WORLDWIDE CLINICAL TRIALS

WORLDWIDE EVIDENCE™

ADVANCING SCIENCE AND STRATEGY AT EVERY STAGE OF THE PRODUCT LIFE CYCLE

Last Update: 04112020

WORLDWIDE
CLINICAL TRIALS

AWARD-WINNING, FULL-SERVICE CRO

Founded by physicians committed to advancing medical science, Worldwide Clinical Trials 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, Worldwide provides world-class, full-service drug development services. With infrastructure and talent spanning 60 countries, we execute predictable, successful studies with operational excellence across a range of therapeutic areas, including central nervous system, cardiovascular, metabolic disorders, 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.

WORLDWIDE EVIDENCE™

The Worldwide Evidence team has designed and undertaken hundreds of projects, including economic models, global patient registries, and observational studies in a broad array of disease categories.

"Does it work under actual practice conditions?"

"Is it worth the price?"

"What's the impact on patients' quality of life?"

"Is it safe in real-world medical practice?"

Life sciences industry professionals turn to Worldwide Evidence™ to document the clinical, economic, and humanistic value of innovative drugs and devices before and after product approval and launch.

With an uncommon combination of global experience, technical expertise, and decades of practical, strategic perspective, our experts work to objectively and credibly establish and communicate evidence of value in actual practice (real-world) settings, using operational approaches that increasingly embrace advanced technology.

- Evidence Strategy & Planning
- Health Economics & Outcomes Research
- Observational Research & Patient Registries
- Post-approval Safety Studies
- Patient Outcome Communities

Generating and communicating clinical, economic, and humanistic value throughout the product life cycle.

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EVIDENCE STRATEGY AND PLANNING

Worldwide Evidence delivers insights that transform data into persuasive evidence.

Worldwide Evidence ensures our clients' evidence strategies are optimized so that documentation of product value is aligned with the needs and information gaps of patients, physicians, payers, and policymakers. Beginning in the preapproval time frame, we establish a portfolio of increasingly persuasive clinical, economic, and humanistic evidence that aligns with clinical and commercial development priorities. Our clients call on us regularly to devise formal assessment processes for patient registries and other non-traditional research initiatives that provide both evidence and engagement and in doing so, help to accelerate product acceptance and adoption.

HEALTH ECONOMICS AND OUTCOMES RESEARCH

Establishing economic value is a requirement for market success. Worldwide Evidence helps inform critical questions pertaining to drugs and devices, such as, "Is it worth it?" and "How can this product impact patient quality of life?" With decades of experience, we have unique insights into stakeholders' needs and expectations for value at all stages of product development.

- Economic and PRO Endpoint Design
- PRO Instrument Design and Validation
- Economic / PRO Literature Reviews
- Economic Modeling
- Cost-of-Illness Studies
- Cost-effectiveness Analyses
- Retrospective Studies
- Product Dossier Development / Updates

OBSERVATIONAL STUDIES AND PATIENT REGISTRY SERVICES

Simply stated, there is not a more experienced team of observational research and registry experts in the industry. Our Worldwide Evidence practice includes pioneers in the field who provide both strategic perspective and practical operational expertise that embraces evolving technological solutions for data acquisition and communications in the real-world setting.

- Disease Landscape Assessment
- Study Design and Scope
- Study Communications (Protocol, etc.)
- Study Branding and Website Development
- Global Regulatory and Approval Planning
- Statistical Analysis Planning and Execution
- Scientific Advisory Panel Management
- Project Management and Reporting
- Data and Technology Management
- Site Recruitment and Management
- Patient Enrollment Management
- Communications (Publications / Presentations)

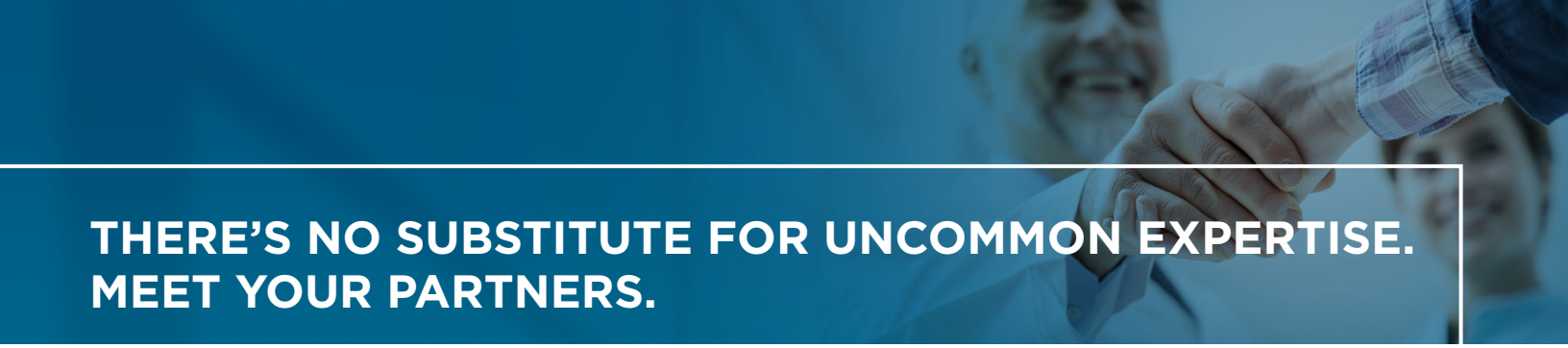
POST-APPROVAL SAFETY STUDIES

Evaluating pre- and post-launch safety implications? Whether as a formal mandate from regulatory authorities or combined with a discretionary research initiative, our global experts design and deliver post-approval research programs to compile safety data in actual practice settings.

- Post-Marketing Surveillance
- Spontaneous ADR (SADR) Processing and Reporting
- Serious Adverse Event (SAE) Processing and Reporting
- REMS/RMP Design and Advisory Consultation
- Periodic Safety Update Reports (PSUR), Annual and Quarterly Report Preparation
- Signal Detection Services
- Argus™ Safety Database

PATIENT OUTCOME COMMUNITIES

We provide a unique, yet essential, link for clients seeking to understand and inform patient-centric outcomes research. Worldwide Evidence has established Patient Outcome Communities for a wide array of disease states and conditions, delivering an essential, data-driven connection between life sciences companies and patient communities. Contact us for more information on sponsorship opportunities.



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

Many large CROs offer "off-the-shelf" advice and solutions to their customers. Worldwide delivers tailored and pragmatic advice, regardless of the size or complexity of the project. Our collaborative, customized project teams with phase- and indication-specific expertise develop successful strategies for even the most novel therapies.

Jeff Trotter, M.B.A.

Senior Vice President, Worldwide Evidence

Jeff Trotter was named Senior Vice President, Worldwide Evidence, following the company's acquisition of Continuum Clinical's Late Stage (Observational Research and HEOR) division that completed in January 2018. Jeff served as president of Continuum since 2014, supporting clients with the critical transition from clinical development to commercialization through research excellence, responsible communications, and a constant focus on business strategy.

As an entrepreneur, researcher, consultant, and innovator with more than 30 years of experience, Jeff has been a pioneer in the evolving health economics and outcomes research community and is an industry leader in the design and implementation of patient registries and observational studies. He has spoken widely in front of varied industry audiences and has published over 50 original articles and research papers — including a book for the American Hospital Association, The Quest for Cost-Effectiveness in Healthcare: Achieving Clinical Excellence While Controlling Cost.