

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

### 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

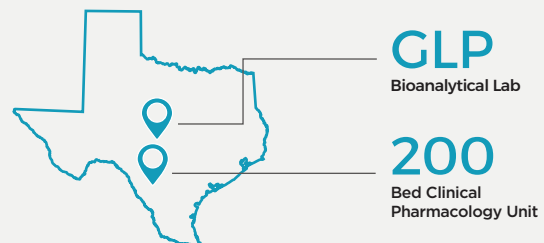
- Study Execution
- Progress, Cost, and Timeline Management
- Multi-site Feasibility and Management
- Project Communication Coordination

#### 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

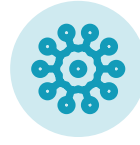
- Quality Issue / CAPA Oversight
- Facilitate Sponsor Audits of Worldwide
- GxP Consultation for Project Teams and Functional Areas
- Q2QA Relationship
- Conduct Internal Process Audits

## 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

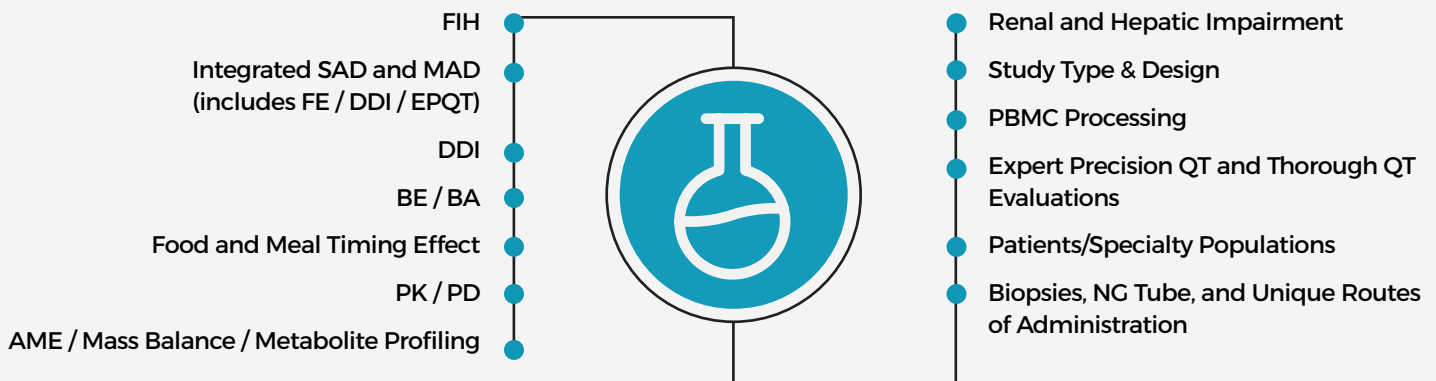
- Mortara Surveyor System (48 channel)
- Holter Monitoring
- 24-hour Telemetry
- Experience with Early Precision QT/TQT Studies



### AME

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

## Full suite of clinical pharmacology studies



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 →



## About 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](http://www.worldwide.com) or connect with us on [LinkedIn](#).