



WORLDWIDE  
CLINICAL TRIALS

**BREATHE EASIER  
DURING YOUR  
PULMONARY  
ARTERIAL  
HYPERTENSION  
CLINICAL TRIAL**



**WORLDWIDE  
CLINICAL TRIALS**

## **PULMONARY ARTERIAL HYPERTENSION (PAH) IS A RARE, PROGRESSIVE DISORDER**

characterized by high blood pressure in the pulmonary arteries for no apparent reason. Symptoms of PAH include shortness of breath (dyspnea), especially during exercise; chest pain; and fainting episodes.<sup>1</sup>

### **AWARD-WINNING CRO**

Our award-winning, specialized cardiopulmonary teams deliver uncommon value, helping emerging and established biopharma, biotech, and pharmaceutical companies test, validate, and de-risk the process of developing better treatments for all forms of PAH.



Capabilities, Compatibility, Expertise,  
Quality, and Reliability

## **WORK WITH A CRO THAT UNDERSTANDS YOUR RARE PATIENT POPULATION**

Worldwide Clinical Trials has extensive experience in rare disease and pulmonary arterial hypertension (PAH) trials, which is derived from our global PAH trial experience and enhanced by our medical and scientific understanding of unique PAH trial requirements.

But a successful PAH trial requires much more than scientific expertise. With rare diseases such as PAH, it's important to consider the day-to-day perspectives and needs of the patient to make their clinical trial participation a positive experience and retain them throughout the duration of the study. PAH patients have certain limitations that Worldwide Clinical Trials recommends evaluating when designing your study:



**Easily tired:** PAH patients get tired quickly, so creating a program where their onsite visits are shorter or strategically planned to make their contribution as simple as possible will enable more patients to participate and provide the necessary data needed for the trial, while not exhausting themselves (more than they already are).



**High density of mature patients:** According to the National Center for Biotechnology Information, the mean age of the patients with IPAH or HPAH in the contemporary registries from the Western world ranged from 45-65 years.<sup>2</sup> Designing a trial that uses minimal or simple technology will enhance participation and retention.



**Reliance on caregivers:** Patients with PAH often have caregivers that are part of their daily lifestyle. Involving caregivers in the trial process can improve the trial experience for the patient as well as the post-trial care from their caregiver because of increased understanding of PAH.



**Disease classification:** There are six different groups that fall into the parent category of PAH, presenting additional challenges when evaluating the efficacy of new treatments. It is important to ensure that each patient and group of patients is considered when designing the trial to ensure that the proper data is produced for actionable, reliable results that enable meaningful treatment or cure.



**WORLDWIDE  
CLINICAL TRIALS**



## UNCOMMON GLOBAL SITE AND INVESTIGATOR NETWORKS FOR FASTER PATIENT RECRUITMENT

Worldwide Clinical Trials employs more than 2,000 professionals around the world, with offices in North and South America, Eastern and Western Europe, Russia, and Asia. Founded by physicians committed to advancing medical science, Worldwide is out to change how the world experiences CROs – in the best possible way. From early phase and bioanalytical sciences through late phase, post-approval, and real-world evidence, we provide world-class, full-service drug development services.

With infrastructure and talent spanning more than 60 countries, we execute predictable, successful studies with operational excellence across a range of therapeutic areas, including central nervous system, cardiovascular, metabolic, general medicine, oncology, and rare diseases.

We never compromise on science or safety. We're never satisfied with the status quo.

We're the Cure for the Common CRO.



## RUNNING A SUCCESSFUL GLOBAL TRIAL IN A VAST REGULATORY LANDSCAPE

Another challenge that PAH drug developers must consider is a changing regulatory environment, so it is helpful to work with a CRO that has practical and global experience with the methodologies.

Worldwide Clinical Trials is a global CRO, with a presence in 60+ countries worldwide. We have built close relationships with patient engagement groups, key opinion leaders and investigational sites, working to bridge science and operational excellence and deliver new solutions to the PAH population.

We have experience conducting studies in the US, Europe, the Middle East, and Asia-Pacific. We believe that our highly-trained staff in these locations is the key to ensuring you have high-quality insight into your clinical program.

In addition, Worldwide Clinical Trials has partnered with PHaware advocacy group to be involved and informed on pulmonary hypertension news and activities among all aspects of PH clinical trials. We also consistently partner with a variety of relevant PH associations, facilitating and supporting their efforts to link the science with patients.

## YOU'RE DEDICATED TO THE DEVELOPMENT OF YOUR THERAPY, AND SO ARE WE

Worldwide Clinical Trials has real PAH trial experience. From trials with 160+ patients globally to PAH drug/device studies, team members and sites all over the globe have received detailed training on very complex protocols. Our flexible approach has enabled us to help sponsors improve timelines and outcomes by implementing the following methodologies:

- Using patient-interfacing technology for PAH trials (when appropriate for the patient population)
- Using a novel, FDA-approved randomized withdrawal model
- Nuanced regulatory submissions for PAH device studies and studies using oxygen