



Academic Clinical Research Organization

- The Duke Clinical Research Institute (DCRI) is an **academic research organization (ARO)** that exists within Duke University providing **full service** research capabilities on a U.S. and global scale.
- Our **mission** is to develop, share, and implement knowledge that improves health around the world through innovative clinical research
- Projects at the DCRI are led by renowned experts and practicing physicians grounded in patient care.
- The research is supported by staff with deep expertise in operationalizing trials, registries, and global studies.

DCRI Participant Research Operations (PRO-CC)

- The Participant Research Operations Call Center (PRO-CC) is a leader in patient-centered approaches to clinical trials and observational registries.
- Offers comprehensive decentralized research support to improve data quality and completeness, including structured patient call visits, remote consenting, clinical data collection, medication reconciliation, and remote administration of quality-of-life instruments.
- Has supported over 50 studies, including the IPF/ILD PRO Registry, a DCRI collaboration with Boehringer Ingelheim.
- The DCRI PRO-CC is a valuable resource for enhancing patient engagement and data quality in lung disease studies.

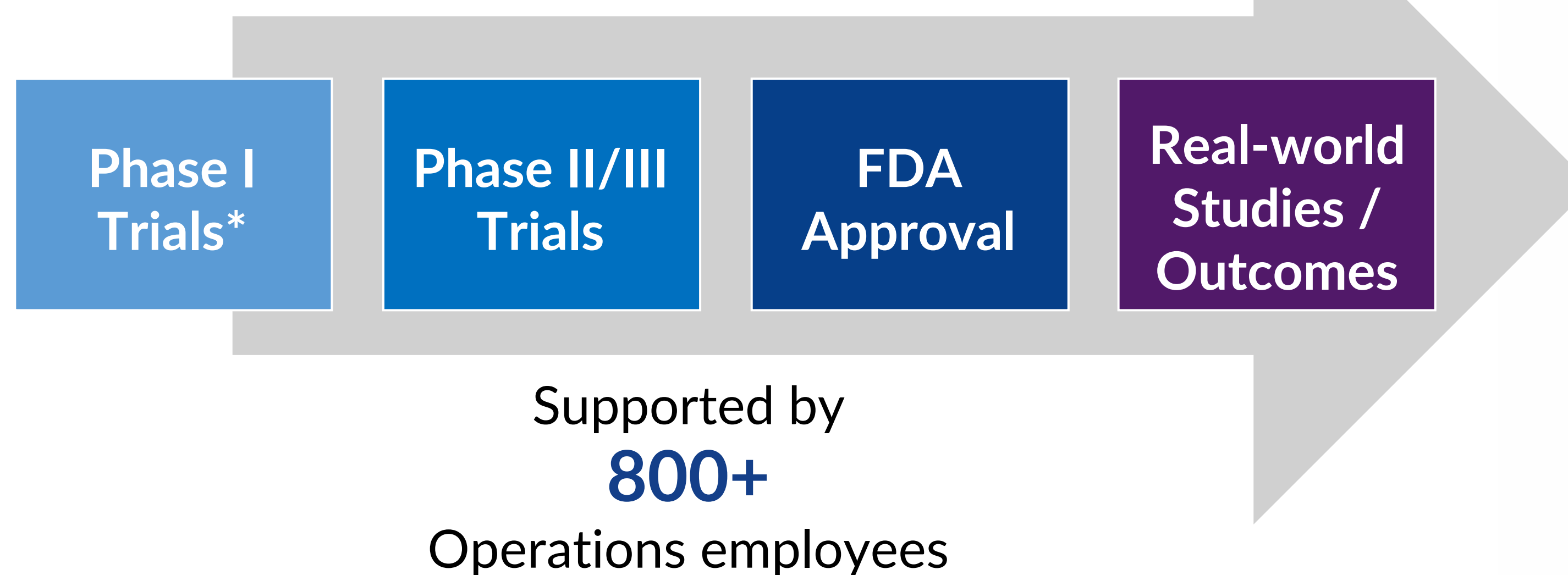
Innovative IPF/ILD Disease Registry

The registry is advancing our understanding of disease through natural history and treatments with patients that are followed five years from diagnosis.

Features include:

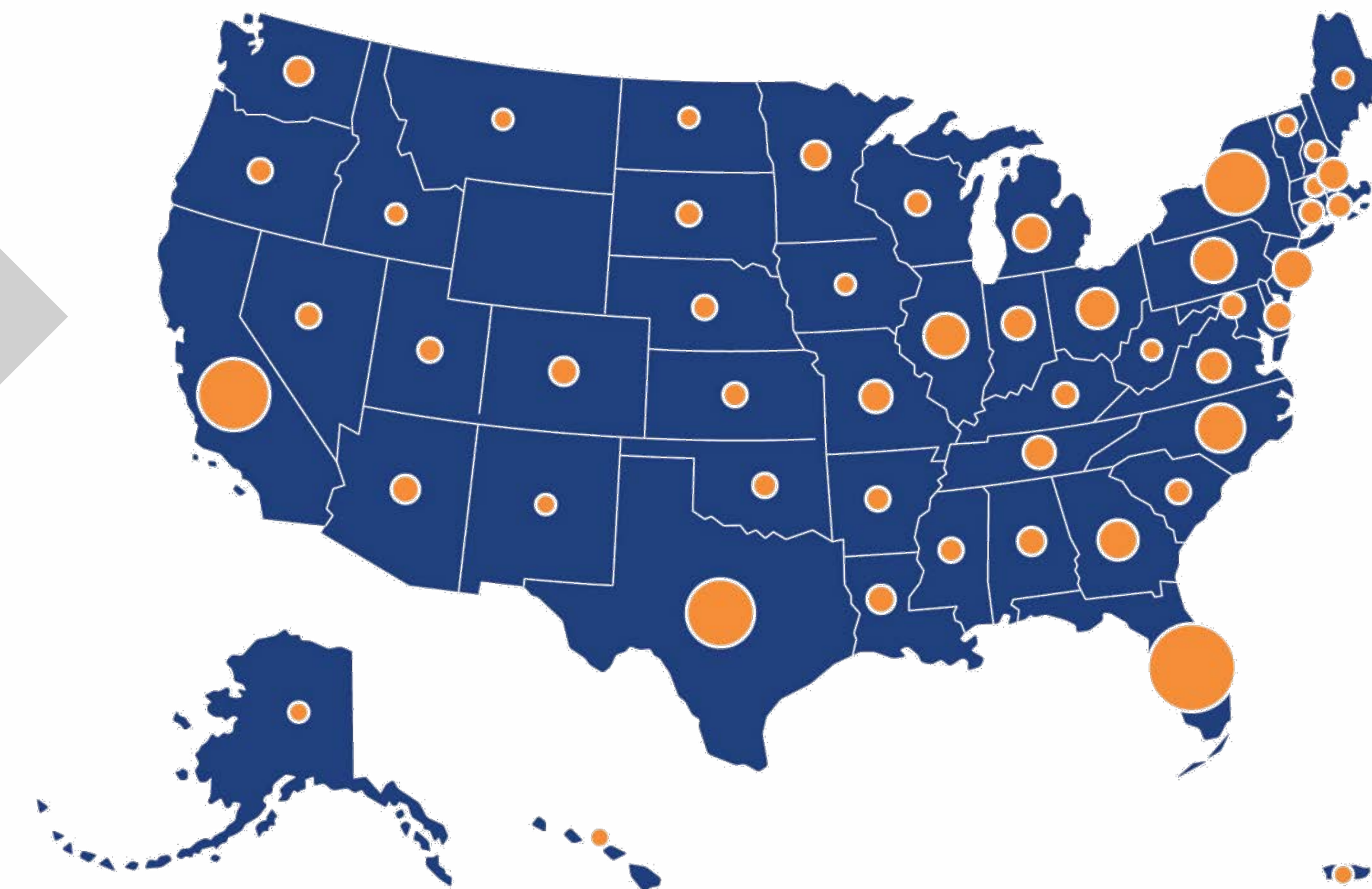
- >1,800 subjects across 50 U.S. sites
 - 1,000 IPF
 - >8,00 PF-ILD (ongoing)
- Prospective sample biorepository supporting biomarker research
- Serial collection of patient-reported outcomes
- Complete long-term follow-up on all enrolled patients through the PRO-CC.
- Serial HRCT images collected on all ILD subjects

DCRI Full Service CRO Capabilities



Core Services

- Study Design
- Protocol Development
- Biostatistics
- Project Management
- Site Monitoring & Management
- Data Management
- Informatics
- Medical Writing
- Safety
- Regulatory Affairs
- Clinical Event Adjudication
- Participant Engagement



IPF/ILD Registry 2024

-  Over **1,800** patients enrolled
-  Over **96** conference abstracts presented
-  **18** manuscripts published

Example of IPF/ILD PRO Research Impact

- Patient reported outcomes predict disease progression
- Novel protein and RNA based predictors of disease progression
- Disparities in access to lung transplant care
- Impact of antifibrotic treatment on disease progression

Research Informed By

DCRI Respiratory partners with NIH and industry sponsors to lead studies in common or rare lung diseases, including COPD, IPF, ILD, sepsis, and lung transplant.

DCRI Respiratory Team

Therapeutic Area Director:

Scott M. Palmer, MD, MHS,*

Key Faculty: Laurie D. Snyder, MD, MHS;

Jamie L. Todd, MD; Aparna Swaminathan, MD, MHS;

Christopher L. Mosher, MD, MHS;

Stephen P. Bergin, MD

Statistical Faculty: Megan L. Neely, PhD