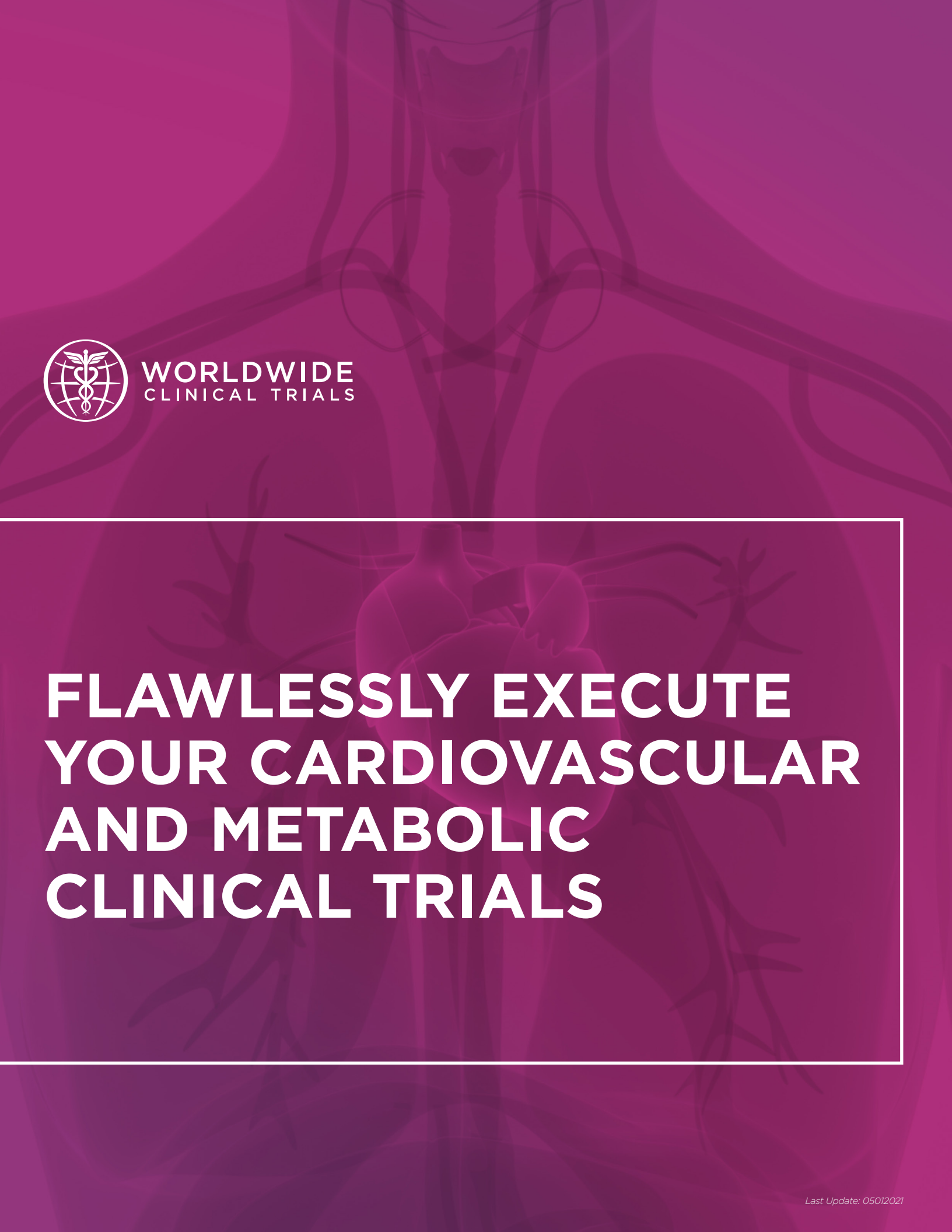

WORLDWIDE CLINICAL TRIALS

FLAWLESSLY EXECUTE YOUR CARDIOVASCULAR AND METABOLIC CLINICAL TRIALS

Last Update: 05012021

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

CRO LEADERSHIP AWARDS2019

Capabilities, Compatibility, Expertise, Quality, and Reliability

ISR reports

RATED OVERALL TOP PERFORMER FOR:

- Budget Factors
- Delivery Factors
- Staff Characteristics
- Accessibility
- Services
- Customer Loyalty

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 ACCELERATION

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.

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 & II
- Diabetic nephropathy
- Dyslipidemia
- Ischemia
- Heart failure
- Heterozygous familial hypercholesterolemia (HeFH)
- Homozygous familial hypercholesterolemia (HoFH)
- Hypercholesterolemia
- Hyperlipidemia
- Hypertension
- Hypertriglyceridemia
- Kidney diseases
- Myocardial infarction (MI)
- Obesity
- Peripheral artery disease (PAD)
- Pulmonary arterial hypertension (PAH)
- Restenosis
- Thrombosis

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 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 involving 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.

[1] https://www.medicalnewstoday.com/articles/319061.php

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

Soneil Guptha, M.D., FACC, FESC, FCCP, AFPM

Senior Medical Director, Medical and Scientific Affairs, Cardiovascular and Metabolic Diseases

Dr. Guptha has 40 years of combined experience in clinical development, medical, and regulatory affairs (US, EU, APAC) in cardiology, nephrology, lipids, diabetes, thrombosis, drug eluting stents, and asthma/COPD as medical monitor to departmental head since graduating in 1976. Prior to joining Worldwide Clinical Trials, he worked as an independent consultant utilizing his expertise as an academician, clinician (interventional cardiologist), and drug and device developer in the US, Europe, and Asia-Pacific. He is very experienced in clinical (cardiovascular and metabolic) medicine; pharmaceutical medicine (clinical, epidemiological and drug and device P2-4 development, research operations, medical affairs, and regulatory affairs), and basic research methodologies.

Karen Hill

Senior Vice President, Project Management, Cardiovascular and Metabolic Diseases

Karen joined Worldwide Clinical Trials in 1993 and is responsible for global project management within the Cardiovascular and Late Phase division. She has more than 23 years of experience in the CRO industry and has worked on numerous large cardiovascular outcome studies, including INJECT; GUSTO III; InTIME-II-TIMI 17; OPUS-TIMI 16; PROVE IT–TIMI 22; CLARITY-TIMI 28; and MERLIN-TIMI 36, where she held the position of Global Project Manager/Director. In 2003, Karen took over as head of the Project Management department, which included the management and supervision of the company's project managers, CRAs, and the IVRS development and support teams. Karen currently leads the Global Cardiovascular and Late Phase Project Management division at Worldwide and continues to supervise global teams working on both large cardiovascular outcome studies, as well as other phase II-IV studies in other cardiovascular indications.

Monika Iten, Ph.D., MSc

Vice President Project Management, Cardiovascular and Metabolic Diseases

Dr. Monika Iten has over 18 years of experience in the CRO industry in clinical operations, performance management, and marketing. Monika has a proven record of successful management, oversight, and conduct of large clinical trials programs in cardiovascular and metabolic diseases, which have led to marketing authorizations in US and EMEA. She is highly experienced in managing complex teams and leading them to success.

Dr. Iten also has been building and leading global Project Management Office and Clinical Performance groups with substantial positive impact on project delivery and team performance. Dr. Iten has an MSc from the ETH Zurich in Switzerland and a Ph.D. in cell biology from the University of Basel in Switzerland.

Nancy Newark, RN

Executive Director, Project Management, Cardiovascular and Metabolic Diseases

Nancy joined Worldwide in July 2010 and has provided operational oversight and leadership for cardiovascular projects and currently serves as a franchise lead within the cardiovascular therapeutic area. Prior to joining Worldwide, Nancy worked at Duke University Medical Center for 25 years. For 11 years, she was a critical care transport nurse for the helicopter and ground ambulance program, and for 14 years, she provided senior operational leadership for global multi-center clinical trials and registries, including direct responsibility for regulatory compliance, and strategic development of project management, site management, and clinical monitoring services at the Duke Clinical Research Institute (DCRI).