WORLDWIDE CLINICAL TRIALS

BUILT FOR SCIENTIFIC INTEGRITY AND SUBJECT SAFETY

AN OVERVIEW OF WORLDWIDE CLINICAL TRIALS' PHASE I SERVICE OFFERINGS

OUR FULL-SERVICE, FIT-FOR-PURPOSE 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 volunteers, patients, and specialty populations. Our volunteer database spans a broad range of specialized populations, including, overweight/obese, post-menopausal/surgically sterile females, healthy elderly, renal impairment, hepatic impairment, metabolic syndrome, T2DM, dyslipidemias, and NASH. Our unit has several distinct differentiating capabilities:

- One-hour travel time by courier to our bioanalytical lab (GLP) for timely sample analysis
- 17-year track record across a wide range of ClinPharm Studies from design to report
- Ability to offer full-service early and late stage development study conduct under one set of SOPs
- Fully validated eSource data collection system
- cGMP Phase I Pharmacy (including sterile prep) allows accelerated timelines due to rapid investigational medicinal product (IMP) preparation
- CLIA Safety Lab onsite provides rapid turnaround of test results (screening and safety)

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

- Telemetry Monitoring
- Processing Laboratory
- Flexible Procedure Space
- Screening and Outpatient Area
- Private Medical History Intake
- Specialized Dosing Unit
- CLIA Safety Laboratory
- cGMP Phase I Pharmacy
- Recreational Area Equipped with WiFi and Entertainment
- Comfortable Overnight Facilities with 24/7 Medical Oversight

COMPREHENSIVE SUPPORT SERVICES FOR PHASE I

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

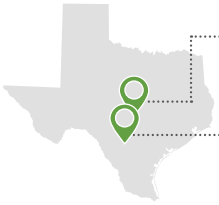
Clinical Conduct
- Worldwide CPU Site
- QA Approved Phase I Global Site Network
- Recruitment of Healthy and Patient Populations

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

Project Management
- Oversees All Aspects of Study Execution
- Tracks Progress, Costs, and Timelines
- Multi-site Feasibility and Management
- Directs Project Communication

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

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



GLP
Bioanalytical Lab

200
Bed Clinical Pharmacology Unit

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, compounding, capsule-fill
- **Documentation/Training:** Established SOPs, work instructions, full IP accountability documents

SAFETY LABORATORY ON SITE FULLY DEDICATED TO RESEARCH STUDIES

- CLIA certified
- **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
- **Reporting:** LabDaq® LIMS exported into ClinSpark®, rapid turnaround time

SPECIAL PROCEDURES AND EVALUATIONS

Below are a few examples of specialty procedures

CNS

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

CSF

- Continuous and Intermittent CSF Collections
  - » Experienced CSF Medical Team
  - » Anesthesiologist
  - » Custom Design 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

- Single Ascending Dose (SAD)
- Multiple Ascending Dose (MAD)
- Drug-Drug Interactions
- Food and Meal Timing Effect
- Bioequivalence/Bioavailability
- Cardiac Evaluations: Full Telemetry, Expert Precision QT and TQT Evaluation
- Radiolabel AME/Mass Balance/ Metabolite Profiling
- CNS Assessments/Monitoring
- Proof of Concept in Patient Populations
- Renal Impairment in Healthy/Patients
- Hepatic Impairment In Healthy/Patients
- Other (e.g. CSF collection and analysis)
- Respiratory

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, Ph.D., R.Ph. | 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 M.S. in health science, and a Ph.D. 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.

Dr. Ingela Danielsson, M.B.A, M.D., Ph.D. | Vice President, Early Phase Medical Management

As VP of Early Phase Medical Management at Worldwide Clinical Trials, Dr. Ingela Danielsson draws on decades of experience in health care and research. Her career has included work in corporate, start-up, government, and community-based organizations, as well as academic and clinical research, including an eight-year tenure at National Institutes of Health. She has led several multi-site clinical trials, located in the U.S. and internationally, and has worked across all phases of study.

Dr. Danielsson received both her M.D. and Ph.D. in neurophysiology and neuroplasticity from the University of Gothenburg and an executive M.B.A. with a major in finance and a minor in hospital management from Rice University. She is certified in Health Care Quality and Management (HCQM) by the American Board of Quality Assurance and Utilization Review Physicians (ABQAURP).

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.

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 **Twitter**, **LinkedIn**, **Facebook**, and **Instagram**.