

PEDIATRIC TRIALS NETWORK

On behalf of the Pediatric Trials Network Steering Committee

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**PEDIATRIC
TRIALS NETWORK**

Making drugs safer & more effective
for use in the youngest patients



Eunice Kennedy Shriver National Institute
of Child Health and Human Development

A project of the Best Pharmaceuticals for Children Act

Mission Statement and Goals

- *Sponsored by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under the auspice of the Best Pharmaceutical for Children Act (BPCA), the Pediatric Trials Network (PTN) is an alliance of clinical research sites cooperating in the design and conduct of pediatric clinical trials.*
- *PTN research provides evidence for optimal use of off-patent medications and devices in infants and children.*

Evidence into Practice

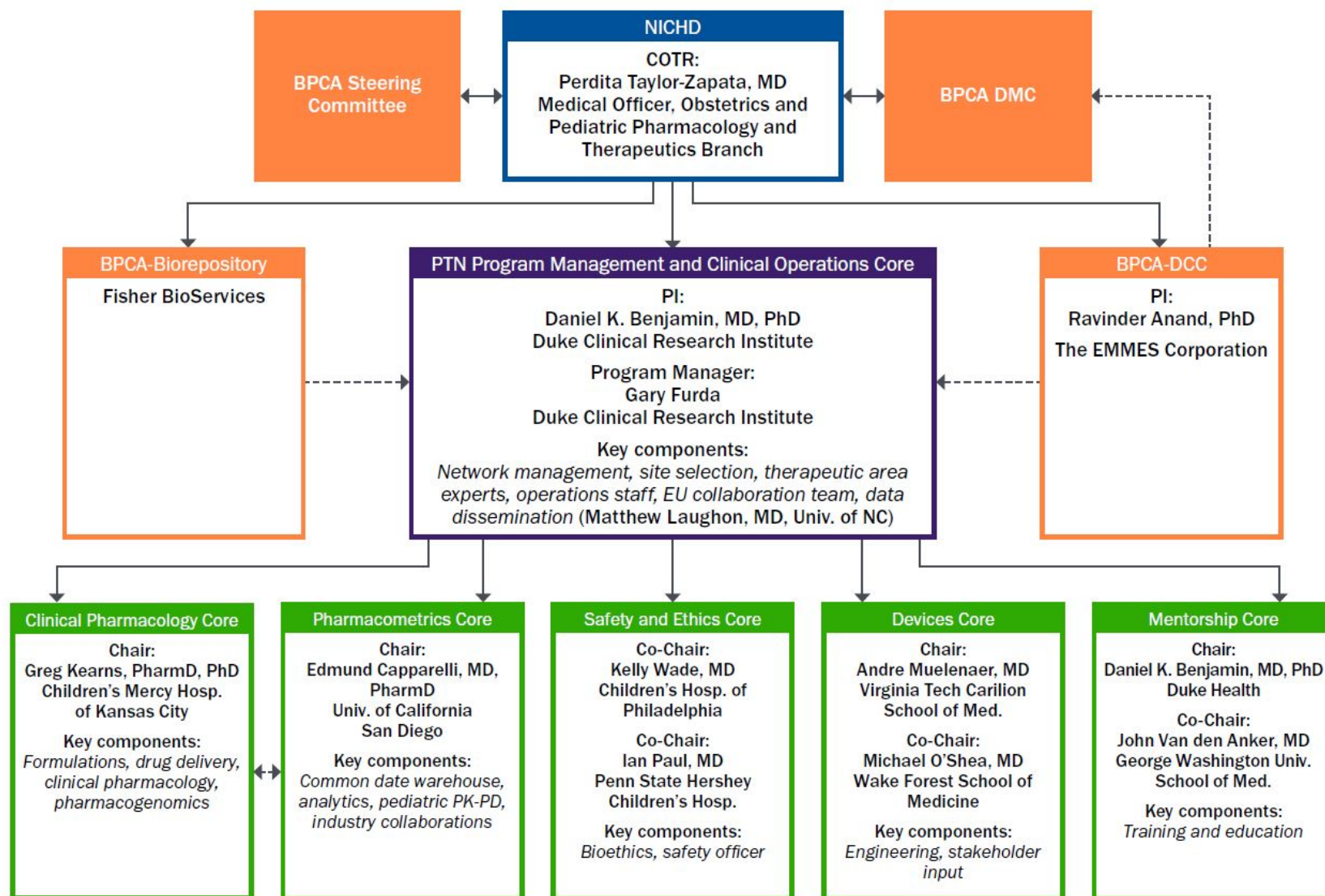
Trial design and conduct → Regulatory submission → Dissemination



Steering Committee

Name	Role	Center
Daniel Benjamin, MD, PhD	Network PI	Duke University, Durham, NC
Gary Furda	Program Manager	Duke University, Durham, NC
John van den Anker, MD, PhD	Chair, Mentorship Core	GWU School of Medicine & Health Science, Washington, DC
Edmund Capparelli, Pharm D	Chair, Pharmacometrics Core	UC San Diego, San Diego, CA
Gregory Kearns, Pharm D, PhD	Chair, Clin. Pharmacology Core	Children's Mercy Hospital & Clinics, Kansas City, MO
Kelly Wade, MD, PhD	Chair, Safety & Ethics Core	Children's Hospital of Philadelphia, Philadelphia, PA
Ian Paul, MD	Member	Penn State College of Medicine, Hershey, PA
Janice Sullivan MD	Member	University of Louisville, Louisville, KY
Christoph Hornik, MD, MPH	Member	Duke University, Durham, NC
Matthew Laughon, MD	Member	UNC Memorial Hospital, Chapel Hill, NC
Chi Dang Hornik, PharmD	Member	Duke University, Durham, NC
Perdita Taylor-Zapata, MD	NICHD COTR	NIH/NICHD, Bethesda, MD
Ravinder Anand, PhD	Data Coordinating Center PI	The Emmes Corporation, Rockville, MD
Gina Simone	Project Director, DCC	The Emmes Corporation, Rockville, MD

Organization Chart



By the numbers



>7000

children enrolled



21

products with data
submitted to the FDA

38

studies



including—

26

clinical trials



45

publications
(as of February 2018)



>70

drugs
studied

Active Trials

Name	Intervention	Therapeutic Area	Phase	Endpoint
AED01	Levetiracetam Valproic acid Topiramate Oxcarbazepine	Seizures	2	PK Safety
ANA01	Hydromorphone Ketamine	Analgesia Anesthesia	1 / 2	PK/PD Safety
BMS01	Multidrug	Lactation	1 / 2	PK/PD Safety
FUR01	Furosemide	BPD	2	Safety PK
LAP01	Aripiprazole Risperidone	Mental Health	4	Safety
POP01	Multidrug	Several	1	PK
SIL01	Sildenafil	BPD	2	Safety PK
TIM01	Topical Timolol	Infantile Hemangioma	3	Efficacy Safety

Collaboration

Trials

- Web-based concept sheet
 - <https://www.pediatrictrials.org/or-health-care-professionals/>
- Screening online site survey
 - https://duke.qualtrics.com/SE/?SID=SV_0GmBrXNstzpydRH&Q_JFE=0
- Network level partnerships
 - IDeA States Pediatric Clinical Trials Network
 - PTN Australia

Data Sharing

- Web-based data sharing request form
 - <https://www.pediatrictrials.org/data-sharing-opportunities/>
- NICHD Data and Specimen Hub (DASH)
 - <https://dash.nichd.nih.gov/>
- Mentorship opportunities