

ADVANCING SCIENCE TOGETHER

Exceptional Experience • Seamless Collaboration • Flexible Communication

Moving a drug candidate forward into preclinical studies is an exciting and resource-intensive step towards human clinical studies. Partnering with a contract research organization (CRO) to start this journey requires careful planning and thorough investigation to find an organization you can trust and that is qualified to conduct your study.

Exceptional Experience

We offer an accomplished scientific staff for your study team. Our PhD, DABT scientific study directors and degreed technicians have on average more than 12 years of tenure at IITRI, some with over 25 years of experience. Our staff has also conducted research for government organizations such as the National Institutes of Health (NIH), the National Cancer Institute (NCI), Biomedical Advanced Research and Development Authority (BARDA), and the United States Army, and have earned long-term privileges of partnering with these institutions.

Seamless Collaboration, Flexible Communication

We offer a true collaborative approach as an extension of your scientific team. We share the same goals—to conduct a high-quality study, and respond quickly and effectively to surprises or pitfalls. Our study directors are easily accessible to discuss pre-study planning, updates during the study, and study outcomes and next steps. There are no administrative layers or obstacles, just direct communication.

All Study Functions Under One Roof

Our areas of specialty expertise include: IND-enabling toxicology, general toxicology, exploratory toxicology, infectious disease

vaccine development, inhalation toxicology, and bioanalytical chemistry. All study functions including analytical and bioanalytical chemistry, microbiology and molecular biology, clinical chemistry, and histopathology, are located at our single location in Chicago, Illinois, facilitating collaboration and communication.

A Collaboration-driven Process

At IITRI, we strive to work closely with you to establish a true partnership for the planning and execution of your study. Collaboration begins with an investigation phase that initiates preliminary discussions of your project to gather important details. Starting from the molecule, disease target and mode of action, we ascertain your short- and long-term drug development goals and strategy. Next, keeping your timelines and budget in mind, we collaboratively assemble your study details and map out your development program. Throughout the process, communication ties the steps together: our study directors are highly accessible during the discovery phase and for study execution and completion, keeping you informed on your study progress and early results.



ABOUT IITRI

- Over the past 40 years, IITRI has established itself as a top-quality nonclinical CRO that provides personalized attention to our sponsors.
- We are located south of the Chicago Loop on the campus of the Illinois Institute of Technology (IIT), accessible by nearby Midway Airport and public transportation.
- We bring an academic approach to your preclinical studies including researching, designing, and executing studies using sound scientific principles.
- Our facilities include 110,000 square feet of laboratory space, with ample capacity to start your study without delay.

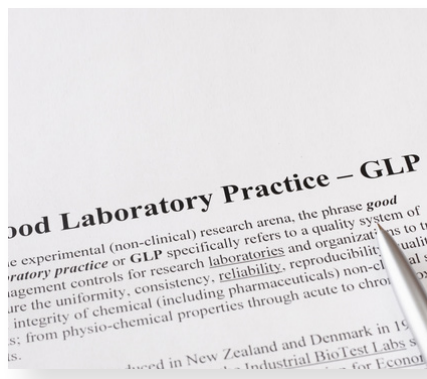


About IITRI



FACILITIES

- 110,000 square feet of laboratory space in a single location in Chicago, IL
- Small and large animal vivarium managed by on-site board-certified veterinarian
- BSL-2/3 facilities for infectious disease and biodefense studies
- Supporting laboratories in analytical chemistry, molecular biology, immunology and virology
- Extensive security measures in place as a Department of Defense (DOD) top secret facility



REGULATORY ENVIRONMENT

Our facilities are routinely inspected by the FDA and EPA with excellent results that are available upon the request of our sponsors. Our facility has the following certifications, accreditations and licenses:

- AAALAC
- OLAW
- USDA
- USDEA
- CDC

IITRI (IIT Research Institute)

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AREAS OF EXPERTISE

We are a trusted outsourcing partner for the pharmaceutical, biopharmaceutical, chemical and biodefense industries. Areas of expertise include:

- IND- and NDA-enabling safety programs
- Cancer drug discovery and development
- Inhalation toxicology
- Biodefense and infectious disease studies
- General toxicology
- Bioanalytical chemistry



IND/NDA-ENABLING PROGRAMS

We offer comprehensive IND- and NDA-enabling safety programs to support filings with the FDA as well as other international regulatory agencies. Our GLP-compliant services include:

- Bioanalytical support
- Repeat-dose toxicology studies
- Safety pharmacology
- Genetic toxicology
- Chronic toxicology studies
- Reproductive toxicology
- Carcinogenicity studies



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