Cardiovascular

About Worldwide Clinical Trials

A full-service CRO, Worldwide Clinical Trials delivers fully integrated clinical development and bioanalytical services for studies small to large, multi-site clinical trial programs, and first-in-human through phase IV clinical research programs, for customers of all sizes. Combining operational acumen, savvy decision-making, deft management, and commercial intelligence, Worldwide distinguishes itself as a medically and scientifically driven CRO, advocating methodological rigor in trial design and execution. Worldwide helps sponsors move from medical discovery into clinical development and commercialization, helping to bring innovative solutions to market that deliver enhanced value and improve patient lives.

Our Expertise Is Your Advantage

Worldwide is a global leader in cardiovascular (CV) clinical research. We have provided exemplary operational, data management, and biostatistical services for Phase II–IV trials for a wide range of CV indications for more than 25 years. Our established relationships with key investigators, regulatory bodies, and academic research organizations in the CV field ensure delivery of high quality and clinically relevant data.

Worldwide Clinical Trials has executed 120 CV trials, delivering clinical monitoring, project management, and/or full clinical research services for 61 trials.

Unrivalled Client Service

Our team of experts have undisputed experience in the clinical practice of cardiology as well as extensive knowledge of the operational and strategic challenges of complex CV clinical research studies. This, coupled with a true commitment to the success of each and every clinical trial, means Worldwide is ideally positioned to be your CV study partner. Our global team includes:

- 100+ Clinical Research Associates/Trial Coordinators
- 19 Project Managers with 5 to 15 years of CV experience
- 12 Medical Monitors with clinical, trial conduct, and trial strategy CV experience[a]

Partners in Excellence

Without strong integration between academic and clinical research organizations, studies are at considerable risk of operational failure so we frequently conduct CV outcome studies in collaboration with renowned academic research organizations (AROs) such as the Thrombolysis in Myocardial Infarction (TIMI) Study Group (Brigham & Women's Hospital); Duke Clinical Research Institute (DCRI); and the Antithrombotic Trials Leadership and Steering (ATLAS) Group. The success of our collaborations is demonstrated by the publication of a number of high-impact scientific papers in which our professionals are recognized alongside ARO members.

CARDIOVASCULAR PORTFOLIO

HEART DISEASE

- Atrial fibrillation
- Coronary artery disease (CAD)
- Ischemic heart disease
- Heart failure
- High-risk CVD

VASCULAR DISORDERS

- Acute coronary syndrome
- Aortic aneurysm
- Arterial hypertension
- Atherosclerotic disease
- Peripheral artery disease (PAD)
- Stroke
- Venous thromboembolism

INTEGRATED TECHNOLOGY

- Clinical Trial Management System (CTMS)
- Electronic Data Capture
- Interactive Voice Response System (IVRS)
- Interactive Web Response System (IWRS)
- IxRS technology

Worldwide is a leader in developing bespoke IxRS solutions for sponsors. With the capability to integrate complex IxRS needs into sponsor data systems, we can reduce costs while enhancing both quality and efficiency.

[a] Including one board-certified cardiologist.

[b] The ATLAS Group comprises an international panel of renowned hematological and antithrombotic experts, CPC Clinical Research, and Worldwide Clinical Trials.

WORLDWIDE CLINICAL TRIALS

A snapshot of our collaborations include:

Pravastatin or Atorvastatin Evaluation and Infection Therapy—Thrombolysis in Myocardial Infarction 22 (PROVE IT–TIMI 22) study

Cannon CP, Braunwald E, McCabe CH, Rader DJ, Rouleau JL, Belder R, Joyal SV, Hill KA, Pfeffer MA, Skene AM. Intensive versus moderate lipid lowering with statins after acute coronary syndromes. *N Engl J Med.* 2004; 350: 1495-1504

Clopidogrel as Adjunctive Reperfusion Therapy—Thrombolysis in Myocardial Infarction 26 (CLARITY-TIMI 26) study

Sabatine MS, Cannon CP, Gibson CM, Lopez-Sendon JL, Montalescot G, Theroux P, Claeys MJ, Cools F, Hill KA, Skene AM, McCabe CH, Braunwald E. Addition of clopidogrel to aspirin and fibrinolytic therapy for myocardial infarction with ST-segment elevation. *N Engl J Med.* 2005; 352: 1179-1189

Trial to Assess the Effects of Vorapaxar in Reducing Atherothrombotic Events in Patients With Atherosclerosis—Thrombolysis in Myocardial Infarction 50 (TRA 2°P–TIMI 50)

Morrow DA, et al. Vorapaxar in the secondary prevention of atherothrombotic events. *N Engl J Med.* 2012; 366: 1404-1413. Worldwide Clinical Trials personnel A Skene, K Hill, and L Bennett are included under Trial Leadership in the supplementary appendix (K Hill as head of clinical operations).

Proficiency in CV Outcome Trials

In many cases, studies will plan to enroll thousands of patients across hundreds of centers around the world, using inclusion/exclusion criteria that are highly specific and outcome measures that are relatively discrete. Therefore, it is critical that study infrastructure is scalable and fully adaptable from country-to-country and site-to-site. Worldwide's operational knowledge is unrivalled, with well-considered team composition, communication strategies (with study sites as well as multiple vendors), collaborative support and proven patient recruitment and retention plans. Our workflow control ensures that we meet objectives and adhere to timelines while remaining flexible in the face of unanticipated challenges.

Worlwide services and infrastructure spanning >7,900 sites and >158,000 patients

Acute coronary syndrome		
OPUS–TIMI 16	10,300 patients	800 sites
PROVE IT–TIMI 22	4,000 patients	300 sites
MERLIN–TIMI 36	6,560 patients	500 sites
PLATO	18,624 patients	862 sites
EMIP-FR	6,270 patients	79 sites
MAGIC	5,600 patients	94 sites
VISTA-16	5,189 patients	362 sites
Heart failure		
PRIME II	1,800 patients	140 sites
COMET	3,000 patients	200 sites
CIBIS III	1,000 patients	120 sites
Thrombolysis		
TRA 2°P–TIMI 50	26,449 patients	1032 sites
InTIME II–TIMI 17	15,000 patients	850 sites
CLARITY–TIMI 28	3,500 patients	319 sites
LATE	5,700 patients	250 sites
INJECT	6,000 patients	210 sites
GUSTO III (Europe)	6,000 patients	250 sites
HERO–2	8,000 patients	90 sites
Venous thromboembolism		
Ongoing	8,000 patients	500 sites
High cardiovascular risk—diabetes, obesity		
PROactive	5,238 patients	321 sites
Ongoing	12,000 patients	700 sites

[a] Worldwide partners with a range of specialized service providers, including centralized clinical and imaging laboratories, drug procurement and management specialists, and logistics support for transfer of temperature-controlled pharmacokinetic samples, etc.

V.2 - Oct 16 - USL

Cardiovascular Disease

KEY SERVICES

- Biostatistical service
- Clinical monitoring
- Data and Safety Monitoring Board charters and management
- Data management
- Endpoint 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[a]

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