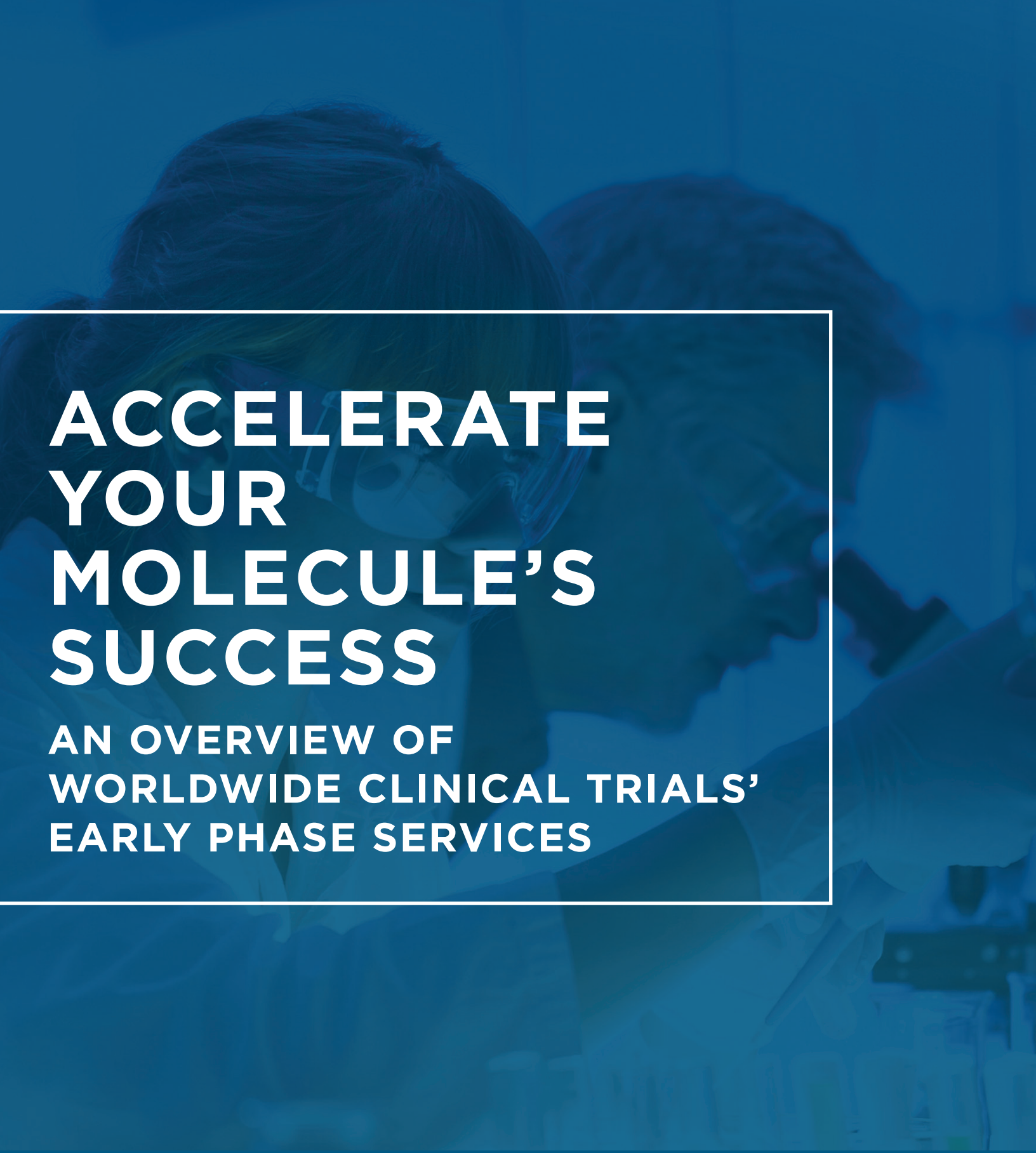

# ACCELERATE YOUR MOLECULE'S SUCCESS

## AN OVERVIEW OF WORLDWIDE CLINICAL TRIALS' EARLY PHASE SERVICES

WORLDWIDE CLINICAL TRIALS

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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

We also have a network of partner sites that provide solutions to additional patient populations.


## A STRONG START TO YOUR CLINICAL TRIALS WITH OUR FULL-SERVICE CLINICAL RESEARCH

With Worldwide Clinical Trials, your journey from First-in-Human through Proof-of-Concept starts with the right design, appropriate research subjects, state-of-the-art facilities, and fast study start-up. We offer:

- A GCP/ICH compliant 300-bed clinical site in San Antonio, TX
- A cGMP Phase 1 pharmacy for on-site manufacturing and dose preparation
- A bioanalytical lab in Austin, TX

Our experts proactively work with you to meet study objectives, data quality, and timeline needs. Our customers find that this uncommon combination of good science plus clinical execution delivers faster results and maximizes development goals. Using Clinspark, your team sees the information fast in order to continue with the next part of your development.

## WE ARE HIGHLY EXPERIENCED IN

- First-in-human single ascending dose/ multiple ascending dose
- Ambulatory blood pressure monitoring study
- Drug-drug interaction
- QT cardiac safety
- Food effect
- PK/PD
- Bioequivalence
- Bioavailability
- Human AME studies

## FULL-SERVICE PHASE I-IIA CLINICAL PHARMACOLOGY

- Protocol design and development
- Early phase trial operation and management
- Pharmacokinetic analysis
- Data management
- Bioanalysis by LC-MS/MS
- Clinical study report production
- Biostatistical analysis



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WORLDWIDE CLINICAL TRIALS

## ACCELERATE YOUR THERAPY TO THE CLINIC WITH BIOANALYTICAL METHOD DEVELOPMENT, GMP PHARMACY SERVICE, AND ON-SITE CLINICAL TESTING

Extensive in-house services at Worldwide Clinical Trials can accelerate your trials from start to finish. Customized bioanalytical methods to measure your drug candidate can be quickly established at our GLP lab, capable of measuring sub pg/mL plasma concentrations. A Phase 1 cGMP compounding pharmacy on site at the research unit can neatly build your API into a formula suitable for administration in capsules, powder in bottle, solutions, suspensions, or injectables to reduce manufacturing lead time by up to 8 months. The on-site CLIA lab also can turn around safety samples in a matter of hours.

## DEDICATED BIOANALYTICAL LABORATORY

Since 1990, Worldwide Clinical Trials' Bioanalytical Sciences has built its reputation on providing competitive LC-MS/MS services with high quality and rapid turnaround. Over 2,600 methods have been validated over the years. Failure rates are kept low by automation, and the lab has a strong regulatory track history.

- Method development/transfer
- Method validation
- High-throughput GLP bioanalysis
- Multi-analyte assays
- Unstable molecules and chiral assays
- Peptides and oligonucleotides
- Same-day sample transfer from clinic to lab via in-house transport service
- Derivatization, immunoprecipitation, and enzymatic hydrolysis
- Mass balance, metabolite profiling, and identification
- Microsampling, including dried blood spots

## RELIABLE PHARMACY SERVICES WITH EXPERIENCED STAFF

Every cGMP project is unique; your project will receive the full attention of an experienced team. We strive to provide sound advice and scientific consultation on all pharmaceutical services projects based upon our extensive experience.

The pharmacy includes an ISO Class 7 clean room with ISO Class 5 laminar flow hood for compounding sterile products and an additional spacious compounding suite for preparing oral and topical dosage forms. The Worldwide pharmacy operates under GCP, U.S. Pharmacopeia 797 Compounding Standards, U.S. Food and Drug Administration (FDA) Good Clinical Practices (GCP), and current Good Manufacturing Practice (cGMP) guidance for Phase I investigational drugs.

### cGMP manufacturing of Phase 1 investigational drugs

- Inventory, proper storage, and accountability
- Retention drug accountability and storage in separate areas
- Licensed for controlled substances - all schedules
- Dedicated areas of radiolabeled drug storage and preparation
- Specialized compounding services, dose weighing, capsule filling, blinding
- All drug storage areas have limited access with continuous temperature and humidity monitoring.

### Pharmacy staff

- Pharmacists and pharmacy technicians
- Dedicated QC staff for documentation review, dispensing, and inventory

## STATE-OF-THE-ART CLINICAL LABORATORY

Worldwide Clinical Trials' Early Phase Services offers the convenience of an on-site CLIA-certified clinical laboratory that can provide a wide variety of high-quality testing services and a rapid turnaround time for results. 99% of the safety tests are conducted on site, and results can be ready within hours.



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# WORLDWIDE'S EARLY PHASE EXPERIENCE

## EXPERTISE WITH SPECIAL PROCEDURES AND EVALUATIONS

It's important to work with a CRO partner than can handle the basics, but what if you need someone with specialty experience? Look no further than Worldwide Clinical Trials for special procedures and evaluations, including:

### Respiratory

- Pulmonary function testing
- Inhalation dose training
- Dedicated dosing team for reliability

### Cardiovascular

- Mortara surveyor system (32 channel)
- U-Scribe digital storage
- Serial ECGs
- Holter
- Telemetry
- Blood pressure monitoring
- Pulse oximetry

### Central Nervous System

- Comprehensive suite of cognitive assessments
- EEG
- Imaging: MRI, fMRI, PET, CT, X-ray

### Cerebrospinal Fluid

- Continuous and intermittent CSF collections (up to 36 hours)
  - Dedicated CSF medical and technical team
  - Anesthesiologist
- Custom design cryovial cooling plates
- Lab analysis for PK and neurotransmitters

## 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.

### RATED OVERALL TOP PERFORMER ISR reports

- Top Performer: Budget Factors
- Top Performer: Delivery Factors
- Top Performer: Staff Characteristics

- Top Performer: Accessibility
- Top Performer: Services
- Top Performer: Customer Loyalty

## SAMPLE STUDY TIMELINE

| Activity | Timing |
|---|---|
| EDC go-live | 4 weeks after final protocol |
| Last CRF to Data Management | 1 week after LSLV |
| Database Lock | 4 weeks after last CRF received |
| Biostatistical Analysis | Draft TLFs within 2 weeks of DB lock |
| QA'd Bioanalytical Data | 3 weeks from receipt of last sample |
| Clinical Study Report | 4 weeks from receipt of final TLFs |



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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. He has also completed 4 TQT studies in a variety of therapeutic areas. In addition, Dr. Atiee has significant experience with antivirals, DDI, BA/BE studies, and medical device studies.

## Tim Martin

**Executive Vice President and General Manager, Early Phase**

Tim Martin has worked across many areas of the healthcare continuum during the past 35 years. At Worldwide Clinical Trials, his responsibilities include overseeing the strategic, financial, and operational direction of the business and managing all aspects of the early phase division's performance. Prior to joining Worldwide in 2017, Tim held CEO and executive roles in the life sciences and pharma services sectors, including positions with AAI Pharma Services, Florida Biologix, and Avista Pharma Solutions. He has also served on various boards and has expertise managing businesses that provide outsourced services and manufacturing to the pharmaceutical and biotechnology industries.

## Shaolian Zhou, Ph.D.

**Senior Vice President and Lab Director for Bioanalytical Services**

Dr. Zhou brings experience and a proven track record of success in the bioanalytical sciences and clinical drug programs. Dr. Zhou has a BS in Chemistry (1983) and a PhD in Analytical Chemistry from the University of Tennessee (2000). Prior to accepting this position, he served as the Global Head of Small Molecule Bioanalytical R&D for Roche Research and Early Development in Basel Switzerland (2015-2018). Dr. Zhou also served as Site Head of Analytical Sciences and as Research Investigator of Metabolism and Pharmacokinetics for Novartis Institutes for Biomedical Research (2005-15). He has CRO experience working as method development manager at Covance Laboratories in Madison, WI. (2000-05).



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