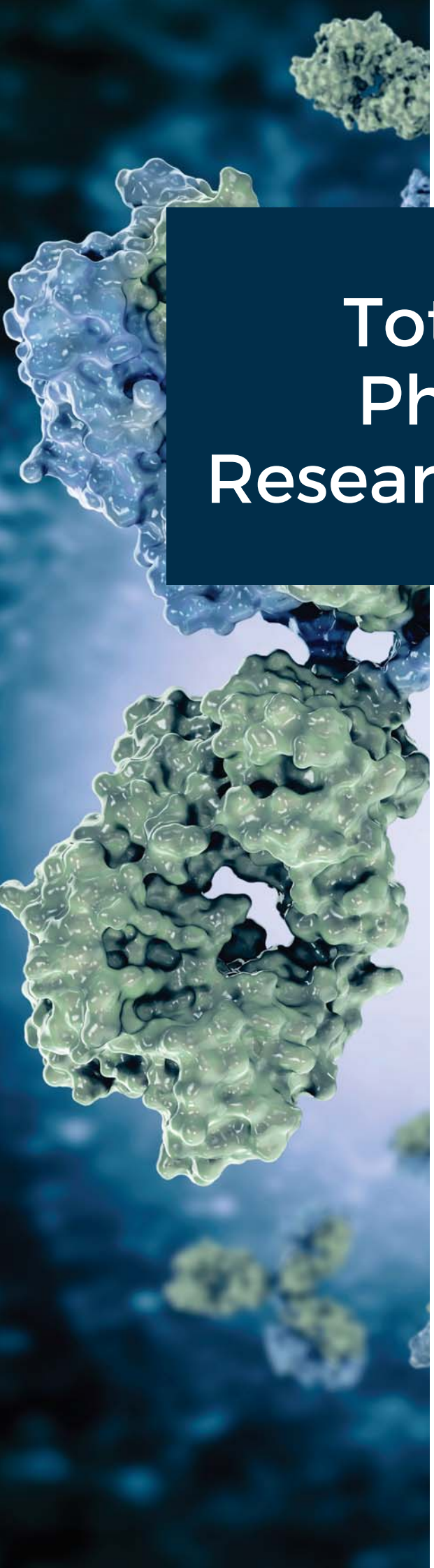

Total Solution for Pharmaceutical Research & Development

Mithra

Mithra

CRO partner for pharmaceutical development

Mithra Biotechnology Inc. is the first Contract Research Organization (CRO) in Taiwan since 1988. We offer integrated and multi-dimensional CRO services, including bioanalytical services for chemical drugs and biologics, full characterization plans for biologics, bioavailability/bioequivalence (BA/BE) studies, and phase I to IV clinical trials to facilitate pharmaceutical development.

Mithra possesses expertise and experience in meeting international standards to serve the fast-growing pharmaceutical industry. We are committed to each project from the very beginning to its completion. It is our goal to exceed clients' expectations and help achieve your long-term goals.

R & D	Assay	Clinical
• CMC • Preclinical	• Bioanalysis • Protein Analysis	• Phase I & BA/BE • Phase IIa - Phase III

▶ Clinical Trial

- PK/BA/BE Studies
- Early Stage (Phase I/II)/Pilot Studies
- Pivotal/Phase III Studies
- Bridging Evaluation/Studies
- Post Market Surveillance (Phase IV)
- Observational/Retrospective Studies

▶ Bioanalysis

- Chemical Drugs
- Protein Therapeutics
- Peptides
- Oligonucleotides

▶ Pharmaceutical Analysis

- Protein Therapeutics
- Peptides
- Biosimilars
- Oligonucleotides

From early preclinical through clinical phase to regulatory approval

Service Portfolio

DMPK Bioanalysis

- Pharmacokinetic studies for small molecules & biologics
- LC-MS/MS & ligand binding assay
- Tier approach immunogenicity assessment
- Biomarker analysis
- Method development & validation
- Non-GLP research oriented study at discovery stage
- Support GLP safety & toxicology animal studies
- Support phase I to IV clinical studies

Mithra has extensive experiences in bioanalytical method development utilizing a variety of chemical generics/new chemical entities (NCE), peptides, and biologics including monoclonal antibodies (mAbs), antibody drug conjugates (ADCs), oligonucleotide, etc. in various biological matrices.

Bioequivalence/505(b)(2) studies

- Lead optimization & formulation consulting
- Study design & protocol development
- Pharmacokinetics & statistical analysis
- A large database of healthy volunteer
- Multiple collaborative clinical units
- Experienced in a wide range of drug formulations
- GCP & GLP compliance for sites & lab

As a recognized BE center by TFDA and NPRA, Mithra has conducted 1000+ human BE studies with 300+ bioanalytical methods developed and validated over the past 30 years. Competitive timeline is promised by our dedicated project management team.

Pharmaceutical Analysis & CMC

- GMP analytical testing for chemical drugs & biologics
- Structural characterization & physicochemical property for biologics
- Biosimilarity & comparability studies
- API & drug product lot release testing
- Impurity analysis & assay for stability evaluation
- CMC analytical method development, transfer, qualification & validation
- Support proteomic research & customized method development

Full characterization plan offered by Mithra is in accordance with ICH Q6B to assist biopharmaceutical / biosimilar development. Equipped with state-of-the-art high resolution mass spectrometers, our lab is able to obtain insight information on protein products for our clients. In addition, our GMP compliant testing has been inspected by USFDA and TFDA.

Clinical Development

- Study design & regulatory consulting
- Site evaluation, management & training
- Study documents development (protocol/IB/ICF/CRF)
- Regulatory & IEC/IRB submission
- Study management, monitoring, safety reporting
- Data management, statistical analysis & pharmacokinetics analysis
- Quality assurance management/audit/inspection
- Medical report writing (CSR/BSER)

Our clinical trial team offers flexible options to help our clients save time and budget on conducting trials smoothly. We can provide our services as a whole package or individual options.

SEAMLESS INTEGRATION

Your Brilliant Choice of CRO Partner

Our Strengths

Quality Assurance

Mithra's commitment to high quality services has been the key to our solid company culture and outstanding performance compliant with global guidelines.

- TFDA & OECD certified GLP laboratory
- NPRA certified BE center
- USFDA & TFDA inspected GMP compliance
- PMDA inspected GCP compliance

Analytical Expertise

30+ years of bioanalytical experience shapes our team's guaranteed expertise in the delivery of robust assay and reliable data, which are indispensable to support preclinical and clinical researches.

- Experienced in various analyte & biological matrices
- Tailored solutions for customers

Project Management

Competitive timeline is made possible by our high throughput capacity and dedication, which also helps you with more flexibility by ensuring each step of your project requirement is fulfilled in an efficient and timely manner.

- Proactive & responsive
- Timely execution

Mithra Biotechnology Inc.

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