WORLDWIDE CLINICAL TRIALS

ACCELERATE YOUR MOLECULE'S SUCCESS

AN OVERVIEW OF WORLDWIDE CLINICAL TRIALS' EARLY PHASE SERVICES

Last Update: 07082020

WORLDWIDE
CLINICAL TRIALS

A FULL-SERVICE EARLY PHASE CRO WITH INTEGRATED CPU & GLP BIOANALYTICAL LAB

As an early phase contract research organization (CRO), we offer a range of services executed by professionals fully dedicated to your early development program. These services include:

- Protocol design and early phase concept and program development
- Protocol writing
- Regulatory and pre-IND/IND meeting consultation services
- Scientific consultation
- Multi-site feasibility support based upon established QA-approved site network
- Dedicated Phase I/early development project management group
- Phase 1-focused data management
- Biostatistics and statistical design planning specific to early development studies
- Pharmacokinetics
- Clinical monitoring
- Pharmacovigilance
- Site management
- Medical writing

EXPERIENCE MATTERS. WORK WITH A PROFICIENT, TRUSTWORTHY PARTNER.

Does your CRO partner have the experience to back up its claims? With an early phase focus for over 20 years, we currently conduct approximately 100 clinical trials annually.

ISR reports

RATED OVERALL TOP PERFORMER FOR:

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

WORLDWIDE CLINICAL TRIALS: AN UNCOMMON EARLY PHASE CRO

In the critical early study phases of your novel drug, you are hyper-focused on proving the viability of your concept and ensuring the safety of your patients. But beyond that, you are laying the groundwork for the advanced phases of the study that are yet to come. To get your compound off on the right foot, the design of your early phase trial must be rigorous, strategic, and the protocol execution must be meticulous. When choosing Worldwide Clinical Trials as your early phase CRO, you will experience firsthand why we call ourselves the Cure for the Common CRO. We are confident that you will receive top-quality data collected under state-of-the-art conditions designed to put safety first while also making the best use of your financial investment.

ONE-STOP SHOP: WORLDWIDE'S IN-HOUSE CLINICAL PHARMACOLOGY UNIT

Our clinical pharmacology unit (CPU) is a state-of-the-art facility located in San Antonio, Texas that integrates clinical pharmacology with bioanalysis. Our professional team has worked with AME, SAD/MAD, DDI, and QTc study designs and has experience with specialized pharmacodynamics assessments, including cognition, psychiatric, QST/pain modeling, and imaging. We are an ERT-certified partner, offering cardiac QT, ABPM, and EEG. We also provide:

- Limited-access Phase I unit
- cGMP Phase I pharmacy
- Full-service clinical laboratory
- Fully equipped sample processing laboratory

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WORLDWIDE CLINICAL TRIALS

CLINICAL PHARMACOLOGY STUDIES

SPECIAL PROCEDURES

- Serial and continuous Cerebrospinal Fluid (CSF) collection
- CNS cognitive evaluations
- Inhalation/intranasal delivery
- Intratympanic injection
- Drug-Alcohol interaction

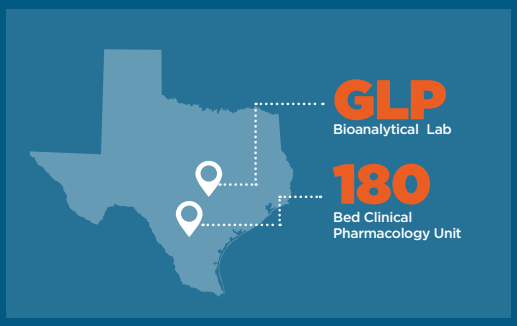
PATIENT AND SPECIAL POPULATIONS

- Impaired hepatic function
- Impaired renal function
- Healthy elderly
- Metabolic syndrome
- Adolescent
- Low testosterone
- Post-menopausal
- NASH/NAFLD

STATE-OF-THE-ART FACILITIES

Our bioanalytical lab is comprised of designated lab areas to provide a degree of separation of activities:

- ADME lab
- Automation labs
- LC-MS/MS labs
- Method Development lab
- Production labs
- Sample Control Unit



GLP BIOANALYTICAL LAB AND CPU: STRATEGICALLY LOCATED FOR SEAMLESS TRANSFER OF SAMPLES

Worldwide's top-ranking bioanalytical laboratory sets the bar for quality, services, and ability to meet customer expectations.

Located in Austin, TX, our bioanalytical lab is a quick ride from our CPU, enabling quick transport of specimens from the CPU to the bioanalytical lab, When your program relies on speed, trust Worldwide.

UNCOMMON AGILITY SETS WORLDWIDE APART AS AN EARLY PHASE CRO

Worldwide Clinical Trials offers a full range of CRO services and has access to patient populations on a global scale. Unlike larger CROs, we provide attentive service and flexibility for execution that you cannot get anywhere else. Our culture of commitment to quality research is demonstrated in our belief that we are "big enough to matter, small enough to care."

INVESTING IN PATIENTS

Because patient care and data quality are our top priorities, we invest heavily in our subject recruitment efforts. Using both traditional and novel approaches, we have access to the healthy volunteers and specialized patient groups that you seek.

DON'T GET LOST IN THE SHUFFLE

Take it from our past clients. In a recent ISR Report, Worldwide Clinical Trials was top-ranked for customer service, loyalty, accessibility, and customer responsiveness. Our uncommon flexibility makes us the CRO you can rely on service our the hands-on attention by professionals personally committed to your project's success. Worldwide provides the customer service you deserve!

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

Sherilyn Adcock, Ph.D., R.Ph.

Executive Vice President, Scientific Solutions

Dr. Adcock has been a top expert in early phase research and Phase 1 cGMP pharmacy manufacturing since 1990. Prior to joining Worldwide in 2001, Dr. Adcock had served in senior-level positions in major contract research organizations. Dr. Adcock's experience in operations and research methods offers valuable expertise from protocol concept and preclinical through transition to Phase II and beyond.

She began her career as a Pharmacist and Clinical Instructor in Pharmacy and was the Pharmacy Services Supervisor at Mother Frances Hospital in Tyler, Texas. In addition to her licensure by the Texas State Board of Pharmacy, Dr. Adcock is certified in basic cardiac life support and sterile products preparation. She is a Member of the American Association of HealthCare Pharmacists, the Drug Information Association (DIA), and the American Association of Pharmaceutical Scientists (AAPS). Dr. Adcock earned her B.S. in pharmacy, a M.S. in health science, and a Ph.D. specializing in community health research, all from the University of Texas at Austin.

George J. Atiee, M.D.

Vice President, Medical and Clinical Lab Director

Dr. Atiee serves as the Medical Director and Principal Investigator. Dr. Atiee has close to 20 years of clinical research experience in both early and late phase drug development. For the past 10 years, Dr. Atiee primarily has been dedicated to Phase I research. He has completed many first-in-human (FIH) trials, including a new antibiotic and three FIH monoclonal antibody trials. In addition, Dr. Atiee has significant experience with antivirals, DDI, BA/BE studies, and medical device studies.

Lona Sheeran

Senior Vice President, Clinical Operations Early Phase

Lona serves as the Senior Vice President of Early Phase Clinical Operations at Worldwide Clinical Trials. With over 20 years operating in early phase environment, Lona has a track record of driving organizational and financial excellence through risk and benefit oversight and Lean Six Sigma techniques. She holds a Bachelor of Science degree from Concordia University in Wisconsin.