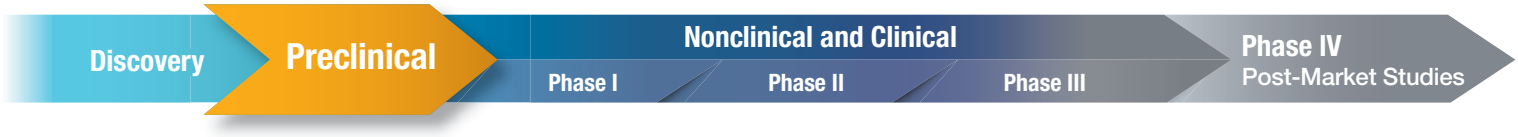
ALTASCIENCES
PRECLINICAL SERVICES

BIOLOGICS SAFETY ASSESSMENT

Altasciences provides a customized, end-to-end pathway for your drug development programs, from discovery to market authorization. Our unique **preclinical**, **clinical**, and **bioanalytical** platform enables you to work with a single, integrated partner to develop large molecules through to human proof of concept, resulting in shorter timelines and reduced costs.



At the Forefront of Preclinical Solutions

Altasciences has more than 25 years' experience conducting a range of safety assessment studies, in all species, for regulatory submission of biologics.

98% On-time reporting

585,000 square feet of purpose-built research facilities

800+ Dedicated preclinical research staff

SEND Report in about 2 weeks

280 Custom-designed animal rooms, including North American and European housing

DEDICATED STUDY TEAM Consistent and regular communication

Altasciences' experienced team helps you accelerate your molecule through safety assessment. Our highly accessible study directors average 15+ years of experience. We work in direct partnership with you to ensure high-quality safety data, delivered on time and within budget.

Routes of Administration

- Parenteral
- Ocular
- Dermal
- Implant
- Intranasal
- Intrathecal
- Intravaginal and intrapenile
- Rectal

Seamless preclinical to clinical integration for efficient, speedy timeline advancement.

contact@altasciences.com
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Preclinical Study Capabilities

Altasciences performs safety assessment studies of six-months' duration and longer if required, in line with the **ICH S6 guidance** from single-dose acute to chronic studies, including dosing rodents and non-rodents.

Investigational drugs include:

- Monoclonal antibodies
- Vaccines
- Peptides
- Oligonucleotides
- Other proteins

GLP-compliant analytical support is available, including analytical and bioanalytical method development and validation, and assessment of a compounds' potential immunogenic or immunotoxic effects.

Study designs may be enhanced with pharmacodynamic and immunogenicity analyses, local tolerance evaluation (Draize measurement), and immunomodulating assessment via KLH challenge (TDAR).

When planning your nonclinical safety assessment, the type of drug candidate under development should be considered.

	Biologic
Species selection	Pharmacology as a primary factor; may be only one species
Dose selection	Based on pharmacology or maximum feasible dose
Pivotal toxicology	One species — up to six months in duration
Safety pharmacology	Part/all may be in toxicology studies. May also be stand-alone
Genetic toxicology	May not be required

***Guidelines:**

FDA Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals

Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals S6(R1)

Laboratory Services

- Formulations
- Analytical Chemistry
- Bioanalysis
- PK/TK Data Analysis

Immunology Services

- TCR/Immunohistochemistry
- Immunochemistry
- Flow Cytometry

SEND Services

Our dedicated SEND team helps streamline your IND/BLA submissions with compliant and reliable toxicology datasets, ready within **three weeks** of study finalization.

- **Technology.** Altasciences uses submit™ software to create datasets, and Pinnacle 21 to ensure data integrity.
- **Expertise.** We are active members of the CDISC SEND Consortium and PhUSE (Pharmaceutical User Software Exchange) nonclinical working groups. Our team contributes to the development of SEND standards and is at the forefront of evolving these standards to support best practices.
- **Rapid turnaround.** We understand the importance of your timelines and can prepare submission-ready files within three weeks. Interim datasets are also available for submission or for data warehousing purposes.
- **Flexibility.** Our team is accustomed to collaborating with third-party labs and your team to ensure all data is captured in your final SEND dataset.

SEND 3.0 is required for IND studies starting on or after December 17, 2017

SEND 3.1 is required for IND studies starting on or after March 15, 2020

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