

DCRI PHARMACOMETRICS CENTER

Trusted
Leadership,
Proven Expertise

The DCRI Pharmacometrics Center (PMC) is uniquely positioned to support the drug development programs of industry, government, and independent investigators through our longstanding experience in:

- Clinical pharmacology
- Clinical trial simulation
- Traditional, population, and physiologically based PK/PD modeling
- Regulatory submissions
- Employment and collaborations with the FDA
- Special populations (e.g., infants and children)

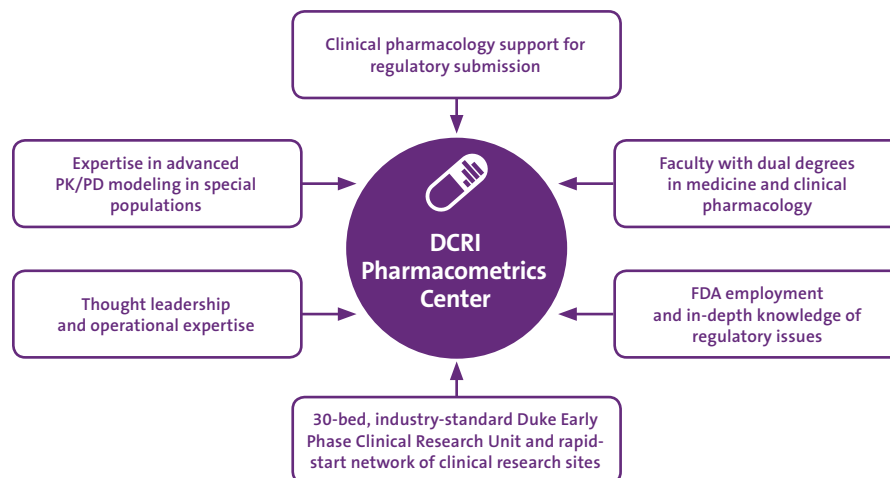
WHAT SETS US APART

- Expertise in clinical trials and developmental pharmacology in infants and children
- Efficient clinical trial design and optimization through simulation
- Extensive experience with opportunistic clinical trials
- Expertise in examining PK/PD of drugs using dried matrix spots
- Frequent use of ultra-low volume assays of novel matrices
- Innovative application of rapid identification tools for PK queries
- Track record of regulatory approval of pediatric studies conducted for exclusivity
- Track record in dose prediction in pediatric populations
- Design study protocols and coordinate multi-center studies

What We Do

We offer a portfolio of clinical pharmacology and pharmacometrics services to meet your specific research and development needs.

- Population PK/PD modeling
- Physiologically based PK/PD modeling
- Pediatric PK/PD modeling
- Non-compartmental analysis
- Intense and sparse PK sampling analyses
- PK-electronic health record analyses



78

projects supported
in 2017



>80%

were pediatric

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Find out more
about the DCRI
Pharmacometrics
Center.

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Our faculty are uniquely qualified to answer clinical pharmacology and pharmacometrics questions associated with clinical trials.

Clinical pharmacology support of study design and conduct

- First in human
- Bioavailability/bioequivalence
- In vivo drug interaction
- Dose response
- Early phase in patients
- Confirmatory PK in late-phase studies

Pharmacometric modeling and simulation

- Non-compartmental analysis
- Population PK/PD
- Physiologically based PK
- Developmental PK/PD (pediatrics, geriatrics)
- PK/PD in special populations

Bioanalytical assays

- Development and validation of GLP bioanalytical assays
- Analysis of ultra-low (<0.03 mL) sample volumes
- Novel biological matrices (e.g., dried matrix spots)

Reporting

- Clinical study reports
- Regulatory-compliant submission of data
- Manuscript preparation
- Presentations at national meetings

Training and knowledge dissemination

- Development of trainees
- Clinical pharmacology support of grant applications
- Pharmacoepidemiologic vigilance



Duke Clinical Research Institute

FROM THOUGHT LEADERSHIP
TO CLINICAL PRACTICE