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**. 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 Capabilities

CORE BATTERY	
STUDY TYPE	**SPECIES**
Cardiovascular Blood pressure, heart rate, and electrocardiogram; methods for repolarization and conductance abnormalities should also be considered	Same as non-rodent* species in toxicology studies.
Central Nervous System Motor activity, behavioral changes, coordination, sensory/motor reflex responses and body temperature	Generally, the same rodent species used in toxicology studies
Respiratory Respiratory rate and other measures of respiratory function (e.g., tidal volume or hemoglobin oxygen saturation)	Same as non-rodent* species in toxicology studies

*Respiratory assessments can be combined with cardiovascular evaluations in the non-rodent species using surgically implanted telemetry.

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.

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 (gastric damage, secretion, pH measurement, emptying, transit time, and contraction) 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
- Dogs
- NHPs

Routes of Administration

- Oral (gavage, capsule)
- Intravenous (bolus, infusion)
- Subcutaneous
- Intramuscular
- Intrathecal
- Topical

Consult our scientists to see how we can assist you with a seamless transition to regulatory submission, and human clinical trials.