

# DEVELOPMENTAL AND REPRODUCTIVE TOXICOLOGY (DART)

Pharmaceuticals • Biologics • Vaccines • Chemicals • Agrochemicals

Nonclinical developmental and reproductive toxicity (DART) evaluations of new pharmaceuticals are often required by the FDA, depending on the target patient population, duration of dosing, pharmacology and toxicity of the compound, or other indications of reproductive risk. Registration of new or existing chemicals for the European Union's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program also requires developmental and reproductive toxicity studies. With the potential successful commercialization of a drug or chemical imminent, it's important to partner with an experienced toxicology team for guidance and study execution.

Our PhD, DABT study directors have conducted a broad range of reproductive toxicology programs in rats and rabbits, including inhalation as the route of administration. IITRI offers a full range of services to evaluate the developmental and reproductive toxicity of small molecule drugs, biologics, vaccines, chemicals, consumer products and agrochemicals.

We work closely with you to develop a customized program to meet your specific needs and meet regulatory requirements for IND and NDA submissions. Our hands-on study directors are highly accessible, keeping you connected to your study from start to finish.

## STUDY TYPES

- Fertility and Early Embryonic Development Toxicity (Segment I, ICH R5(R2))
- Embryo-fetal Developmental Toxicity (Segment II, ICH R5(R2))
- Pre- and Post-Natal Reproductive Toxicity (Segment III, ICH R5(R2))
- Juvenile Toxicity
- Reproduction/Developmental Toxicity Screening Test (OECD 421)
- Extended One-Generation Reproductive Toxicity (OECD 443)

## LABORATORY SUPPORT

- Bioanalytical
- Clinical pathology
- Immunology

## SPECIALTY ROUTES

- Dermal
- Inhalation

## ACCREDITATIONS

- AAALAC, USDA, NIH (OLAW), USDEA, CDC

## THE IITRI ADVANTAGE

- Highly experienced and tenured scientific staff providing a seasoned and stable project team for your study
- Direct interaction with PhD, DABT study directors throughout study duration
- Experience with all relevant routes of administration including inhalation in mice, rats and rabbits
- Large historical control database
- Technical advisory and support regarding interpretation of study results



# CORE SERVICES

## IITRI (IIT Research Institute)

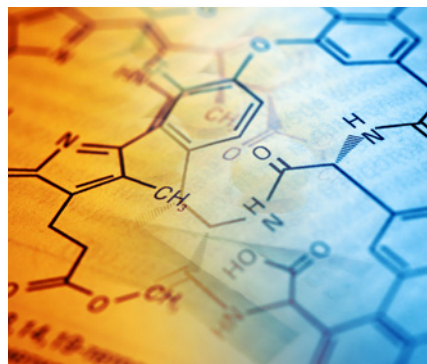
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## BIOANALYTICAL

Our in-house team of analytical scientists has extensive experience in the development, transfer and optimization of bioanalytical methods.

- Dose formulation analysis
- Method development
- Method validation
- Method cross-validation for different species
- Toxicokinetic analysis and modeling
- Clinical sample analysis



## TOXICOLOGY

We have one of the most experienced toxicology teams in the industry with PhD, DABT study directors, and technical support staff averaging 10 years of experience in preclinical toxicology.

- Exploratory toxicology
- Repeat-dose toxicology studies
- All relevant routes of administration including inhalation, dermal
- All relevant species (rodent, non-rodent, NHP)
- Clinical pathology and immunology support



## IND-ENABLING PROGRAMS

We offer complete GLP-compliant IND-enabling programs to meet FDA requirements for regulatory submissions.

- Genetic toxicology
- Single dose, dose escalation toxicology
- Safety pharmacology
- Repeat dose toxicology
- Toxicokinetic studies
- Chronic toxicology



## NDA-ENABLING PROGRAMS

High-quality, GLP-compliant nonclinical toxicology studies are routinely conducted for NDA submissions, including:

- Reproductive toxicology
- Carcinogenicity studies (2-year rat and 6-month rasH2 mouse)