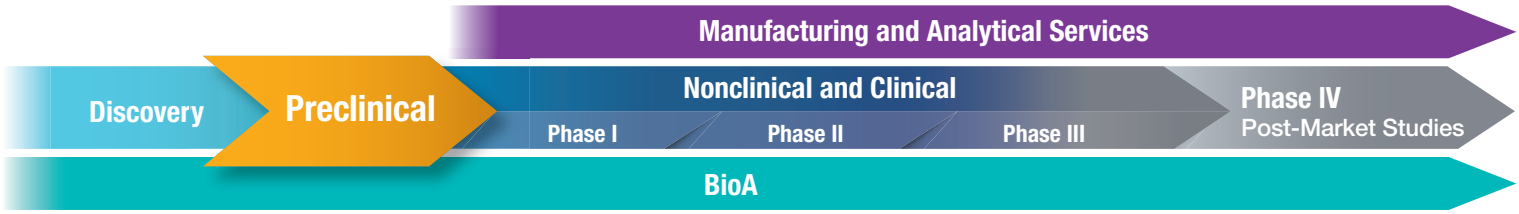
ALTASCIENCES
PRECLINICAL SERVICES

# SMALL MOLECULE SAFETY ASSESSMENT

Altasciences is an integrated drug development solution company offering pharmaceutical and biotechnology companies a proven, flexible approach to preclinical and clinical pharmacology studies, including formulation, manufacturing, and analytical services. Our full-service solutions include bioanalysis, program management, medical writing, biostatistics, and data management, all tailored to specific sponsor requirements. Altasciences helps sponsors get better drugs to the people who need them, faster.




## At the Forefront of Preclinical Solutions

Altasciences has over 25 years' experience conducting pivotal toxicology studies in all species required for regulatory submission worldwide.

### Species

- Rats
- Mice
- Guinea pigs
- Rabbits
- Swine
- Dogs
- NHPs

### Multiple Routes of Administration

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

## Planning Your Safety Assessment Program

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

| | Small Molecule* |
|---|---|
| **Species Selection** | Metabolism as a primary factor (rodent and non-rodent) |
| **Dose Selection** | Based on toxicity (maximum tolerated dose) |
| **Pivotal Toxicology** | Required using two species and ranging from two weeks to three months |
| **Safety Pharmacology** | Usually stand-alone studies |
| **Genetic Toxicology** | Required |

*Guideline as per FDA guidance for Industry M3(R2) ***Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals***

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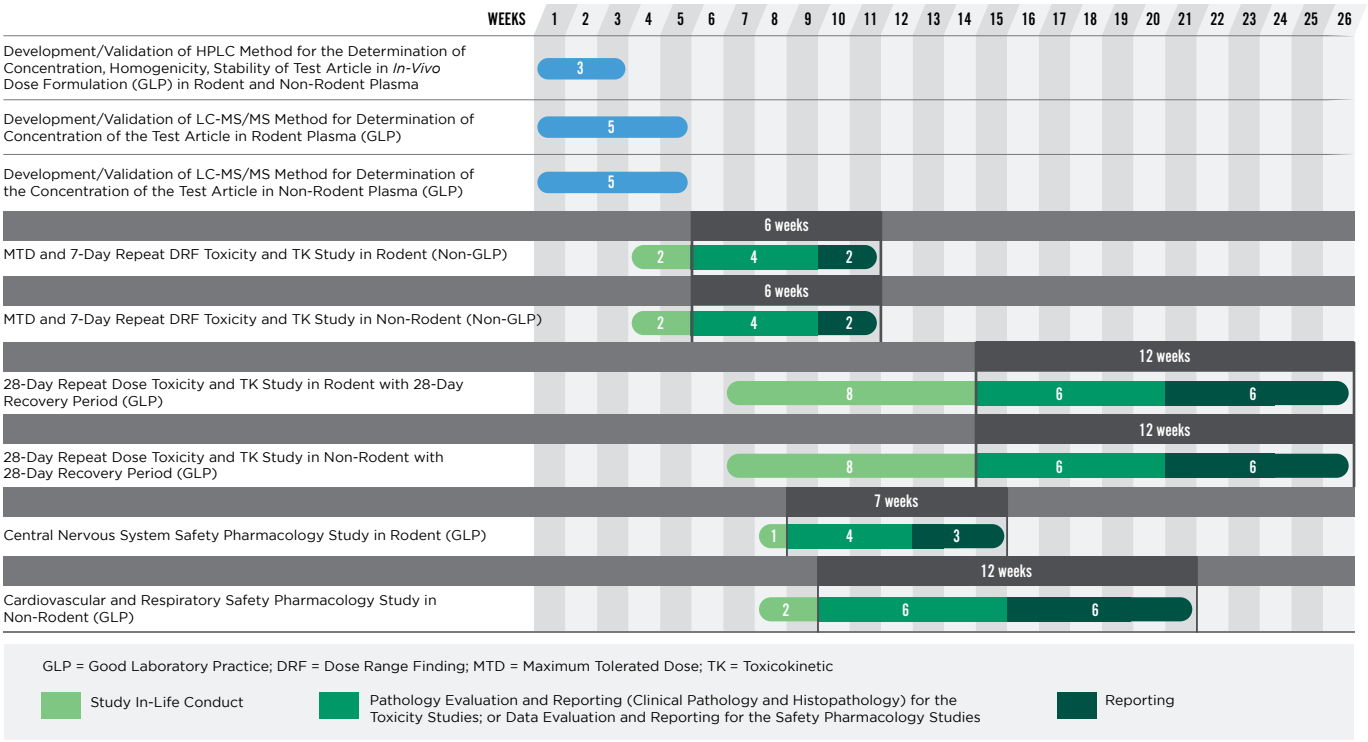
# ALTASCIENCES ACCELERATES YOUR PROGRAM

## Required nonclinical activities and timelines to move your molecule towards regulatory submission

We work in close collaboration with you to accelerate your timeline. We can complete in approximately six months (or less), by using the approach proposed in the chart below, the *in vivo* portion of your IND program for submission to the FDA.




## As a partner on your pivotal toxicology studies, Altasciences will:

1. Develop analytical and bioanalytical methods for your preclinical toxicology program.
2. Determine the acute toxicity of your drug in rodent and non-rodent species.
3. Conduct pivotal toxicity studies ranging from two weeks to three months, depending on your clinical duration.
4. Run a core battery of CNS, respiratory, and cardiovascular studies as well as a hERG assay. Tier II safety pharmacology studies may also be required depending on your clinical indication or findings in the core battery.
5. Conduct genetic toxicology to include *in vitro* tests (Ames Test and the Chromosome Aberration Assay) and *in vivo* rodent test for chromosome damage (Rat Micronucleus Test) — this can also be incorporated into your main toxicology study.
6. Prepare SEND dataset packages for your nonclinical study data.

The Standard for Exchange of Nonclinlcal Data (SEND) is an implementation of the CDISC Standard Data Tabulation Model (SDTM) for nonclinical studies.

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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