DCRI **PHARMACOMETRICS CENTER**

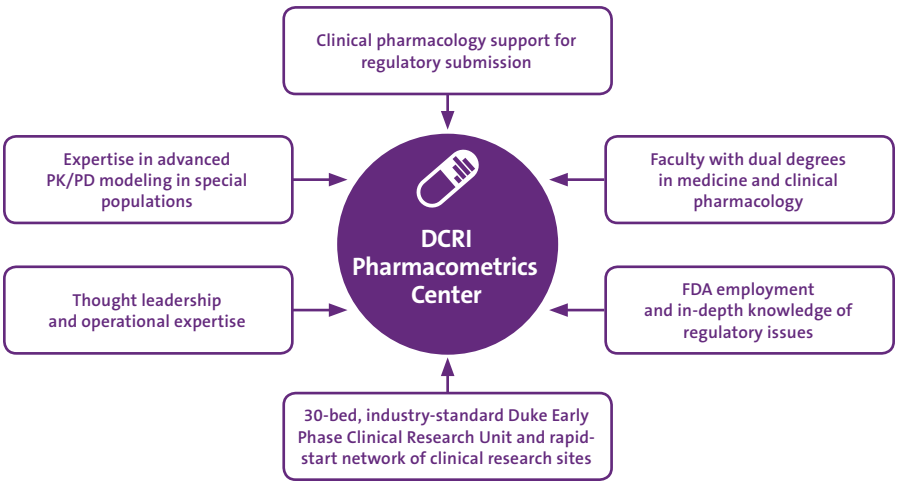
Trusted Leadership, Proven Expertise

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 and dose optimization
- Traditional, population, and physiologically based PK/PD modeling
- Regulatory strategy and submissions
- Employment and collaborations with the FDA
- Special populations (e.g., infants, children, and pregnancy)
- Pre-clinical support including extrapolation

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 including pediatric studies conducted for exclusivity
- Track record in dose prediction in pediatric and other special populations
- Potocol consultation and regulatory strategy
- Bioanalytical consulting



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

76

projects supported in 2018

>80%

were pediatric

DCRI **PHARMACOMETRICS CENTER**

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

Find out more about the DCRI Pharmacometrics Center.

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