Veeda™
Lifesciences

SUPPORTING PEDIATRIC DRUG Development Through Juvenile Toxicology Expertise

Background

A U.S.-based pharmaceutical company partnered with Veeda Lifesciences company to conduct a juvenile toxicology and toxicokinetic study in seven-day-old rat pups (PND7). This developmental stage is considered comparable to pre-term human neonates born before 37 weeks of gestation.

The study involved intranasal administration of the test article to closely mimic the intended clinical route of delivery for pediatric use.

Regulatory Context

Juvenile toxicity studies are a critical component of nonclinical safety evaluation for pharmaceuticals intended for pediatric populations. Regulatory agencies require these studies to identify potential postnatal developmental toxicities that may not be adequately characterized through standard reproductive toxicity assessments.

According to S11 guidance, juvenile animal studies support the development of small molecules and biotechnology-derived pharmaceuticals intended for pediatric indications.

These studies help generate essential safety data while addressing ethical and practical limitations associated with pediatric clinical trials.

Project Scope

- Single-dose toxicity study in PND7 rat pups
- Toxicokinetic evaluation following intranasal administration
- GLP-compliant study execution
- Clinical pathology and histopathological evaluations
- Generation of regulatory-aligned nonclinical safety data

Challenges

Juvenile toxicology studies in neonatal animals require:

- Specialized handling and dosing expertise
- Precise intranasal administration techniques in very young animals
- Careful monitoring of developmental and toxicological endpoints
- Integration of toxicokinetic assessments in limited biological matrices
- Strict compliance with global regulatory expectations

Veeda Lifesciences' Solution

Veeda Lifesciences successfully conducted the single-dose toxicity and toxicokinetic study in seven-day-old rat pups under GLP conditions.

The study included:

- Intranasal administration aligned with the intended clinical route
- Comprehensive clinical observations and body weight monitoring
- Gross pathology and histopathological evaluation
- Toxicokinetic sample analysis and interpretation
- Regulatory-compliant data generation and reporting

Our experienced toxicology team ensured accurate study execution, high animal welfare standards, and robust scientific evaluation throughout the program.

Outcome

- Successful completion of the juvenile toxicology and toxicokinetic study
- High-quality GLP-compliant data generated to support pediatric drug development
- Robust nonclinical safety package delivered for future regulatory submissions
- Strong client satisfaction with the technical expertise and study execution

Scientific Highlights

- Expertise in juvenile and pediatric nonclinical safety studies
- Specialized capabilities in neonatal animal handling and dosing
- Intranasal toxicology study experience
- Integrated toxicokinetic and histopathological evaluation
- Regulatory-aligned study execution under GLP conditions

Key Guidelines & References

- ICH S11: *Nonclinical Safety Testing in Support of Development of Paediatric Pharmaceuticals* (Adopted: 14 April 2020)
- U.S. Food and Drug Administration Guidance for Industry: *Nonclinical Safety Evaluation of Paediatric Drug Products* (February 2006)

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