

DUKE EARLY PHASE CLINICAL RESEARCH

The Path to Proof

A Comprehensive Approach

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 34-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

Clinical Research Unit

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

Standard Services

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

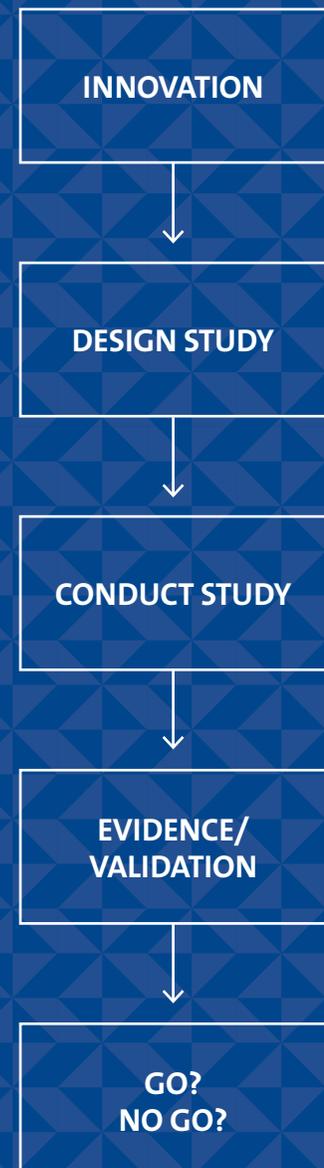
Specialized Services

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

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 subject matter 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: ALA-certified respiratory therapists
- Human physiology lab
- On-site anesthesiologist
- Invasive and noninvasive hemodynamic monitoring

We bring clinical validation to innovation for a new path to proof.



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Find out more about
Duke Early Phase
Clinical Research.

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Analytics

In addition to our research unit, we accurately collect, analyze, and interpret data from humans using industry-standard methods.

Statistics

- Streamlined approach to data analysis and reporting of early phase studies using real-time safety monitoring and FDA reporting requirements

Clinical pharmacology

- 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



Michael Cohen-Wolkowicz, MD, PhD
Faculty Director,
Duke Early Phase Clinical Research



Jeffrey Guptill, MD
Faculty Associate Director,
Duke Early Phase Clinical Research



Donna Hamel, RCP, FAARC, FCCM
Director of Operations,
Duke Early Phase Clinical Research