DUKE **EARLY PHASE CLINICAL RESEARCH**

The Path to Proof

Duke Early Phase Clinical Research combines clinical and operational expertise to accelerate the availability of therapies, diagnostics, and medical devices to humans. As part of the Duke Clinical Research Institute—the world's largest academic research organization—the Early Phase team partners with pharmaceutical, biotech, medical device, government agencies, foundations, and academic centers to conduct a broad range of early phase studies.

From our state-of-the-art 30-bed research unit to robust analytics, we offer our partners a new path to proof by building on our strength of expertise and experience, including:

- Thought leadership and scientific insight in early phase clinical research
- Duke practicing physicians who see patients every day
- Full-service capabilities and customized study design grounded in the reality of clinical care
- Access to healthy and diverse disease-specific patient populations
- FDA regulatory oversight and compliance

ACCELERATED STUDY START UP

~18 days to Duke IRB approval

10 weeks for institutional approval

ROBUST VOLUNTEER REGISTRY

>8,500 Eligible participants

>55% Healthy

>60% Female

~36% African American

DIVERSE THERAPEUTIC AREA EXPERIENCE

- Cardiology
- Endocrinology
- Rheumatology
- Pulmonology
- Neurology
- Genetics
- Hematology
- Infectious Diseases
- Physiology
- Nephrology
- Psychiatry
- Gastroenterology
- Radiology
- Rare Diseases

A CLEAR PATH FORWARD

Experience by the numbers

(average per year)

80 active studies

3,500 outpatient visits

820 confinement visits

21,000 lab samples processed

5 non-FDA audits (47 since inception)

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Find out more about Duke Early Phase Clinical Research.

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Clinical Research Unit

Conducting more than 70 active studies annually, our state-of-the-art, hospital-based research unit is located in a world-renowned academic medical environment that offers both standard and specialized services.

Standard Services

- Proof-of-concept studies
- Phase 1
- First-in-human
- Escalating dose
- Bioavailability/bioequivalence
- Drug-drug interaction
- Food effect

Specialized Services

- Phase 0
- Patient/hybrid studies
- Invasive procedures/monitoring
- Novel PD endpoints
- Device/app validation
- Imaging studies (CT, echo, MRI)
- Endotoxin
- Pediatrics/geriatrics
- Sleep
- Adaptive design

Our dedicated functional teams, including nursing, recruitment, nutrition, laboratory, and study coordination, enable us to execute high-intensity and procedure-heavy studies. In addition to our early phase expertise, our research unit offers:

- Short- and long-term confinement
- Outpatient visits
- Cohort study capabilities
- 24/7 emergency medical personnel
- Wireless ECG telemetry
- On-site investigational pharmacy
- Laboratory collection and processing
- Metabolic kitchen
- Pulmonology function laboratory
- On-site anesthesiologist
- Human physiology and invasive/ noninvasive hemodynamic monitoring
- Access to Duke Core Labs for novel PD end points
- On-site core laboratory

Analytics

We accurately collect, analyze, and interpret data from humans using industry-standard methods.

Statistics: real-time safety monitoring and FDA reporting requirements to streamline data analysis and reporting of early phase studies.

Clinical pharmacology: partnership with the DCRI Pharmacometrics Laboratory to develop standard and specialized PK/PD analyses, use of validated software, and reports that meet FDA requirements.

Bioanalysis: Extensive expertise in bioanalytical assay development and validation quality control based on FDA guidance.

LEADERSHIP

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

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