DCRI PEDIATRICS

Measured Answers to Pediatric Dosing Questions

As a mission-driven organization, the DCRI is committed to developing and sharing knowledge through innovative clinical research that advances child health. The DCRI conducts pediatric clinical research on an unprecedented scale, enrolling tens of thousands of children worldwide in our studies—harnessing DCRI's reach in order to provide concrete answers to the most important questions in pediatric medicine.

DCRI's pediatric research experience ranges from pharmacokinetic studies in neonates to large, multicenter trials and outcomes studies in every developmental life stage. Our faculty are renowned, experienced researchers in all of the most crucial therapeutic areas and are also practicing physicians, overseeing the implementation of newfound evidence into daily clinical practice. At the DCRI, we strive to be the most impactful pediatric clinical research program in the country, improving research and care for the benefit of our youngest patients.

TRIALS

- Protocol development
- Regulatory compliance
- Network collaboration
- Rapid-start network of pediatric sites
- Streamlined contracting process
- Feasibility assessments
- Government- and industry-funded
- Master and opportunistic protocols
- Direct-to-family trials
- Real-world data (including regulatory-grade registries)

OPERATIONS

- Pediatric operational experts
- Long-term site relationships
- Study design and feasibility
- Data and Safety Monitoring Board services
- Safety surveillance
- Pediatric-specific case report forms
- Clinical event adjudication
- Health Services Research
- Dedicated participant engagement program

THOUGHT LEADERSHIP

- Internationally recognized faculty
- Trialists and therapeutic area leaders
- Faculty with FDA employment in pediatric therapeutics
- Domestic and global experience
- Family and patient engagement
- Coordinating center leadership (e.g., ECHO, PTN, Global PCTN, TIC/TIN)
- COVID-19 research (e.g., RADx-UP)

PEDIATRIC CLINICAL PHARMACOLOGY

- Clinical trial simulation and trial design
- Clinical pharmacology from newborns to adolescents
- Intense, sparse, and opportunistic PK sampling
- Population PK/PD and physiologically-based PK/PD modeling
- Ultra-low volume and dried matrix bioanalyses
- Regulatory compliant analyses and reports

Therapeutic Areas

Analgesia and Anesthesia

Cardiology

Critical Care

Dermatology

Gastroenterology

Infectious Disease

Neonatology

Nephrology

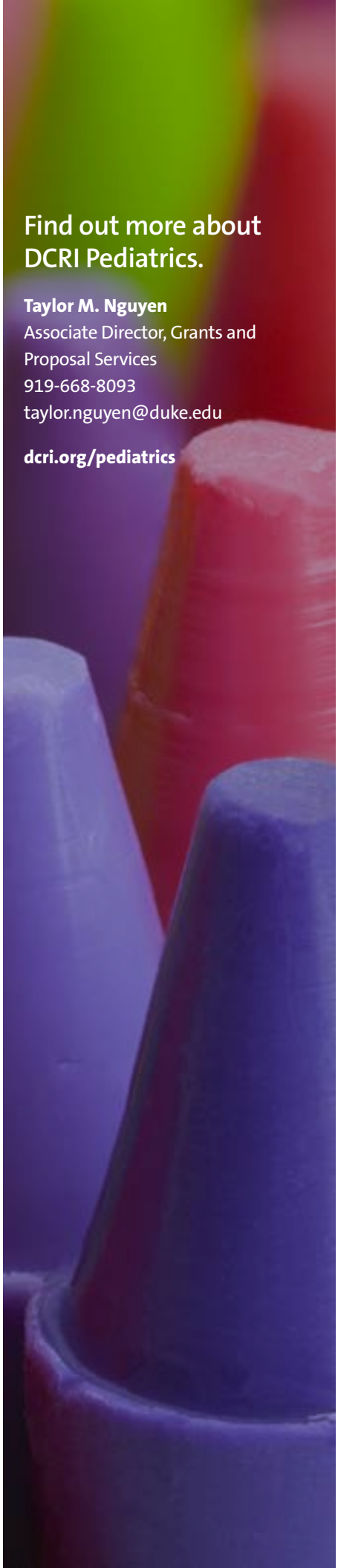
Neurology

Primary Care

Psychiatry

Pulmonology

Rheumatology



DCRI **PEDIATRICS**

Find out more about DCRI Pediatrics.

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dcri.org/pediatrics

NUMBERS THAT MATTER

75,000+
pediatric patients enrolled

60+
pediatric trials

250+
pediatric sites

26+
FDA submissions

75+
pediatric-specific PK/PD analyses

1.1k+
pediatric publications

FACULTY

Sarah Armstrong, MD: Obesity

Stephen Balevic, MD: Rheumatology

Mara Becker, MD, MSCE: Rheumatology

Danny Benjamin, MD, PhD, MPH: Infectious Disease

Michael Cohen-Wolkowiez, MD, PhD: Infectious Disease

Rachel Greenberg, MD, MHS: Neonatology

Kevin Hill, MD: Cardiology

Chi Hornik, MD, PhD, MPH: Critical Care

Christoph Hornik, MD, PhD, MPH: Cardiology

Karan Kumar, MD: Critical Care

Priya Kishnani, MD, MBBS: Genetics

Jason Lang, MD, MPH: Pulmonology

Jennifer Li, MD: Cardiology

Laura Schanberg, MD: Rheumatology

Brian Smith, MD, MPH, MHS: Neonatology

Charlene Wong, MD, MSHP: Health Services Research

Kanecia Zimmerman, MD, MPH: Critical Care

Duke Clinical Research Institute | FROM **THOUGHT LEADERSHIP** TO **CLINICAL PRACTICE**

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