Worldwide Clinical Trials

Phase I Services and Solutions

Built for Scientific Integrity and Subject Safety

Full-service Clinical Pharmacology Unit (CPU)

Operating since 2005, Worldwide's CPU in San Antonio, TX, is a 200-bed, fit-for-purpose facility. Within this unit, studies are conducted in healthy participants, patients, and specialty populations. Our participants database spans a broad range of specialized populations, including, overweight/obese, post-menopausal/surgically sterile females, vasectomized males, healthy elderly, renal impairment, hepatic impairment, metabolic syndrome, T2DM, dyslipidemias, and PGx. Our unit has several distinct differentiating capabilities:

- One-hour travel time by courier to our bioanalytical lab (GLP) for timely sample analysis
- 20-year track record across a wide range of ClinPharm Studies from design to report
- Fully validated eSource data collection system
- cGMP Phase I Pharmacy (including sterile prep) allows accelerated timelines due to rapid investigational medicinal product (IMP) preparation
- On-site CAP/CLIA Safety Lab provides rapid turnaround of test results (screening and safety)

Our CPU has adaptable procedure spaces and additional functional areas specific for successful conduct of pharmacology studies:

- Telemetry/Holter Monitoring
- Flexible Procedure Space
- Screening and Outpatient Area
- Private Medical History Intake
- Specialized Dosing Unit
- Dedicated Sterile and Non-Sterile Procedure Spaces
- CAP/CLIA Safety Laboratory
- cGMP Phase I Pharmacy
- Recreational Area Equipped with WiFi and Entertainment
- Comfortable Overnight Facilities with 24/7 Medical Oversight
- PBMC Processing
- Catering Services and Nutritionist Oversight for Protocol-Driven Dietary Needs
- Psychedelic Treament Rooms

Comprehensive services

Medical and Scientific Consultation
- Concept and Regulatory Approach
- Protocol Design
- Program Development

Regulatory
- Pre-IND/IND Services
- Ethics Review Board Submission

Scientific and Medical Writing
- Protocols and Synopsis
- Informed Consent Document
- Clinical Study Reports

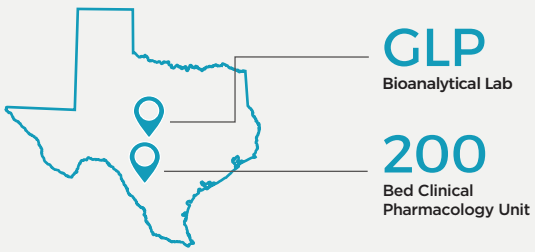
Clinical Conduct
- Worldwide CPU Site with 200 beds
- QA Approved Phase I Global Site Network
- Recruitment of Healthy and Patient Populations
- Participant Retention via Participant Experience Management, Ground Transport, and Travel Support Coordination

Clinical and Medical Oversight
- Medical Monitoring
- Clinical Monitoring
- Pharmacovigilance

Project Management
- Study Execution
- Progress, Cost, and Timeline Management
- Multi-site Feasibility and Management
- Project Communication Coordination

Data Management and Biostatistics
- Phase I Focus and Expertise
- Dedicated Phase I Teams

Pharmacokinetic Team
- PK/PD/Tox Analysis and Reports
- Consultation Services



Pharmacy services on site fully dedicated to research studies

- **Personnel:** Full-time licensed pharmacists, technicians, and QC staff, 24/7 as needed
- **Facility:** Limited-access, HVAC monitored, HEPA filtration, amber lighting
- **Secured drug storage areas:** Ambient, refrigerated, frozen
- **Dedicated areas:** Sterile, non-sterile, and radiolabel labs
- **Equipment:** Analytical balances, laminar flow hoods, sonication/mixing and compounding
- **Documentation/Training:** Established SOPs, work instructions, full IPnaccountability documents

Safety laboratory on site fully dedicated to research studies

- CAP/CLIA-accredited
- Personnel: Full-time medical technologists and technicians, 24/7 as needed
- Facility: Limited-access, established in 2005 with full upgrade in 2018
- Tests: Chemistry, hematology, serology, urinalysis, drugs of abuse screens, Covid PCR, coagulation
- Reporting: LabDaq® LIMS exported into ClinSpark®, rapid turnaround time

Clinic and Bioanalytic Lab Quality Assurance

- Quality Issue / CAPA Oversight
- Facilitate Sponsor Audits of Worldwide
- GxP Consultation for Project Teams and Functional Areas
- Q2QA Relationship
- Conduct Internal Process Audits

Special procedures and evaluations

CNS

- Comprehensive Suite of Cognitive Assessments
- EEG
- Imaging: MRI, CT, X-ray

CSF

- Continuous and Intermittent CSF Collections
  - Experienced CSF Medical Team
  - Anesthesiologist
  - Cryovial Cooling Plates
- Blood and CSF PK Comparisons

CV

- Mortara Surveyor System (48 channel)
- Holter Monitoring
- 24-hour Telemetry
- Experience with Early Precision QT/TQT Studies

AME

- Radiation Safety Officer
- Radiologist
- Pharmacy Drug Preparation
- Radioanalysis

Full suite of clinical pharmacology studies

- FIH
- Integrated SAD and MAD (includes FE / DDI / EPQT)
- DDI
- BE / BA
- Food and Meal Timing Effect
- PK / PD
- AME / Mass Balance / Metabolite Profiling

- Renal and Hepatic Impairment
- Study Type & Design
- PBMC Processing
- Expert Precision QT and Thorough QT Evaluations
- Patients/Specialty Populations
- Biopsies, NG Tube, and Unique Routes of Administration

With the ever-increasing complexity of Phase I trials, Worldwide has you covered. It is our mission to deliver better data faster, without compromising quality, allowing your asset to accelerate to the next step.

Discover More ⟶

Meet Your Partners

Our industry thought leaders and seasoned professionals are ready to consult and advise your next project to optimize data and give you the competitive advantage you deserve. Meet a few of our team members:

Dr. Sherilyn Adcock, PhD, RPh

Chief Scientific Officer, Early Phase Development

With a background in pharmacy and clinical operations, Dr. Adcock has dedicated her career to early phase development. She has been an integral part of Worldwide's Early Phase business transformation from a small clinical site operation focused on generic compounds to the highly innovative business it is today. Dr. Adcock has been instrumental in expanding the Early Phase business to an integrated 200+ bed, highly flexible, fit for service, clinical pharmacology unit, pharmacy compounding services, specialty pharmacy services, and full bioanalysis laboratory renowned for its medical and scientific foundation and its services, staff, and accessibility.

Before joining Worldwide, Dr. Adcock served in executive clinical research roles for SCIREX Corporation and Biomedical Research Group (now Premier Research), Phoenix International Life Sciences (now Celerion), HealthQuest Therapy and Research Institute, and Pharmaco International (now PPD). Prior to entering clinical research, she spent several years working in hospital and clinical settings as a pharmacist and development and oversight of specialty pharmacy services.

Dr. Adcock earned her B.S. in pharmacy, an MS in health science, and a PhD specializing in community health and biostats, all from the University of Texas. She is licensed by the Texas State Board of Pharmacy and holds certifications in sterile product preparation, immunization, and pharmacogenomics.

Lona Sheeran

Senior Vice President, Clinical Operations Early Phase

Lona Sheeran brings more than two decades of operational and financial excellence to her role as Senior Vice President, Clinical Operations Early Phase, at Worldwide Clinical Trials. Lona applies her deep analytical skills honed through years of risk and benefit oversight and experience with Lean Six Sigma techniques to ensure the company's clinical pharmacology unit in San Antonio, Texas, continues to exceed customer expectations.

Worldwide
Clinical Trials

Worldwide Clinical Trials (Worldwide) is a leading full-service global contract research organization (CRO) that works in partnership with biotechnology and pharmaceutical companies to create customized solutions that advance new medications – from discovery to reality.

Anchored in our company's scientific heritage, we are therapeutically focused on cardiovascular, metabolic, neuroscience, oncology, and rare diseases. Our deep therapeutic knowledge enables us to develop flexible plans and quickly solve problems for our customers.

For more information on Worldwide, visit www.worldwide.com or connect with us on LinkedIn.