As the world’s largest academic research organization, the Duke Clinical Research Institute (DCRI) is known for conducting groundbreaking multinational clinical trials, managing major national patient registries, and performing landmark outcomes research. We combine the clinical expertise and academic leadership of a premier teaching hospital with the full-service operational capabilities of a major contract research organization.

**What Sets Us Apart**

The close integration of clinical faculty into the design, conduct, and interpretation of clinical trials contributes to the DCRI’s unique success. Our research faculty are practicing Infectious Disease (ID) physicians who treat patients, giving them real-world insights into effective and innovative study design.

The DCRI provides comprehensive clinical development services with expertise at every stage of the process by providing study design, regulatory services, and execution. We offer:

- World-renowned ID faculty provide scientific leadership, as well as therapeutic and strategic oversight across multiple therapeutic areas
- Experienced and consistent clinical operations teams expertly manage all aspects of global clinical trials
- Impeccable data integrity and biostatistical expertise yield credible study results that may change clinical practice
- Unparalleled experience in operationalizing multicenter ID research
- Experience in designing and coordinating adaptive trials

**Real-World Expertise**

In the past 10 years, the DCRI’s ID team has completed or is currently involved in more than 250 phase I–IV trials across the world, as well as networks, registries, and other research projects.

The DCRI offers unsurpassed expertise in operationalizing multicenter ID research in key areas:

- ABSSSI
- Candida bloodstream infections
- Community acquired bacterial pneumonia
- Diagnostics
- Endocarditis
- HIV, HCV, HBV
- Invasive aspergillosis
- Multidrug resistance
- Mycology
- Osteomyelitis (bone and joint infections)
- Postoperative sternal and abdominal wound infections
- Respiratory viral pathogens, including influenza and RSV
- Sepsis
- Staphylococcus aureus
- Therapeutic vaccines
DCRI INFECTIOUS DISEASES

Operational Excellence

Our therapeutically-aligned Clinical Operations group includes project teams trained in ID by Duke faculty. We have long-standing relationships with key global opinion leaders and sites, and have successfully coordinated ID studies with more than 10,000 patients enrolled across 800 global sites.

The DCRI’s ID Operations team works with a robust network of sites to leverage capabilities and enhance efficient enrollment across a variety of ID studies. Led by the DCRI, the ID Research Network includes ~200 sites, 116 of which have a Rapid Start Network Agreement in place. Additionally, the Antibacterial Resistance Leadership Group (ARLG) has received therapeutic data from more than 550 survey responses from 256 different principal investigators.

OPERATIONAL CAPABILITIES INCLUDE:

- Full-service expertise across all phases of development (phases I–IV)
- Pharmacometrics
- U.S. Rapid Start Network
- Therapeutically-focused project leadership and site management
- Global regulatory support
- Pharmacogenomics
- Health outcomes research
- Adaptive trial designs
- Event adjudication
- Safety
- Viral monitoring

Our Faculty

Our faculty are practicing physicians with hands-on experience treating patients and a track record of successful partnerships with industry, government, and academia. Appointed faculty members within the DCRI have advanced degrees in epidemiology, statistics, ethics, and regulatory compliance, as well as expertise across key infectious diseases areas.

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*The ARLG is supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health.