V. Pharmacokinetics of Anti-Epileptic Drugs in Obese Children Phase I. The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) a part of the National Institutes of Health (NIH), is paying for this study through a contract with Duke University. Protocol# NICHD-2015-AED01, HSPPO# 16.1154, \$19,085.
- 2016 2020 Sharma V, Raj A, Barbour M, Sullivan JE, Cheerva A, Huang M, McGowan K, Mullinax J. CDC Public Health Surveillance for Bleeding Disorders Registry for Bleeding Disorders Surveillance. CDC, Protocol# N/A, HSPPO# 15.0898, \$19,417
- 2016 2017 Espinosa CM, <u>Sullivan JE</u>, Smith M. A Randomized, Double-Blind, Placebo-Controlled, Multicenter Dose-Ranging Study of ALX- 0171 in Infants and Young Children Hospitalized for Respiratory Syncytial Virus Lower Respiratory Tract Infection. Ablynx NV, Protocol# ALX0171-C201, Closed before site activated.
- 2016 2017 Shickler K, Sullivan JE, Condurache CT, Schmidt K. A Long-Term, Open-Label, Follow-Up Study of Tofacitinib for

Treatment of Juvenile Idiopathic Arthritis (JIA). Pfizer, Inc., Protocol# A3921145, HSPPO# 15.0991, \$108,364.

- 2016 2019 Raj A, Panigrahi A, <u>Sullivan JE</u>, Condurache CT. An Open-Label Extension Study to Evaluate the Safety of Rivipansel (GMI-1070) in the Treatment of One or More Vasoocclusive Crises in Hospitalized Subjects with Sickle Cell Disease. Pfizer, Protocol# B5201003, HSPPO# 16.1043, \$195,215.
- 2016 2019 Raj A, Panigrahi A, Sullivan JE, Condurache CT, Cheerva A, Huang M, McGowan K. A Phase 3, Multicenter, Randomized, Double-blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Rivipansel (GMI-1070) in the Treatment of Vaso-Occlusive Crisis in Hospitalized Subjects with Sickle Cell Disease. Pfizer, Protocol# B5201002, HSPPO# 16.0412, \$249,732.
- Puri V, Sullivan JE, Condurache CT. A Multicenter, Open-label Study to Investigate the Safety and Tolerability of Intravenous Lacosamide as Replacement for Oral Lacosamide in Children (≥4 to < 17 Years of Age) with Epilepsy. UCB Biosciences Inc., Protocol# EP0060, HSPPO # 17.0731, \$205,033.
- 2016 2017 Arumugam C, Sullivan JE, Condurache CT. A Multicenter, Double Blind, Randomized, Single Dose, Active Control Study to Investigate the Efficacy and Safety of Synthec Surfactant (CHF 5633) in Comparison to Porcine Surfactant (Poractant Alfa, CUROSURF®) in the Treatment of Preterm Neonates with Respiratory Distress Syndrome. Chiesi Framaceutici S.p.A., Protocol# CCN-5633AA1-02, HSPPO # 16.0071, \$159,277.
- 2016 2019 Barnes GN, Sullivan JE, Condurache CT, Farber D, Puri V. An open label extension study to investigate the safety of cannabidiol (GWP42003-P; CBD) in children and adults with inadequately controlled Dravet or Lennox-Gastaut Syndromes. GW Research LTD, Protocol# GWEP1415, HSPPO# 16.0339, \$120,142.
- 2016 2020 Stewart D, <u>Sullivan JE</u>, Condurache CT, Singh T. Intravenous Remodulin (Treprostinil) as Add-on Therapy for the Treatment of Persistent Pulmonary Hypertension of the Newborn: A Randomized, Placebo-Controlled, Safety and Efficacy Study. United Therapeutics Corp., Protocol# RIV-PN-201, HSPPO#16.1178, \$222,753.
- Espinosa C, Smith M, Sullivan JE, Condurache CT. "A Phase 2/3, Randomized, Open-Label, Multi-center Study to Determine the Safety and Efficacy of Solithromycin in Adolescents (12 to 17 years of age, inclusive) and Children (≥2 months to <12 years of age) with Suspected or Confirmed Community-Acquired Bacterial Pneumonia." Cempra Pharmaceuticals, Inc, Protocol # CE01-203, HSPPO# 16.0268, \$306,237.
- Raj A, Condurache CT, Sullivan JE, Panigrahi AR. "Evaluation of Repeat Administration of Purified Poloxamer 188 in Vaso-occlusive Crisis of Sickle Cell Disease (EPIC-E): an Open-label Safety Extension Trial Assessing Repeat Administration of MST-188 (Purified Poloxamer 188) Injection in Subjects with Sickle Cell Disease Experiencing Vaso-occlusive Crisis." Mast Therapeutics, Inc., Protocol# MST-188-04, HSPPO# 16.0694, \$293,109.
- 2015 2019 Panigrahi A, Raj A, Cheerva A, Mullinax J, McGowan K, Huang M, Sullivan JE. An Open-Label, Multicenter Evaluation of the Safety and Efficacy of Recombinant Coagulation Factor IX Fc Fusion Protein (rFIXFc; BIIB029) in the Prevention and Treatment of Bleeding in Previously Untreated Patients with Severe Hemophilia B. Biogen Idec, Protocol# 998HB303, HSPPO# 14.0963, \$122,449.
- 2015 2019 Porter MB, Sullivan JE, Berkenbosch JW, Ruppe M, McDonald MJ, Tzanetos D. Hypothermia's Impact on Pharmacology 2 (HIP 2). Athena Zuppa, MD, MSCE, The Children's Hospital of Philadelphia. Protocol# N/A, HSPPO# 15.0976, \$3,600.
- 2015 2021 Panigrahi A, Lucas K, Cheerva A, Raj A, Myers S, Elster J, Mullinax J, McGowan K, Huang M, Sullivan JE, Burnett D. Prospective Multi-Center Evaluation of the Duration of Therapy for Thrombosis in Children. All Children's Hospital Johns Hopkins Medicine (All Children's Hospital Foundation). Protocol# Kids DOTT; HSPPO# 15.0907, \$6,000.
- 2015 2019 Stewart DL, <u>Sullivan JE</u>, Condurache CT, Fischer H. A Multicenter, Randomized, Open-Label, Controlled Trial to Assess the Safety and Tolerability of Lucinactant for Inhalation in Preterm Neonates 26 to 28 Weeks PMA. Discovery Laboratories, Inc., Protocol# 03-CL-1401, HSPPO#15.0983, \$180,106.
- 2015 2020 Sullivan JE, Condurache CT, Jeffries A, Stutts J, Stephen T, Morton R, O'Hagan A. "A Phase 2, Double-Blind, 12 Week, Multicenter Study to Assess the Safety and Effectiveness of Daily Oral Administration of Dexlansoprazole Delayed-Release Capsules in Pediatric Subjects Aged 1 to 11 Years with Symptomatic Nonerosive Gastroesophageal Reflux Disease." Takeda Development Center Americas, Inc., Protocol# TAK-390MR_204, HSPPO# PENDING, \$188,802.
- 2015 2020 Sullivan JE, Condurache CT, Jeffries A, Stutts J, Stephen T, Morton R, O'Hagan A. "A Phase 2, Double Blind, Up to 40 Week, Multicenter Study to Assess the Safety and Effectiveness of Daily Oral Administration of Dexlansoprazole

Delayed-Release Capsules for Healing of Erosive Esophagitis (EE) and Maintenance of Healed EE in Pediatric Subjects Aged 1 to 11 Years with EE." Takeda Development Center Americas, Inc., Protocol# TAK-390MR_205, HSPPO# PENDING, \$119,240.

- 2015 2017 Espinosa C, Smith M, <u>Sullivan JE</u>, Condurache CT. "A single blind, randomized, multi-centre, active controlled, trial to evaluate safety, tolerability, pharmacokinetics and efficacy of ceftazidime and avibactam when given in combination with metronidazole, compared with meropenem, in children from 3 months to less than 18 years of age with complicated intra-abdominal infections (cIAIs)." AstraZeneca, Protocol# D4280C00015, HSPPO# 15.0277, \$108,417.
- 2015 2020 Sullivan JE, Condurache CT, Jeffries A, Stutts J, Stephen T, Morton R, O'Hagan A, Jeffries A. "A Phase I, Randomized, Open-Label, Parallel-Design, Multicenter Study to Evaluate the Pharmacokinetics, Safety, and Pharmacodynamics of Dexlansoprazole Delayed-Release Capsules in Infants Aged 1 to 11 Months with Acid-Related Diseases." Takeda Development Center Americas, Inc. Protocol# TAK-390MR 108, HSPPO# 15.0276, \$81,319.
- 2015 2017 Smith MJ, Espinosa CM, <u>Sullivan JE</u>, Condurache CT. "A Phase 1, Non-comparative, open-label study to characterize the pharmacokinetics of a single intravenous dose of ceftolozane/tazobactam in pediatric patients receiving standard of care antibiotic therapy for proven or suspected gram-negative infection or for peri-operative prophylaxis. Cubist Pharmaceuticals, Inc. Protocol# CXA-PEDS-13-08, HSPPO# 15.0411, \$60,238.
- 2014 2020 Panigrahi A, Raj A, McGowan, Mullinax K, Cheerva A, Huang M, <u>Sullivan JE</u>. My Life Our Future: A Hemophilia Genotyping Initiative Data and Sample Research Repository. Biogen Idec, Protocol# MLOF, HSPPO# 14.0358, \$3,500.
- 2014 2019 Puri V, Farber D, Skjei K, Sims S, Bishop A, <u>Sullivan JE</u>, "A Randomized, Active-Controlled, Open-Label, Flexible-Dose Study to Assess the Safety and Tolerability of Topiramate as Monotherapy compared with Levetiracetam as Monotherapy in Pediatric Subjects with New or Recent- Onset Epilepsy" Janssen Research & Development LLC, Protocol TOPMATEPY4067, HSPPO# 14.0988, \$128,195.
- 2014 2016 Espinosa CM, <u>Sullivan JE</u>, Smith MJ, Condurache CT. "The SENTINEL 1 Study: An Observational, Non-Interventional Study in the United States to Characterize Respiratory Syncytial Virus Hospitalizations among Infants Born at 29 to 35 Weeks Gestational Age Not Receiving Immunoprophylaxis" AstraZeneca. Protocol# D4800L00009, HSPPO# 14.1268, \$39,000.
- 2014 2018 Johnsrude C, <u>Sullivan JE</u>. "Multicenter Study of the Intermediate-Term Follow-up of the Medtronic 3830 Pacing Lead Used for Cardiac Pacing in Children and Young Adults. Does the 3830 Pacing Lead Offer a Survival Advantage Compared with Other Available Transvenous Pacing Leads?" Protocol# Cardiac 3830, HSPPO# 14.0337, \$2000.
- **2014 2016** Tzanetos D, Stewart DL, <u>Sullivan JE</u>. "The Use of Atryn in Pediatric and Neonatal ECMO Patients a Single Center Experience" rEVO Biologics, Inc. HSPPO#14.0621, \$21,000.
- 2014 2018 Sullivan JE, Berkenbosch JW, Condurache CT, Raj A. "A Phase 1, Open-Label, Single-Dose, Non-Randomized Study to Evaluate Pharmacokinetics and Pharmacodynamics of Edoxaban in Pediatric Patients" Daiichi Sankyo Pharma Development. Protocol# DU176b-A-U157, HSPPO# 14.0589, \$75,190.
- 2013 2021 Robinson T, Schumacher EA, <u>Sullivan JE</u>, Stewart DL, Adamkin D, Gravari E, Schultz S, Singh T, Schuschke L. "Preterm Epo Neuroprotection Trial (PENUT Trial)", University of Washington, PENUT TRIAL, HSPPO #13.0202, \$181,686.
- 2013 2020 Stewart DL, <u>Sullivan JE</u>, Robinson T, Wasser L. "A 48-52 Month Blinded-Outcomes Follow up Study of Subjects Having Received Investigational Product (IP) or Placebo in Clinical Trial 64,185-204" InfaCare Pharmaceutical Corporation. Protocol # 64,185-205, HSPPO # 13.0321, \$186,460.
- **2013 2021** Wintergerst KA, Berkenbosch JW, <u>Sullivan JE</u>, Calhoun A "Coagulation and Fibrinolysis in a Pediatric Insulin Titration Trial (CAF-PINT)", NIH/National Heart Lung and Blood Institute, Protocol N/A. HSPPO#13.0389, \$10,000.
- 2013 2017 Schikler KN, Schmidt KM, <u>Sullivan JE</u>, Condurache CT. "Pediatric Vasculitis Initiative (PedVas) Chronic Childhood Vasculitis: Characterizing the Individual Rare Diseases to Improve Patient Outcomes", Canadian Institutes of Health Research (CIHR), Protocol N/A. HSPPO #13.0268, \$4,520.
- **2013 2020** Wintergerst KA, Berkenbosch JW, <u>Sullivan JE</u>, Calhoun A. "Heart and Lung Failure Pediatric Insulin Titration Trial (HALF-PINT), NIH & National Heart Lung and Blood Institute, Protocol N/A. HSPPO #13.0245, \$205,000.

- **2012 2018** Sobczyk W, <u>Sullivan JE.</u> "Adult and Congenital Heart Disease Quality Enhancement Research Initiative." Actelion and CHRC. Protocol CHRC2011-ACHD001. HSPPO #12.0451. \$20,200.
- 2012 2018 <u>Sullivan JE</u>, Condurache CT, Stewart DL, Devlin-Phinney LA. "Pharmacokinetics of Anti-staphylococcal Antibiotics in Infants." DCRI. Protocol NICHD-2012-02; Phase I. HSPPO #12.0592. \$44,000.
- 2012 2018 <u>Sullivan JE</u>, Condurache CT, Berkenbosch JW. "A Single-Dose Study to Evaluate the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of Apixaban in Pediatric Subjects at Risk for a Venous or Arterial Thrombotic Disorder." BMS. Protocol CV185118. Phase I. HSPPO #12.0472. \$52,311.
- 2012 2021 Sullivan JE (PI), Condurache CT. "Pharmacokinetics of Understudied Drugs Administered to Children per Standard of Care." National Institute of Child Health & Human Development (subcontract with Duke Clinical Research Institute). Protocol NICHD-POPS01. Phase N/A. HSPPO #11.0300. \$82,500.
- 2012 2016 Schikler KN, Sullivan JE, Condurache CT, "A Phase I Pharmacokinetic and Safety Study of Tocilizumab (TCZ) for 12 weeks in Patients with Active Systemic Juvenile Idiopathic Arthritis (sJIA) Less Than 2 years Old." Roche. Protocol NP25737. Phase I. HSPPO #11.0738. \$68,618.
- 2011 2019 Goodin KM, Sullivan JE, Asamoah A, Gowans GC, Condurache CT. "Long-term Extension of a Phase 2, Open-label Dose-finding Study to Evaluate the Safety, Efficacy, and Tolerability of Multiple Subcutaneous Doses of rAvPAL-PEG in Subjects with PKU." BioMarin Pharmaceutical, Inc. Protocol PAL-003. Phase II. HSPPO #11.0335. \$363,630.
- 2010 2017 Porter MB, Sullivan JE, Berkenbosch JW, Calhoun AW, Montgomery VL, Ruppe MD, Padmanabhan P, McDonald MJ, Orman K, Potter KE, Hardin AO, Sears LL, Peterson E, Owen E, Puri V. "Therapeutic Hypothermia After Pediatric Cardiac Arrest: The THAPCA Trials." Subcontract with the University of Michigan. NIH. Protocol N/A. Phase N/A. HSPPO #10.0464. \$47,423.
- 2016 2019 Espinosa C, Sullivan JE, Condurache CT, Smith MJ. Phase 1, Single-Administration Pharmacokinetic and Safety Study of Oral and IV Tedizolid Phosphate in Hospitalized Subjects 2 to <12 Years Old. Merck Sharp & Dohme Corp. and Cubist Pharmaceuticals, LLC, Protocol# TR701-120; MK1986-013, HSPPO#16.0546, \$50,267.

- 2015 2019 Barnes GN, Sullivan JE, Condurache CT, Farber D, Puri V. "A randomized, double-blind, placebo-controlled study to investigate the efficacy and safety of cannabidiol (GWP42003-P) in children and young adults with Dravet syndrome" GW Pharmaceuticals, Protocol# GWEP1424 HSPPO# 15.0579, \$133,328.
- 2014 2019 Sullivan JE, Condurache CT, Berkenbosch JW, "A Randomized, Double-Blind, Efficacy and Safety Study of AR 14 (AZILSARTAN MEDOXOMIL) Treatment and Withdrawal, Followed by an Open-Label Extension, in Children 6 to Less Than 18 Years of Age with Hypertension." Arbor Pharmaceuticals, LLC. Protocol# AR14.001, HSPPO# 14.1112, \$41,348.
- 2013 2019 Goodin KM, Gowans GC, <u>Sullivan JE</u>, Condurache CT, Calvery M. "A Three-Part, Phase 3, Randomized, Double-Blind, Placebo-Controlled, Four-Arm, Discontinuation Study to Evaluate the Efficacy and Safety of Subcutaneous Injections of BMN 165 Self-Administered by Adults with Phenylketonuria", BioMarin Pharmaceuticals Inc., Protocol 165-302. Phase III, HSPPO# 13.0394, \$231,664.
- 2017 2018 Kingery S, Sullivan JE, Wintergerst K. A multicenter, Phase 3, randomized, open-label, active-controlled, parallel-group trial investigating the safety, tolerability, and efficacy of TransCon hGH administered once a week versus standard daily hGH replacement therapy over 52 weeks in prepubertal children with growth hormone deficiency (GHD). Ascendis Pharma Endocrinology Division A/S, Protocol# TransCon hGH CT-301, HSPPO# 17.0254, \$27,164.
- 2017 2018 Morton R, O'Hagan A, <u>Sullivan JE</u>, Bickel S. A Phase 3, Randomized, Open-Label, Assessor-Blind, Non Inferiority, Active-Comparator Study Evaluating the Efficacy and Safety of Liprotamase in Subjects with Cystic Fibrosis-Related Exocrine Pancreatic Insufficiency. Anthera Pharmaceuticals, Inc., Protocol# AN-EPI3333, HSPPO# 17.0575, \$23,065.
- 2016 2018 Panigrahi AR, <u>Sullivan JE</u>, Cheerva A, Elster JD, Huang MA, Lucas KG, McGowan KK, Mullinax J, Myers SN, Raj A. An Open-Label, Multicenter Evaluation of the Safety and Efficacy of Recombinant Coagulation Factor VIII Fc Fusion Protein (rFVIIIFc; BIIB031) in the Prevention and Treatment of Bleeding in Previously Untreated Patients with Severe Hemophilia A. Biogen Idec, Inc., Protocol# 997HA306, HSPPO# 14.1163, \$31,334.
- 2016 2018 Shah S, Gupta S, <u>Sullivan JE</u>. An Open-label, Single-dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Etelcalcetide (AMG 416) in Paediatric Subjects Aged 2 to less than 18

Years with Secondary Hyperparathyroidism (sHPT) Receiving Maintenance Haemodialysis. Amgen Inc., Protocol# 20140336, HSPPO# 17.0098, \$19,858.

- 2016 2018 Jeffries A, Condurache CT, Stephen T, Stutts J, <u>Sullivan JE.</u> A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group, Safety and Efficacy Study of a Range of Linaclotide Doses Administered Orally to Children, Ages 6 to 17 Years, Who Fulfill Modified Rome III Criteria for Child/Adolescent Functional Constipation (FC). Forest Research Institute, Inc. Protocol# LIN-MD-62, HSPPO#16.0169, \$33,515
- 2016 2018 Morton R, O'Hagan A, <u>Sullivan JE</u>, Bickel S. A Phase 3, Open-Label Study Evaluating the Efficacy and Safety of Liprotamase in Subjects with Cystic Fibrosis-Related Exocrine Pancreatic Insufficiency PART B. Anthera Pharmaceuticals, Inc. Protocol# AN-EPI3332. HSPPO# 16.0895, \$26,611.
- 2016 2018 O'Hagan A, Morton R, <u>Sullivan JE</u>, Condurache CT. A Multi-center, Randomized, Placebo-Controlled, Ascending Dose Phase I Study Designed to Assess the Safety, Tolerability, and Pharmacokinetics of PTI-428 in Subjects with Cystic Fibrosis. Proteostasis Therapeutics, Protocol# PTI-428-01, HSPPO#16.0547, \$160,933.
- 2015 2018 Raj A, Condurache CT, Lucas KG, <u>Sullivan JE</u>, Cheerva A, Panigrahi AR, Myers S, Ayyanar K, Mullinax J, Elster J. "A Phase 3b Continuation study of the Safety and Efficacy of PEGylated Recombinant Factor VIII (PEG-rFVIII; BAX 855) in Prophylaxis of Bleeding in Previously Treated Patients with Severe Hemophilia A. Baxter Healthcare Corporation/ Baxter Innovations GmbH. Protocol# 261302; HSPPO#15.0281 \$34,996.
- 2015 2018 Gowans G, Sullivan JE, Goodin K, Asamoah A. "Morquio A Registry Study (MARS)" BioMarin Pharmaceutical Inc. Protocol # 110-504, HSPPO # 15.0052, \$ 10,070.
- 2015 2018 Statler VA, Woods C, Stephen T, Condurache TC, <u>Sullivan JE</u>. "A Phase 2, Open-Label, Multicenter, Multi-cohort Study to Investigate the Safety and Efficacy of Ledipasvir/Sofosbuvir Fixed Dose Combination in Adolescents and Children with Chronic HCV-Infection." Gilead Sciences, Inc., Protocol# GS-US-337-1116, HSPPO# 15.0391, \$44,620.
- 2015 2018 Lohr WD, Condurache TC, <u>Sullivan JE</u>. "A Double-blind, Placebo- and Active-Controlled Evaluation of the Safety and Efficacy of Levomilnacipran ER in Adolescent Patients with Major Depressive Disorder" Forest, Protocol# LVM-MD-11, HSPPO# 15.1189, \$16,268.
- 2015 2018 Schickler K, Sullivan JE, Condurache CT, Schmidt K. "Efficacy, safety and tolerability of tofacitinib for treatment of polyarticular course juvenile idiopathic arthritis (JIA) in children and adolescent subjects." Pfizer, Inc., Protocol #A3921104, HSPPO # 15.0991, \$14,521.
- 2014 2018 Schikler KN, Schmidt KM, <u>Sullivan JE</u>. "Enteric Flora in Newly Diagnosed Spondyloarthritis: A Collaborative Study" Childhood Arthritis and Rheumatology Research Alliance (CARRA) (subcontract with University of Alabama at Birmingham). HSPPO#14.0011, \$1,300.
- 2014 2018 Sullivan JE, Espinosa CM, Smith MJ, Condurache CT. "A Phase 3, Multicenter, Investigator-blind, Randomized, Parallel Group Study to Investigate the Safety and Efficacy of Fidaxomicin Oral Suspension or Tablets Taken q12h, and Vancomycin Oral Liquid or Capsules Taken q6h, for 10 Days in Pediatric Subjects with Clostridium difficile-associated Diarrhea" Astellas Pharma Europe B.V. (APEB), Protocol# 2819-CL-0202 HSPPO#14.1027, \$72,148.
- 2014 2018 Skjei K, Farber D, Puri V, <u>Sullivan JE</u>, Sims S, Johnson P. "A Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study of the Efficacy and Safety of Pregabalin as Adjunctive Therapy in Children 1 Month through <4 Years of Age with Partial Onset Seizures" Pfizer, Protocol#A0081042, HSPPO#14.1021, \$19,180.
- 2014 2018 Johnsrude C, Sullivan JE. "Outcomes in Timothy Syndrome (long QT syndrome type 8)" HSPPO #14.0169, Unfunded.
- **2014 2018** Berkenbosch JW, <u>Sullivan JE</u>. "Comparison of Outcomes During MRI Sedation with Midazolam Dexmedetomidine Versus Ketamine Dexmedetomidine" HSPPO#14.0315, Unfunded.
- 2013 2018 Craft LT, <u>Sullivan JE</u>. "The Fragile X Clinical and Research Consortium (FXCRC) FORWARD Registry and Database." National Fragile X Foundation, Protocol FXCRC FORWARD. HSPPO #13.0046, \$6,080.
- 2013 2018 Schikler KN, Sullivan JE, Condurache CT, Schmidt KM. "A phase IIa, International, Multicenter, Open-Label, Uncontrolled Study to Evaluate the Safety and Pharmacokinetics of 4 x 375 mg/m2 Intravenous Rituximab in Pediatric Patients with Severe Granulomatosis with Polyangiitis (Wegener's) or Microscopic Polyangiitis." Roche, Protocol WA25615. Phase 2, HSPPO #13.0275. \$46,525.

- 2016 2017 Panigrahi AR, <u>Sullivan JE</u>, Cheerva A, Elster JD, Huang MA, Lucas KG, McGowan KK, Mullinax J, Myers SN, Raj A. A Randomized, Open-Label Study to Evaluate the Pharmacokinetics and Safety of Recombinant Factor VIII Fc Fusion Protein (rFVIIIFc; BIIB031) Manufactured at 15K Scale and at Different Vial Strengths in Previously Treated Subjects with Severe Hemophilia A. Biogen MA Inc., Protocol # 997HA309, HSPPO # 15.1212, \$23,447.
- 2016 2017 Morton R, O'Hagan A, <u>Sullivan JE</u>, Condurache CT. A Phase 3, Randomized, Open-Label, Assessor-Blind, Non-Inferiority, Active-Comparator Study Evaluating the Efficacy and Safety of Liprotamase in Subjects with Cystic Fibrosis- Related Exocrine Pancreatic Insufficiency. Anthera Pharmaceuticals, Inc. Protocol# AN-EPI3331, HSPPO# 15.0994, \$19,290.
- 2016 2017 Skjei K, Farber D, Ehret A, Puri V, <u>Sullivan JE</u>, Condurache CT. A randomized, double-blinded, placebo-controlled study to evaluate the efficacy and safety of SAGE-547 injection in the treatment of subjects with super-refractory status epilepticus. Sage Therapeutics, Protocol# 547-SSE-301, HSPPO# 15.0911, \$99,519.
- 2016 2017 Raj A, Condurache CT, <u>Sullivan JE</u>, Panigrahi AR. Phase 3, prospective, randomized, multi-center clinical study comparing the safety and efficacy of BAX 855 following PK-guided prophylaxis targeting two different FVIII trough levels in subjects with severe Hemophilia A. Baxalta U.S. Inc/ Baxalta Innovations GmbH, Protocol# 261303, HSPPO# 16.0696, \$28,613.
- **2016 Porter M, Sullivan JD, Owen E.** Point Prevalence of Platelet Transfusions in Critically III Children. Plasma Transfusion Organization. Protocol # ICCD170349. HSPPO#16.0901. Unfunded.
- 2015 2017 Jeffries AM, Condurache CT, Stephen TC, Stutts J, <u>Sullivan JE</u>. "A Multicentre, Long-term Safety, Efficacy, and Pharmacokinetics Study of Lubiprostone in Paediatric Subjects Aged ≥ 6 Years to < 18 Years with Functional Constipation" Sucampo AG. Protocol# SAG/0211PFC-11S1, HSPPO# 15.0144, \$56,316.
- 2015 2017 Espinosa C, Sullivan JE, Condurache CT, Smith M. "A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of a Human Monoclonal Antibody, REGN2222, for the Prevention of Medically Attended RSV Infection in Preterm Infants." Regeneron Pharmaceuticals, Inc., Protocol# R2222-RSV-1332, HSPPO# 15.1242, \$90,127.
- Wintergerst KA, <u>Sullivan JE</u>, Condurache CT, Foster M, Kingery S, Omoruyi A. "A Multicenter, Randomized, Partial-Blinded, Placebo-Controlled Study to Evaluate the Safety and Efficacy of a Human Plasma-Derived Alpha1-Proteinase Inhibitor in Subjects with New-Onset Type I Diabetes Mellitus" Grifols USA, LLC. Protocol# GTI1302, HSPPO# 14.0107, \$49,831.
- 2014 2017 Berkenbosch JW, <u>Sullivan JE</u>, Condurache CT. "Open-label evaluation of the pharmacokinetic profile, safety, and efficacy of tapentadol oral solution for the treatment of post-surgical pain in children aged from birth to less than 2 years" Grünenthal GmbH. Protocol# KF5503-72; R33133PAI2007, HSPPO# 14.0642, \$51,699.
- 2012 2017 Owen E, Sullivan JE, Anderson J, Mayes S, McDonald M. "Safety of Endotracheal Lidocaine in Critically Ill Children." Funded through the Department of Pediatrics, HSPPO #12.0004, \$8,000.
- 2012 2018 Sobczyk W, <u>Sullivan JE</u>. "Eisenmenger Quality Enhancement Research Initiative (QuERI)." –Primer. Protocol CHRC2011-ES002. HSPPO #12.0525. \$13,900.
- 2008 2018 Jeffries A, Stewart DL, Stutts J, Condurache CT, Sullivan JE. A Multi-Center, Open-Label, Single-Dose Pharmacokinetic Study of Intravenous Pantoprazole in Preterm Infants and Infants 0-11 Months with a Clinical Diagnosis of Gastroesophageal Reflux Disease (GERD) or the need for Acid Suppression. Wyeth Investigator Grant Award, HSPPO #08.0372. \$185,000 (2%).
- 2007 2018 Calhoun A, Sullivan JE, Stewart DL, Stephen T, Gravari E, Robinson T. "Omegaven Treatment for PN Associated Liver Disease in Children: A Longitudinal Study." (IND 69,208) HSPPO # 07.0117. Unfunded.
- 2015 2017 Johnsrude C, <u>Sullivan JE</u>. "AV nodal reentrant tachycardia (AVNRT) in patients with congenital heart disease: relationship with specific types of CHD and implications for treatment including catheter ablation." Conducted through PACES. Subcontract with Children's Mercy Hospital, Kansas City, MO. HSPPO#15.0063; Unfunded.
- 2015 2017 O'Hagan A, Morton R, <u>Sullivan JE</u>, Condurache TC. "A Point Prevalence Study to Evaluate the Prevalence of Antibodies to Selected Porcine Viruses in Patients with Cystic Fibrosis Who Are Receiving Porcine-Derived Pancreatic Enzyme

Replacement Therapy: A Harmonized Protocol Across Sponsors." AbbVie Inc., Janssen Research & Development, LLC and Aptalis Pharma U.S. Inc., Protocol# JSPP-12-01, HSPPO# 14.0958, \$23,886.

- 2014 2017 Espinosa CM, Smith MJ, <u>Sullivan JE</u>, Condurache CT. "A Phase 1, Open-label, Multi-center Study to Determine the Pharmacokinetics and Safety of Solithromycin as Add-on Therapy in Adolescents and Children with Suspected or Confirmed Bacterial Infection" Cempra Pharmaceuticals, Inc. and Biomedical Advanced Research and Development Authority (BARDA). Protocol# CE01-120, HSPPO#14.0885, \$36,858.
- 2014 2017 Berkenbosch JW, <u>Sullivan JE</u>, Condurache CT. An evaluation of the efficacy and safety of tapentadol oral solution in the treatment of postoperative acute pain requiring opioid treatment in pediatric subjects aged from birth to less than 18 years old. Grünenthal GmbH and Depomed. Inc. Protocol# KF5503/65; R331333PAI3037, HSPPO# 14.1111, \$10,041.
- 2014- 2017 O'Hagan A, Morton R, <u>Sullivan JE</u>, Condurache CT. "Long Term Administration of Inhaled Mannitol in Cystic Fibrosis

 A Safety and Efficacy Trial in Adult Cystic Fibrosis Subjects" Pharmaxis Limited. Protocol# DPM-CF-303 HSPPO#14.0594, \$35,224.
- 2013 2017 Stewart DL, Sullivan JE, Robinson T, Wasser L. "A Phase 2b, Multicenter, Single Dose, Randomized, Double Blind, Placebo Controlled, Parallel Group Study Evaluating the Safety and Efficacy of Two Doses of Stannsoporfin in Combination with Phototherapy in Neonates." InfaCare Pharmaceutical Corporation, Protocol# 64,185-204, HSPPO# 13.0304, \$104,447.
- **2013 2017** Barnes GN, Condurache CT, <u>Sullivan JE</u>, Sears LL, Williams PG, Lohr WD. "Treatment of children with autism spectrum disorders and epileptiform EEG with divalproex sodium." Simons Foundation. HSPPO#13.0779, \$34,098.
- 2012 2017 Stewart DL, <u>Sullivan JE</u>, Condurache CT. "Pharmacokinetics of Sildenafil in Premature Infants." DCRI. Protocol NICHD-201-01-SIL01. Phase I. HSPPO #13.0076. \$16,419.
- 2012 2017 O'Brien A, <u>Sullivan JE</u>. "Evaluation of the Utility of Routine Post-Thoracostomy Tube Removal Chest Radiographs in Patients in the Pediatric Intensive Care Unit", HSPPO #12.0002, Unfunded.
- 2015 2016 Gupta S, Sullivan JE, Condurache CT, Shah S. "A Multicenter Single-arm Extension Study to Characterize the Long-term Safety of Cinacalcet Hydrochloride in the Treatment of Secondary Hyperparathyroidism in Pediatric Subjects with Chronic Kidney Disease On Dialysis." Amgen Inc., Protocol# 20140159, HSPPO# 15.0995, \$8,750.
- 2015 2016 Puri V, Condurache CT, <u>Sullivan JE</u>. "P261-202 An Open-Label, Phase I, Pharmacokinetic Study of Single Doses of Intranasal Midazolam (Usl261) in Pediatric Subjects with Epilepsy." Upsher Smith Laboratories, Inc./INC Research, LLC, Protocol# P261-202, HSPPO# 15.0505, \$16,758.
- 2014 2016 Schikler KN, Schmidt KM, <u>Sullivan JE</u>, Condurache CT, "ß-SPECIFIC 4 Patients: Study of Pediatric Efficacy and Safety with First-line use of Canakinumab; An open-label canakinumab (ACZ885) dose reduction or dose interval prolongation efficacy and safety study in patients with Systemic Juvenile Idiopathic Arthritis (SJIA)" Novartis. Protocol# CACZ885G2306, HSPPO# 15.0053, \$21,503.
- 2014 2016 Johnsrude C, <u>Sullivan JE</u>. "PVC Induced Adverse Cardiac Left ventricular Cardiac Remodeling in Children" Cardiac PACEs, HSPPO #14.0110, Unfunded.
- 2014 2016 Skjei K, Farber D, Puri V, <u>Sullivan JE</u>, Sims S, Johnson P. "A Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study of the Efficacy and Safety of Pregabalin as Adjunctive Therapy in Children 4-16 years of age with Partial Onset Seizures" Pfizer, Protocol#A0081041, HSPPO#14.0970, \$30,438.
- 2013 2016 O'Hagan AR, Morton RL, <u>Sullivan JE</u>. "An Ocular Safety Study of Ivacaftor-Treated Pediatric Patients 11 Years of Age or Younger with Cystic Fibrosis", Vertex Pharmaceutical Incorporated, Protocol VX12-770-115. HSPPO #13.0238, \$17,546.
- 2013 2016 Raj A, Condurache CT, Cheerva A, <u>Sullivan JE</u>. "Evaluation of Purified Poloxamer 188 In Children in Crisis (Epic): A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Multicenter Clinical Trial Of Anx-188 (Purified Poloxamer 188) Injection In Children With Sickle Cell Disease Experiencing Vasoocclusive Crisis", Adventrx Pharmaceuticals, Inc., Protocol ANX-188-01. Phase III, HSPPO#13.0300, \$115,827.
- **2013 2016** Johnsrude C, Sobczyk W, Leahy R, Kim E, <u>Sullivan JE</u>. "Catecholaminergic Polymorphic Ventricular Tachycardia Multicenter Data Collection". HSPPO#13.0971, Unfunded.

- 2013 2016 Goodin KM, Gowans GC, <u>Sullivan JE</u>, Condurache CT, Calvary M. "A Phase 3, Open-Label, Randomized, Multi-Center Study to Assess the Safety and Tolerability of an Induction, Titration, and Maintenance Dose Regimen of BMN 165 Self-Administered by Adults with Phenylketonuria Not Previously Treated with BMN 165", BioMarin Pharmaceuticals Inc., Protocol 165-301. Phase III, HSPPO#13.0311, \$88,890.
- 2013 2016 Wintergerst KA, <u>Sullivan JE</u>, Foster MB, Condurache CT. "A Phase III, Multicenter, Double-Blind, Randomized, Placebo and Metformin-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Sitagliptin in Pediatric Patients with Type 2 Diabetes Mellitus with Inadequate Glycemic Control", Merck Sharp & Dohme Corp., Protocol 083-01. Phase III, HSPPO #13.0287, \$8,800.
- 2013 2016 Wintergerst KA, Sullivan JE, Foster MB, Condurache CT. "A Phase III Multicenter, Double-Blind, Randomized, Placebo-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-0431A XR (a Fixed-Dose Combination Tablet of Sitagliptin and Extended-Release Metformin) in Pediatric Subjects with Type 2 Diabetes Mellitus with Inadequate Glycemic Control on Metformin Monotherapy", Merck Sharp & Dohme Corp., Protocol 289-00. Phase III, HSPPO #13.0186, \$22,301.
- 2012 2016 Berkenbosch JW, Condurache CT, <u>Sullivan JE</u>. "An Open-label, Multicenter Study of the Safety, Pharmacokinetics, and Efficacy of Buprenorphine Transdermal System (BTDS) in Children from 7 to 16 Years of Age, Inclusive, Who Require Continuous Opiod Analgesia for Moderate to Severe Pain." Purdue. Protocol BUP3031, Phase IIIB HSPPO #12.0192. \$42,966.
- **2012 2016** Raj A, <u>Sullivan JE</u>. "A Phase II Trial of Losartan to Reverse Sickle Nephropathy." Children's Hospital Medical Center. Phase II. HSPPO 12.0125. \$14.600.
- 2012 2016 Sullivan JE (PI), Condurache CT, Gupta S. "An Open-label, Single-arm Study to Assess the Safety and Tolerability of Cinacalcet HCI in Addition to Standard of Care in Pediatric Subjects Age 28 Day to <6 Years with Chronic Kidney Disease and Secondary Hyperparathyroidism Receiving Dialysis." Amgen. Protocol 20110100, Phase II, HSPPO #12.0067. \$14,539.
- **2012 2016** Lucas K, <u>Sullivan JE</u>, Cheerva AC, Raj A, "A Phase I Trial Combining Decitabine and Vaccine Therapy of Patients with Relapsed/Refractory Neuroblastoma and Sarcoma." Solving Kids Cancer. Phase I. HSPPO #12.0363. \$78,000.
- 2012 2016 Sullivan JE, Condurache CT, Berkenbosch JW. "A Randomized, Placebo Controlled, Multi-Center Study of the Efficacy, Pharmacokinetics (PK), and Pharmacodynamics (PD) of Intravenous (IV) Acetaminophen for the Treatment of Acute Pain in Pediatric Patients" Cadence. Protocol CPI-APA-353. Phase III. HSPPO #12.0228. \$228,000.
- Obi OA, Stewart D, Gravari E, Condurache CT, Sullivan JE, Radmacher P. "A randomized, double-blind, placebo-controlled, multicentre trial exploring the efficacy and safety of intra-nasal administration of FE 202767 in increasing milk production in maternal subjects with preterm delivery and inadequate milk production." Ferring Pharmaceuticals A/S, Protocol # 000050, Study closed prior to opening, \$2,513.
- Gupta S, <u>Sullivan JE</u>, Condurache CT, Shah S. "An Open-label, Single-dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Cinacalcet HCl in Pediatric Subjects Aged 28 Days to < 6 Years with Chronic Kidney Disease Receiving Dialysis" Amgen Inc. Protocol #20090005, HSPPO 15.0142, \$68,312.
- 2015 2016 Barnes G, <u>Sullivan JE</u>, Condurache CT, Sears L, Farber D, Skjei K. Cognitive AED Outcomes in Pediatric Localization Related Epilepsy (COPE). Patient Centered Outcomes Research Institute (PCORI). Protocol: N/A, HSPPO 15.0344, \$1,500.
- 2015 2016 Stewart DL, <u>Sullivan JE</u>, Condurache CT, Fisher H. "A Multicenter, Randomized, Open-Label, Controlled Trial to Assess the Safety and Tolerability of Lucinactant for Inhalation in Preterm Neonates" Discovery Laboratories, Inc. Protocol # 03-CL-1201, HSPPO # 15.0143, \$108,993.
- 2014 2016 Gupta S, <u>Sullivan JE</u>, Condurache CT, Shah S. "A Randomized, Open-label, Controlled Study to Assess the Efficacy and Safety of Cinacalcet HCl in Pediatric Subjects with Secondary Hyperparathyroidism and Chronic Kidney Disease Receiving Dialysis" Amgen Inc. Protocol# 20130356, HSPPO# 14.0553, \$10,448.
- 2014 2016 Jeffries A, Stutts J, Stephen T, <u>Sullivan JE</u>, Condurache CT. "A Multicentre, Randomized, Placebo-controlled, Double-blind Study of the Efficacy, Safety, and Pharmacokinetics of Lubiprostone in Paediatric Subjects Aged ≥ 6 Years to < 18 Years with Functional Constipation", Sucampo AG, Protocol# SAG/0211PFC-1131. HSPPO# 14.0007, \$73,924.

- 2014 2016 Lucas KG, Elster J, Cheerva A, Krishnadas DK, Raj A, Panigrahi A, Mullinax J, Huang M, Sullivan JE. A Phase I/Pilot II Trial Combining Decitabine and Vaccine Therapy for Patients with Relapsed or Refractory Pediatric High Grade Gliomas, Medulloblastomas, and CNS PNETs. HSPPO# 14.0885, \$50,000
- Raj A, Condurache CT, Lucas KG, <u>Sullivan JE</u>, Cheerva A, Panigrahi AR, Myers S, Ayyanar K, Mullinax J, Elster J. "A Phase 3, prospective, uncontrolled, multicenter study evaluating pharmacokinetics, efficacy, safety, and immunogenicity of BAX 855 (Pegylated full-length recombinant FVIII) in previously treated pediatric patients with severe hemophilia A. Baxter Healthcare Corporation/ Baxter Innovations GmbH. Protocol# 261202 HSPPO#14.0622, \$23,670.
- 2014 2015 Skjei K, Farber D, Puri V, <u>Sullivan JE</u>, Sims S, Johnson P. "A 12-Month Open-Label Study to Evaluate the Safety and Tolerability of Pregabalin as Adjunctive Therapy in Pediatric Subjects 1 Month to 16 Years of Age with Partial Onset Seizures and Pediatric and Adult Subjects 5 to 65 Years of Age with Primary Generalized Tonic-Clonic Seizures" Pfizer, Protocol#A0081106, HSPPO#14.0986, \$22,119.
- 2014 2015 Porter MB, Sullivan JE, Condurache CT, Berkenbosch JW. "A Prospective, Randomized, Multi-Center, Controlled, Open-Label Study to Evaluate the Safety of Kedbumin 25% Compared to Normal Saline Solution in the Treatment of Post-Surgical Hypovolemia in Pediatric Patients Undergoing Major Elective Surgery" Kedrion S.p.A. Protocol # KB058, HSPPO # 14.0022, \$75,132.
- 2014 2015 O'Hagan A, Morton R, Condurache CT, <u>Sullivan JE</u>. "A randomized, double blind placebo-controlled study to assess the safety, tolerability, pharmacokinetics, and preliminary pharmacodynamics of single and multiple ascending doses of QBW251 in healthy subjects and multiple doses in cystic fibrosis patients." Novartis Pharmaceuticals Corp., Protocol # QBW251, HSPPO # 14.0392 \$17,015.
- 2014 2015 Berkenbosch JW, <u>Sullivan JE</u>, Condurache CT. "A Phase I, Open-Label, Multicentre Study to Assess the Pharmacokinetics and Safety of Naloxegol in Paediatric Patients Ages ≥ 6 Months to < 18 Years Receiving Treatment with Opioids" AstraZeneca. Protocol # D3820C00016, HSPPO # 15.0234, \$8,190.
- 2014 2015 Panigrahi AR, Ayyanar K, Elster J, Lucas K, Cheerva A, Myers S, Mullinax J, Raj A, Sullivan JE, Condurache CT, "Study of Prophylaxis, ACtivity and Effectiveness (SPACE) in Hemophilia Patients Currently Treated with ADVATE or RIXUBIS" Baxter Healthcare Corporation. Protocol # 061302, HSPPO # 14.0976, \$8,127.
- 2014 Porter MB, Sullivan JE. Prevalence of Nasogastric Feeding Tube Use in US Pediatric Hospitals. American Society for Parenteral and Enteral Nutrition. HSPPO#14.0029. Unfunded.
- 2013 2015 Sullivan JE, Condurache CT, Smith MJ. "A Phase 1, Open Label, Single Dose Study to Investigate the Pharmacokinetics, Safety And Tolerability Of Dalbavancin In Hospitalized Children Aged 3 Months To 11 Years Receiving Standard Intravenous Anti-Infective Treatment For Bacterial Infections", Durata Therapeutics, Inc., Protocol DUR001-106. Phase I, HSPPO #13.0375, \$61,903.
- Raj A, Sullivan JE, Condurache CT, Panigrahi AR, Ayyanar K, Elster J, Lucas K, Cheerva A, Myers S, Mullinax J, Moffett P. "A Phase II, Multicenter, Randomized, Placebo-Controlled, Double-Blind, 12-Month Study to Assess Safety and Efficacy of SelG1 with or Without Hydroxyurea Therapy in Sickle Cell Disease Patients with Sickle Cell-Related Pain Crises", Selexys Pharmaceuticals Corp., Protocol SelG1-00005. Phase II, HSPPO #13.0598, \$8,524.
- 2013 2015 Condurache CT, Gupta S, <u>Sullivan JE</u>. "A Phase 3, Open-Label, Multicenter Study to Evaluate the Safety of Paricalcitol Capsules in Pediatric Subjects Ages 10 to 16 with Stage 5 Chronic Kidney Disease Receiving Peritoneal Dialysis", AbbVie, Protocol M11-612. Phase III, HSPPO #13.0575, \$141,561.
- 2013 2015 Sullivan JE, Condurache CT, Smith M, Espinosa CM. "A Phase I Study to Assess the Pharmacokinetics, Safety and Tolerability of a Single Dose of Ceftazidime-Avibactam (CAZ-AVI) in Children from 3 Months of Age to <18 Years Who Are Receiving Systemic Antibiotic Therapy for Suspected or Confirmed Infection", AstraZeneca, Protocol D4280C00014. Phase I, HSPPO #13.0243, \$36,464.
- 2013 2015 Gowans GC, Condurache CT, Sullivan JE, Goodin KM. "A Multicenter, Open-label BMN 110 US Expanded Access Program (BMN 110 US EAP) to Provide BMN 110 to Patients Diagnosed with MPS IVA", BioMarin Pharmaceutical Inc., Protocol 110-503. HSPPO #13.0210, \$64,545.
- 2013 2015 Goodin KM, Sullivan JE, Asamoah A, Gowans GC, Raj AB, Leahy RA, Condurache CT, Hersh JH, Keller BB, Cheerva AC.

"A Phase 4, Open-Label, Prospective Study in Patients with Pompe Disease to Evaluate the Efficacy and Safety of Alglucosidase Alfa Produced at the 4000 L Scale." Genzyme. Protocol AGLU09411. Phase 4, HSPPO #13.0088. \$75,013.

- 2012 2017 Sullivan JE, Condurache CT, Auden S, Overbey E. "A Phase IIb, Partially-Blinded, Randomized, Active Comparator-Controlled Study to Evaluate the Pharmacokinetics/Pharmacodynamics, Safety, and Tolerability of Aprepitant in Pediatric Patients for the Prevention of Post-Operative Nausea and Vomiting." Merck Sharp & Dohme Corp. Protocol MK0869219-00. Phase II. HSPPO #12.0552. \$15,300.
- 2012 2015 Schikler KN, Sullivan JE, Condurache CT, Schmidt KM. "A Multicenter, Open-Label study to assess the Pharmacokinetics, Safety, and Efficacy of Certolizumab Pegol in children and adolescents with moderately to severly active Polyarticular-Course Juvenile Idiopathic Arthritis" UCB BioSciences. Protocol RA0043. Phase III. HSPPO #12.0093. \$12,460.
- 2012 2015 Schmidt KM, <u>Sullivan JE</u>, Condurache CT, Schikler KN. "Improved Understanding of the Biology and Use of TNF Inhibition in Children with JIA." National Institute of Health (subcontract with Cincinnati Children's Hospital Medical Center). Protocol N/A. Phase N/A. HSPPO #12.0005. \$11,000.
- 2012 2015 Morton RL, Condurache CT, Sullivan JE, Eid N, O'Hagan A, Folz R, Hiestand D. "A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Repeat-Dose Study of KB001-A in Subjects with Cystic Fibrosis Infected with Pseudomonas Aeruginosa." KaloBios Pharmaceuticals Inc. Protocol KB001A-05. Phase II. HSPPO#12.0556, \$82,195.
- 2012 2014 Sullivan JE, Condurache, CT. "A Multicenter, 52 to 104 Week Extension Study to Evaluate the Long Term Growth and Development of Pediatric Hypertensive Patients 6 to 17 Years of Age Treated Previously with Aliskiren." Novartis. Protocol CSPP100A2365E2. Phase III. HSPPO #11.0640. \$6,950.
- 2012 2014 Craft L, Condurache CT, Sullivan JE. "A Randomized, Parallel Group, Double-Blind, Placebo-Controlled, Safety and Efficacy and Pharmacokinetic, Study of RP4917523 in Pediatric Patients with Fragile X Syndrome." F. Hoffman-La Roche LTD. Protocol NP28571. Phase II. HSPPO #12.0557, \$81,159.
- 2012 2014 Sullivan JE, Condurache CT, Jeffries A, Stutts J, Stephen T. "A Phase 2, Multicenter, 36-Week Study to Assess the Safety and Effectiveness of Daily Oral Administration of Dexlansoprazole Delayed-Release Capsules for Healing of Erosive Esophagitis and Maintenance of Healed Erosive Esophagitis and Relief of Heartburn in Adolescent Subjects Aged 12 to 17 Years." Takeda Global Research Inc (and Centre (Europe) Ltd). Protocol TAK-390MR_207. Phase II. HSPPO #12.0430. \$8,262.
- 2012 2014 Sullivan JE, Condurache CT, Berkenbosch JW, McDonald M, Calhoun A, Porter M. "A Phase III, Double-Blind, Randomized, Placebo-Controlled, Multi-Center, Dose-Titration Study to Assess the Efficacy, Safety, and Pharmacokinetics of Intravenous Conivaptan (Vaprisol®) in Pediatric Subjects with Euvolemic or Hypervolemic Hyponatremia." Astellas. Protocol ISN 087-CL-096. Phase III. HSPPO #11.0514. \$10,710.
- 2012 2017 Wintergerst K, Condurache CT, Foster M, Sullivan JE. "A Randomized, Multi-Center, Parallel Group, Single-Dose, Pharmacokinetics and Pharmacodynamics Study of Dapagliflozin in Children and Adolescents Aged 10 to 17 Years with Type 2 Diabetes Mellitus." BMS. Protocol MB102091. Phase I. HSPPO #12.0380. \$31,110.
- 2012 2014 Sullivan JE, Condurache CT, Woods C, Bryant K, Smith M, Espinosa C. "A Phase 2A, Multi-Center, Open-Label, Uncontrolled Study to Determine the Safety, Tolerability, and Pharmacodynamics of Fidaxomicin Oral Suspension or Tablets in Pediatric Subjects with Clostridium difficile-associated Diarrhea (CDAD)." Optimer Pharmaceuticals. Protocol OPT-80-206. Phase II. HSPPO #12.0276. \$44,650.
- 2012 2014 Wintergerst K, Condurache CT, Foster M, <u>Sullivan JE</u>. "A Randomized, Double-Blind, Placebo Controlled Trial to Assess Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Lixisenatide in Pediatric (10-17 years old) and Adult Patients with Type 2 Diabetes." Sanofi Aventis. Protocol PKD11475. Phase I. HSPPO #12.0277. \$28,648.
- 2010 2015 Sullivan JE (PI), Condurache CT. "A multicenter, double-blind, randomized, 52-week extension study to evaluate the long term safety, tolerability and efficacy of aliskiren compared to enalapril in pediatric hypertensive patients 6-17 years of age." Novartis Pharmaceuticals Corp. Protocol CSPP100A2365E1. Phase III. HSPPO #10.0404. \$23,400.
- 2010 2014 Sullivan JE (PI), Condurache CT. "A multicenter, randomized, double-blind, 8 week study to evaluate the dose response, efficacy and safety of aliskiren in pediatric hypertensive patients 6-17 years of age." Novartis Pharmaceuticals Corp. Protocol CSPP100A2365. Phase III. HSPPO #10.0306. \$35,220.

- 2010 2015 Schikler KN, Sullivan JE, Schmidt KM, Condurache CT. "A 6-month, Open-label, Safety Trial of Pregabalin in Adolescent Patients with Fibromyalgia." Pfizer. Protocol A0081231. Phase IV. HSPPO #10.0115. \$17,148.
- 2010 2015 Schikler KN, Schmidt KM, Sullivan JE, Condurache CT, Sears L, Calvery M. "A 15 Week, Randomized, Double Blind, Parallel-Group, Placebo-Controlled, Flexible-Dose, Safety and Efficacy Study of Pregabalin in Adolescents (12-16 Years Old) with Fibromyalgia." Pfizer. Protocol A0081180. Phase IV. HSPPO# 10.0116. \$47,740.
- 2010 2015 <u>Sullivan JE (PI)</u>, Condurache CT, Bryant KK. "An Open-Label, Multi-Center, Single Arm Study to Evaluate the Safety and Tolerability of Intravenous Zanamivir in the Treatment of Hospitalized Adult, Adolescent and Pediatric Subjects with Confirmed Influenza Infection." GlaxoSmithKline. Protocol NAI113678. Phase II. HSPPO# 10.0167. \$7,767.
- 2009 2014 Schikler KN, Sullivan JE, Condurache CT, Schmidt KM. "A 24 Week Randomized Double-Blind, Placebo Controlled Withdrawal Trial with a 16 Week Open Label Lead-In Phase, and 64 Week Open Label Follow-Up, to Evaluate the Efficacy and Safety of Tocilizumab in Patients with Active Polyarticular-Course Juvenile Idiopathic Arthritis." F. Hoffman-La Roche Ltd. Protocol WA19977A. Phase III. HSPPO# 09.0570. \$66,727.
- 2009 2015 Sullivan JE, Condurache CT, Gupta, S. "A Phase 3, Prospective, Randomized, Double-blind, Placebo-controlled Multicenter Study to Evaluate the Pharmacokinetics, Safety and Efficacy of Paricalcitol Capsules in Decreasing Serum Intact Parathyroid Hormone Levels in Pediatric Subjects Ages 10 to 16 years with Moderate to Severe Chronic Kidney Disease." Abbott Laboratories. Protocol M10-149. Phase III. HSPPO #10.0091. \$27,303.
- 2008 2014 Condurache CT, Sullivan JE, Gupta S. "A Multicenter, Double-Blind, Randomized Study Evaluating De Novo Weekly and Once Every 2 Week Darbepoetin alfa Dosing for the Correction of Anemia in Pediatric Subjects with Chronic Kidney Disease Receiving and Not Receiving Dialysis. Amgen, CRO: NAPRTCS. Protocol 20050256. Phase III. HSPPO #08.0440. \$17,532.
- 2008 2015 <u>Sullivan JE (PI)</u>, Condurache CT, Gowans G, Das BB, Raj AB, Asamoah A. "An Exploratory Study of the Safety and Efficacy of Immune Tolerance Induction (ITI) in Patients with Pompe Disease Who Have Previously Received Myozyme." Genzyme Corporation. Protocol #AGLU03707. Phase IV. HSPPO #09.0069. \$9,089.
- **2009 2017** Wintergerst KA, <u>Sullivan JE</u>, Berkenbosch JW, Montgomery VL. "Hyperglycemic control in critically ill children." Investigator Initiated QA. Protocol N/A. Phase N/A. HSPPO #09.0529. Unfunded.
- 2008 2017 Sullivan JE (PI), Bertolone S, Cheerva A, Condurache CT. "A Three Month Prospective, Open-Label Study of Therapy and Fragmin® (Dalteparin Sodium Injection) In Children with Malignancies and Venous Thromboembolism." Eisai Inc. Protocol FRAG-A001-201. Phase II. HSPPO #08.0607. \$25,575.
- Morton RL, Condurache CT, Sullivan JE, O'Hagan AR, Eid NS. "A Phase II, Randomized, Double Blind Placebo Controlled Study of Aerovanc for the Treatment of Persistent Methicillin Resistant Staphylococcus Aureus Lung Infection in Cystic Fibrosis Patients" Savara. Protocol # SAV005-02, HSPPO # 14.0104, \$10,935.
- 2011 2014 Wintergerst KA, <u>Sullivan JE</u>, Foster MB, Condurache CT, Kingery S, Adetokunbo, O. "A Comparative, Randomized, Open-Label, Multi-Center, Single Dose Pharmacokinetic, Pharmacodynamic and Safety Study of Alogliptin (12.5 mg and 25 mg) between Children, Adolescents, and Adults with Type 2 (Non-Insulin Dependent) Diabetes Mellitus." Takeda Global Research & Development Center, Inc. Protocol SYR-322_104. Phase I. HSPPO #10.0637. \$59,326.
- 2011 2014 Radmacher PG, Sullivan JE, Adamkin DH. "The Neonatal and Necrotizing Enterocolitis." National Institute of Health. Subcontract with Washington University School of Medicine. Protocol N/A. Phase N/A. HSPPO #11.0136. \$72,064 (yr 1); \$315,000 (yr 2); \$315,000 (yr 3).
- Morton RL, Eid NS, O'Hagan AR, Sullivan JE, Condurache CT. "A Phase 3, Rollover Study to Evaluate the Safety And Efficacy Of Long-Term Treatment With Lumacaftor In Combination With Ivacaftor In Subjects Aged 12 Years And Older With Cystic Fibrosis, Homozygous or Heterozygous For F508del-CFTR Mutation" Vertex Pharmaceuticals, Protocol # VX12-809-105, HSPPO #13.0644, \$6,131.
- 2013 2014 Espinosa C, Smith MJ, <u>Sullivan JE</u>, Condurache CT. "A Phase 1, Open-label, Multi-center Study to Determine the Pharmacokinetics and Safety of Solithromycin as Add-on Therapy in Adolescents with Suspected or Confirmed Bacterial Infection", Cempra Pharmaceuticals, Inc., Protocol CE01-119. Phase I, HSPPO #13.0601, \$7,144.
- **2013 2014** Espinosa CM, Condurache CT, Smith MJ, <u>Sullivan JE</u>. "Randomized, Parallel Dose, Phase 1/2 Safety and Pharmacokinetics Study of Inhaled Laninamivir Octanoate TwinCaps® Dry Powder Inhaler in Children with Naturally

Acquired Influenza A or B", Biota Scientific Management Pty Ltd., Protocol BTA51-350-203. Phase 1/2, HSPPO #13.0959, \$5,087.

- 2013 2014 Morton RL, Condurache CT, Sullivan JE, O'Hagan AR, Eid NS. "A Phase 2, Multicenter, Double-Blind, Placebo-Controlled, Multiple-Dose Study to Evaluate the Safety, Tolerability, Efficacy, Pharmacokinetics, and Pharmacodynamics of Lumacaftor Monotherapy, and Lumacaftor and Ivacaftor Combination Therapy in Subjects with Cystic Fibrosis, Homozygous or Heterozygous for the F508del-CFTR Mutation" Vertex Pharmaceuticals. Protocol # VX09-809-102, HSPPO #13.0444, \$10,651.
- 2013 2014 Raj A, Condurache CT, Lucas KG, <u>Sullivan JE</u>, Cheerva A, Panigrahi AR, Myers S, Ayyanar K, Mullinax J, Elster J. "A Phase 3, Double-Blind, Randomized, Efficacy and Safety Comparison of Prasugrel and Placebo in Pediatric Patients with Sickle Cell Disease" Eli Lilly and Company. Protocol # H7T-MC-TADO, HSPPO # 13.0439, \$12,839.
- Raj A, <u>Sullivan JE</u>, Condurache CT. "A Phase 2/3, Multi-Center, Open Label Study of Efficacy, Safety, and Pharmacokinetics of PEGylated Recombinant Factor VIII (BAX 855) Administered for Prophylaxis and Treatment of Bleeding in Previously Treated Patients with Severe Hemophilia A" Baxter Pharmaceuticals Protocol # 26201, HSPPO # 13.0436, \$8,782.
- 2013 2014 O'Hagan A, Sullivan JE, Condurache CT, Morton R, Eid N. "A Phase 3, Rollover Study to Evaluate the Safety and Efficacy of Long-term Treatment with Lumacaftor in Combination with Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Homozygous or Heterozygous for the F508del-CFTR Mutation", Vertex Pharmaceuticals Inc., Protocol VX12-809-105. Phase III, HSPPO #13.0644, \$6,131.
- 2013 2014 Raj A, Condurache CT, <u>Sullivan JE</u>. "A Phase 2/3, Multi-Center, Open Label Study of Efficacy, Safety, and Pharmacokinetics of PEGylated Recombinant Factor VIII (BAX 855) Administered for Prophylaxis and Treatment of Bleeding in Previously Treated Patients with Severe Hemophilia A", Baxter Healthcare Corporation, Protocol 261201. Phase 2/3, HSPPO #13.0436, \$10,206.
- OHagan AR, Condurache CT, Sullivan JE, Morton RL, Eid NS. "A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Lumacaftor in Combination with Ivacaftor in Subjects Aged 12." Vertex Pharmaceuticals Incorporated, Protocol VX12-809-103, HSPPO# 13.0257, \$6,171.
- 2012 2014 Craft L, Condurache CT, Sullivan JE, Calvary M. "A Randomized, Double-blind, 12-week, Parallel Group, Placebo-controlled Study of the Efficacy and Safety of RO4917523 in Patients with Fragile X Syndrome." Roche. Protocol NP27936. Phase II. HSPPO #12.0336. \$47,823.
- 2012 2014 Williams PG, Condurache CT, <u>Sullivan JE</u>, Calvery M, Sears L. "An Open-Label Extension Study of the Safety and Tolerability of Memantine in Pediatric Patients with Autism, Asperger's Disorder, or Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS) Previously Treated with Memantine." Forest. Protocol MEM-MD-69. Phase II. HSPPO #12.0339. \$59,924.
- 2012 2014 Williams PG, Condurache CT, <u>Sullivan JE.</u> "An Open-Label Study of the Safety and Tolerability of Memantine in Pediatric Patients with Autism, Asperger's Disorder, or Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS) Previously Treated with Memantine." Forest. Protocol MEM-MD-91. Phase II. HSPPO #12.0338. \$78,164.
- 2012 2014 Sullivan JE, Condurache CT, Jeffries A. Stutts, J. "A Phase 2, Open-label, Multicenter, 4-Week Study to Assess the Safety and Effectiveness of Daily Oral Administration of Dexlansoprazole Delayed-Release Capsules for Relief of Heartburn in Adolescent Subjects Aged 12 to 17 Years with Symptomatic Non-Erosive Gastroesophageal Reflux Disease." Takeda Global Research & Development Center Inc (and Centre (Europe) Ltd). Protocol TAK-390MR_206. Phase II. HSPPO #12.0426. \$8,262.
- 2011 2014 Goodin KM, <u>Sullivan JE</u>, Asamoah A, Gowans G, Hersh JH, Condurache CT. "A Phase 2, Open-Label Study to Evaluate the Safety, Tolerability, and Efficacy of Subcutaneous Dose Levels of rAvPAL-PEG Administered Daily in Subjects with Phenylketonuria." BioMarin Pharmaceutical Inc. Protocol PAL-004. Phase II. HSPPO #10.0546. \$41,905.
- 2010 2014 Sullivan JE (PI), Condurache CT, Bryant KK, Woods CR, Wiesenauer CA. "A Randomized, Double-blind, Multicenter Trial to Evaluate the Safety and Efficacy of Sequential (Intravenous, Oral) Moxifloxacin versus Comparator in pediatric Subjects with Complicated Intra-abdominal Infection." Bayer HealthCare Pharmaceuticals. Protocol BAY 12-8039/11643. Phase IIIa. HSPPO# 10.0374. \$8,977.
- 2010 2014 Sullivan JE (PI), Condurache CT. "A Comparative Single-Dose Pharmacokinetic and Safety Study of TAK-491 Between

- Infants, Children, and Adolescents with Hypertension and Healthy Adults." Takeda. Protocol TAK-491-109. Phase I. HSPPO# 10.0053. \$130,864.
- 2009 2014 Sullivan JE, Condurache CT, Berkenbosch JW. "Identification of New Mechanistic of Adverse Response to Acetaminophen." Subcontract ACH-NIH. Protocol N/A. Phase N/A. HSPPO #09.0558. \$3,000 (Yr1), \$12,632 (Yr 2), \$12,633 (Yr 3), \$25,995 (Yr 4).
- 2009 2014 <u>Sullivan JE (PI)</u>, Condurache CT, Bryant KK, Woods CR. "Safety, Tolerability and Pharmacokinetics of Single Dose Intravenous Moxifloxacin in Pediatric Patients." Bayer HealthCare Pharmaceuticals. Protocol BAY 12-8039/11826. Phase I. HSPPO# 09.0581. \$33,030.
- 2013 <u>Sullivan JE</u>. "ACCU-CHEK® Performa (No Code) Glucose Monitoring System with the ACCU-CHEK® Performa Test Strip Newborn/Neonate Hospital Evaluation." Roche, Protocol D01792-01-12-01. HSPPO #13.0115, \$15,677.
- 2013 <u>Sullivan JE</u>. "ACCU-CHEK Aviva (No Code) Glucose Monitoring System with the ACCU-CHEK Aviva Plus Test Strip Newborn/Neonate Hospital Evaluation." Roche, Protocol D01792-01-12-01. HSPPO #13.0114, \$15,662.
- 2012 2017 Raj A, Huang M, Mullinax J, Panigrahi AR, Cheerva A, McGowans K, <u>Sullivan JE.</u> An Open Label Study Evaluating the Safety and Efficacy of Long-Term Dosing of Romiplostim in Thrombocytopenic Pediatric Subjects with Immune (Idiopathic) Thrombocytopenia Purpura (ITP). Amgen Inc., Protocol# 20090340, HSPPO# 12.0498, \$117,971.
- 2012 2013 Berkenbosch JW, Condurache CT, <u>Sullivan JE</u>. "A Multicenter, Open-Label, Safety and Pharmacokinetic Study of Oral Codeine Sulfate Administration in Pediatric Subjects 2 years old through 17 years old with Post-Procedural Pain." Roxane Laboratories Inc. Protocol CODE-OS+T-(2-17)-SPK-1. Phase III. HSPPO #12.0454, \$12,505.
- 2012 2013 Berkenbosch JW, Condurache CT, <u>Sullivan JE</u>. "Open-Label Evaluation of the Pharmacokinetic Profile and Safety of Tapentadol Oral Solution for the Treatment of Postsurgical Pain in Children and Adolescents Aged from 6 to Less than 18 Years." Janssen Research & Development LLC. Protocol R331333-PAI-2005. Phase II. HSPPO #12.0508, \$7,689.
- 2012 2013 Wintergerst K, Foster M, Condurache CT, Sullivan JE. "Evaluation of the Pharmacokinetics of Saxagliptin, 5-Hydroxy Saxagliptin, and Metformin in Children and Adolescents Aged 10 to 17 Years with Type 2 Diabetes Mellitus Following Oral Administration of Saxagliptin and Metformin XR Fixed Dose Combination Tablet and Co-Administration of Saxagliptin and Glucophage® (Metformin) IR Tablets." BMS. Protocol CV181153. Phase I. HSPPO #12.0381, \$14,254.
- 2012 2013 Williams PG, Condurache CT, Sullivan JE. "A Double-Blind, Placebo-Controlled, Randomized Withdrawal Study of the Safety and Efficacy of Memantine in Pediatric Patients with Autism, Asperger's Disorder, or Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS) Previously Treated with Memantine." Forest. Protocol MEM-MD-68. Phase II. HSPPO #12.0337. \$20,476.
- 2012 2013 Schikler KN, <u>Sullivan JE</u>, Schmidt KM, Condurache CT. "A Multicenter, Double Blind, Randomized-Withdrawal Trial of Subcutaneous Golimumab, A Human Anti-TNFa Antibody, in Pediatric Subjects with Active Polyarticular Course Juvenile Idiopathic Arthritis (JIA) Despite Methotrexate Therapy." Centocor Research & Development, Inc. Protocol CNTO148JIA3001. Phase III. HSPPO #11.0109, \$25,124.
- 2011 2013 Cross KP, Berkenbosch J, <u>Sullivan JE</u>, Caperell K, Kim I, Lee G, Montgomery V, Owen E, Paul R, Stevenson M, McClain S. "Pilot Study of Magnesium Infusions for Moderate-to-Severe Asthma". HSPPO #11.0641.
- 2011 2013 Sullivan JE (PI), Berkenbosch JW, Condurache CT. "An Open-label, Non-randomized, Multicenter, Ascending Dose by Age, Single- and Multiple-dose Evaluation of the Effectiveness, Safety, and Tolerability of Oral Liquid Oxymorphone HCI Immediate-release Oral Liquid for Acute Postoperative Pain in Pediatric Subjects." Endo Pharmaceutical. Protocol EN3319-302. Phase III. HSPPO #10.0548, \$9,255.
- 2011 2013 <u>Sullivan JE</u> (PI), Bryant KK, Stewart, DL, Condurache CT. "Pharmacokinetics of a Single Dose of Ceftaroline fosamil in Children Ages Birth to Younger than 12 Years with Suspected or Confirmed Systemic Infection." Cerexa, Inc. Protocol P903-21. Phase I. HSPPO #11.0018, \$27,405.
- 2010 2013 Goodin KM, <u>Sullivan JE</u>, Asamoah A, Gowans GC, Hersh JH, Condurache CT. "An Exploratory Study of the Safety and Efficacy of Prophylactic Immunomodulatory Treatment in Myozyme-naïve CRIM(-) Patients with Infantile-Onset Pompe Disease. "Genzyme. Protocol AGLU03807. Phase IV. HSPPO #10.0545, \$111,306.
- 2010 2013 Condurache CT, Sullivan JE, Eid NS. "Effects of Educational Intervention on Long Term Outcomes of Hospitalized

- Children with Asthma." Passport Health Plan 955 (iHOP, Improving Health Outcomes Program). Protocol N/A. Phase N/A. HSPPO #11.0063. \$50,000.
- **2010 2013** Wintergerst KA, <u>Sullivan JE</u>, Foster MB, Condurache CT. "Pediatric Critical Illness Hyperglycemia and Glycemic Control Registry." Emory now transferred to Indiana University. Protocol N/A. Phase N/A. HSPPO #10.0556, \$1,762.
- 2010 2013 <u>Sullivan JE (PI)</u>, Berkenbosch JW, Condurache CT. "A Multi-Center, Randomized, Open-Label, Parallel, Active Comparator, Multiple Dose Trial to Determine the Efficacy, Safety, and Pharmacokinetics of Intravenous Ibuprofen in Pediatric Patients." Cumberland Pharmaceuticals, Inc. Protocol CPI-CL-012. Phase III. HSPPO #10.0174. \$28,103.
- **2010 2013** Montgomery VL, <u>Sullivan JE</u>, Condurache CT. "Influenza Vaccine Effectiveness in High-risk Children." PALISI Network. Protocol N/A. Phase N/A. HSPPO #10.0561. \$99,900.
- 2009 2013 Schikler KN, <u>Sullivan JE</u>, Schmidt KM, Condurache CT. "An open-label extension study of canakinumab (ACZ885) in patients with Systemic Juvenile Idiopathic Arthritis (SJIA) and active systemic manifestations." Novartis Pharmaceuticals. Protocol CACZ885G2301E1. Phase III. HSPPO# 09.0393. \$122,408.
- 2009 2013 Montgomery VL, <u>Sullivan JE</u>. "National Association of Children's Hospitals and Related Institutions (NACHRI) Ventilator Associated Pneumonia Registry (VAPOR)." NACHRI. Protocol N/A. HSPPO# 09.0109. Unfunded.
- 2009 2013 <u>Sullivan JE (PI)</u>, Auden S, Berkenbosch J, Condurache CT. "A Multicenter, 2-Part Study to Evaluate the Pharmacokinetics Safety and Tolerability of Aprepitant in Pediatric Patients Undergoing Surgery." Merck & Co. Inc. Protocol #148-00. Phase I. HSPPO# 09.0124. \$66,965.
- 2009 2013 Schikler KN, Sullivan JE, Condurache CT, Schmidt KM. "A Phase 4, 6-Week, Randomized, Double-blind, Multicenter, Active-controlled Trial to Evaluate the Effects of Celecoxib (Celebrex®) or Naproxen on Blood Pressure in Pediatric Subjects with Juvenile Idiopathic Arthritis." Pfizer. Protocol A3191342. Phase IV. HSPPO# 09.0417. \$19,952.
- **2008 2013** Williams PG, <u>Sullivan JE</u>, Sears LL, Casanova MF. "Double-Blind, Placebo-Controlled, Crossover Study of Glutathione in Children with Autism and Severe Behavior." Cumberland Pharmaceuticals. HSPPO #08.0220. Unfunded.
- 2008 2013 Williams PG, <u>Sullivan JE</u>, Sears LL, Casanova MF, Crespo F, Calhoun A. "Double-Blind, Placebo-Controlled, Crossover Study of Glutathione Vitamin C and Cysteine in Children with Autism and Severe Behavior Problems." Children's Hospital Foundation. HSPPO #08.0220. \$284,999.
- 2012 2012 Stewart DL, <u>Sullivan JE</u>, Condurache CT, Berkenbosch JW, Roberts JL, Singh T, "A Phase II/III, Open-Label, Multicenter, Safety, and Efficacy Study of Dexmedetomidine in Preterm Subjects Ages > 28 Weeks to < 36 Weeks Gestational Age." Hospira. Protocol DE 11-06. Phase II/III. HSPPO 12.0064, \$29,143.
- 2012 2012 Wintergerst KA, Foster M, Condurache CT, <u>Sullivan JE</u>. "A Trial Investigating the Efficacy and Safety of Insulin Degludec in Children and adolescents with Type 1 Diabetes Mellitus." Novo Nordisk. Protocol NN1250-3561. Phase IIIb. HSPPO #12.0065, \$6,131.
- 2012 <u>Sullivan JE (PI)</u>. "A Phase 1, Open-label, Multi-center, Two-part, Single-dose, Parallel-design, Safety, Tolerance, and Pharmacokinetic Study of Orally and Intravenously Administered TR-701 FA in 12 to 17 Year Old Adolescent Patients. Trius Therapeutics, Inc. Protocol TR701-111. Phase I. HSPPO #11.0383, \$1,690. (Cancelled per sponsor).
- 2011 2012 Sullivan JE (PI), Condurache CT, Jeffries AM, Calhoun AW, Owen EB. "A Multicenter, Open Label, Ascending 7 Day-repeated Dose Study to Investigate Efficacy, Safety and Pharmacokinetics of Nepadutant in Infants with Feeding Intolerance." Menarini Richerhe S.p.A. Protocol NIC-04. Phase IIa. HSPPO #11.0348, \$48,614.
- 2011 2012 Sullivan JE (PI), Condurache CT, Cheerva AC, Bryant KK, Woods CR. "A Prospective, Randomized Trial Comparing the Safety, Tolerability, and Efficacy of Voriconazole and Anidulafungin in Combination to that of Voriconazole Alone When Used for Primary Therapy of Invasive Aspergillosis in Pediatric Subjects Aged 2 to 17 Years." Pfizer. Protocol A1501095. Phase III. HSPPO #10.0633. \$2,505.
- Morton RL, Sullivan JE, Eid NS, Condurache CT. "A Phase 3, Open-label, Randomized Trial to Evaluate the Safety and Efficacy of MP-376 Inhalation Solution (Aeroquin™) versus Tobramycin Inhalation Solution (TIS) in Stable Cystic Fibrosis Patients." Mpex Pharmaceuticals. Protocol MPEX-209. Phase III. HSPPO #11.0180. \$9,286.
- 2011 2012 Schikler KN, Sullivan JE, Schmidt KM, Condurache CT. "A Multicenter, Open-label, 52-week Extension Study to Evaluate the Safety and Efficacy of Milnacipran in Pediatric Patients with Primary Fibromyalgia." Forest Research Institute, Inc. Protocol MLN-MD-29. Phase II. HSPPO #11.0299. \$15,780.

- 2011 2012 Schikler KN, <u>Sullivan JE</u>, Schmidt KM, Condurache CT. "A Multicenter, randomized, Double-blind, Placebo-controlled Withdrawal Study to Evaluate the Safety, Tolerability, and Efficacy of Milnacipran in Pediatric Patients with Primary Fibromyalgia." Forest Research Institute, Inc. Protocol MLN-MD-14. Phase II. HSPPO #11.0298. \$48,045.
- Morton RL, Sullivan JE, Eid NS, Condurache CT. "A Phase 3, Multi-center, Multinational, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of MP-376 (Levofloxacin Inhalation Solution; Aeroquin™) in Stable Cystic Fibrosis Patients." Mpex Pharmaceuticals. Protocol MPEX-207. Phase III. HSPPO #11.0085. \$28,179.
- 2011 –2012 Sullivan JE (PI), Condurache CT, Bryant KK, Woods CR. "A Pharmacokinetic/Pharmacodynamic and Safety Evaluation of Investigational Intravenous Peramivir in Children with Influenza Disease (CASG 117)." National Institutes of Allergy and Infection Disease. BioCryst Pharmaceuticals, Inc. DMID Protocol 09-0064. BioCryst Protocol BCX 1812-205. Phase I/II. HSPPO #10.0171. \$3,000.
- **2011 2012** Wintergerst KA, <u>Sullivan JE</u>, Condurache CT. "DEFEND-2: Durable-Response Therapy Evaluation for Early- or New-Onset Type 1 Diabetes." Tolerx. Protocol TRX4 DM 018 US 10. HSPPO 11.0084. \$5,700.
- 2011 2012 Williams PG, <u>Sullivan JE</u>, Condurache CT. "Safety and Efficacy of Aripiprazole in the Long-term Maintenance Treatment of Pediatric Patients with Irritability Associated with Autistic Disorder." Bristol-Myers Squibb R&D. Protocol CN138603. Phase III. HSPPO #11.0235. \$1,176.
- 2011 2012 <u>Sullivan JE (PI)</u>, Condurache CT, Jeffries AM. "A Pharmacokinetic, Pharmacodynamic and Safety Study of Single and Multiple Doses of Rabeprazole in Pediatric Subjects with GERD 1 to 11 Months Old, Inclusive." Johnson & Johnson Pharmaceutical R&D. Protocol RABGRD1003. Phase I. HSPPO #11.0386. \$9,765.
- 2011 2012 <u>Sullivan JE (PI)</u>, Berkenbosch JW, Condurache CT. "Multiple-Dose Study to Evaluate the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of Apixaban in Pediatric Subjects with an Indwelling Central Venous Catheter." Bristol Myers Squibb. Protocol CV185079. Phase I. HSPPO #10.0448 \$9,135.
- 2011 2012 <u>Sullivan JE (PI)</u>. "A Multi-center, Open-label, Study of the Pharmacokinetics and Safety of Intravenous Ibuprofen Administered over 10 Minutes in Pediatric Subjects Under Two Years or Age. Cumberland Pharmaceuticals. Protocol CPI-CL-017. Phase I. HSSPO #11-0506. \$1,436.
- Sullivan JE (PI). "A Phase 1, Randomized, Open-label, Parallel Design, Multicenter Study to Evaluate the Pharmacokinetics and Safety of Dexlansoprazole Delayed Release Capsules in Pediatric Subjects Ages 1 to 11 Years Old with Symptomatic Gastroesophageal Reflux Disease." Takeda Global Research & Development Center, Inc. Protocol T-P107-174. Phase I. HSPPO N/A. \$8,190.
- 2011 2012 Sullivan JE (PI). "An Open-label Study to Characterize the Pharmacokinetics and Safety of Oxycodone Hydrochloride q12h Controlled-Release (ORF) Tablets in Pediatric Patients Aged 6 to 16 Years Inclusive, Who Require Opioid Analgesia." Purdue Pharma L.P. Protocol OTR1020. Phase I. HSPPO #11.0199. \$1,352.
- 2011 2012 Berkenbosch JW, <u>Sullivan JE</u>. "A Multicenter, Inpatient, Open-label Study to Characterize the Pharmacokinetics, Safety, and Efficacy of Intravenous Dosing of Buprenorphine in Pediatric Patients Aged from Birth to 6 Years of Age (inclusive) Who Require Opioid Analgesia for Acute Moderate to Severe Pain." Purdue Pharma L.P. Protocol BUP3030. Phase III. HSPPO #11.0438. \$1,397.
- 2010 2012 Sullivan JE (PI), Stewart DL, Stutts JT, Jeffries AM, Condurache CT. "A Pharmacokinetic, Pharmacodynamic and Short-term Safety Study of Single and Multiple Day Doses of Rabeprazole Sodium in Neonates and Pre-term Infants with a Corrected Age of Less than 44 Weeks with a Diagnosis of GERD." Johnson and Johnson. Protocol RABGRD1005. Phase I. HSPPO #10.0230. \$10,196.
- 2010 2012 Sullivan JE (PI), Bryant KK, Condurache CT. "An Open Label, Prospective, Pharmacokinetic/Pharmacodynamic and Safety Evaluation of Intravenous Oseltamivir (Tamiflu®) in the Treatment of Infants Less Than One Year of Age with Influenza Infection." Hoffman-La Roche. Protocol NP25138. Phase Ib. HSPPO #10.0094. \$7,709.
- 2010 2012 <u>Sullivan JE (PI)</u>, Bryant KK, Condurache CT. "An Open Label, Prospective, Pharmacokinetic/Pharmacodynamic and Safety Evaluation of Intravenous Oseltamivir (Tamiflu®) in the Treatment of Children 1 to 12 Years of Age with Influenza Infection." Hoffman-La Roche. Protocol NP25139. Phase Ib. HSPPO #10.0024. \$8,525.
- 2010 2012 Wintergerst KA, Sullivan JE, Condurache CT, Foster MB. "Liraglutide: A Randomized, Double-blind, Placebo

Controlled Trial to Assess Safety/Tolerability, PK & PD of Liraglutide in Pediatric (10-17 years old) and Adult Subjects with Type 2 Diabetes." Novo Nordisk. Protocol NN2211-1800. Phase I. HSPPO# 10.0134. \$35,970.

- 2010 2012 Stewart DL, Sullivan JE, Condurache CT, Berkenbosch JW. "A Phase II/III, Open-Label, Multicenter, Safety, Efficacy and Pharmacokinetic Study of Dexmedetomidine in Neonates Ages ≥ 28 Weeks to ≤ 44 Weeks Gestational Age." Hospira. Protocol DEX-09-08. Phase II/III. HSPPO #10.0550. \$14,321.
- 2010 2012 Berkenbosch JW, <u>Sullivan JE</u>, Montgomery VL, Condurache CT. "A Phase III, Randomized, Double-Blind, Dose-Controlled, Multicenter, Study Evaluating the Safety and Efficacy of Dexmedetomidine in Intubated and Mechanically Ventilated Pediatric Intensive Care Unit Subjects." Hospira. Protocol DEX-08-05. Phase III. HSPPO# 09.0586. \$52,599.
- 2010 –2012 <u>Sullivan JE (PI)</u>, Condurache CT, Shoemaker LR, McKenney DW. "Methodological Improvement in measuring Efficacy Outcome in Antihypertensive Trials in Children." NIH (subcontract with Case Western Reserve University School of Medicine). Protocol N/A. Phase I. HSPPO #10.0114. \$5,000.
- 2010 2012 <u>Sullivan JE (PI)</u>, Condurache CT, Shoemaker LR, McKenney DW. "Effect of Body Mass Index (BMI) on Exposure-Response Relationships to Lisinopril in Children." NIH (subcontract with Case Western Reserve University School of Medicine). Protocol N/A. Phase N/A. HSPPO #10.0166. \$5,131.
- 2010 2011 Sullivan JE (PI). "Analytical Performance Evaluation of the cobas b 123 POC system Bilirubin parameter using Neonatal blood." Roche Diagnostics. Protocol CIM RD001142. Phase N/A. HSPPO #10.0469. \$43,816.
- 2010 2011 Sullivan JE (PI), Stewart DL. "ACCU-CHEK® Inform II Glucose Meter Evaluation using Freedom II 7mm (ACCU-CHEK Performa) Test Strips Neonate Blood CLIA Waiver Study." Roche Diagnostics. Protocol D8026-10-01. Phase N/A. HSPPO #10.0273. \$67,917.
- 2010 <u>Sullivan JE (PI)</u>. "Welch Allyn Blood Pressure Cuff Functional Equivalence Study in Neonates and Infants." Welch Allyn. Protocol FPBC002. Phase N/A. HSPPO #10.0275. \$26,775.
- 2009 2012 Schikler KN, <u>Sullivan JE</u>, Schmidt KM, Condurache CT. "A randomized, double-blind, placebo controlled, withdrawal study of flare prevention of canakinumab (ACZ885) in patients with Systemic Juvenile Idiopathic Arthritis (SJIA) and active systemic manifestations." Novartis Pharmaceuticals. Protocol CACZ885G2301. Phase III. HSPPO# 09.0394. \$17,123.
- 2009 2012 Sullivan JE (PI), Condurache CT, Jeffries AM, Stutts JT, Stephen TC, Dillard RP, Morton RL. "A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Withdrawal Study to Evaluate the Safety and Efficacy of Delayed-Release Rabeprazole in 1- to 11-Month-Old Pediatric Subjects with Symptomatic/Erosive Gastroesophageal Reflux Disease (GERD)." Johnson and Johnson. Protocol RAB-GRD-3004. Phase III. HSPPO# 09.0582. \$73,282.
- 2009 2012 Sullivan JE (PI), Dillard R, Jeffries A, Stephen T, Stutts J, Condurache CT. "A Multi-Center, Double-Blind, Parallel-Group Study to Evaluate Short-Term Safety and Efficacy and Long-term Maintenance of Two Dose Levels of Rabeprazole Sodium Delayed-Release Pediatric Bead Formulation in 1- to 11-Year-Old Pediatric Subjects with Endoscopically Proven GERD." Johnson and Johnson. Protocol #RABGRD3003. Phase III. HSPPO #09.0409. \$63,130.
- 2009 2012 Schickler KN, Sullivan JE, Schmidt KM, Condurache CT. "A randomized, double-blind, placebo controlled, single dose study to assess the initial efficacy of canakinumab (ACZ885) with respect to the adapted ACR Pediatric 30 criteria in patients with Systemic Juvenile Idiopathic Arthritis (SJIA) and active systemic manifestations." Novartis Pharmaceuticals. Protocol CACZ885G2305. Phase III. HSPPO# 09.0375. \$14,066.
- 2009 2012 <u>Sullivan JE (PI)</u>, Condurache CT, Balasa VV, Linder MW. "Warfarin Pharmacogenetics in Pediatric Patients: Development and Testing of a Pharmacogenetic-Based Dosing Algorithm Phase I." NIH--subcontract with Children's Hospital of Milwaukee. Protocol N/A. Phase N/A. HSPPO# 09.0584. \$4,550.
- 2008 2012 Wintergerst K, Condurache CT, Foster M, Sullivan JE. "A Phase III, 3-Arm, Randomized, Double-Blind, Placebocontrolled, Multicenter Study, to Investigate the Impact of Diamyd® on the Progression of Diabetes in Patients Newly Diagnosed with Type 1 Diabetes Mellitus." Diamyd Therapeutics AB. Protocol # D/P3/07/5. Phase III. HSSPO # 08.0503. \$551,427.
- 2008 2012 <u>Sullivan JE (PI)</u>, Berkenbosch J, Condurache TC, Stewart DL. "Pilot Study: Codeine and Morphine Pharmacokinetics, Pharmacogenetics & Pharmacodynamics in Infants & Children (Group I-Infants with Hydrocephalus; Group II-EVD)." PPRU. HSPPO # 08.0015. Unfunded.

- 2008 2012 Schikler K, Condurache T, Schmidt KM, Sullivan JE. "Compassionate Use Study of Adalimumab in Children 2 to <4 Years Old or Age 4 and Above Weighing Less than 15kg with Active Juvenile Idiopathic Arthritis (JIA)." Abbott Laboratories. Protocol #M10-444. Phase IIIb. HSPPO# 09.0134. \$4,850.
- 2008 2012 Stewart D, Bryant KA, Condurache CT, Sullivan JE, Schumacher E, Devlin-Phinney LA, Singh T, Schuschke LA, Bibb KW. "Fluconazole Prophylaxis for the prevention of Candidiasis in Infants <750 Grams Birth Weight." Subcontract with DCRI (NICHD). Protocol NICHD PPRU. Phase III. HSSPO # 08.0429. \$1,414.
- 2008 2012 Stevenson M, Sullivan JE, Condurache CT. "07-0037 Prospective Multi-Center Study of Bronchiolitis Admissions: Etiology & Disposition (MARC-30)." Massachusetts General Hospital. Protocol 07-0037 MARC-30. HSSPO # 08.0454. \$9,387.
- 2007 –2012 Stewart DL, Sullivan JE, Berkenbosch J, Condurache CT. "Optimizing Pain Treatment in Pre-Term Neonates." NICHD. Children's National Medical Center. Protocol #5 R01 HD048689-03. Phase II. HSPPO # 07.0113. \$28,412.
- **2009 2011** Montgomery VL, <u>Sullivan JE</u>, Condurache CT. "Novel Influenza A (H1N1) Surveillance Registry." NHLBI/Boston Children's. Protocol N/A. Phase N/A. PALISI Network. HSPPO# 09.0585. \$3,280.
- 2009 2011 Sullivan JE (PI), Stephen TC, Stutts JT, Dillard RP, Jeffries AM, Condurache CT "A Randomized, Double-blind, Parallel-group Study to Assess the Safety and Efficacy of Asacol® (1.2 to 4.8g/day) 400mg Delayed-release Tablets Given Twice Daily for 26 Weeks to Children and Adolescents for the Maintenance of Remission of Ulcerative Colitis." Procter & Gamble Pharmaceuticals. Protocol 2008085. Phase III. HSPPO# 09.0415. \$22,993.
- 2009 2011 Sullivan JE (PI), Condurache CT, Berkenbosch JW, Raj AB. "An Open-Label Safety and Tolerability Study of Immediate-Release and Extended-Release Oxymorphone in Opioid-Tolerant Pediatric Subjects with Chronic Pain." ENDO Pharmaceuticals. Protocol EN3202-036. Phase III. HSPPO# 09.0210. \$14,450.
- 2009 2011 Sullivan JE (PI), Condurache CT, Stewart DL. "Freedom II 7 mm (ACCU-Chek® Performa) Glucose Monitoring System Newborn/Neonate Hospital Evaluation." Roche Diagnostics. Protocol D8026-09-19. Phase N/A. HSPPO# 09.0603. \$67,918.
- 2008 2011 Sullivan JE (PI), Jeffries A, Stutts J, Dillard R, Stephen T, Condurache CT. "A Randomized, Double-blind, Parallel-Group Study to Assess the Safety and Efficacy of Asacol® (1.2 to 4.8 g/day) Administered as 400 mg Delayed-Release Tablets Given Every 12 Hours for 6 Weeks to Children and Adolescents with Mildly-to-Moderately Active Ulcerative Colitis." Procter & Gamble, Inc. Protocol #2007017. HSPPO #08.0193. \$12,904.
- 2008 2011 Sullivan JE (PI), Berkenbosch JW, Montgomery VL, Calhoun AW, Gupta M, Condurache CT. "A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Determine the Pharmacodynamics of Sodium Nitroprusside During Prolonged Infusion in Pediatric Subjects." DCRI. Protocol NICHD-2003-09-LT. Phase II. HSSPO #08.0367. \$53,000.
- 2008 2011 Sullivan JE (PI), Condurache CT, McKenney D, Muchant DG, Shoemaker LR. "An 8 day open-label, multiple-dose, multi-center study to evaluate the safety/tolerability and pharmacokinetics of aliskiren in hypertensive pediatric and adolescent patients 6-17 years of age." Novartis. Protocol CSSP100A2256. Phase II. HSPPO # 08.0646. \$1,578.
- 2009 2010 Morton RL, <u>Sullivan JE</u>, Condurache CT, Eid NS. "An Open-Label Study to Evaluate the Single-Dose Pharmacokinetics and Safety of Doripenem in Pediatric Subjects 6 to 17 Years of Age, Inclusive, With Cystic Fibrosis." Johnson and Johnson R&D. Protocol DORI-PED-1001. Phase I. HSPPO# 09.0482. \$7,650.
- 2009 2010 Sullivan JE (PI), Condurache CT, Bryant KK, Woods CR. "An Open-Label Study to Evaluate the Single-Dose Pharmacokinetics and Safety of Ceftobiprole in Pediatric Subjects ≥3 Months to <18 Years of Age Undergoing Treatment with Systemic Antibiotics." Johnson and Johnson R&D. Protocol 30982081CSI1006. Phase I. HSPPO# 09.0483. \$1,578.
- 2009 2010 Sullivan JE (PI), Condurache CT, Woods CR. "A Phase 3, Multicenter, Randomized, and Double-blind Study to Evaluate the Safety of Tigecycline versus a Ceftriaxone Regimen in the Treatment of Complicated Intra-abdominal Infections and Community-acquired Pneumonia in Pediatric Subjects Ages 8 to 1 7 Years Old." Wyeth. Protocol 3074K4-3340-WW. Phase III. HSPPO #09.0372. \$5,979.
- **2009 2010** Sullivan JE (PI), Condurache CT, Woods CR. "A Phase 3, Multicenter, Randomized, Double-blind Study to Evaluate the Safety and Efficacy of Tigecycline versus Clindamycin for the Treatment of Complicated Skin and Skin Structure

Infections, including those due to MRSA, in Pediatric Subjects Ages 8 to 17 Years Old." Wyeth. Protocol 3074K4-3339-WW. Phase III. HSPPO #09.0373. \$5,979.

- 2009 2010 Morton RL, <u>Sullivan JE</u>, Condurache CT, Eid NS. "A Phase 1B, multi-center, open label study to evaluate the safety, tolerability and pharmacokinetics of MP-376 inhalation solution given daily for 14 days to stable pediatric cystic fibrosis patients." Mpex Pharmaceuticals. Protocol MPEX-206. Phase Ib. HSPPO# 09.0182. \$15,641.
- 2009 2010 Sullivan JE (PI), Berkenbosch JW, Calhoun AW, Stewart DL. "NIBP System Efficacy by Comparison with Intra-arterial Measurement in the Infant/Neonate Population." Welch Allyn. Protocol# Mod G 058P/20088121/REV E. Phase N/A. HSPPO# 09.0293. \$10,925.
- 2009 2010 Sullivan JE (PI), Condurache CT, Bryant KK, Cheerva AC. "An open-label, intravenous to oral switch, multiple dose study to evaluate the pharmacokinetics, safety and tolerability of voriconazole in immunocompromised children aged 2 to <12 years who are at high risk for systemic fungal infection." Pfizer. Protocol#: A1501088. Phase II. HSPPO# 09.0215. \$9,405.
- 2009 2010 Sullivan JE (PI), Condurache CT, Berkenbosch JW, Stewart DL. "An Open-Label, Study to Evaluate the Single-Dose Pharmacokinetics, Safety and Tolerability of Doripenem in Infants (Term and Preterm), Less Than 12 Weeks Chronological Age." Johnson and Johnson R&D. Protocol DORI-PED-1003. Phase I. HSPPO# 09.0516. \$8,190.
- 2008 2010 Sullivan JE (PI), Berkenbosch JW, Condurache CT. "PK and PD of Terbutaline given as a continuous IV infusion in severe status asthmaticus." Wayne State. HSPPO #08.0407. Unfunded.
- 2008 2010 <u>Sullivan JE (PI)</u>, Berkenbosch JW, Condurache CT. "Measurement of Nitrotyrosine Adducts and Cytokines in Acetaminophen Overdose Patients." Arkansas Children's Hospital. HSPPO #08.0412. \$20,430.
- 2008 2010 Sullivan JE (PI), Dillard R, Jeffries A, Stephen T, Stutts J, Condurache CT. "A Pharmacokinetic and Safety Study of Single and Multiple Doses of Rabeprazole in Pediatric Subjects with GERD 1 to 11 Years Old, Inclusive." Johnson & Johnson. Protocol RABGRD1002. Phase I. HSPPO # 08.0363. \$25,166.
- **2008 2010** Morton R, Condurache CT, Eid N, <u>Sullivan JE</u>. "The use of formula fortified with docosahexaenoic acid (DHA) in infants with cystic fibrosis (CF)." University of Massachusetts. HSPPO# 09.0020. \$4,000.
- 2007 2010 <u>Sullivan JE (PI)</u>, Stewart DL, Bryant KA, Myers AB, Condurache CT. "Antimicrobial Pharmacokinetics in High Risk Infants." Duke University. PPRU #10824. HSPPO #657.06. Unfunded.
- 2007 2010 Sullivan JE (PI), Austin E, Recto MRO, Mascio C, Myers AB, Condurache CT. (CLARINET) "International Randomized Study Evaluating the Efficacy and Safety of Clopidogrel 0.2mg/kg Once Daily Versus Placebo in Neonates and Infants/Toddlers with Cyanotic Congenital Heart Disease Palliated with a Systemic-to-Pulmonary Artery Shunt (e.g. Modified Blalock Taussing Shunt)." Sanofi-Aventis. Protocol EFC5314: Phase III. HSPPO #052.07. \$90,453.
- 2007 2010 Woods C, <u>Sullivan JE</u>, Condurache TC. "A Multi-Center, Open-Label, Ascending Multiple-Dose Study to Assess the Pharmacokinetics, Safety, and Tolerability of Tigecycline in Patients 8 to 11 Years of Age with Selected Serious Infections." Wyeth Pharmaceuticals, Inc. Protocol #3074K4. Phase II. HSPPO #07.0122. \$7,315.
- 2008 2009 Sullivan JE (PI), Condurache CT, Stevenson M, Warkentine F. "The INcreased Flow Utilizing Subcutaneously-Enabled Pediatric Rehydration II (INFUSE-Pediatric Rehydration II) Study: Subcutaneous Rehydration with Recombinant Human Hyaluronidase (hylenex) compared to Intravenous Rehydration in Infants and Young Children with Mild to Moderate Dehydration." Baxter Healthcare Corp. Protocol HZ2-08-03. HSSPO # 08.0573. \$14,389.
- 2008 2009 <u>Sullivan JE (PI)</u>, Berkenbosch J, Condurache TC, Stewart DL. "Pilot St. Codeine and Morphine Pharmacokinetics, Pharmacogenetics & Pharmacodynamics in Infants & Children (Group I-Infants with Hydrocephalus; Group II-EVD)." Children's Hospital Foundation. HSPPO #08.0015. \$13,558.
- 2008 2009 <u>Sullivan JE (PI)</u>, Condurache TC. "Pilot Study to Evaluate the Oral Absorption, Safety and Tolerability of Nepadutant Administered as Single Oral Doses to Infants with Colic." PPRU. Menarini Ricerche S.P. A. HSPPO # 08.0083. \$9,400.
- 2008 2009 Morton R, Condurache CT, Eid N, <u>Sullivan JE</u>. "A double-blind, randomized, multicenter, placebo-controlled crossover study to assess the efficacy and safety of Creon® 12,000 unit capsule in subjects 7 11 years old with pancreatic exocrine insufficiency due to cystic fibrosis." Solvay Pharmaceuticals. Protocol S245.3.127. Phase III. HSPPO #08.271. \$47,411.
- 2008 2009 Sullivan JE (PI), Condurache CT, Woods C. "Pharmacokinetics of a Single-Dose of Ceftaroline in Subjects 12 to 17

Years of Age Receiving Empiric Parenteral Antibiotic Therapy for Suspected Infections." Cerexa Pharmaceuticals, Inc. Protocol P903-15. HSPPO # 08.0160. \$31,605.

- 2008 2009 Sullivan JE (PI), Condurache CT. "A Single-dose, Open-label, Multi-center Study Evaluating the Pharmacokinetics of Doxylamine Succinate in Children Ages 2 to <18 Years." Proctor & Gamble Company. Protocol #2008014. Phase I. HSPPO# 09.0070. \$15,303.
- 2008 2009 <u>Sullivan JE (PI)</u>, Condurache CT, Morton R. "A Multicenter, Open-Label, Single Dose Study to Evaluate the Safety, Tolerability, and Plasma Concentration Profiles of MK-0633 in Asthmatic Children Aged 6 to Less Than 12 Years." Merck. Protocol MK-0633. Phase I. HSSPO #08.0567. \$5,000.
- 2008 2009 Morton R, Condurache CT, Eid N, <u>Sullivan JE</u>. "A Phase 2, Multi-Center, Randomized, Double-blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability and Efficacy of Three Dosage regimens of MP-376 Solution for Inhalation Given for 28 days to Stable Cystic Fibrosis Patients." MPEX Pharmaceuticals. Protocol MP-204. HSPPO # 08.0238. \$10,092.
- 2008 2009 Sullivan JE (PI), Condurache CT, Woods C. "Phase I, Open-Label, Single-Dose Study to Investigate the Pharmacokinetics, Safety and tolerability of Dalbavancin in Hospitalized Adolescents, Aged 12 through 17 Years Receiving Standard Intravenous Anti-Infective Treatment for Bacterial Infections." Pfizer, Inc. Protocol A8441004. HSPPO # 08.0309. \$13,952.
- 2008 2009 Schikler K, Schmidt K, Condurache CT, Sullivan JE. "A 12-Week Randomized, Double-Blind, Placebo-Controlled, Parallel Group, 2-Arm Study to Evaluate the Efficacy and Safety of Tocilizumab in Patients with Active Systemic Juvenile Idiopathic Arthritis (SJIA); with a 92-Week Single-Arm Open-Label Extension to Examine the Long Term Use of Tocilizumab." F. Hoffmann-LA Roche LTD. Protocol WA18221. HSPPO # 08.0199. \$3,586.
- 2008 2009 Morton R, Condurache CT, Eid N, <u>Sullivan JE</u>. "A_Randomized Double-Blind (Withdrawal) Phase 3 Study to Evaluate the Efficacy and Tolerability of PANCREASE® MT Capsules Compared with Placebo in the Treatment of Subjects with Cystic Fibrosis-Dependent Exocrine Pancreatic Insufficiency." Johnson & Johnson Pharma Research & Development. LLC. Protocol PNCRLP-CYS-3001. HSPPO # 08.0262. \$151,612.
- 2008 2009 Sullivan JE (PI), Stewart DL, Bryant KA, Condurache CT. "Multiple Dose Pharmacokinetic Study or Meropenem in Young Infants (<91 days) with Suspected or Complicated Intra-abdominal Infections." Duke University/NIH. Protocol NICHD-2005-18. Phase II. HSPPO # 08.0212. \$391,750.
- 2008 2009 Sullivan JE (PI), Berkenbosch JW, Condurache CT. "Genetic polymorphisms for histamine degradation in children who have a history of vancomycin associated red man syndrome (RMS)." Children's Mercy Hospital. Protocol PPRU 10914. HSPPO #08.0410. Unfunded.
- 2007 2009 <u>Sullivan JE (PI)</u>, Shoemaker LR, Muchant DG, McKenney DW, Wintergerst KA, Myers AB. "A Randomized, Double-Blind, Parallel, Placebo or Amlodipine-Controlled Study of the Effects of Losartan on Proteinuria in Pediatric Patients with or without Hypertension." Merck & Co, Inc. Protocol MK-0954A 326-01. Phase III. HSPPO #304.07. \$74,462.
- 2007 2009 Sullivan JE (PI), Bryant KA, Condurache CT. "A Multi-Center, Open-Label, Single-Arm Study to Evaluate the Single-Dose Pharmacokinetics, Acceptability and Safety of Famciclovir Oral Pediatric Formulation in Infants 1 Month to <1 Year of Age with Herpes Simplex or Varicella Zoster Virus Infections." Novartis Pharmaceuticals. Protocol #CFAM810B2301. Phase IIa. HSPPO #181.07. \$4,130.
- 2007 2009 Sullivan JE (PI), Bryant KA, Myers AB, Condurache CT, Stewart DL. "A Phase I, Open-Label Study of the Safety and Pharmacokinetics of Repeated-Dose Micafungin (FK463) in Infants and Toddlers (≥ 4 Months to < 24 Months of Age) with Esophageal Candidiasis or Other Invasive Candidiasis." Astellas Pharma US, Inc. Protocol ISN 9463-CL-2102. Phase I. HSPPO #138.07. \$27,342.
- 2007 2009 Sullivan JE (PI), Stutts J, Berkenbosch J, Jeffries A, Morton RL, Condurache CT, Dillard RP. "A Randomized, Open-Label Study to Evaluate the Pharmacokinetics of Repeated IV Doses of Esomeprazole in Pediatric Patients 0 to 17 Years Old, Inclusive." AstraZeneca AB. Protocol # D9615C00021. Phase I. HSPPO #353.07. \$43,940.
- 2007 2009 Sullivan JE (PI), Myers AB, Stutts J, Stephen T, Jeffries A. "A Phase III, Multi-Center, Randomized, Placebo-Controlled, Parallel-group, Treatment-withdrawal Study to Evaluate the Efficacy and Safety of Esomeprazole for the Treatment of Gastroesophageal Reflux Disease (GERD) in Infants Ages 1 to 11 Months, Inclusive." AstraZeneca AB. Protocol # D9614C00096. Phase III. HSPPO #218.07. \$29,409.

- 2007 2009 Sullivan JE (PI), Shoemaker LR, Muchant DG, McKenney DW, Myers AB. "A Randomized, Double-Blind, Active Comparator Study to Evaluate the Antihypertensive Efficacy and Safety of Losartan/HCTZ Combination as Compared to Losartan Monotherapy in Pediatric Patients with Essential Hypertension." Merck & Co, Inc. Protocol MK-0954A 327-00. Phase III. HSPPO #07.0067. \$6,000.
- 2007 2009 <u>Sullivan JE (PI)</u>, Berkenbosch J, Montgomery V, Shoemaker LR, McKenney DW, Muchant DG, Condurache TC. "A Randomized, Double-Blinded, Placebo-Controlled, Dose-Ranging Study of Cardene IV in Pediatric Subjects with Hypertension." PDL BioPharma, Inc. Protocol Cardene IV 1406. Phase II. HSPPO # 07.0183. \$5,500.
- **2006 2009** Berkenbosch J, Montgomery VL, Slusher TM, Orman KL, Hardin AO, Ahuja S, <u>Sullivan JE</u>. "The Effects of Pretreatment with Midazolam on Ketamine-Induced Intracranial Hypertension." HSPPO# 246.06. Unfunded.
- **2006 2009** Berkenbosch J, Montgomery VL, <u>Sullivan JE</u>. "Experience with Nurse Practitioner-Driven Ketamine Administration for Pediatric Procedural Sedation." Unfunded.
- 2006 2009 Williams PG, Sullivan JE, Myers AB, Sears L, Condurache CT. "A 52-Week, Open-Label, Multi-Center Study of the Safety and Tolerability of Aripiprazole Flexibly Dosed in the Treatment of Children and Adolescents with Autistic Disorder." Bristol-Myers Squibb. Protocol #CN138-180. HSPPO #536.06. \$47,080.
- 2004 2009 Schikler K, Schmidt KM, <u>Sullivan JE</u>. "A Randomized Clinical Trial in Juvenile Fibromyalgia." National Institutes of Health. Subcontract with Cincinnati Children's Hospital, Cincinnati, Ohio. HSPPO #290.04. \$31,611.
- 2004 2009 Sullivan JE (PI), Montgomery VL, Berkenbosch, JW. "A Multi-Center, Randomized, Observer Blinded Clinical Trial to Determine the Overall Safety of Lorazepam Administered as a Continuous Infusion or Intermittent Boluses, and Midazolam Administered as a Continuous Infusion for Sedation of Critically III, Mechanically Ventilated Pediatric Patients." Subcontract with Case Western University, Cleveland, Ohio. BPCA Protocol #NICHD-2003-11. PPRU #10774. HSPPO #547.04. \$136,713.
- 2004 2009 Kennedy MJ, <u>Sullivan JE</u>. "The Role of Drug Bioactivation and Detoxification in the Pathogenesis of Adverse Drug Reactions in Children." Subcontract with Children's Mercy Hospitals and Clinics PPRU, Kansas City, MO. PPRU #10606b. HSPPO #296.04. \$39,375.
- **2004 2009** Kennedy MJ, <u>Sullivan JE</u>, Hein D, Sublett J, Badgett JT. "Histamine Pharmacogenetics in African-American Children with A-topic Dermatitis." PPRU #10744. HSPPO #147.03. Unfunded.
- 2004 2009 <u>Sullivan JE (PI)</u>, Montgomery V. "A Non-Randomized, Open-Label, Dose-Escalation Study of Renal and Hemodynamic Effects, Safety, Tolerability and Pharmacokinetics of Continuous Infusion of Fenoldopam in Pediatric Patients." PPRU #10656S. Unfunded. HSPPO #287.04. Unfunded.
- Morton R, Condurache CT, Eid N, <u>Sullivan JE</u>. "An open label, multi-center study to assess the safety and tolerability of Pancrelipase Delayed Release Capsules in infants and children less than seven years of age with pancreatic exocrine insufficiency due to cystic fibrosis." Solvay Pharmaceuticals. Protocol S245.3.128. Phase III. HSSPO # 08.0600. \$29,916.
- 2008 <u>Sullivan JE (local PI)</u>. "Pediatric Trial of Preventing Hypertension: Clinical Coordination Center 1 of 2." Thomas Jefferson University. Protocol RFA/PA07-070. Phase III. HSPPO Pending. Grant not awarded.
- 2008 Sullivan JE (PI), Condurache CT, Muchant D, McKerney D, Shoemaker L. "The Role of Ambulatory Blood Pressure Monitoring (ABPM) in Interventional Trials Conducted in Children with Hypertension: Detection of 'White Coat' Hypertension, Comparison of ABPM and Casual Measurements, and Investigation of the Placebo Effect in Children with Borderline to Mild Hypertension." Arkansas Children's Hospital. Protocol PPRU. HSPPO #08.0437. Unfunded.
- 2007 2008 Sullivan JE (PI), Berkenbosch J, Condurache TC. "A Phase III, Open-Label, Single-Arm Study of Tenectaplase for Restoration of Function in Dysfunctional Central Venous Access Catheters." Genentech. Protocol #N3699g. Phase III. HSPPO #08.0021. \$4,100.
- 2007 2008 Berkenbosch J, <u>Sullivan JE</u>, Condurache CT. "A Single-Dose Pharmacokinetic, Tolerability and Safety Study of ULTRAM ER® at Two Dose Levels in Children Seven to Eleven Years Old, Inclusive with Pain." Johnson & Johnson Pharmaceutical Research & Development. Protocol #TRAMAPPAI1002. Phase I. HSPPO # 07.0193. \$40,303.
- 2007 2008 Berkenbosch J, <u>Sullivan JE</u>, Condurache CT. "A Single-Dose Pharmacokinetic, Tolerability and Safety Study of ULTRAM ER® at Two Dose Levels in Adolescents Twelve to Seventeen Old, Inclusive with Pain." Johnson & Johnson

- Pharmaceutical Research & Development. Protocol #TRAMAPPAI1003. Phase I. HSPPO # 07.0194. \$13,905.
- 2007 2008 <u>Sullivan JE (PI)</u>, Berkenbosch J, Woods C, Condurache TC. "Derivation of a Clinical Prediction Rule for Bacterial Pulmonary Infection in Mechanically Ventilated Children." NIAID. University of Alabama at Birmingham. Protocol #BAMS64-03. HSPPO 07.0112. \$5,000.
- 2007 2008 <u>Sullivan JE (PI)</u>, Condurache CT. "An Observational Follow-Up Study of Pediatric Patients Who Participated in a Previous Respiratory Syncytial Virus (RSV)-Induced Bronchiolitis Study of Montelukast." Merck. Protocol #MK0476/PN 374. HSPPO # 07.0115. \$32,832.
- 2007 2008 Sullivan JE (PI), Berkenbosch J, Condurache CT, Bryant K, Woods C. "A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate a Single Intravenous Dose of Motavizumab (MEDI-524) a Humanized Enhanced Potency Monoclonal Antibody Against Respiratory Syncytial Virus (RSV) for the Treatment of Children Hospitalized with RSV Illness." MedImmune. Protocol #MI-CP141. Phase II. HSPPO # 07.0114. \$7,745.
- 2007 2008 Sullivan JE (PI), Recto M, Condurache CT, Bryant K. "A Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Immunogenicity of MEDI-524, a Humanized Enhanced Potency Monoclonal Antibody Against Respiratory Syncytial Virus (RSV) in Children with Hemodynamically Significant Congenital Heart Disease." MedImmune. Protocol #MI-CP124-S2. Phase II. HSPPO #374.07. \$21,939.
- **2007 2008** Kennedy MJ, <u>Sullivan JE</u>, Stewart DL, Bryant KA, Myers AB. "Urinary Proteomics in Antimicrobial/Antifungal-Treated Newborns Add-On Study to the Antimicrobial Pharmacokinetics in High-Risk Infants Study." PPRU #10824. University of Louisville. Unfunded.
- 2007 2008 Puri V, Sullivan JE. "A Randomized, Double-Blind, Placebo-Controlled, Fixed Dose-Ranging Study to Access the Safety, Tolerability, and Efficacy of Oral Liquid and Sprinkle Formulations as an Adjunct to Concurrent Anticonvulsant Therapy for Infants (1 to 23 Months of Age, Inclusive) with Refractory Partial-Onset Seizures, with Open-Label Extension." Johnson & Johnson Pharmaceutical Research & Development, LLC. PPRU #10800. HSPPO #300.05. \$125,354.
- 2007 2008 Morton R, <u>Sullivan JE</u>, Condurache CT, Eid N. "A Double-Blind, Randomized, Multi-Center, Placebo-Controlled, Cross-Over Study to Assess the Efficacy and Safety of Pancrelipase Delayed Release 24,000 Unit Capsule in Subjects with Pancreatic Exocrine Insufficiency Due to Cystic Fibrosis. Solvay Pharmaceuticals." Protocol #S245-3-126. Phase III. HSPPO # 07.0123. \$5,000.
- 2006 2008 Sullivan JE (PI), Stutts J, Stephen T, Jeffries A, Stewart D, Myers A. "A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Treatment-Withdrawal Study of the Efficacy and Safety of Pantoprazole Sodium Enteric-Coated Granules in Infants (1 Through 11 Months) with Symptomatic GERD." Wyeth Research. Protocol #3001B3-329-WW. Phase III. HSPPO #559.06. \$48,580.
- 2006 2008 Stewart D, Sullivan JE, Stutts J, Stephen T, Jeffries A, Myers A, Condurache CT. "A Multi-Center, Open-Label PK, PD and Clinical Symptoms, and Safety Study of Pantoprazole Delayed-Released Granules Administered as a Suspension in Neonates and Preterm Infants with a Clinical Diagnosis of GERD." Wyeth Research. Protocol #3001K3-331-WW. PPRU #10844. Phase III. HSPPO #434.06. \$80,833.
- 2006 2008 Sullivan JE (PI), Shoemaker L, Muchant D, McKenney D, Theriot J, Sayat J, Carothers B, Franco S, Kurbasic M, Jones F, Howard M. "A Prospective, Randomized, Double-Blind, Placebo-Controlled, Evaluation of the Safety, Efficacy, and Pharmacokinetics of MICARDIS (Telmisartan) in Children and Adolescents with Hypertension After Four Weeks of Treatment." Boehringer Ingelheim. Protocol #502-403. Phase III. HSPPO #325.06. \$14,636.
- 2006 2008 Sullivan JE (PI), Stutts J, Stephen T, Myers A, Jeffries A, Condurache CT. "A Multi-Center, Randomized, Double-Blind Study of the Safety, Tolerability, Pharmacokinetics and Clinical Outcomes of Multiple Doses of Pantoprazole Sodium Enteric-Coated Spheroids in Children (1 to 4 years old) with Endoscopically Proven Symptomatic GERD." Wyeth Research. Protocol #3001B3-328-NA. Phase III. HSPPO #261.06. \$36,285.
- 2006 2008 Sullivan JE (PI), Myers A, Stephen T, Stutts J, Jeffries A, Stewart DL, Eid N, Morton R, Condurache TC. "A Multi-Center, Open-Label, Safety Study of 2 Doses of Pantoprazole Sodium Enteric-Coated Spheroid Suspension in Infants Aged 1 Through 11 Months with Presumed GERD." Wyeth Research. Protocol #3001B3-335-US. Phase III. HSPPO #980.05. \$42,585.
- 2006- 2008 Williams PG, Sullivan JE, Myers AB, Sears L. "A Multi-Center Double-Blind, Randomized, Placebo-Controlled, Flexible-

Dosed, Parallel-Group Study of Aripiprazole Flexibility Dosed in the Treatment of Children and Adolescents with Autistic Disorder." Bristol-Myers Squibb. Protocol #CN138-178. Phase III. HSPPO #514.06. \$63,010.

- 2005 2008

 Puri V, Sullivan JE. "A Randomized, Open-Label, Multi-Center Study with Open-Label Extension of the Pharmacokinetics and Safety of Topiramate Administered as the Oral Liquid and Sprinkle Formulations as an Adjunct to Concurrent Anticonvulsant Therapy in Infants (Aged 1 to 23 Months, Inclusive) with Refractory Partial Onset Seizures." Johnson & Johnson Pharmaceutical Research & Development, LLC. PPRU #10800. HSPPO #299.05.
- 2005 2008 Myers A, <u>Sullivan JE (PI)</u>, Jones V, Franco S. "A Multi-Center, Open-Label, Single-Arm, Two-Step Study to Evaluate the Safety and Single-Dose Pharmacokinetics of and Multiple-Dose Safety After Administration of Famciclovir Oral Pediatric Formulation to Children 1 to 12 Years of Age with Herpes Simplex Infection." Norvartis. PPRU #10790. Protocol # CFAM810B2303. Phase III. HSPPO #083.05. \$8,009.
- 2005 2008 Sullivan JE (PI), Shoemaker L, Muchant D, McKenney D, Myers A. "An Open-Label Study of the Single- Dose Pharmacokinetics of Olmesartan Medoxomil in Pediatric Patients with Hypertension." Sankyo Pharma, Inc. PPRU #10802. Protocol #CS-086-A-U102. Phase IIIb. HSPPO #358.05. \$21,686.
- 2005 2008 Sullivan JE (PI), Myers A, Stephen T, Stutts J, Jeffries A, Stewart DL, Eid N, Morton R, Condurache TC. "A Multi-Center, Randomized, Open-Label, Single and Multiple Dose Study of the Pharmacokinetics and Pharmacodynamics of 2 Dose Levels of Pantoprazole Sodium Enteric-Coated Spheroid Suspension in Infants Aged 1 Through 11 Months with Presumed GERD." Wyeth Research. Protocol #3001B-333-US. PPRU #10818. Phase Ib. HSPPO #539.05. \$124,773.
- 2005 2008 Sullivan JE (PI), Myers A, Stephen T, Stutts J, Jeffries A. "A Multi-Center, Randomized, Open-Label, Single and Multiple Dose Study of the Safety and Pharmacokinetics of 2 Dose Levels of Pantoprazole Sodium in Children Aged 1 through 11 Years with Endoscopically Proven GERD." IND 68,011. Wyeth Research. Protocol No. 3001B3-334-US. PPRU #10812. Phase III. HSPPO #520.05. \$25,014.
- 2004 2008 Sullivan JE (PI), Kennedy MJ, Gozal D, Myers A, Condurache TC. "An Open-Label, Single-Dose, Dose Rising, Multi-Center Study to Assess the Tolerability and Pharmacokinetics of Ropinirole Immediate Release in Adolescent Patients with Restless Legs Syndrome (RLS)." GlaxoSmithKline Pharmaceuticals. Protocol #101468/253. Phase II. PPRU #10764. HSPPO #500.04. \$37,670.
- **2003 2008** Muchant, D, Shoemaker L, <u>Sullivan JE</u>. "Focal Segmental Glomerulosclerosis Trial." NIH--Subcontract with Children's Hospital of Montefiore, Bronx, New York. HSPPO #800.03. \$1,600.
- 2001 2008 Sullivan JE (PI), Montgomery VL, Paul RI, Bosse G. "Measurement of Nitrotyrosine Adducts and Cytokines in Acetaminophen Overdose Patients (Substudy)." Arkansas Children's Hospital University of Arkansas for Medical Sciences. PPRU #10368 and 10369S. HSPPO #08.0412. Unfunded.
- 2007 <u>Sullivan JE (PI)</u>, Shoemaker LR, Muchant DG, McKenney DW, Myers AB. "A Randomized, Double–Blind, Placebo-Controlled, Multi-Center, Parallel-Arm Study Assessing the Efficacy, Safety, and Dose-Response of Ramipril for the Treatment of Hypertension in Children and Adolescents." King Pharmaceuticals Research and Development, Inc. Protocol K726-06-4003. Phase III. HSPPO #202.07. \$21.647.
- 2007 <u>Sullivan JE (PI)</u>, Stutts J, Jeffries A, Stephen T. "Psychometric Validation of the Pediatric Gastroesophageal Reflux Disease Symptom and Quality of Life Questionnaire (PGSQ)." TAP Pharmaceuticals. Protocol A2-4277. Phase N/A. HSPPO #274.07. \$14,180.
- Bryant KA, <u>Sullivan JE</u>, Stewart DL, Myers AB. "A Phase 1, Open-Label Study of the Safety and Pharmacokinetics of Repeated-Dose Micafungin in Neonates." Astellas Pharma US, Inc. Protocol ISN 9463-CL-2104. Phase I. HSPPO #103.07. \$5,040.
- Sullivan JE (PI), Myers AB, Stutts J, Stephen T, Jeffries A. "A Multi-Center, Randomized, Open-Label, Single and Multiple-Dose Study of the Pharmacokinetics and Safety of Two Dose Levels of Pantoprazole Sodium Tablets in Adolescents Aged 12 Through 16 Years with a Clinical Diagnosis of GERD." Wyeth Research. Protocol #3001A3-337-US; PPRU #10858. Phase III. HSPPO #096.07. \$15,091.
- 2006 2007 Sullivan JE (PI), Bryant KA, Stewart DL. "A Multi-Center, Open-Label PK Study of Fluconazole in Infants." CHOP PPRU. PPRU # 10826. HSPPO #196.06. Unfunded.
- 2006 2007 <u>Sullivan JE (PI)</u>, Berkenbosch J, Montgomery V, Yarberry B. "Pediatric Pharmacy Advocacy Group (PPAG) Collaborative Research Project: "Testing of a "Trigger Tool" to Detect Adverse Events (AEs) and Adverse Drug Events

- (ADEs) in the Pediatric Critical Care Unit (PICU): A Multi-Site Trial". HSPPO #282.06. Unfunded.
- 2006 2007 Sullivan JE (PI), Davis DA, Foster M, Myers A. "A Randomized, Single-Blind, Dose-Rising, Placebo-Controlled, Crossover Study to Evaluate the Pharmacokinetics, Pharmacodynamics, and Tolerability of Exenatide in Adolescent Subjects with Type 2 Diabetes Mellitus." Amylin. Protocol # 2993-124. Phase II. PPRU #10836. HSPPO #609.05. \$29,525.
- 2006 2007 <u>Sullivan JE (PI)</u>, Bertolone S, Raj A. "An Open-Label, Parallel Group, Pilot Study to Evaluate the Pharmacokinetics, Pharmacodynamics and Tolerability of ICA-17043 in Pediatric Subjects with Sickle Cell Disease." Icagen, Inc. Protocol #ICA-17043-07. Phase I. HSPPO #129.06. \$26,483.
- 2004 2007 <u>Sullivan JE (PI)</u>, Stewart DL, Montgomery VL. "An Open-Label Study of Argatroban Injection to Evaluate the Safety and Effectiveness in Pediatric Patients Requiring Anticoagulant Alternatives to Heparin." GlaxoSmithKline Pharmaceuticals. Protocol #105043. HSPPO #200.04. \$44,446.
- 2004 2007 <u>Sullivan JE (PI)</u>, Auden S, Myers A, Jusufbegovic E. "An Open-Label, Randomized, Phase IIIB, Multi-Center Trial to Evaluate the Pharmacodynamic Parameters of Intubation Bolus, and Bolus and Infusion Maintenance Doses of Zemuron[®] in Pediatric and Adolescent Subjects." Akzo Nobel. Protocol # 21048. Phase IIIb. HSPPO #048.05. \$27,540.
- 2004 2007 Sullivan JE (PI), Shoemaker L, Muchant D, Franco S, Howard M, Sayat J, Theriot J, Carothers B, Frazier E, Patel P, Jones V, Kurbasic M, McKenney D, Myers A. "A Dose-Ranging and Safety Study of Candesartan Cilexetil in Hypertensive Pediatric Subjects 1 to Less Than 6 Years of Age: A 4-week, Multi-Center, Randomized, Double-Blind Study with a 1-year, Open-Label, Follow-up Period." Astra Zeneca Pharmaceuticals. Protocol # 328. HSPPO #403.03. \$7,500.
- 2003 2007 Sullivan JE (PI), Harrison C, Buchanan B, Jones F, Franco S, Kurbasic M, Theriot J, Dodds C, Valdes X. "An Open-Label, Single-Dose, Multi-Center, Pharmacokinetic, Safety and Tolerability Study of Valaciclovir Oral Suspension in Infants and Children." GlaxoSmithKline. Protocol #HS210914. Phase I. HSPPO #110.03. \$5,506.
- 2006 <u>Sullivan JE (PI)</u>, Stephen T, Stutts J. "Feasibility Testing of Two Caregiver Questionnaires Assessing GERD Symptom in Infants and Young Children." Pilot Testing. Wyeth Research. Protocol #3001B3-336-US. HSPPO #557.05. \$9,090.
- 2005 2006 Eid NS, Sullivan JE, Kennedy MJ, Morton R. "A Single-Dose, Multi-Center, Randomized, Crossover, Five-Period, Double-Blind, Double-Dummy, Placebo-Controlled, Dose-Ranging Efficacy Comparison of Albuterol-HFA-BOI and Albuterol-HFA-MDI in Children 4-11 Years of Age with Mild Persistent-to-Moderate Persistent Asthma." IVAX. Protocol #IXR-204-25-167. Phase II. HSPPO #377.05. \$8,444.
- 2005 2006 Sullivan JE (PI), Shoemaker L, Muchant D, McKenney D. "A Randomized, Double-Blind, Placebo Withdrawal, Parallel Group, Dose Response Study to Evaluate the Efficacy and Safety of Eplerenone in the Treatment of Hypertension in Children." Pfizer. Protocol # A6141001 1083. Phase I. HSPPO #209.05. \$6,500.
- 2005 2006 Sullivan JE (PI), Recto M, Austin E. "Platelet Aggregation Inhibition in Children on Clopidogrel (Picolo)." Bristol Myers Squibb/Sanofi-Synthelabo. Protocol # PDY4422. Phase I. PPRU #10778. HSPPO #111.05. \$6,312.
- 2004 2006 Bryant KA, <u>Sullivan JE</u>. "A Pivotoal Phase 3 Study of MEDI-524 (Numax), an Enhanced Potency Humanized Respiratory Syncytial Virus (RSV) Monoclonal Antibody, for the Prophylaxis of Serious RSV Disease in High-Risk Children." MedImmune. Phase III. PPRU #10772. HSPPO #384.04.
- 2004 2006 Sullivan JE (PI), Shoemaker L, Jones F, Kurbasic M, Patel P, Myers A. "The Role of Ambulatory Blood Pressure Monitoring (ABPM) in Interventional Trials Conducted in Children: Detection of "White Coat" Hypertension, Comparison of ABPM and Casual Measurements and Investigation of the Placebo Effect in Children with Borderline to Mild Hypertension." PPRU #10668S. HSPPO #08.0437. Unfunded.
- 2004 2006 Sullivan JE (PI). Morton R, Eid N. "A Randomized, 3-Period, Multiple Dose, Multi-Center, Study to Evaluate the Safety, Tolerability and Plasma Concentration Profile of Montelukast Administered Once Daily as Oral Granules in Children Aged 1 to 3 months." Merck. Protocol #297-00. HSPPO #595.04. \$8,000.
- 2003 2006 Sullivan JE (PI), Shoemaker L, Franco S, Jones F, Theriot J, Muchant D, Myers A. "A Multi-Center, Multinational, Open-Label Study of the Efficacy, Safety, and Pharmacokinetics of Candasartan Cilexetil in Hypertensive Pediatric Subjects 6 to <17 years of age." Astra Zeneca. Protocol #261B. HSPPO #404.03. \$35,300.
- 2003 2006 Sullivan JE (PI), Morton R, Eid N. "A Randomized 2-Period, Multi-Center, Double-Blind, Parallel-Group Study Comparing the Effects of 2 Doses of Montelukast Granules and Placebo in the Treatment of Respiratory Symptoms

Associated with the Respiratory Syncytial Virus-Induced Bronchiolitis in Children Aged 6 –18 months." Merck. Protocol#MK-0476. Phase III. HSPPO #487.03. \$23,606.

- 2003 2006 Shoemaker L, <u>Sullivan JE</u>. "A Randomized controlled trial of Mycophenolate Mofetil in patients with IgA Nephropathy." Southwest Pediatric Nephrology Study Group. HSPPO #189-03. \$1,500.
- 2003 2006

 Austin E, Sullivan JE, Robinson T. "A Comparative, Evaluator-Masked, Randomized, Parallel, Multi-Center Study to Determine the Safety and Effectiveness of REPEL-CV for Reducing Post-Operative Adhesions Following Cardio Thoracic Surgery." Life Medical Sciences, Protocol #LMS0103RCV. HSPPO #379.03. \$49,282.
- 2002 2006 Kennedy MJ, <u>Sullivan JE</u>, Clark P. "Effect of Recombinant Human Growth Hormone (rhGH) Therapy on Hepatic Drug Metabolism in Children with Idiopathic Growth Hormone Deficiency." Children's Mercy Hospital. Protocol #437-02. PPRU #10734. HSPPO #437.02. Unfunded.
- 2005 <u>Sullivan JE (PI)</u>, Myers AB. "A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Confirm the Effectiveness and Safety of Algrx 3268 in Pediatric Subjects." AlgoRx Pharmaceutical Protocol #3268-3-004-1. Phase III. HSPPO #105.05. \$1,500.
- 2004 2005 Stewart D, <u>Sullivan JE</u>, Stutts J, Stephen T, Louthan M. "A Phase 1, Single-and Repeated-Dose, Randomized, Open-Label, Multi-center Study to Evaluate the Pharmacokinetics, Pharmacodynamics, and Safety of Lansoprazole in Neonates with Clinically-Evident Gastroesophageal Reflux Disease." TAP Pharmaceutical. Protocol # C03-042. Closed prior to UofL approval.
- 2004 2005 Sullivan JE (PI), Stewart D, Stutts J, Stephen T, Louthan M. "A Phase 1, Single and Repeated-Dose, Randomized, Open-Label, Multi-center Study to Evaluate the Pharmacokinetics, Pharmacodynamics and Safety of Lansoprazole in Infants with Clinically-Evident Gastroesophageal Reflux Disease." TAP Pharmaceutical. Protocol # C03-043. Closed prior to UofL approval.
- 2003 2005 Morton R, Sullivan JE, Eid N. "A Randomized, Double-Blind, Double Dummy, Placebo-Controlled, Parallel Group, Multi-Center Clinical Trial of Four Weeks Treatment with SEREVENT® Inhalation Aerosol, 25mcg BID, 50 mcg BID and Placebo Administered via a Valve Holding Chamber with Facemask in Subjects with Asthma Age 6 to 23 Months." GlaxoSmithKline. Protocol # SMS 30077. Phase III. HSPPO #593.03. \$2,490.
- 2003 2005 Morton RL, <u>Sullivan JE</u>, Eid NS, Valdes X. "A Stratified, Multi-Center, Randomized, Double-Blind, Parallel Group, 4-Week Comparison of Fluticasone Propionate/Salmeterol DISKUS Combination Product 100/50mcg BID Versus Fluticasone Propionate DISKUS 100mcg BID in Pediatric Subjects with Activity-Induced Bronchospasm." GlaxoSmithKline. Protocol #SFA100316. HSPPO #774.03. \$8,368.
- 2003 2005 Harrison C, <u>Sullivan JE</u>, Buchanan B, Jones F, Franco S, Kurbasic M, Theriot J, Dodds C, Valdes X. "An Open-Label, Multiple-Dose, Multi-Center, Pharmacokinetic, Safety and Tolerability Study of Valaciclovir Oral Suspension in Infants and Children with HSV Infection." GlaxoSmithKline. Protocol #HS210915. HSPPO#109.03. \$9,300.
- 2003 2005 Harrison C, Sullivan JE, Buchanan B, Jones F, Franco S, Kurbasic M, Theriot J, Dodds C, Valdes X. "An Open-Label, Multi-Dose, Multi-Center, Pharmacokinetic, Safety and Tolerability Study of Valaciclovir Oral Suspension in Infants and Children with VZV Infection." GlaxoSmithKline. Protocol #HS210916. HSPPO#108.03. \$11,329.
- 2003 2005 Sullivan JE (PI), Shoemaker L, Franco S, Jones F, Theriot J, Muchant D, Myers A. "A Dose-Ranging and Safety Study of Candasartan Cilexetil in Hypertensive Pediatric Subjects 6-<17 Years of Age: A 4-week, Multinational, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study." Astra Zeneca. Protocol #261A. HSPPO #403.03. \$55,714.
- 2002 2005 <u>Sullivan JE (PI)</u>, Montgomery V, Davis JC, Stewart D. "Investigation of the Efficacy and Safety of Drotrecogin Alfa (Activated) in Pediatric Severe Sepsis." Eli Lilly and Company. Protocol #F1K-MC-EVBP. Phase III. HSPPO #500.02. \$45,767.
- Montgomery VL, <u>Sullivan JE</u>, "A Multi-Center, Epidemiological, Observational Survey of the Management of Anemia in Critically Ill Pediatric Patients." Johnson & Johnson Pharmaceuticals. Protocol EPO-ICP-30. HSPPO #433.04.
- 2004 <u>Sullivan JE (PI)</u>, Shoemaker L, Muchant D. "Study of the Pharmacokinetics of Sirolimus Administered Orally to Stable Renal Transplant Pediatric Subjects." Wyeth. Protocol # 0468E1-188-US. Phase I. PPRU #10740. HSPPO #162.04. \$18,891.

- 2003 2004 Kennedy MJ, <u>Sullivan JE</u>, Vos Louthan M, Stutts J. "A Single and Multiple Dose Pharmacokinetics and Safety Study of Rabeprazole Sodium in 12-16 Year Old Subjects." EISAI Medical Research. Protocol # E3810-A001-119. Phase I. PPRU #10700. HSPPO #350.03. \$16,681.
- 2003 2004 Sullivan JE(PI), Valdes X, Carothers B, Jones VF, Theriot J, Franco S, Dodds C, Kurbasic M, Eid NS, Morton RL. "A Placebo-Controlled Comparison of the Efficacy, Safety and Pharmacokinetics of the Current US Version of Pulmicort (Budesonide) Turbuhaler in Asthmatic Children and Adolescents." Astra Zeneca. Protocol #SD004-0726. HSPPO #028.04.
- 2001 2004 Sullivan JE (PI), Bryant K. "A Prospective, Randomized, Open-Label, Comparative Study to Evaluate the Safety, Tolerability and Efficacy of Ertapenem Sodium (MK-0826) Versus Ticarcillin/Clavulanate in the Treatment of Hospital Acquired Pneumonia, Complicated Intra-Abdominal Infections, and Acute Pelvic Infections in Pediatric Patients." Merck Research Laboratories. Protocol # 036-01. Phase II. HSPPO #491.01. \$48,584.
- 2001 2004 <u>Sullivan JE (PI)</u>, Shoemaker L, Jones F, Theriot J. "A Dose Escalation, Randomized Double-Blind Withdrawal Study of the Efficacy, Dose-Response and Safety of Ramipril for the Treatment of Hypertension in Children and Adolescents (TOPHAT)." King Pharmaceuticals. Protocol # K726-01-4002. Phase IV. HSPPO #722.01. \$56,561.
- 2001 2004 <u>Sullivan JE (PI)</u>, Shoemaker L, Jones F, Theriot J. "A Randomized, Open-Label Study of the Pharmacokinetics, Safety, and Tolerability of a Single-Dose of Ramipril in Infants, Children and Adolescents from 1 Month to 16 Years of Age (TOPHAT)." King Pharmaceuticals. Protocol # K726-01-4001. Phase I. HSPPO #224.02. \$4,219.
- Shoemaker L, <u>Sullivan JE</u>. "An Open-Label, Randomized, Non-inferiority Study of Novel Erythropoiesis Stimulating Protein (NESP) and Recombinant Human Erythropoietin (r-HuEPO) for the Treatment of Anemia in Pediatric Subjects with Chronic Renal Insufficiency (CRI) or End-Stage Renal Disease (ESRD) Receiving Dialysis." Amgen. Protocol #20000100. HSPPO #400.03.
- 2003 <u>Sullivan JE (PI)</u>, Morton R, Eid N. "A Cumulative Dose Tolerability Study of Levalbuterol HFA and Racemic Albuterol HFA in Pediatric Subjects with Asthma." Sepracor / PPD Development. Protocol # 051-311. Phase II. HSPPO #788-02. \$9,963.
- 2002 2003 Sullivan JE (PI), Auden S, Kennedy MJ. "A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of Intravenous Ondansetron Hydrochloride 0.1 mg/kg for the Prevention of Postoperative Emesis in Pediatric Surgical Subjects Age 1 Month to 24 Months Who are Undergoing routine Surgery Under General Anesthesia." GlaxoSmithKline. Protocol #S3A40323. Phase N/A. HSPPO #574.02. \$38,170.
- 2001 2003 Sullivan JE, Bryant K, Fallat M, Bond S, Nagaraj N. "A Prospective, Multi-Center, Double-Blind Randomized, Comparative Study to Evaluate the Safety, Local Tolerability and Clinical Outcomes of Ertapenem Sodium (MK-0826) Versus Ceftriaxone Sodium in Pediatric Patients with Complicated Urinary Tract Infection, Skin and Soft Tissue Infection or Community Acquired Pneumonia." Merck Research Laboratories. Protocol # 038-01. Phase II. HSPPO #283.01. \$26,854.
- 1999 2003 <u>Sullivan JE (PI)</u>, Boland K, Montgomery V, McDonald M. "An Open-Label Administration of Human Botulism Immune Globulin." California Department of Health Services. HSPPO #349.99.
- 2002 <u>Sullivan JE (PI)</u>, Shoemaker L. "A Safety, Tolerability and Pharmacokinetics Study of Toprol-XL (Metoprolol Succinate) Extended-Release Tablets in Hypertensive Pediatric Subjects: A Multi-Center, Open-Label Extension of Protocol 307A." Astra Zeneca Pharmaceuticals. Protocol #307B. Phase I. HSPPO #338.02. \$1,550.
- 2002 <u>Sullivan JE (PI)</u>, Shoemaker L. "Dose-Ranging, Safety and Tolerability of Toprol-XL, Extended-Release Tablets in Hypertensive Pediatric Subjects: A Multi-Center, Double-Blind, Placebo-Controlled, Randomized, Parallel-Group Study." Astra Zeneca Pharmaceuticals. Protocol #307A. Phase I. HSPPO #338.02. \$1,550.
- 2002 <u>Sullivan JE (PI)</u>, Shoemaker L. "A Multi-Center, Open-Label, Single-Dose Study of the Safety, Tolerability and Pharmacokinetics of Metoprolol Succinate and Metoprolol Tartrate IV Solution in Pediatric Subjects." Astra Zeneca Pharmaceuticals. Protocol #308. Phase I. HSPPO #132.02. \$1,550.
- Schikler KN, <u>Sullivan JE</u>. "Efficacy and Safety of Leflunomide Versus Methrotrexate in the Treatment of Pediatric Patients with Juvenile Rheumatoid Arthritis." Aventis Pharamceuticals. Protocol #486/3503. Phase III. HSPPO #130.02. \$1,550.
- 2002 Schikler KN, Sullivan JE. "Double-Blind, Eight Month Extension Study to Collect Durability of Efficacy Data and

Additional Safety Data in Patients with JRA Completing the Double-Blind Comparison Study HWA 486/3503 of Leflunomide Versus Methotrexate." Aventis Pharmaceuticals. Protocol #486/3504. Phase III. HSPPO #436.02. \$1,550.

- 2001 2002 Schikler K, <u>Sullivan JE</u>. "A 12 Week Double-Blind Randomized Trial, with a 12 Week Open-Label Extension, to Investigate the Efficacy and Safety of Meloxicam Oral Suspension Administered Once Daily and Naproxen Oral Suspension Administered Twice Daily in Children with Juvenile Rheumatoid Arthritis." Boehringer-Ingelheim. Protocol #107-235. Phase III. HSPPO #415.01. \$12,239.
- 2001 2002 <u>Sullivan JE (PI)</u>, Whatley V. "A Safety, Tolerability and Efficacy Study of Levalbuterol and Racemic Albuterol in Pediatric Subjects Birth to 48 Months Old with Reactive Airways Disease in an Acute Setting." Sepracor. Protocol # 051-033. Phase III. HSPPO #63.01. \$3,592.
- 2001 <u>Sullivan JE (PI)</u>, Bryant K, Stewart D. "Pharmacokinetics, Safety, and Tolerance Study of Three Doses of FK463 in Premature Infants." Fujisawa Healthcare, Inc. Protocol #99-0-063. Phase I. HSPPO #721.01. \$1,550.
- 2001 Sullivan JE (PI), Stutts J, Stephens T. "An Open-Label, Randomized, Parallel, Multi-Center Pharmacokinetic (PK) Study of Axid® (Nizatidine) in Pediatric Subjects Age 5 days-12 years with Gastroesophageal Reflux (GERD) Symptoms." Reliant Pharmaceuticals, LLC. Protocol # AX 9008. Phase II. HSPPO #47-02. \$1,550.
- Harrison C, <u>Sullivan JE</u>. "A Randomized, Investigator-Blinded, Multi-Center, Comparative Study of Gatifloxacin Versus High-Dose Amoxicillin/Clavulanate in the Treatment of Recurrent Otitis Media and Acute Otitis Media Treatment Failures in Children." SmithKline-Beecham # BRL 025000.
- Harrison C, <u>Sullivan JE</u>. "A Randomized, Investigator-Blind, Multi-Center Study to Assess the Efficacy of Oral Augmentin ES-600 Twice Daily for 10 Days Versus Oral Zithromax® Once Daily for 5 Days in the Treatment of Acute Otitis Media in Infants and Children." SmithKline-Beecham # BRL 025000.
- 2001 <u>Sullivan JE (PI)</u>, Bryant K, Stewart D. "Fluconazole Prophylaxis to Prevent Candidemia in Neonates." Fugisawa. \$1,550.
- 2001 <u>Sullivan JE (PI)</u>, Montgomery VL, Ameri A, Stewart D. "A Safety Trial using Recombinant Urokinase (ABT-120, Urokinase Alpha) in the Treatment of Occluded Central Catheters." Abbott Laboratories. \$1,550.
- 2001 Sullivan JE (PI), Montgomery VL, A meri A, Stewart D. "Recombinant Urokinase (ABT-120, Urokinase Alpha) in the Treatment of Occluded Central Venous Catheters, Safety and Efficacy Trial." Abbott Laboratories. Protocol # 2000-042. \$1,550.
- 2001 Sullivan JE (PI), Stutts J, Stephens T. "An Open-Open, Single and Multiple Dose Study of the Pharmacokinetics, Pharmacodynamics, and Tolerability of Axid® (Nizatidine) 150 mg Bid in Adolescents 12-18 Years of Age with Symptomatic Gastroesophageal Reflux Disease (GERD)." Reliant Pharmaceuticals LLC. Protocol #AX 9001. Phase I. HSPPO #588.01. \$1,550.
- Bryant K, Campbell A, <u>Sullivan JE</u>. "Linezolid IV/PO versus Vancomycin IV for the Treatment of Resistant Gram-Positive Bacterial Infections in Children." Pharmacia & Upjohn. M/1260/0082.
- 2001 Sullivan JE (PI), Stewart D. "Assessment of Linezolid Single-Dose Pharmacokinetics in Young Infants, Full-Term and Pre-term Neonates." Pharmacia & Upjohn. M/1260/0064. (Multi-Center Study). HSPPO #885-00. \$32,614.
- 2001 <u>Sullivan JE (PI)</u>, Stutts J, Stephens T. "A Randomized, Double-Blind, Parallel, Multi-Center Pediatric Study of Axid® (Nizatidine) Versus Placebo in the Treatment of Gastroesophageal Reflux Disease (GERD) in Children Age 1-12." Reliant Pharmaceuticals, LLC. Protocol # AX 9000. Phase IIIb. HSPPO #209.01. \$6,385.
- 2000 2001 Sullivan JE (PI), Bertolone S. "A Study to Assess the Safety, Dose Conversion and Titration of Duragesic® (Fentanyl Transdermal System) in Pediatric Subjects with Chronic Pain Requiring Opioid Therapy." Janssen Pharmaceuticals. Protocol # Fen-USA-87. HSPPO #521-00. \$21,875.
- 2000 2001 Sullivan JE (PI), Theriot J, Jones F. "A Double-Blind, Randomized, Placebo-Controlled Surveillance Study of Asthma Event Outcomes in Subjects Receiving Either Usual Pharmacotherapy Of Asthma Or Usual Pharmacotherapy Plus Salmeterol 42mcg (2 Puffs) Twice Daily." GlaxoSmithKline, Protocol #SLGA5011. HSPPO #699.00. \$2,400.
- 2000 2001 <u>Sullivan JE (PI),</u> Montgomery V. "A Double-Blind Evaluation of the Northstar Lidocaine Iontophoretic Drug Delivery System in Adult and Pediatric Subjects." Becton-Dickinson. Protocol #99-68. HSPPO #701-00. \$31,999.

2000 – 2001	Sullivan JE (PI), Shoemaker L, Harrison H. "A Double-Blind, Randomized Dose Response Study of Losartan in Children
	with Hypertension." Merck, Protocol #227-00. HSPPO #367.00. \$1,550.

- **2000 2001** Montgomery VL, Boland K, <u>Sullivan JE</u>. "A Multi-Center Prospective, Blinded, Randomized Trial Evaluating the Safety and Efficacy of Infasurf (Calfactant) in Pediatric Respiratory Failure." Ony.
- 2000 <u>Sullivan JE (PI)</u>, Shoemaker L, Harrison H. "A Double-Blind, Randomized Dose Response Study of Lisinopril in Children with Hypertension," Merck, Protocol #115-00. \$4,910.
- 1999 2000 <u>Sullivan JE (PI)</u>, Shoemaker L, Harrison H. "A Double-Blind, Randomized Dose Response Study of Enalapril in Children with Hypertension." Merck Protocol #167-00. \$4,101.
- 1996 2000 Sullivan JE (PI), Montgomery VL, Ross MP, Rodgers GC. "A Multi-Center Randomized Controlled Study of the Safety and Efficacy of Partial Liquid Ventilation (PLV) with AF0141 (Sterile Perflubron) in Children with Acute Parenchymal Lung Injury." Alliance Pharmaceutical Corp. \$36,835.
- 1998 1999 Montgomery V, Boland K, <u>Sullivan JE</u>, McDonald M. "Comparison of End Tidal Carbon Dioxide Measurement to Arterial Carbon Dioxide Measurement."
- 1997 1999 <u>Sullivan JE (PI)</u>, Givens T. "Antigenic Biomarker Identification of Acetaminophen Hepatotoxicity in Children".
- Sullivan JE (PI), Montgomery V, Ross M, Rodgers G. "Characterization of Mucus Material Obtained from Subjects Treated with Perflubron PLV" an Addendum to "A Multi-Center Randomized Controlled Study of the Safety and Efficacy of Partial Liquid Ventilation (PLV) with AF0141 (Sterile Perflubron) in Children with Acute Parenchymal Lung Injury." Alliance Pharmaceuticals Corp.
- Ross MP, Tarantino MD, Rodgers GC, Montgomery VL, <u>Sullivan JE</u>. "A Prospective, Randomized, Placebo-Controlled, Multi-Center Trial Examining the Role of Antithrombin III Treatment in the Management of Meningococcal Purpura Fulminans." Bayer Pharmaceuticals. \$7.000.
- Ross MP, Montgomery VL, <u>Sullivan JE</u>, Rodgers GC. "A Multi-Center, Comparative, Randomized Trial to Determine the Overall Safety and Efficacy of 1% Diprivan Versus 2% Diprivan Versus Standard Agents without Disodium Edetate for Sedation of Trauma, Postsurgical, or Critically III Subjects." Zeneca Pharmaceuticals.
- 1991 1995 <u>Sullivan JE (PI)</u>, Wells T, Yamashita TS, Myers CM, Blumer JL. "Pharmacokinetics and Pharmacodynamics of Bumetanide in Critically III Children."
- 1991 1995 <u>Sullivan JE (PI)</u>, Witte MK, Yamashita TS, Myers CM, Blumer JL. "Pharmacokinetics and Pharmacodynamics of Bumetanide in Critically III Infants."

Consultant

2015 Sullivan JE. Pfizer Advisory Board.

2013 Sullivan JE and Berkenbosch JW. Gruenthal Pharmaceuticals Advisory Board.

2010 Sullivan JE. Merck Pharmaceuticals Advisory Board.

2010 Sullivan JE. Sanofi-Aventis Advisory Board.

2009 <u>Sullivan JE</u>. "Diagnosing Adverse Drug Reactions in Pediatric ICUs" Wayne State University. Detroit, MI.

2009 <u>Sullivan JE</u>. "A multinational, randomized, open-label study to evaluate the efficacy and safety of AVE 5026 for the prevention of thromboembolism in pediatric patients with central venous line (CVL) and additional prothrombotic

risk factors." Sanofi-Aventis. Advisory Board.

2008 Sullivan JE. Hylenex Advisory Board. Advogent/Baxter.

EDITORIAL WORK

2021 – Present Associate Editor, Journal of Clinical Pharmacology

2018 Abstract Reviewer: PAS

1998 – 2009 Abstract Reviewer: American Society of Clinical Pharmacology and Therapeutics

	Journal	Number of Reviews
2018	Pediatric Drugs	1
2014	JAMA	1
2014	Drugs in R&D	1
2009	Journal of Clinical Forensic Medicine	1

2009	Canadian Journal of Clinical Pharmacology	1
2009 - Present	Journal of Critical Care	3
2003 – Present	Clinical Pharmacology & Therapeutics	7
2007 – Present	The Pediatric Infectious Disease Journal	8
2005 – Present	Pediatrics	7
2005, 2010 – 2011	ACTA Pediatrics	3
1999 – Present	Current Therapeutic Research®	5
1997 – Present	The Journal of Pediatrics	5

ABSTRACTS AND PRESENTATIONS (List in chronological order and number)

ORAL PRESENTATIONS

National/International Meetings

- 3/13/2021 Rahman S, Paul I, Sullivan JE, Hornik CD, Wade K, Delmore D, Zimmerman KO. Minority Representation in Pediatric Studies Funded under the Best Pharmaceuticals for Children's Act (BPCA). ASCPT Virtual meeting.
- 4/28/2019 Sullivan JE. ISPCTN-PTN: Network to Network Support. Presented at DCRI Symposium, PAS, Baltimore, MD.
- 5/5– 9/2017 O'Brien ARW, Williams SG, Hawkins SM, Mascio C, Austin EH, Siddiqui HM, Berkenbosch JW, <u>Sullivan JE</u>. "The Utility of Post-Thoracostomy Tube Removal Chest Radiographs in Pediatric Intensive Care Patients." Presented at PAS, San Francisco.
- 5/5-9/2017 Autmizguine J, Chiara M, Hornik CP, Dallefeld S, Harper B, Yogev R, Sullivan JE, Atz A, Mendley S, Poindexter B, Lewandowski A, Delmore P, Cohen-Wolkoweiz M, Gonzalez D. "Population Pharmacokinetics of Trimethoprim-Sufamethoxazole in Infants and Children." Presented at PAS, San Francisco.
- 10/05/2016 Autmizguine J, Chiara M, Hornik CP, Dallefeld S, Harper B, Yogev R, Sullivan JE, Atz A, Mendley S, Poindexter B, Lewandowski A, Delmore P, Cohen-Wolkoweiz M, Gonzalez D. "Population Pharmacokinetics of Trimethoprim-Sufamethoxazole in Infants and Children."
- **02/24-28/2016** Morgan L, <u>Sullivan JE</u>, Keller B. "Validation of point-of-care INR testing versus clinical venipuncture: a prospective cohort pilot study." Presented at Annual Update on Pediatric and Congenital Cardiovascular Disease, Orlando, FL.
- **05/1-20/2015** Berkenbosch J, Yakkanti R, Farrell D, Gilliland F, Hignite J, <u>Sullivan JE</u>. "Bolus vs Bolus+Infusion Use of Dexmedetomidine for Pediatric MRI Sedation." Presented at Society for Pediatric Sedation Conference, St. Louis, MO; Crit Care Med. 2014; 42(12 (Suppl):662.
- 01/17/2015 Berkenbosch J, Yakkanti R, Farrell D, Gilliland F, Hignite J, <u>Sullivan JE</u>. "Bolus vs Bolus+Infusion Use of Dexmedetomidine for Pediatric MRI Sedation." Presented at SCCM, Phoenix, AZ, January 17, 2015; Crit Care Med. 2014; 42(12 (Suppl):662.
- 09/25/2014 Condurache CT, Sullivan JE, Burger A, Eid NS. Effects of Educational Intervention on Functional Outcomes of Hospitalized Children with Asthma: A Randomized- Controlled Trial. Platform presentation: Irish and American Pediatric Society/Irish Pediatric Association, Cork Ireland, Sep 25, 2014.
- O6/25/2014 Condurache CT, Sullivan JE, Burger A, Eid NS. Effects of Educational Intervention on Functional Outcomes of Hospitalized Children with Asthma: A Randomized- Controlled Trial. Platform presentation: Pediatric Hospital Medicine Meeting, Orlando, FL, July 25, 2014.
- *Sullivan, JE. "Lorazepam Trial: Challenges of Pediatric Sedation Scores." Clinical Development Programs for Sedation Products: Public Workshop. FDA Sedation Workshop for Center for Drug Evaluation and Research. Silver Springs, MD.
- **12/04/2009** *Sullivan JE. "Antipyresis: Yes, No or Maybe." Vitoria, Brazil.
- *Sullivan JE. "Update on Pediatric Clinical Pharmacology Research." Medical School UNIPAC, Juiz De Fora, MG, Brazil.
- **10/29/2007** *Sullivan JE. "Combination Therapy: Acetaminophen & Ibuprofen." American Academy of Pediatrics, SOCPT Section Program, San Francisco, California.

^{*}Invited talks and meetings I helped to organize.

Michalczyk KE, Ahuja S, <u>Sullivan JE</u>, Berkenbosch J. "Effect of Midazolam Pretreatment on Ketamine Induced Intracranial Pressure Changes." Pediatr Crit Care Med 2007; 8:602. Presented at the American Academy of Pediatrics National Convention, San Francisco, California.

10/2007 Berkenbosch J, Walls KM, Schoonover JJ, <u>Sullivan JE</u>, Montgomery VL. "Independent Provision of Procedural Sedation by Nurse Practitioners – A New Sedation Model." Pediatr Crit Care Med 2007; 8:601. Presented at the American Academy of Pediatrics National Convention, San Francisco, California.

10/08/2004 Myers A, Koller D, Kennedy MJ, <u>Sullivan JE</u>, Gadambe S. "Comparison of Three Oral Oxycodone Doses for Treatment of Orthopedic Injury Related Pain in Children." Platform presentation, American Academy of Pediatrics, San Francisco, California.

05/2004 Louthan M, <u>Sullivan JE</u>, McClain C. "Decreased Hepatic Mitochondrial Function in Overweight Children." (107591 Oral Presentation) Digestive Disease Week, New Orleans, Louisiana.

*Rule of 6's. NACHRI Pharmacy Focus Group. Alexandria, Virginia.

03/31/1994 Pharmacokinetics and Pharmacodynamics of Bumetanide Dose-Ranging Study in Infants. American Society for Clinical Pharmacology and Therapeutics, 95th Annual Meeting, Pediatric and Perinatal Pharmacology Section Meeting, New Orleans, Louisiana.

Local/Regional Meetings

7/25/2018 Dorcin S, Beechinor RJ, Gerhart JG, Mendley S, Hornik CP, Sullivan JE, Atz A, Melloni C, Cohen-Wolkowiez M, Gonzalez D; on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee. Dried Blood Spot Analysis of Metoclopramide in Infants, Children and Adolescents. Presented at UNC Research Symposium.

7/18/2018 "Pediatric Clinical Trials & Opportunities: What is in it for You?". Work in Progress (WIP), University of Louisville, PRI.

*What's New? Pharmacology Updates. Just for Kids' 2017 Pediatric Care Symposium, Sponsored by Norton Children's Hospital and University of Louisville School of Medicine.

11/11/2013 "ABC's in Clinical Research & Current Opportunities" Research Seminar. University of Louisville Department of Pediatrics

03/29/2013 *"Case Presentations and Panel Discussion." Moderator; Pediatric Pharmacology Symposium. Louisville, Kentucky

*"Making Life Better for Children." Invited Speaker at the Kosair Charities W. Barnett Owen Society Luncheon. Louisville, KY

*"Case Presentations and Panel Discussion." Moderator; Pediatric Pharmacology Symposium. Louisville, Kentucky

04/15/2011 *"Case Presentations and Panel Discussion." Moderator; Pediatric Pharmacology Symposium. Louisville, Kentucky

01/08/2010 *"Antipyresis: Yes, No or Maybe." Pediatric Pharmacology Symposium. Louisville, Kentucky.

07/17/2009 Pediatric Pharmacology Research. WHAS Health Expo. Louisville, Kentucky.

09/05/2008 Use of Medications and Clinical Research in Pediatric Patients. WFPL Radio Show "State of Affairs," Louisville, Kentucky.

04/15/2008 Transport Management of Poisonings and Snakebites in Pediatrics. Transport Medicine Conference, Kosair Children's Hospital, Louisville, Kentucky.

01/17/2007 1st Annual Pediatric Clinical Bioethics Forum: "Defining Medical Futility," Kosair Children's Hospital, Louisville, Kentucky.

04/05/2006 E'lytes--How It all Works. Cardiac Lecture Series, Kosair Children's Hospital, Louisville, Kentucky.

02/05/1999 Pharmacologic Management of the Cardiovascular Patient, Pediatric Cardiovascular Seminar, Kosair Children's Hospital, Louisville, Kentucky.

10/13/1999 Poisonings and Snakebites. University of Kentucky Pediatric Transport Nurse Course. University of Kentucky, Lexington, Kentucky.

11/07/1997 PALS. Fifth Newborn and Pediatric Symposium, Louisville, Kentucky.

10/12/1997 Ingestions. The First Annual Adult/Pediatric Trauma & Critical Care Symposium, Louisville, Kentucky.

06/11/1997 Partial Liquid Ventilation Theory. 32nd Annual Postgraduate Nursing Symposium, Louisville, Kentucky.

05/08/1997 Pharmacology Frontiers in Emergency Care: Is Newer Better? Trauma Symposium, Louisville, Kentucky.

04/22,24/1997 What Is That Drug? (Part 2). Pediatric Critical Care Course, Louisville, Kentucky.

04/22,24/1997 Oh, the Problems with IV Infusions! Pediatric Critical Care Course, Louisville, Kentucky.

12/04/1996 Inhalant Abuse in the '90's. Regional Toxicology Conference Sponsored by the Kentucky Regional Poison Center,

Louisville, Kentucky.

11/09/1996 Poisonings in the '90's. Fourth Neonatal and Pediatric Symposium, Louisville, Kentucky.

POSTERS

National/International Meetings

5/1/2019 Sullivan JE representing ISPCTN POPS (POP01) Committee. Update on IDeA States Pediatric Network and the POP01 Protocol. NIH IDeA States Pediatric Network Meeting. Washington, DC.

4/30/2019 Pettit N, Bryant K, Espinosa CM, Sullivan JE, Duong JT. Oral Gentamicin and Bloodstream Infections of Infants Hospitalized in a Neonatal Intensive Care Unit (NICU). PAS, April 2019, Baltimore, MD.

4/30/2019 Snowden J, Sullivan JE, Knight LM, Arnett RD, Cowan K. Pediatric Research Capacity Improvements in the IDeA States Pediatric Clinical Trial Network. PAS, April 2019, Baltimore, MD.

5/1-4/2019 Barnes G, Sullivan JE, Sears L, VanLandingham K, Knappertz V, Guy G. Safety and Tolerability of GWP42006 (Cannabidivarin [CBDV]) in Subjects with Drug Resistant Epilepsy and Autism Spectrum Disorders. Presented at the INSAR 2019 Annual Meeting at the Palais des congress de Montreal, Quebec, Canada.

2/6/2019 Sullivan JE representing ISPCTN POPS (POP01) Committee. Update on IDeA States Pediatric Network and the POP01 Protocol. NIH IDeA States Pediatric Network Meeting. Washington, DC.

Barnes G, Sullivan JE, Sears L, VanLandingham K, Knappertz V, Guy G. Safety and Tolerability of GWP42006 (Cannabidivarin [CBDV]) in Subjects with Drug Resistant Epilepsy and Autism Spectrum Disorders. Presented at the 2018 Annual Meeting of the American Epilepsy Society, New Orleans, LA.

9/18/2018 Sullivan JE representing ISPCTN POPS (POP01) Committee. IDeA States Pediatric Network and the POP01 Protocol. NIH IDeA States Pediatric Network Meeting. Washington, DC.

9/23-24/2018 Ge S, Mendley S, Gerhart JG, Melloni C, Hornik CP, Sullivan JE, Atz A, Delmore P, Tremoulet A, Poindexter B, Harper B, Payne E, Lin S, Cohen-Wolkowiez M, Gonzalez D; on behalf of the Best Pharmaceuticals for Children Act–Pediatric Trials Network Steering Committee. Population Pharmacokinetics of Metoclopramide in Infants, Children, and Adolescents. American College of Clinical Pharmacology, Bethesda, MD. Presentation #018. Abstract was ranked amongst the top 16 Student Abstracts. Published in Clinical Pharmacology in Drug Development 2018;7(S1):1-104.

10/26-30/2016 Gonzalez D, Bradley JS, Blumer J, Yogev R; Watt KM, James LP, Palazzi DL, Bhatt-Mehta V, <u>Sullivan JE</u>, Zhang L, Murphy J, Ussery XT, Puttagunta S, Dunne MW, Cohen-Wolkowiez M. Dalbavancin Pharmacokinetics and Safety in Children 3 Months to 11 Years of Age. Poster presented at ID Week; October 26-30, 2016; New Orleans, LA.

O4/25-28/2015 Smith MJ, Gonzalez D, Goldman JL, Yogev R, Sullivan JE, Reed MD, Anand R, Martz K, Berezny K, Smith PB, Cohen-Wolkowiez M, Watt K, on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network. Pharmacokinetics of Multiple-Dose Intravenous Clindamycin in Obese Children (Abstract #: 751266) Presented April 28, 2015 at PAS, San Diego, CA.

01/17/2015 Berkenbosch J, Hignite J, Gilliland F, Farrell D, Yakkanti R, <u>Sullivan JE</u>. Impact of Ketamine Co-administration During Dexmedetomidine Sedation for Pediatric MRI. Presented at SCCM, Phoenix, AZ.; January 17, 2015; Crit Care Med. 2014; 42(12 (Suppl):36.

07/26/2014 Condurache CT, <u>Sullivan JE</u>, Burger AK and Eid NS. Asthma Knowledge Retention Rates in Parents of Hospitalized Children with Asthma: A Randomized-Controlled Trial. Presented at Pediatric Hospital Medicine Meeting, Orlando, FL, July 26, 2014.

- **05/06/2014** Condurache CT, <u>Sullivan JE</u>, Burger AK, Eid N. Effects of Educational Intervention on Functional Outcomes of Hospitalized Children with Asthma: A Randomized-Controlled Study. Presented at PAS, Vancouver, Canada.
- **03/2014** Lettieri J, <u>Sullivan JE</u>. Safety, tolerability and pharmacokinetics (PK) of single dose intravenous Moxifloxacin in pediatric patients. Atlanta, GA. March 21, 2014.
- O1/2014 Rigby M, Leong T, <u>Sullivan JE</u>, Preissis C, Gillespie S, Rider C, Maher K, Wintergerst K. Multicenter Evaluation of a Glycemic Control Protocol in Pediatric Critical Care. Society of Critical Care Medicine's 43rd Critical Care Congress Abstracts, San Francisco, CA. January 2014.
- **04/2013** Valentine K, Lieh-Lai M, <u>Sullivan JE</u>, Blumer J. Pharmacokinetics of Terbutaline in Critically III Children with Asthma Admitted to the Pediatric Intensive Care Unit. Detroit, MI. April 2013.
- 09/2012 Rigby MR, Leong T, <u>Sullivan JE</u>, Rotta A, Nitu M, Wintergerst KA. De novo adoption of a hyperglycemic protocol by 2 pediatric intensive care units. Pediatric Critical Care Colloquium Meeting. Santa Monica, CA. September 2012.
- James LP, <u>Sullivan JE</u>, Letzig L, Abdul-Rahman S, Capparelli E, Yan K, Simpson PM, Roberts DR. "Acetaminophen Protein Adducts in Hospitalized Children Receiving Acetaminophen." American Society for Clinical Pharmacology & Therapeutics Annual Meeting. National Harbor, Maryland. March 12-17, 2012.
- **05/22-24/2011** Anderson J, Mayes S, Owen E, <u>Sullivan JE</u>. "Safety of Endotracheal Lidocaine in Critically III Children." ACCP Virtual Poster Symposium.
- 11/12-13/2011 Nishisaki A, Sanders R, <u>Sullivan JE</u>, et al. "Pediatric ICU tracheal intubation process of care and safety outcomes: Multicenter data from National Emergency Airway Registry for Children (NEAR4KIDS)." American Heart Association's Resuscitation Science Symposium 2011, Orlando, Florida.
- 09/19/2011 Bradly J, Blumer J, Purohit VS, Dunne MW, <u>Sullivan JE</u>. A Phase I, Open-label, Single Dose Study to Investigate the Pharmacokinetics (PK), Safety and Tolerability of Dalbavancin in Adolescents Age 12 to 17 Years. Interscience Conference on Antimicrobial Agents and Chemotherapy. Chicago, Illinois.
- **05/02/2011** Redwine KM, <u>Sullivan JE</u>, et al. "Effects of Placebo on Ambulatory Blood Pressure Monitoring in Children." Pediatric Academic Societies' and Asian Society for Pediatric Research Joint Meeting, Denver, Colorado.
- **06/17-20/2011** Sullivan JE, Keefe D, Zhou Y, Satlin L., Yan J. Safety and Efficacy of Aliskiren in Children: An 8-Day, Multiple-Dose, Open-Label Study. European Meeting on Hypertension. Milan, Italy.
- 10/2010 Berkenbosch JW, Morton RL, Stutey KM, Ewing B, <u>Sullivan JE</u>. "The Effect of Obesity on ICU Course in Pediatric Patients with Status Asthmaticus." American College of Chest Physicians Annual Meeting, Vancouver, Canada.
- **01/09-13/2010** Berkenbosch JW, Stutey K, Ewing B, <u>Sullivan JE</u>. "Factors Affecting the ICU Course in Pediatric Patients with Status Asthmaticus." Society of Critical Care Medicine's 39th Critical Care Congress Abstracts, Miami Beach, Florida.
- **01/09-13/2010** Berkenbosch JW, Eldridge M, Calhoun AW, Montgomery VL, <u>Sullivan JE</u>. "Effect of Sedation Protocolon Duration of Mechanical Ventilation and Sedative medication use in Critically III Children." Society of Critical Care Medicine's 39th Critical Care Congress Abstracts, Miami Beach, Florida.
- **06/07-10/2009** Berkenbosch JW, Michalczyk KE, Ahuja S, <u>Sullivan JE</u>. "Pretreatment with Midazolam Blunts Ketamine-Induced Increases in Intracranial Pressure." 4th International, Multidiciplinary Conference on Pediatric Procedural Sedation, Society for Pediatric Sedation, Philadelphia, Pennsylvania.
- **06/07-10/2009** Berkenbosch JW, Michalczyk KE, Ahuja S, <u>Sullivan JE</u>. "Factors Affecting Ketamine Dose Requirements During Procedural Sedation for Pediatric Oncology Patients." 4th International, Multidiciplinary Conference on Pediatric Procedural Sedation, Society for Pediatric Sedation, Philadelphia, Pennsylvania.
- O6/01/2009 Comer GM, Baker RD, Tsou VM, Tung J, Li H, Wang W, Rath, NJ, Maguire MK, <u>Sullivan JE</u>. "Randomized, Double-Blind Clinical Outcomes, Safety, and Tolerability Study of Pantoprazole Delayed-Release Granules in Children Aged 1 to 5 Years with Endoscopically Proven Symptomatic GERD." Digestive Disease Week, American Gastroenterological Association, Chicago, Illinois.
- **06/01/2009** Comer GM, Kierkus J, <u>Sullivan JE</u>, Furmaga-Jablonskia W, Rath NJ, Fu C, Wang W, Maguire MK. "Pharmacodynamics and Safety of Pantoprazole Delayed-Release Granules in Infants Aged 1 Through 11 Months with a Clinical Diagnosis

of Gastroesophageal Reflux Disease." Digestive Disease Week, American Gastroenterological Association, Chicago, Illinois.

10/05/2008 Tammara B, Sullivan JE, Springer MA, Kierkus J, Rath N, Fu C, Meng X, Maguire M, Comer G. "Pharmacokinetics of 2 Dose Levels of Pantoprazole Delayed-Release Granules for Oral Suspension in Infants Aged 1 Through 11 Months with Presumed Diagnosis of GERD." Accepted for poster presentation at the American College of Gastroenterology, Orlando. Florida.

02/17-21/2007 Berkenbosch, J, Walls KM, Schoonover JJ, Michalczyk KE, <u>Sullivan JE</u>. "Experience with Independent Ketamine Administration by Advance Practice Registered Nurses for Pediatric Procedural Sedation." Crit Care Med December 2006;34(Suppl 12):A159. Society of Critical Care Medicine, Orlando, Florida.

O2/17-21/2007 Sullivan JE, Walls K, Berkenbosch J. "Independent Use of Ketamine by Nurse Practitioners for Pediatric Procedural Sedation." Pediatr Crit Care Med. 2007;8(3)Suppl. Society of Critical Care Medicine, Orland, Florida.

02/17-21/2007 Berkenbosch, J, Michalczyk KE, <u>Sullivan JE</u>. "Factors Affecting Variability of Ketamine Dosing Requirements for Pediatric Oncology Procedural Sedation." Crit Care Med December 2006; 34 (Suppl 12):A158. Society of Critical Care Medicine, Orlando, Florida.

01/07-11/2006 Polavarapu N, <u>Sullivan JE</u>, Walls K, Schoonover JJ, Berkenbosch J. "Age-related Effects of Pentobarbital for Non-invasive Pediatric Procedural Sedation." Crit Care Med, December 2005;33(Suppl 12):A177. Society of Critical Care Medicine, San Francisco, California.

Myers AB, <u>Sullivan JE</u>, Koller DM, Godambe SA, Kennedy MJ. "Correlation of CYP2D6 Genotype with Response to Oxycodone in Orthopedic Injury Related Pain." Clin Pharmacol Ther 2006;79(2):18.

2006 Kennedy MJ, <u>Sullivan JE</u>, Doll MA, Griffin A, Hein DW. "Slow Acetylator N-acetyltransferase 2 Genotype is Associated with Atopic Dermatitis (AD) in Children." Clin Pharmacol Ther 2006;79(2):6.

Kennedy MJ, Smith NB, Pierce WM, Lin Y, Pearce RE, Gaedigk A, Sullivan JE. "Chronic Intermittent Nocturnal Hypoxemia Alters Activities of Hepatic Cytochrome P4501A2 (CYP1A2), N-acetyltransferase 2 (NAT2) and Xanthine Oxidase (XO) in Children with Obstructive Sleep Apnea." Clin Pharmacol Ther 2006;79(2):33.

Potter KE, Sullivan JE, Raj A. "Argatroban Use for (258-T) Thrombocytopenia (HIT) in Pediatric Patients on Extracorporeal Life Support (ECLS). Crit Care Med December 2005;33(Suppl 12):A183.

10/2004 Kennedy MJ, Loehle JA, <u>Sullivan JE</u>, Doll MA, Hein DW. "Histamine N-methyltransferase (HNMT) C314T Gene Polymorphism is Associated with Atopic Dermatitis in Caucasian Children." American College of Clinical Pharmacy Annual Meeting, Dallas, Texas.

07/2004 Louthan MV, <u>Sullivan JE</u>, Stutts J, McClain CJ. "Decreased Prevalence of NAFLD in Black, Obese Children." Accepted for poster presentation at North American Society for Pediatric Gastroenterology, Hepatology and Nutrition World Congress.

O7/2004 Louthan MV, <u>Sullivan JE</u> Hill D, McClain, CJ. "Decreased Hepatic Mitochondrial Function in Overweight Children." Gastroenterology 2004;126(4)(Suppl2)A-68. Accepted for poster presentation at North American Society for Pediatric Gastroenterology, Hepatology and Nutrition World Congress.

05/19/2001 Mattingly JE, <u>Sullivan JE</u>, Spiller HA, Bosse GM. "Intermediate Syndrome after Exposure to Chlorpyrifos in 16-Month-Old Female." ESPCCT, Barcelona, Spain.

09/18/2000 James L, Farrar H, <u>Sullivan JE</u>, Kearns G, Hinson J, Pumford N. "Cytokine Responses Following Acute Acetaminophen Overdoses." NACCT, Tucson, Arizona.

02/11-15/2000 McDonald MJ, Montgomery VL, Boland KA, <u>Sullivan JE</u>. "A Comparison of End Tidal and Blood Gas Carbon Dioxide in Mechanically Ventilated Children." Crit Care Med, 1999;27 (Suppl 12):A114. Society of Critical Care Medicine, Orlando, Florida.

09/1999 McDonald MJ, Montgomery VL, Boland KA, <u>Sullivan JE</u>. "A Comparison of End Tidal and Blood Gas Carbon Dioxide in Mechanically Ventilated Children." Clin Intens Care 1999;10(4):151. Pediatric Critical Care Colloquium, Portland, Oregon.

- **03/18-20/1999** James L, Farrar H, <u>Sullivan JE</u>, Kearns G, Hinson J, Pumford N. "Antigenic Biomarker Identification of Acetaminophen Hepatotoxicity in Children." American Society for Clinical Pharmacology and Therapeutics, San Antonio, Texas.
- **02/18-20/1999** James L, Farrar H, <u>Sullivan JE</u>, Kearns G, Hinson J, Pumford N. Antigenic biomarker identification of acetaminophen hepatotoxicity in children. Southern Society for Pediatric Research, New Orleans, Louisiana.
- **09/20/1997** Montgomery VL, Oliver R, Reisner A, Fallat M, Ross MP, <u>Sullivan JE</u>. "The Effect of Severe Traumatic Brain Injury on the Family." Pediatric Critical Care Colloquium, Hot Springs, Arkansas.
- **09/20/1997** Montgomery VL, Strotman JM, Buchino JJ, <u>Sullivan JE</u>. "Cardiac Troponin (CTnl) as a Prognostic Indicator Following Open Heart Surgery in Children. Pediatric Critical Care Colloquium, Hot Springs, Arkansas.
- **09/14-18/1997** Villafane J, Beck CM, Montgomery VL, <u>Sullivan JE</u>. "Adenosine Infusion: A Potentially New Treatment for Supraventricular Tachycardia." XVI Interamerican Congress of Cardiology, Fajardo, Puerto Rico.
- **05/11-15/1997** Villafane J, Beck CM, Montgomery VL, <u>Sullivan JE</u>. "Adenosine Infusion: A Potentially New Treatment for Supraventricular Tachycardia." Second World Congress of Pediatric Cardiology and Cardiac Surgery, Honolulu, Hawaii.
- 06/23-26/1996 Sullivan JE, Witte MK, Yamashita TS, Myers CM, Blumer JL. "Analysis of the Variability in the Pharmacokinetics and Pharmacodynamics of Bumetanide in Critically III Infants." Intens Care Med 1996;22(Suppl 2):S230:115. 2nd World Congress on Pediatric Intensive Care, Rotterdam, The Netherlands.
- 06/23-26/1996 Sullivan JE, Witte MK, Yamashita TS, Myers CM, Blumer JL. "Dose-ranging Evaluation of Bumetanide Pharmacodynamics in Critically III Infants." Intens Care Med 1996;22(Suppl 2):S230:116.2nd World Congress on Pediatric Intensive Care, Rotterdam, The Netherlands.
- O6/23-26/1996 Sullivan JE, Witte MK, Yamashita TS, Myers CM, Blumer JL. "Pharmacokinetics of Bumetanide in Critically III Infants. Intens Care Med 1996;22(Suppl 2):S230:117. 2nd World Congress on Pediatric Intensive Care, Rotterdam, The Netherlands.
- **O3/15-17/1995** Sullivan JE, Yamashita TS, Wells TG, Blumer JL. "Pharmacokinetics and Pharmacodynamics of Bumetanide in Critically Ill Children." Clin Pharmacol Ther 1995;57(2):180. American Society for Clinical Pharmacology and Therapeutics, 96th Annual Meeting, San Diego, California.
- 03/15-17/1995 Sullivan JE, Witte MK, Yamashita TS, Myers CM, Blumer JL. "Effects of Age and Disease on Pharmacokinetics and Pharmacodynamics of Bumetanide in Critically III Infants." Clin Pharmacol Ther 1995;57(2):180. American Society for Clinical Pharmacology and Therapeutics, 96th Annual Meeting, San Diego, California.
- **07/24-29/1994** Sullivan JE, Witte MK, Yamashita TS, Blumer JL. "Dose-Related Effects of Bumetanide (B) in Infants with Volume Overload." Can J Phys Pharm 1994;72(Suppl 1):205. XIIth International Congress of Pharmacology, Montreal, Canada.
- **03/30–4/1/1994** Sullivan JE, Witte MK, Yamashita TS, Blumer JL. "Pharmacokinetic (PK) & Pharmacodynamic (PD) Bumetanide (B) Dose-Ranging Study in Infants." Clin Pharmacol Ther 1994;55(2):179. American Society for Clinical Pharmacology and Therapeutics, 95th Annual Meeting, New Orleans, Louisiana.
- 03/24-26/1993 Reed MD, Farrar HC, Marx CM, Kyllonen K, <u>Sullivan JE</u>, Blumer JL. "Monitoring Serum Vancomycin (IV) Concentrations: To Be or Not to Be!." Clin Pharmacol Ther 1993;53(2):149. American Society for Clinical Pharmacology and Therapeutics, 94th Annual Meeting, Honolulu, Hawaii.

Local/Regional Meetings

- 8/24-25/2018 KY AAP meeting in Berea, KY. Secured a booth through the IDeA Grant and provided information to providers related to involving underserved and rural populations in clinical research in 5 main focus areas: pre-,peri-, and post-natal; neurodevelopmental; upper/lower airway; obesity; and positive child health.
- 10/2007 Michalczyk KE, <u>Sullivan JE</u>, Ahuja S, Berkenbosch J. "Effects of Midazolam on Ketamine-induced Intracranial Pressure (ICP) Changes." Presented at Research Louisville, Department of Pediatrics, University of Louisville School of Medicine, Louisville, Kentucky.
- **08/20/2004** Challenges in Pediatric Drug Development and Clinical Research, Clinical Pharmacology Symposium, University of Louisville and Kosair Children's Hospital, Louisville, Kentucky.

PUBLICATIONS

Publications (Peer-Reviewed)

(*Publication for which mentored student is listed as first author)

- 1. Maharaj AR; Wu H; Zimmerman KO; Muller WJ; Sullivan JE; Sherwin CMT; Autmizguine J; Rathore MH; Hornik CD; Al-Uzri A; Payne EH; Benjamin DK; Hornik CP, PhD. Pharmacokinetics of Ceftazidime in Children and Adolescents with Obesity. June 2021; Accepted for publication, Pediatric Drugs.
- Son MBF, Murray N, Friedman K, Young CC, Newhams MM, Feldstein LR, Loftis LL, Tarquinio KM, Singh AR, Heidemann SM, Soma VL, Riggs BJ, Fitzgerald JC, Kong M, Doymaz S, Giuliano JS Jr, Keenaghan MA, Hume JR, Hobbs CV, Schuster JE, Clouser KN, Hall MW, Smith LS, Horwitz SM, Schwartz SP, Irby K, Bradford TT, Maddux AB, Babbitt CJ, Rowan CM, McLaughlin GE, Yager PH, Maamari M, Mack EH, Carroll CL, Montgomery VL, Halasa NB, Cvijanovich NZ, Coates BM, Rose CE, Newburger JW, Patel MM, Randolph AG. Multisystem Inflammatory Syndrome in Children Initial Therapy and Outcomes. N Engl J Med. 2021 Jul 1;385(1):23-34. doi: 10.1056/NEJMoa2102605. Epub 2021 Jun 16. PubMed PMID: 34133855; PubMed Central PMCID: PMC8220972.
- 3. Ganguly S, Edginton AN, Gerhart JG, Cohen-Wolkowiez M, Greenberg RG, Gonzalez D. Physiologically Based Pharmacokinetic Modeling of Meropenem in Preterm and Term Infants. Clin Pharmacokinet. 2021 Jun 22;. doi: 10.1007/s40262-021-01046-6. [Epub ahead of print] PubMed PMID: 34155614.
- 4. Abdel-Rahman SM, Paul IM, Hornik C, Sullivan JE, Wade K, Delmore P, Sharma G, Benjamin DK, Zimmerman KO. Racial and Ethnic Diversity in Studies Funded Under the Best Pharmaceuticals for Children Act. Pediatrics. 2021 May;147(5). doi: 10.1542/peds.2020-042903. Epub 2021 Apr 12. PubMed PMID: 33846237.
- 5. LaRovere KL, Riggs BJ, Poussaint TY, Young CC, Newhams MM, Maamari M, Walker TC, Singh AR, Dapul H, Hobbs CV, McLaughlin GE, Son MBF, Maddux AB, Clouser KN, Rowan CM, McGuire JK, Fitzgerald JC, Gertz SJ, Shein SL, Munoz AC, Thomas NJ, Irby K, Levy ER, Staat MA, Tenforde MW, Feldstein LR, Halasa NB, Giuliano JS Jr, Hall MW, Kong M, Carroll CL, Schuster JE, Doymaz S, Loftis LL, Tarquinio KM, Babbitt CJ, Nofziger RA, Kleinman LC, Keenaghan MA, Cvijanovich NZ, Spinella PC, Hume JR, Wellnitz K, Mack EH, Michelson KN, Flori HR, Patel MM, Randolph AG. Neurologic Involvement in Children and Adolescents Hospitalized in the United States for COVID-19 or Multisystem Inflammatory Syndrome. JAMA Neurol. 2021 May 1;78(5):536-547. doi: 10.1001/jamaneurol.2021.0504. PubMed PMID: 33666649; PubMed Central PMCID: PMC7936352.
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