Worldwide Clinical Trials | Bioanalytical Laboratory

Biomarker Development and Assessment

Biomarker assays are an increasingly used resource for gaining insights into drug mechanisms of action, pharmacodynamics, and assessing the efficacy and safety of diverse therapeutic agents. However, selecting relevant biomarkers, validating assays, and successfully applying them in clinical trials require unique strategies, laboratory capabilities, and staff expertise.

Worldwide's biomarker team embodies 25 years of academic and industry experience in implementing biomarker testing services in drug development programs. Whether intended as a measure of primary or secondary endpoints or used in exploratory research, our team of experienced scientists will ensure rigorous and scientifically sound support for biomarker assays to support biomarker testing.

Staffing Excellence and a Collaborative Network

Worldwide emphasizes high-quality staffing to ensure the best results for any biomarker investigation. Your biomarker study is in the hands of an excellent team, including:

- Experienced analytical scientists
- Method development and transfer scientists
- Assay validation scientists
- Sample management team
- Dedicated bioanalytical study managers

Experience

We support various biomarker types, including pharmacodynamic (PD) markers under GCLP and exploratory markers to support clinical research. Our expertise covers the following therapeutic areas:

- Neurological disorders
- Oncology
- Autoimmune diseases
- Infectious diseases
- Obesity
- Cardiovascular diseases
- Metabolic disorders

We have complete in-house capabilities for sample processing and biomarker assessments through peripheral blood specimens (whole blood, serum, plasma), cerebrospinal fluid (CSF), and urine.

Worldwide's Bioanalytical Lab

Our 60,000 sq ft laboratory has state-of-the-art equipment, automation, and is located in Austin, TX, an hour's drive from our 200-bed clinical pharmacology unit. Our bioanalytical lab has a history of excellence with sponsor and FDA audits and a 100% sponsor audit pass rate. Moreover, the laboratory meets regulatory requirements spanning FDA and European standards, such as:

- **FDA: GLP, GCP compliance**
- **European Clinical Trials Directive 2001/20/EC**
- **Commission Directive 2005/28/EC**
- **UK Medicines and Healthcare Products Regulatory Agency (MHRA)**

Our instrumentation facilitates rapid, accurate, and validated biomarker readouts by using the following:

- **Mass spectrometry (Oribitrap, Sciex)**
- **Microplate reader (Colorimetric, Fluorometric and Luminescence)**
- **Meso scale discovery**
- **Real-Time PCR**
- **Liquid handling automation**

Your biomarker investigation has several validated methods available for use, such as:

- **Ligand-biding assays**
- **Enzyme-linked immunosorbent assays (ELISA)**
- **SISCAPA**
- **Singleplex or multiplex**
- **Gene expression**
- **Single nucleotide polymorphisms (SNP)**

Setting Your Biomarker Project Up for Success

Worldwide provides a collaborative and tailored approach to working with you as a team. We offer end-to-end bioanalytical services, including reagents, labeling, characterization, PD data analysis, and reporting. Our laboratory has ample space, technology, and staffing to accommodate your biomarker investigation.

Want further reading about our biomarker validation capabilities? Discover more ⟶

Worldwide
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Why Partner with the Bioanalytical Lab at Worldwide?

At Worldwide, we work with you to provide a personalized approach unique to your study-specific needs, drawing from our scientists' expertise in biomarker development. Our experts save you the time, costs, and stress of managing multiple third-party vendors, which encompasses risk/safety, diagnostic, predictive, prognostic, and PD/response, all under one lab. With our extensive history of successful biomarker development and assessment, we prioritize strategies that streamline development and validation.

Worldwide Clinical Trials

Meet the Team

Jayaprakash (JP) Kotha, MBBS, PhD, ASCP (SH)
Vice President, Bioanalytical Laboratory

- Brings more than 25+ years of diagnostic and research laboratory experience in cardiovascular, hematology, oncology, and immunology
- Extensive experience in the development and validation of bioanalytical assays for pharmacodynamic, pharmacokinetic, biomarker, and immunogenicity testing for novel therapeutics on diverse technological platforms

Tom Zhang, PhD
Chief Scientific Officer, Large Molecule Bioanalysis

- Responsible for evaluating and recommending analytical platforms to support quantitative large molecule work
- Actively promotes technical development programs to keep Worldwide at the forefront of technology
- Leads our large molecule bioanalytical sciences as an industry-recognized expert
- Maintains state-of-the-art knowledge of large molecule bioanalytical methodologies

Shuangling Chen, PhD, MD
Biomarker Lead, Large Molecule Bioanalysis

- Over 20 years of experience in bioanalysis and research laboratories
- Specializes in oncology, immunology, molecular biology, and cell biology
- Expert in developing fit-for-purpose biomarker testing strategies
- Proficient in validating analytical methods for pharmacodynamic, pharmacokinetic, and biomarker assessments across various technological platforms

Jingguo Hou, PhD
Expert Scientist, Method Development

- Over 16 years of experience in the CRO space
- Expert in chromatography and chiral separation
- Extensive experience in cGLP bioanalysis
- Proficient in LC-MS/MS method development for small molecules, peptides, and biomarkers

Leimin (Perry) Fan, PhD
Associate Director, Method Development

- Over 27 years of experience in the pharmaceutical industry
- Skilled in providing analytical support in preclinical and clinical bioanalysis, CMC development, and ADME