WORLDWIDE
CLINICAL TRIALS

BUILT FOR SCIENTIFIC INTEGRITY AND SUBJECT SAFETY

AN OVERVIEW OF WORLDWIDE CLINICAL TRIALS' CLINICAL PHARMACOLOGY UNIT

Last Update: 23092019

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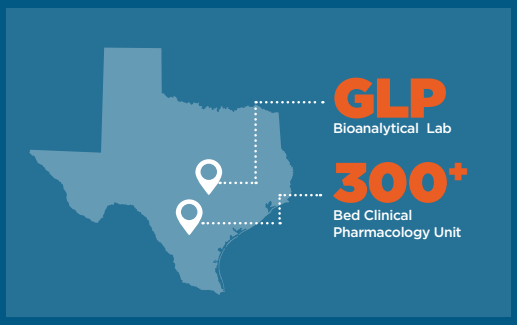
OFFERING FULL-SERVICE EARLY PHASE PROGRAM SUPPORT

We offer a range of early development contract research organization (CRO) services executed by professionals fully dedicated to early development. 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



OUR FULL-SERVICE FIT-FOR-PURPOSE CLINICAL PHARMACOLOGY RESEARCH UNIT

Your early phase program needs a clinical pharmacology unit (CPU) that's renowned for its services, staff, and accessibility. Worldwide Clinical Trials has been top-ranked by its early phase customers for these qualities in the latest Early Phase CRO Quality Benchmarking Report by Industry Standard Research, making it the "go-to" CRO for your early phase program.

Established over 25 years ago Worldwide's Clinical Research Unit in San Antonio, TX, is a 300-bed, highly flexible, fit-for-purpose clinical pharmacology unit. Within this unit, more than 100 studies in healthy volunteers, patients, and specialty populations are conducted each year. The patient database capabilities span a broad range of specialized populations, including CNS, cardiovascular, and metabolic patient populations. The Worldwide unit has several distinct differentiating capabilities, including:

- An on-site cGMP Phase I compounding pharmacy service, allowing for accelerated timelines due to rapid investigational medicinal product (IMP) preparation
- On-site CLIA safety lab providing rapid turnaround of test results (screening and safety)
- Conveniently located by Bioanalytical Lab (GLP) for seamless sample transfer

A STATE-OF-THE-ART FACILITY FOR YOUR PROGRAM

- Restrictive-access Phase I unit
- Flexible procedure areas based on study design
- cGMP Phase I compounding pharmacy
- ISO class 8 pharmacy
- Federal and state Schedule I-V drug licensure
- Full-service moderate complexity clinical laboratory
- Fully equipped sample processing laboratory
- Security-alarmed -70°C and -20°C freezers
- 32 channel mortare telemetry system
- 21CRF Part II compliant electronic capture system

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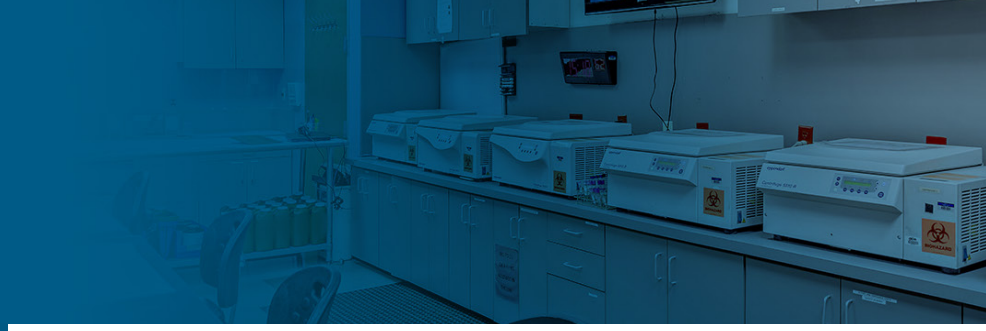

CLINICAL PHARMACOLOGY STUDY EXPERIENCE

We are highly experienced in:

- First-in-human single ascending dose/multiple ascending dose
- Drug-drug interaction
- QT cardiac safety
- Food effect
- PK/PD
- Bioequivalence
- Bioavailability
- AME studies (radiolabeling)
- Renal/hepatic-impaired patient populations

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**

Our CPU has adaptable procedure spaces and a fully equipped sample processing lab that has successfully delivered 600,000 samples in a year. In addition, the pharmacokinetics lab features 14 centrifuges and handles more than 300,000 samples per year.

Within the facility is a 1,200 square-foot pharmacy with an ISO Class 7 clean room and ISO Class 5 laminar flow hood. The pharmacy operates under GCP, USP 797, and FDA cGMP Guidance for Phase I investigational drugs. Its compounding suite houses analytical balances with capabilities as low as 2mg.

CLIENTS CHOOSE WORLDWIDE FOR ITS SPECIALIZED CLINICAL PHARMACOLOGY PROCEDURES

When you require a CRO partner with uncommon experience, look no further than Worldwide Clinical Trials. Our staff is trained to handle specialty clinical pharmacology procedures, including:

- Serial and continuous cerebrospinal fluid (CSF) collection
- CNS cognitive evaluation
- Inhalation/intranasal delivery
- Intratympanic injection
- Drug-alcohol interaction
- Female OC-drug interaction

WORLDWIDE CAN SUPPORT YOUR PATIENT AND SPECIAL POPULATIONS

We have experience supporting trials with these rare and specialty patient groups:

- Flexible procedure areas based on study design
- Impaired renal/hepatic function
- Healthy elderly
- Metabolic syndrome
- Adolescent
- Low testosterone
- Post-menopausal
- NASH/NAFLD
- Obesity
- T2DM & T1DM

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.