

IND-ENABLING PROGRAMS

Bioanalytical • Toxicology • Safety Pharmacology • Genetic Toxicology

Comprehensive IND Services

Development of a lead candidate through a preclinical program for an IND submission requires a significant investment of time and resources. Working with a CRO with a highly experienced and qualified team for the design, planning and execution of the nonclinical toxicology and safety studies required by the FDA, is essential to the success of the program.

IIT Research Institute (IITRI) is a full-service provider of GLP-compliant preclinical toxicology and drug safety evaluation services to the pharmaceutical and biotechnology industries. We offer a comprehensive program of preclinical services to support IND submissions to the FDA and other regulatory agencies, and have been offering GLP-compliant services since the guidelines were first instated in 1979.

Our toxicology team is one of the most experienced and stable in the industry, with an average tenure at IITRI of over 15 years. This combination of experience, credentials, and direct partnership with senior personnel provides you with a well-established and informed study team that truly acts as an extension of your scientific development program and will guide you through the IND process.

Our PhD, DABT study directors are a single point of contact for your study from initiation through provision of the final report. Our scientists provide the personalized attention and flexibility in collaboration that you would expect from a true partner.

IND Studies

BIOANALYTICAL

- Method development, transfer, and validation
- Formulation analysis and troubleshooting
- Immunogenicity analysis

NON-GLP STUDIES

- PK / metabolism / biodistribution
- Large animal species selection analysis
- Pilot toxicology studies

GLP STUDIES

- Genetic toxicology
- Single-dose and dose-range finding toxicology
- 14- and 28-day repeat dose toxicology studies
- Safety pharmacology

Drug Classes

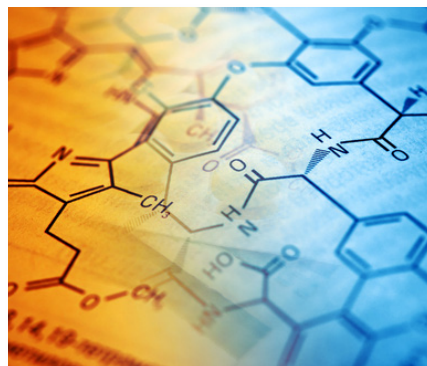
- Small molecule
- Biologics
- Vaccines
- Gene therapy
- CAR-T/immunotherapies

THE IITRI ADVANTAGE

- We provide a highly experienced team of scientists for each study, with each toxicology technician having greater than 10 years of experience in GLP preclinical toxicology.
- Our hands-on study directors are easily accessible and work closely with you, keeping you personally connected to your study.
- We offer rapid study initiation and mid-study troubleshooting.
- We offer preclinical advisory, including study design guidance, IND program optimization and pre-IND meeting support.



Core Services



ANALYTICAL/ BIOANALYTICAL

Our team of analytical scientists has extensive experience in the development, transfer and optimization of bioanalytical methods from your laboratory to ours.

- Dose formulation analysis
- Method development, method validation
- Quantitation in complex tissues
- Toxicokinetic analysis and modeling
- Immunogenicity testing (ADA, neutralization assays)
- Assessment of biomarkers
- Cell-mediated immune response assays



TOXICOLOGY

We have one of the most experienced toxicology teams in the industry with each technician having over 10 years experience in preclinical toxicology.

- Repeat-dose toxicology studies
 - All relevant routes of administration including inhalation
 - Rodents, non-rodents (canine, mini-pig), non-human primates
- Immunotoxicology
- Clinical pathology
- Histopathology



SAFETY PHARMACOLOGY

We offer the core battery of safety pharmacology tests. These can be performed as stand-alone studies or integrated into repeat-dose studies.

- Central nervous system
 - FOB
 - Expanded neurotoxicity
- Cardiovascular
 - Telemetry
 - hERG assay
- Respiratory
 - Plethysmography



GENETIC TOXICOLOGY

Flexible programs are available to meet your specific needs, from complete GLP test battery to non-GLP assays and individual test options.

- Ames assay
- Structural chromosomal aberration assay
- Rat micronucleus assay
- Mouse micronucleus assay
- Mouse lymphoma assay

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