

# Bioanalytical Solutions from Preclinical to Clinical Stage

Leveraging over 30 years of experience of our GLP and GCP compliant laboratory, Mithra has the expertise to analyze both chemical drugs and protein drugs, to develop bioanalytical method from scratch and to support method validation and large scale sample analysis from preclinical to early and late clinical research.

## Per Your Study Stage



### Preclinical

Non-GLP & GLP Toxicology Study

- Single dose/Repeat dose/DRF
- Dose formulation analysis
- Immunogenicity assessment
- Animal study management
- Pharmacokinetics
- Toxicokinetics
- Pharmacodynamics
- PK/PD modeling



### Clinical

FIH or phase I to IV

- Pharmacokinetics in SAD/MAD/FE
- Immunogenicity assessment
- Biomarker & Cytokine analysis
- Clinical trial supply

## Per Type of Molecules



### NCE, Peptides & New modality drugs

Mass Spectrometry

- Method development/validation
- PK & PD bioanalysis
- Exploratory metabolite profiling
- Protein binding & Blood plasma partitioning
- Customized development and experimental design



### Biotherapeutics

Ligand Binding Assay

- Method development/validation
- PK & PD bioanalysis
- Immunogenicity assessment
- Antibody titers
- Biomarker & Cytokine analysis



## Immunogenicity (Anti-drug Antibody) for Biotherapeutics

ELISA, Electrochemiluminescence (MSD)

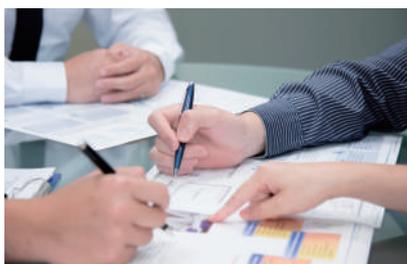
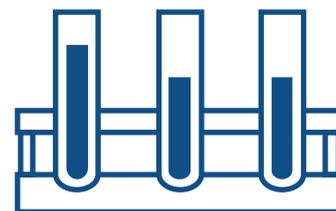
Tiered approach from screening, confirmatory, titration & neutralization

- Assay development & validation
- Drug tolerance assessment
- Cut-point determination
- Sensitivity navigation & optimization

## Biomarkers & Cytokines

LC-MS/MS, Ligand binding assay, MSD, Flow cytometry (CBA)

- Multiplex detection of biomarkers & cytokines
- Tailored and integrated solution for biomarker analysis
- Method qualification or Fit-for-purpose assay development



## What we support for your clinical trial :

- ◆ PK/PD modeling and dosage determination in FIH study
- ◆ Customized manual for specimen collection and handling instructions
- ◆ Clinical trial management & Site staff training
- ◆ Lab kit design and supply



**Mithra**

明生生物科技股份有限公司  
Mithra Biotechnology Inc.

Analytical Expertise · Quality Output  
Dedicated Project Management

