

Non-Clinical Safety Assessment, IND & NDA Enabling Studies With Bioanalysis (Non-Clinical & Clinical)



Intox is an OECD GLP-certified preclinical safety assessment service provider with 25+ years of expertise in conducting safety assessment studies for small and large molecules. The state-of-the-art facility is spread across 45,000 sq ft in Pune, India. Our scientific team of experts includes board-certified toxicologists (DABTs), pathologists (ACVP and DIBTP), study directors, study personnel, veterinarians, analysts, and QA personnels

Over the years, we have conducted more than 16,000 GLP studies for a wide range of industries including pharmaceutical, bio-pharmaceutical, medical device, agrochemical, industrial chemical, nutraceuticals /dietary supplements, cosmetics and others.

Snap Shot

Subsidiary of Aragen Life Sciences

Track record of successful data submissions to regulatory agencies of US-FDA, US-EPA, Canada, European Union, UK, Brazil, Argentina, Japan, India, Australia and China

State-of-the-art, ABSL2-compliant vivarium with multispecies capacity, enabling you to start up to several hundred animal studies at a given time

AAALAC accredited and CCSEA compliant facilities

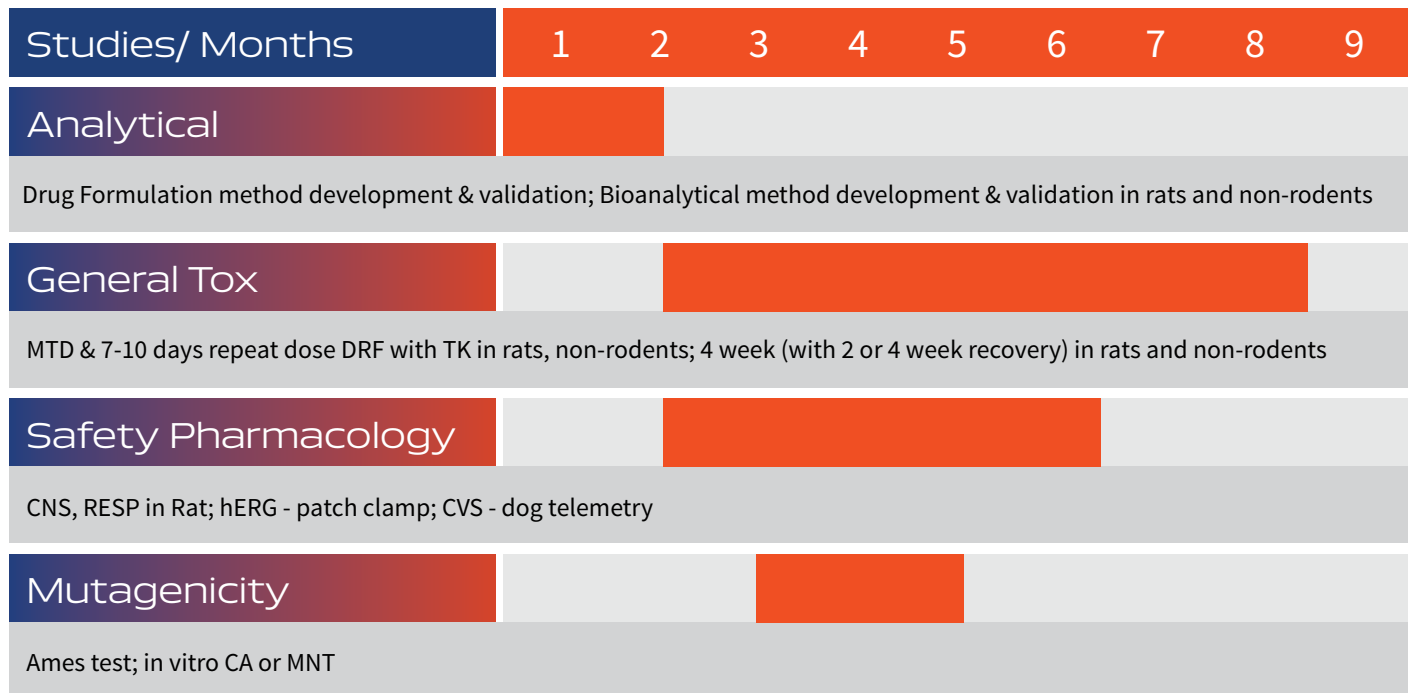
25,000 square feet vivarium

SPF rodents from Charles River Inc., Taconic and Jackson Laboratories

25 Years of expertise in GLP safety assessment, IND enabling studies, carcinogenicity & clinical bioanalysis

Nonclinical Safety Assessment of New Chemical Entities (NCE)

IND in 9 Months



Timeline can be optimised upon understanding of molecule and regulatory pathway

Regulatory Compliances



Test systems and routes of exposure

Test Species

- Rats, mice, guinea pigs, rabbits, hamsters
- Dogs, Minipigs and Non-Human Primates, available through our collaborating test facilities

Routes of Exposure

- Oral (gavage & dietary), dermal, inhalation, parenteral (IV/SC/IM/ID)
- Other – Intranasal, ocular, intra-vitreous, otic, intra-articular
- Implantation

Bioanalytical / Bioassay Services:

- Single/Repeated Dose Pharmacokinetics
- Toxicokinetics
- Immunogenicity (ADA)
- Immunotoxicology
- Biomarkers
- Acute Phase Proteins
- Biodistribution/Persistence

Safety Pharmacology:

- hERG Assay
- CVS-Dog Telemetry
- CNS- Modified Irwin Test
- RESP-Whole Body Plethysmography

Studies offered

Acute Toxicity

- Acute oral, dermal, and inhalation toxicity

Subacute/ Subchronic / Chronic Toxicity / Carcinogenicity

- 7-day (DRF), 14-day, 28-day, 90-day, 180-day and 12-month repeat dose studies
- 18-month/24-month carcinogenicity bioassays
- Tg.rasH2 6 months Carcinogenicity.
- Implantation studies on medical devices

Reproductive Toxicity

- Segment I
- Segment II
- Segment III

Genotoxicity

- In-vitro / in-vivo studies
- Gene mutation - Bacterial (Ames test); mammalian cells
- Chromosome Aberration; Micronucleus Test

Bioanalytical Services

Services:

Toxicokinetics / Pharmacokinetics

- Small and Large Molecules
- Rodents, Dogs, Rabbits & NHPs

Method Development / Validation / Sample Analysis

blood, urine and other matrices

Toxicokinetic /Pharmacokinetic analysis

WinNonlin software for TK analysis and reporting

Immunogenicity (Anti-drug Antibodies), Biodistribution, Bioassay and Biomarker analysis

- Biosimilars
- Vaccines
- Novel biologics

Assay Platforms:



Track record of evaluation of biosimilars vaccines and NCEs

BIO-PHARMACEUTICALS

- Insulins / rH-Insulin Analogs
- Interferon
- Filgrastim#
- PEG-Filgrastim#
- Interleukin-11
- Teriparatide (PTH)
- Liraglutide
- PEG-Erythropoietin
- Erythropoietin
- Asparaginase
- PEG- Asparaginase
- Anakinra

ANTIBODIES

- Trastuzumab
- Rituximab
- Ranibizumab
- Adalimumab
- Omalizumab
- Bevacizumab
- Cetuximab
- Denosumab
- Golimumab
- Ustekinumab
- Pertuzumab
- Aflibercept

VACCINES (Recombinant & Non-Recombinant)

- Influenza H1N1 Inactivated Vaccine
- Influenza H1N1 Live attenuated Vaccine
- Meningitis - A Conjugate Vaccine
- Meningococcal polysaccharide vaccine
- Rabies Vaccine Inactivated
- JAIVAC-1 (Plasmodium falciparum Pff2+PIMSPI19 Formulated in Montanide ISA720).
- Malaria Vaccine
- 10-valent Pneumococcal Polysaccharide Conjugate Vaccine
- Recombinant Epsilon Toxoid Vaccine (Veterinary Product)
- Diphtheria, Tetanus and acellular Pertussis (DTaP) vaccine
- SARS CoV-2 VLP, protein, antiserum, Vector, mRNA and DNA vaccines

New Chemical Entitles

- Simultaneous methods for prodrugs and its two active metabolites
- 6-substituted-3h-1,3-benzothiazole
- Bisbenzimidazole HCL
- Gemcitabine
- 6-Substituted dimethyl pyridine 3 sulfonamide

