ALTASCIENCES
PRECLINICAL SERVICES

SAFETY PHARMACOLOGY STUDIES

The safety pharmacology experts at Altasciences can help you prepare a robust program, including combination studies where appropriate, and supplemental studies if needed.

Safety pharmacology studies are designed to investigate the effects of the test substance on vital functions and conducted before human exposure, in accordance with **ICH S7A** and **S7B**. They are usually performed in the same species used in the program toxicology studies. The vital organ systems typically investigated are the cardiovascular, respiratory, and central nervous systems (CNS), and are considered the core battery of safety pharmacology. In some instances, based on scientific rationale, the core battery need not be implemented or should be supplemented.

Altasciences' Safety Pharmacology Offerings by Site

Columbia, MO

- Telemetry: dog or minipig implanted animals
  - Non-GLP screening and GLP studies
  - Cardiovascular or cardiovascular/pulmonary studies
- Rat FOB

Seattle, WA

- Telemetry: dog or NHP implanted animals
  - Non-GLP screening and GLP studies
  - Cardiovascular studies: dog or NHP
  - Cardiovascular/pulmonary studies: dog
  - JET system
- Rat FOB
- Rat gastrointenstinal motility: charcoal meal
- Rat gastrointenstinal irritation: indomethacin

Scranton, PA

- Telemetry: dog cardiovascular
- Dog, rat, or mouse FOB or Irwin
- Rat respiratory: head-out plethysmography
- Rat gastrointestinal motility: charcoal meal/glass beads
- Rat or mouse gastrointestinal irritation/ulcer
- Rat renal function
- Rat or mouse neuropulmonary study: CNS and respiratory
- Other CNS tests in rat or mouse
  - Anymaze tests
  - Novel object recognition
  - Rotarod
  - Spontaneous motor activity
  - Nociception
  - Opioid withdrawal
  - Opiate tolerance
  - Seizures
- Sleep time

Combination of the cardiovascular and respiratory assessments in the selected non-rodent species is also a suitable approach, using surgically implanted animals. This combination permits study of time-dependent effects, and allows for insight into possible mechanisms of action. In addition, since two of the three core assessments can be combined, this approach can have beneficial impacts on decreasing the number of animals used (3Rs), cost, and other resources.

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Supplemental Studies
(Implementation based on scientific rationale)

Follow-up studies may be required based on the pharmacological properties of the test article, or if concerns arise from the core battery studies, clinical trials, pharmacovigilance, or other sources. Those include supplemental CNS testing, GI assessment, and renal/urinary evaluation. Other organ systems should be investigated only where there is cause for concern.

Alternative Approaches

Including safety pharmacology endpoints in general toxicity studies can deliver efficiencies in time and resources, as well as provide certain analytical advantages. In some cases, combination studies can also be a practical approach for safety pharmacology studies.

Altasciences' scientific teams will ensure that all necessary criteria are met, and that in the design of your integrated studies, the safety pharmacology requirements do not confound interpretation of general toxicology endpoints, and vice versa.

Experience the possibilities:

Ask us about our
combined
cardiovascular/respiratory
safety pharmacology
capabilities.

Species

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

Routes of Administration

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

Consult our scientists and let us assist you with a seamless transition to regulatory submission, and human clinical trials.

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