FLAWLESSLY EXECUTE YOUR CARDIOVASCULAR AND METABOLIC CLINICAL TRIALS

WORLDWIDE CLINICAL TRIALS

WORLDWIDE CLINICAL TRIALS

- Biostatistical service
- Clinical monitoring
- Data and Safety Monitoring Board charters and Management
- Data management
- End point adjudication process
- Global project management
- Investigator meetings
- Medical monitoring/ pharmacovigilance
- Medical writing
- Protocol design
- Protocol feasibility assessment
- Regulatory affairs (includes consultancy)
- Safety monitoring
- Scientific consultancy
- Site identification
- Third-party collaborations

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CARDIOVASCULAR AND METABOLIC TRIALS: RUNNING LIKE CLOCKWORK?

The highly competitive field of cardiovascular and metabolic research is making it imperative that clinical trials run flawlessly and efficiently to meet demanding timelines. The high risk of trial failure means that drug developers, with their keen focus on innovation in science, must ensure that the many moving parts of their drug approval process are managed as seamlessly, timely, and cost-effectively as possible while maintaining regulatory integrity.

AN INDUSTRY OF ACCLERATION

While drug developers are focused on precision in research, the pharmaceutical industry is accelerating. New developments in science, standards of care, and clinical technology require faster productive trial phases conducted with increased expertise and flexibility.

Timeline compression in any research project requires in-depth and flexible strategies to optimize patient recruitment, compliance, and retention. These aspects have an especially high impact on timely completion of a trial. Despite having a well-thought-out strategy, it's important to establish leading signals to identify early operational failure in any key aspect. Adjustments may require unconventional thinking and agile organizational flexibility to achieve the goals of the trial within a sponsor's timeline.

Medical and scientific expertise comprises the foundation for sound protocol design and implementation, especially in complex trials. Engaging physicians with relevant scientific and practical experience early in the design process can reveal protocol elements that should be reconsidered before they are implemented in the field or used as end points.

Navigating the changing regulatory landscape requires knowledge of recent regulatory trends and tendencies. Anticipating regulatory queries and local nuances can noticeably accelerate the startup phase, which is why it's important to involve local regulatory experts who can articulate and navigate the optimal submission process and pathway.

Increased collaboration among academic researchers, sponsors, investigators, and patient advocacy groups results in practical and meaningful inclusion/exclusion criteria, clinical end points, and patient-centric trial conduct. Bringing this collective knowledge together translates to higher recruitment and retention rates, increased data and outcomes integrity, and a better subject participation experience.

Advanced and agnostic data technologies enable smoother integration of data across organizations and promote clear and rapid insights for early decisions affecting safety, trial viability, and patient compliance.

In the evolving cardiovascular research space, deep medical and scientific expertise, proven agility, and integrated technology conducted in an unwavering collaborative partnership are the minimum requirements for success, regardless of trial size or indication.

WORLDWIDE
CLINICAL TRIALS

WHAT CAN WORLDWIDE CLINICAL TRIALS DO FOR YOU?

With so much at stake, you want a CRO partner you can trust to successfully manage the many moving parts of your cardiovascular trial. What qualifies us to be your partner?

OUR FOCUS ON SMALL AND MIDSIZE PHARMA AND BIOTECH

We focus on the areas in which we excel. We're nimble, we provide tailored solutions, and we're decisive. Our flat organizational structure enables us to make decisions quickly and effectively in close collaboration with our industry partners.

OUR UNWAVERING COMMITMENT TO METHODOLOGICAL RIGOR

We're founded on medicine and science and dedicated to operational therapeutic alignment. Our medical and scientific expertise positively impacts how we engage with sponsors, view protocols, consider patient care, analyze data, and ensure quality.

OUR GLOBAL SUCCESS AND INFRASTRUCTURE

With more than 30 years of experience in in cardiovascular and metabolic research, our full-service capabilities extend throughout the clinical trial process. Worldwide has a presence in more than 60 countries around the world with global trial experience in all phases iinvolving more than 26,000 patients in a single trial. Our global team comprises clinical research associates and trial coordinators, medical monitors with experience in clinical trial conduct and strategy, and project managers with practical cardiovascular and metabolic experience.

GLOBAL AND LOCAL REGULATORY EXPERTISE

Our understanding of regulatory considerations includes variations among regional laws and standards of care, and our strong relationships with local investigative sites mean we are keenly aware of sites that are best suited for clinical trials. Our close relationships with regulatory stakeholders keep us informed of developments and trends.

SMART RECRUITMENT

Worldwide can do more than screen patients for inclusion/exclusion criteria. Using emerging predictive analytics technology, we identify study subjects most likely to comply with study protocol and stay the course of the trial. A high compliance rate reduces enrollment costs and can potentially shorten trial duration.

INDUSTRY AND ACADEMIC COLLABORATION

In addition to our reputation among satisfied sponsor partners, Worldwide's history of collaboration with regulatory bodies, academic research organizations, and key investigators has given us a reputation within the industry as a reliable research partner. Through our relationships with academic research organizations such as the Duke Clinical Research Institute, the TIMI Study Group, the ATLAS Group, and Canada's Population Health Research Institute, we are aware of current developments within the cardiovascular and metabolic space.

INTEGRATED DATA MANAGEMENT TECHNOLOGIES

Given our technology-agnostic approach, we can integrate with a variety of sponsor and vendor technologies. Having broad experience with technology solutions for clinical trials, we can recommend and source data collection solutions and trial management systems best suited to your needs.

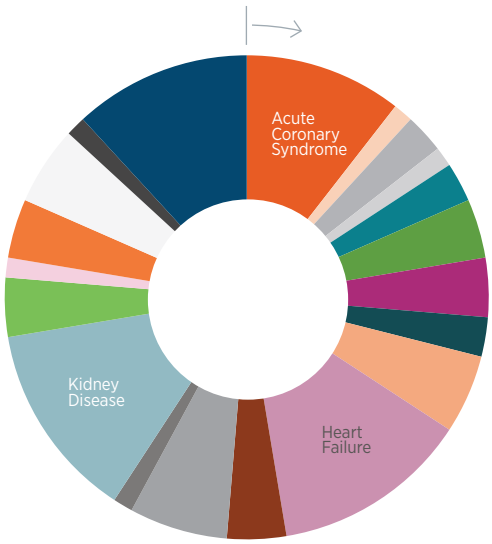
CARDIOVASCULAR AND METABOLIC PORTFOLIO

- Acute coronary syndrome (ACS)
- Acute ischemic stroke
- Angina
- Atherosclerosis
- Atrial fibrillation
- Coronary artery disease (CAD)
- Deep vein thrombosis (DVT)
- Diabetes type I
- Diabetes type II
- Diabetic Nephropathy
- Dyslipidemia
- Ischemia
- Heart failure
- Heterozygous familial hypercholesterolemia (HeFH)
- Homozygous familial hypercholesterolemia (HoFH)
- Hypercholesterolemia
- Hyperlipidemia
- Hypertension
- Hypertriglyceridemia
- Myocardial infarction (MI)
- Obesity
- Peripheral artery disease (PAD)
- Pulmonary arterial hypertension (PAH)
- Restenosis
- Thrombosis

WORLDWIDE CARDIOVASCULAR AND METABOLIC EXPERIENCE

Studies by Indication

Indication	Studies	Sites	Patients
Acute Coronary Syndrome	8	321	14,407
Acute Intracranial Hemorrhage	1	100	440
Angina	2	68	985
Arrhythmias	1	71	640
Atherosclerosis	2	120	720
Congenital Adrenal Hyperplasia	3	33	382
Diabetes Type 2	3	54	646
Dyslipidemia	2	76	580
Gaucher's Disease	4	11	64
Heart Failure	10	479	3,089
Hypercholesterolemia	3	203	2,601
Hypertension	5	65	651
Hypertension, Pulmonary	1	16	29
Kidney Disease	10	428	3,055
Metabolic Conditions	3	52	145
Mucopolysaccharidoses	1	2	8
Myocardial Infarction	3	171	6,961
Myocardial Ischemia	4	441	9,796
Obesity	1	8	260
Vascular Disease	9	1,713	25,795
Total	**76**	**4,432**	**71,254**



Studies by Phase

Study Phase	Studies	Sites	Patients
Phase I	1	12	50
Phase II	27	776	5,270
Phase III	33	1,300	27,681
Phase IV-Interventional	7	2,158	36,350
Phase IV Non-Interventional	8	186	1,903
Total	**76**	**4,432**	**71,254**

76

Full-service* cardiovascular and metabolic trials conducted

Worldwide has extensive experience with the successful management and execution of clinical trials. Worldwide has conducted 76 full-service ccardiovascular and metabolic trials globally, including sites in North and South America, Western Europe, Central and Eastern Europe, the Commonwealth of Independent States, and the Middle East and Northern African and Asia Pacific regions.

Q4 2018
DATA VALID THROUGH 31-JANUARY-2019

THERE'S NO SUBSTITUTE FOR UNCOMMON EXPERTISE. MEET YOUR PARTNERS.

Worldwide is committed to delivering uncommon value. We go above and beyond to deliver solutions and services that exceed your expectations.

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