
WORLDWIDE
CLINICAL TRIALS
ONCOLOGY
IN THE FIGHT TO BRING INNOVATIVE THERAPIES TO PATIENTS

IN THE FIGHT FOR PATIENTS

END-TO-END SUPPORT

BIOANALYTICAL LAB

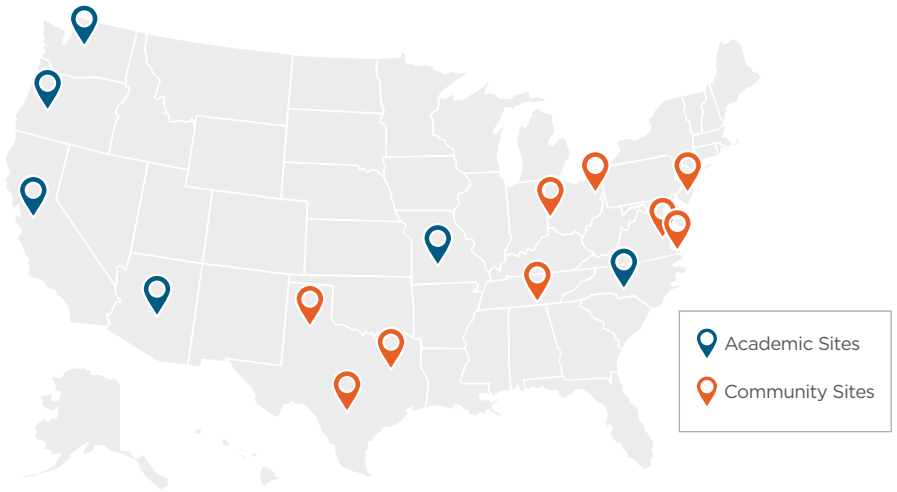
PHASE I → PHASE II → PHASE III

REAL-WORLD EVIDENCE

BIOANALYTICAL LAB SERVICES

- 2,500 LC-MS/MS assays developed, including marketed oncology drugs
- Deep expertise in molecularly targeted anti-cancer agents (e.g. kinase inhibitors)
- PK/PD relationships in animal anti-tumor efficacy studies
- Regulated bioanalysis in GLP-Toxicology studies of both large and small animal studies
- Experience in pharmacokinetics data analysis
- Quantitation of cytotoxic payloads of antibody-drug conjugates (ADCs)
- Assays for relevant biomarkers in oncology (e.g., CEA, CA-125, PSA, p-MEK, p-ERK)
- Multi-analyte assays, including metabolites
- Radiolabeled AME (absorption, metabolism, & excretion) oncology studies
- Biomarkers for both patient stratification and pharmacodynamics, including peptides, proteins, and phospho-proteins
- Bioanalysis (tumor, tissues, CSF, synovial fluid) for site-of-penetration and target organ studies
- Novel platforms available for therapeutic antibodies (SISCAPA and nSMOL)
- Microsampling, including plasma microcapillaries, and dried blood spot analysis
- Chiral separation and quantitation of enantiomers

EARLY PHASE SITE NETWORK



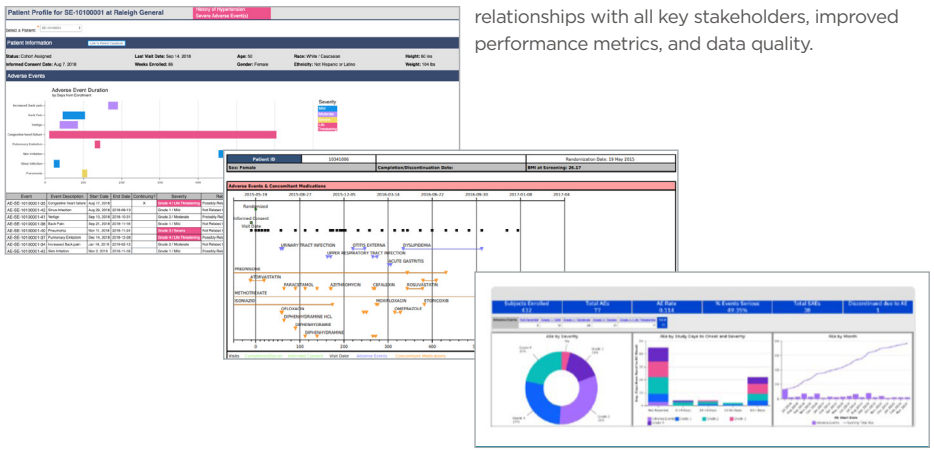
PREFERRED USA ONCOLOGY SITES FOR ~
30% FASTER START-UPS

CLINICAL METHODOLOGY: A GUIDE FROM "BENCH TO MARKET"

- Michael F. Murphy, MD, PhD, one of Worldwide's original founders and current Chief Medical & Scientific Officer, has for the past 24 years been on the teaching faculty at Harvard/MIT in a fellowship program dedicated to clinical trial methodology
- A comprehensive review of the sequence of studies as they would inform clinical research methodology from lead optimization, IND enabling research, through IND or CTA applications, to NDA or MAA
- New chemical or biological entities, advanced therapy medicinal products (ATMP), and repurposed assets under 505B2 regulations
- Methods of estimating first dose, dose escalation, safety surveillance, and study design exploiting the properties of the test agent, mapped against the patient population
- Support trial designs across a spectrum encountered within the oncology R&D space

DATA VISUALIZATION

Data is extremely important to our biotechs. Even more important is accessibility and customization of your data. We get that. Worldwide offers a variety of strategies to support access to your data as well as data visualization tools for analysis of trends, patterns, and outliers to facilitate quick and informative decision-making.



TRAINING & SPECIALIZATION

Early phase oncology has evolved significantly over the years. Worldwide's dedication within Oncology offers specialization to our sponsors and exceptional training to our teams. CRAs on our oncology team attend a multifaceted and scenario-based accreditation program focusing on the fundamentals of and "gray areas" in early phase oncology. As a result, our CRAs have stronger relationships with all key stakeholders, improved performance metrics, and data quality.

IN THE FIGHT FOR PATIENTS

MEETING PATIENTS WHERE THEY ARE

Worldwide Clinical Trials delivers an innovative data-driven approach, in-region expertise and operational acumen to ensure on-time delivery for each study.

3,000+

Professionals

Oncology Experienced Resources in Offices Globally including Emerging Markets with Minimal Competition and High Demand for Oncology Trials

60+

Countries

- Asia
- Australia
- Europe
- North America
- South America

300+

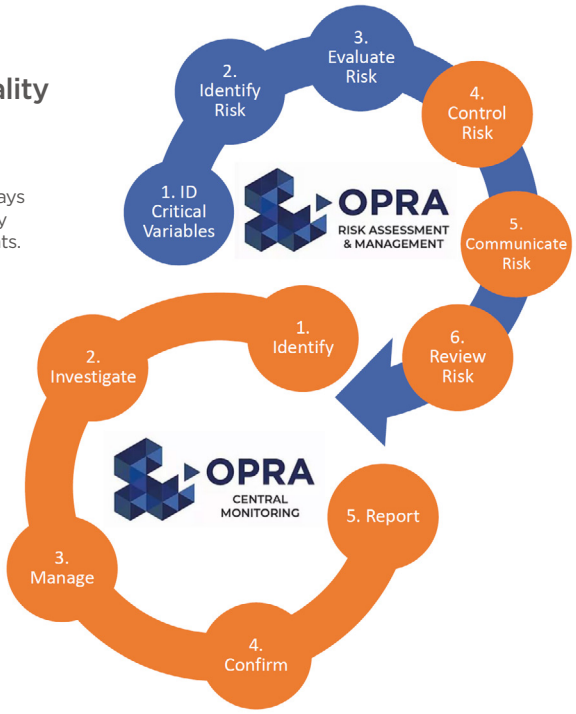
Clinical staff with 2+ years' experience in oncology and hematology trials

QUALITY BY DESIGN

Commitment to Increased Quality Via Risk Management

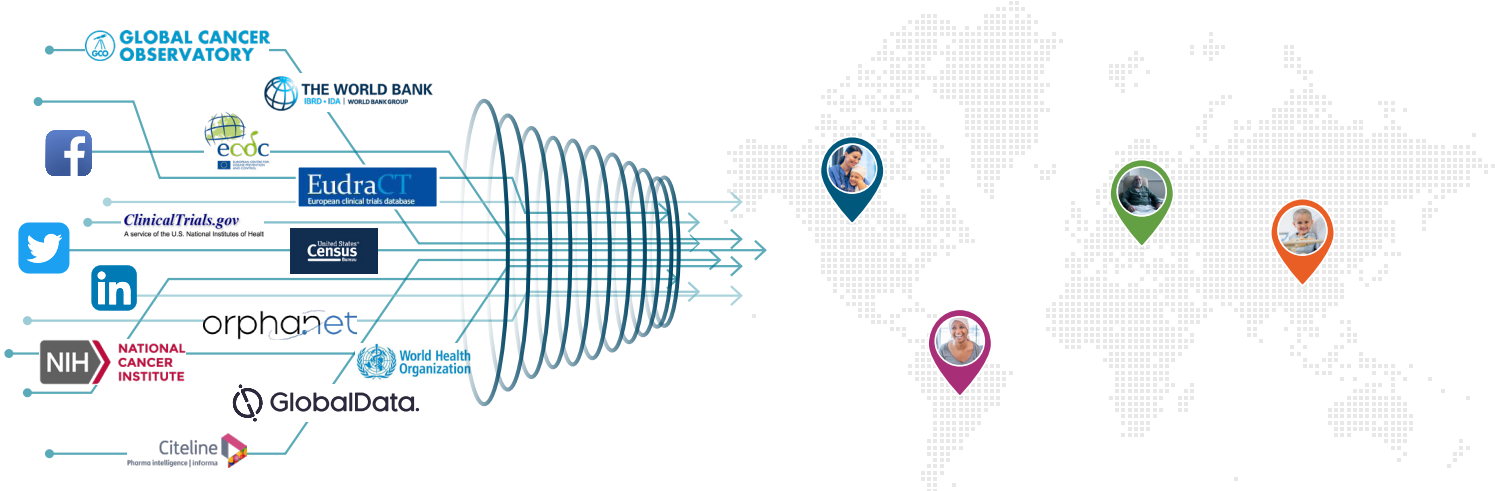
Building risk assessments and monitoring plans that focus on what is important into trial design lays the groundwork for a successful drug program by increasing data integrity and safeguarding patients. Our risk-based quality management (RBQM) capabilities ensure that:

- Risks to critical data and processes are identified early
- Functional areas each have unique and defined monitoring strategies
- A validated, closed system (TRI OPRA) manages the process with access control and a full audit trail
- A risk log that gives the option to add integrated forward-looking indicators for Central Monitoring of potential risks in near real time



DATA-DRIVEN STRATEGIES FOR PATIENT IDENTIFICATION

Worldwide Clinical Trials leverages our proprietary data lake and algorithm for optimal identification of patients and sites globally.



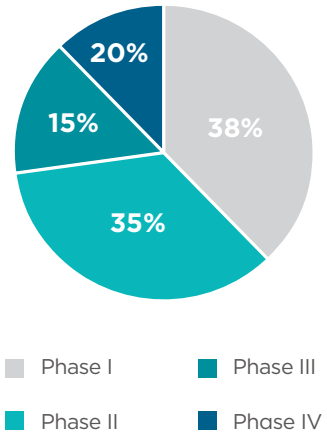
REAL-WORLD EVIDENCE FOR REGISTRATION & POST-MARKETING STUDIES

Changes in the oncology therapeutic landscape have raised critical questions about access, comparative value, and selection of the best treatment option for each patient. Our Worldwide Evidence core business unit leads the industry in real world evidence (RWE) expertise, with 100+ studies and 500+ publications and presentations completed by the team. Our stable, service-oriented team executes real-world solutions combining the best in medical expertise, science, methodological rigor, and operational infrastructure, delivering more — and better — evidence of real-world effectiveness and safety.

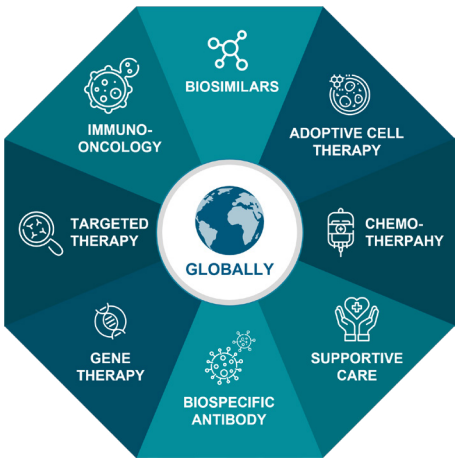
DEDICATED TO THE FIGHT

WORLDWIDE CLINICAL TRIALS ONCOLOGY EXPERIENCE

STUDIES BY PHASE



AREAS OF EXPERTISE



STUDIES BY COMPANY

100% BIOTECH

85% REPEAT CLIENT BUSINESS

INDICATIONS

- Bladder Cancer
- Breast Cancers
- Gynecologic Cancers
- Colorectal Cancer
- Gastric Cancers
- Gliomas
- Hepatocellular Carcinoma
- Idiopathic Thrombocytopenic Purpura
- Leukemia/ Lymphoma
- Lung Cancers
- Melanomas
- Myelodysplastic Syndrome
- Other Solid Tumors
- Pancreatic Cancer
- Post-Essential Thrombocythemia Myelofibrosis
- Prostate Cancer
- Sickle Cell Disease

WORLDWIDE CLINICAL TRIALS DELIVERS A COMBINATION OF EXPERTISE AND PARTNERSHIP TO ACHIEVE RESULTS. BEING FLEXIBLE, WORKING HARD, AND GOING ABOVE AND BEYOND IS JUST HOW WE DO BUSINESS.

TOGETHER FOR ALL
PATIENTS

GREAT BREAKTHROUGHS REQUIRE A GREAT TEAM

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.

25+ years

Worldwide Oncology team average years' experience

100%

Database targets met in last 2 years

100%

Oncology experience from leadership to CRAs

OUR TEAM'S COLLECTIVE ACCOMPLISHMENTS

225+

Peer Journals

500+

Clinical Trials

Sarah Anderson

Executive Director, Oncology Strategy Lead

Georgia, USA

- 18+ years' of oncology-focused industry experience,
- Providing global project development/oversight and clinical management in both CROs and pharmaceutical companies
- Extensive experience with all phases of solid tumors, hematological malignancies, and oncology supportive care

Cheryl Chapman

Executive Director, Project Management, Oncology

England, UK

- 20+ years' experience
- Expertise across all phases from early phase dose escalation to global programs
- Broad range of hematological malignancy and solid tumor indications various treatment modalities, including monoclonal antibodies, nucleotide DNA inhibitors, targeted therapies, orphan drugs, and oncolytic vaccines

Steve Chriscoe

Vice President, Project Management, Oncology

North Carolina, USA

- 25+ years' experience
- Expertise across all phases from early phase dose escalation to global programs
- Broad-range experience in solid tumor indications and various MOAs - immuno-oncology therapies and CAR-T therapies

Jim Eamma

Senior Director, Project Management, Oncology

Texas, USA

- 20+ years' experience
- Expertise across all phases, specializing in large, global, multi-site oncology clinical trials
- Experienced oncology investigator and project manager with frontline understanding of the clinical and investigative strategies

TOGETHER FOR ALL
PATIENTS

ISR reports

RATED OVERALL TOP PERFORMER FOR:

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

CRO LEADERSHIP AWARDS 2022

Capabilities, Compatibility, Expertise, Quality, and Reliability

Gary Fishbein, MD, MPH

Executive Medical Director, Therapeutic Area Medical Lead, Medical Affairs

Pennsylvania, USA

- Board-certified oncologist with 20+ years' experience contributing to range of oncology trials
- Expertise in feasibility studies, protocol and study design, clinical trial execution and monitoring, as well as post-market evidence

Wioletta Laszczewska, PhD

Senior Medical Director, Medical Affairs

Warsaw, Poland

- 20+ years' experience supporting 200+ oncology trials across all stages of development
- Expertise in range of indications: NSCLS, SCLC, breast, prostrate, pancreatic, head and neck, ovarian, endometrial cancers, osteosarcoma, and chondrosarcoma, MDS, AML , CLL, HL, NHL, and DLBCL

Clare Wallis

President of Oncology Business Unit

Minnesota, USA

- 20+ years of industry experience
- Strategically aligned to develop innovative delivery strategies for oncology clients
- Executive sponsor and global therapeutic area lead

WORLDWIDE CLINICAL TRIALS | ONCOLOGY

GREAT BREAKTHROUGHS REQUIRE GREAT TEAMS.

TOGETHER FOR ALL PATIENTS

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WORLDWIDE
CLINICAL TRIALS

About Worldwide Clinical Trials

Worldwide Clinical Trials is a global, midsize contract research organization (CRO) that provides top-performing bioanalytical and Phase I-IV clinical development services to the biotechnology and pharmaceutical industries.

Founded in 1986 by physicians committed to advancing medical science, our full-service clinical experience ranges from early phase and bioanalytical sciences through late phase studies, post approval, and real-world evidence. Major therapeutic areas of focus include cardiovascular, metabolic, neuroscience, oncology, and rare diseases. Operating in 60+ countries with offices in North and South America, Eastern and Western Europe, and Asia, Worldwide is powered by its more than 3,000 employee experts.

For more information, please visit **www.worldwide.com** or connect with us on **LinkedIn** and **Twitter**.