

Clinical Research in PEDIATRICS

Measured Answers
to Pediatric Dosing
Questions

As a mission-driven organization, the DCRI is developing and sharing knowledge that improves the care of patients around the world through innovative clinical research. The DCRI conducts pediatric clinical trials on an unprecedented scale. Thousands of people from across the globe have been enrolled in our trials, harnessing the reach of the DCRI to provide concrete answers to the most important questions in pediatric medicine.

DCRI pediatric research experience ranges from pharmacokinetic studies in neonates to large, multicenter trials in adolescent populations. 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.

TRIALS

- Protocol development through FDA submission
- Network collaboration
- Rapid-start network
- Streamlined contracting process
- Feasibility assessments
- Government- and industry-funded
- Master and opportunistic protocols



OPERATIONS

- Pediatric operational experts
- Long-term site relationships
- Protocol design
- Data and Safety Monitoring Board services
- Safety surveillance
- Pediatric-specific case report forms
- Clinical Events Classification



THOUGHT LEADERSHIP

- Internationally recognized faculty
- Trialists and therapeutic area leaders
- FDA employment in pediatric therapeutics
- Domestic and global experience



PEDIATRIC CLINICAL PHARMACOLOGY

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



Therapeutic Areas

Analgesia and Anesthesia

Cardiology

Critical Care

Dermatology

Gastroenterology

Infectious Disease

Neonatology

Nephrology

Neurology

Primary Care

Psychiatry

Rheumatology



DCRI PEDIATRICS

Find out more about
DCRI Pediatrics

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dcri.org/pediatrics

NUMBERS THAT MATTER



12,000+

pediatric patients
enrolled



50+

pediatric
trials



150+

pediatric
sites



15+

molecules submitted
data to the FDA



30+

pediatric-specific
PK/PD analyses



800+

pediatric
publications

LEADERSHIP



Danny Benjamin, MD, PhD, MPH

Kiser-Arena Distinguished
Professor of Pediatrics
Chair, Pediatric Trials Network
Faculty Associate Director, DCRI



Michael Cohen-Wolkowicz, MD, PhD

Associate Professor of Pediatrics
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Brian Smith, MD, MPH, MHS

Professor of Pediatrics
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Duke Clinical Research Institute

FROM THOUGHT LEADERSHIP
TO CLINICAL PRACTICE