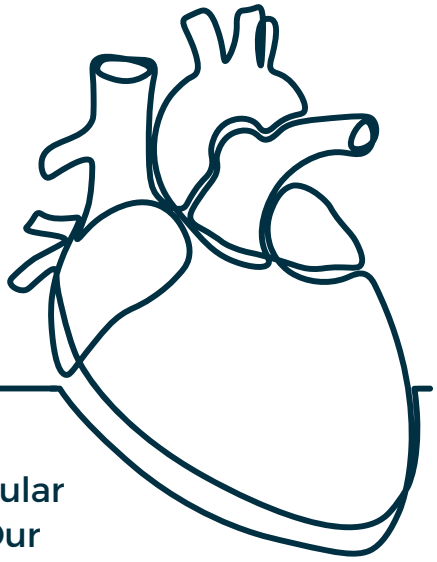
Worldwide Clinical Trials

Cardiovascular Clinical Development at Worldwide Clinical Trials



At Worldwide, we are dedicated to advancing cardiovascular therapies through every phase of clinical development. Our team of therapeutic experts possesses deep experience across many cardiovascular indications, ensuring your program's success from strategic planning to Phase IV and beyond.

Our cardiovascular clinical development services encompass:

Strategic Planning & Protocol Design

Expert guidance on study design, regulatory strategy, data management, drug safety, medical monitoring, project management services, and program governance.

Pre-IND/IND-Enabling Support

Full support for Phase I development, including biostatistics, clinical monitoring, and regulatory submissions and interactions.

Phase I-IV Clinical Trials

Robust execution capabilities for trials of all sizes and complexities, including outcome trials.

Post-Marketing & Real-World Evidence Studies

Comprehensive services to support the full lifecycle of cardiovascular compounds and products.

Global Cardiovascular Experience

With more than 30 years of experience in cardiovascular studies, we bring a wealth of knowledge to your drug development program. Our indication expertise includes:

Heart Failure (HF)

- Chronic heart failure
- Acute decompensated heart failure
- Heart failure with reduced ejection fraction
- Conducted trial leading to the revision of guidance for treatment of HF patients

Coronary Artery Disease

- Acute coronary syndrome
- Stable coronary artery disease

Pulmonary Arterial Hypertension (PAH)

- Known patient paths and patients needs

Hypertension

- Resistant hypertension

Dyslipidemia & Hyperlipidemia

- Includes rare patient populations: Homozygouse Familial Hypercholesterolemia (HoFH) and Heterozygous Familial Hypercholesterolemia (HeFH)
- Experience with Lp(a)
- Modern lipid treatment- i.e., siRNA

Cardiovascular Outcome Trials (CVOT)

- Proof record of high retention rate
- Efficient interaction with Adjudication Committees, flexible setting to manage influx of events
- Versed in managing complex composite endpoints

Patient Settings

- ICU experience, in- & out-patient settings

Our team provides local regulatory intelligence and engagement, including pre-submission meetings with global regulatory agencies. We leverage expedited pathways and programs for cardiovascular therapies, ensuring efficient development timelines.

Experience by Phase

Our team has executed 79 full-service cardiometabolic trials in the past five years, involving over 43,000 patients across 3,230 sites globally.

I Phase	II Phase	III Phase	IV Phase
3 Studies	**21** Studies	**18** Studies	**14** interventional and non-interventional studies
178 Patients	**2,514** Patients	**8,057** Patients	**32,295** Patients

Global Network & Key Relationships

Network of Sites & KOLs

Access to a global network of leading investigators and key opinion leaders (KOLs) in cardiovascular research.

In-House Bioanalytical Lab

Located in Austin, TX, with validated methods for cardiovascular biomarkers.

Patient-Centric Approach

Strong relationships with patient advocacy groups and a focus on reducing patient burden through innovative trial designs.

Partnership with AROs

Strong relationships and proof of record working successfully with AROs like TIMI, CPC, and others.

Clinical Pharmacology Unit (CPU)

Located in San Antonio, TX, a fit-for-purpose unit with 200 beds.

Image Vendors

Experience and knowledge of working with and managing image vendors necessary to support CV studies.

Worldwide Clinical Trials

To discuss your cardiovascular program and learn how our capabilities can support your clinical trial, contact us today.

Contact Us