Sub-chronic Toxicity Studies (90-Day Repeat Dose)

Enabling Confident Clinical Progression Through Robust Safety Evaluation

Overview

Sub-chronic toxicity studies are a critical component of nonclinical safety assessment, designed to evaluate the effects of repeated exposure over 90 days.

At **Veeda Lifesciences,** these studies are conducted with a focus on scientific rigour, regulatory compliance, and strategic insight, supporting a seamless transition from preclinical to clinical development.

Our Capabilities

- 90-day repeat dose toxicity studies in **rodent & non-rodent models**
- Multiple routes of administration aligned with clinical indication
- Integrated Toxicokinetics (TK), Immunogenicity & Recovery assessments
- Support for **small molecules, biologics, & complex modalities**

Study Design Excellence

- Control, Low, Mid, High dose groups
- Ideal target species/strain selection
- Satellite groups for TK and reversibility
- Flexible study customization based on regulatory strategy

Comprehensive Evaluations

In-Life & Functional Assessments

- Body weight, food consumption
- Functional Observation Battery (FOB)
- Clinical observations, morbidity & mortality
- Ophthalmological evaluation

Clinical Pathology

- Hematology
- Clinical chemistry
- Urinalysis

Toxicokinetics

- Systemic exposure profiling
- Dose proportionality assessment

Pathology & Histopathology

- Organ weight analysis
- Gross and microscopic evaluation (40+ tissues)

Regulatory Alignment

Studies conducted in accordance with:

- OECD TG 408 / 409 / 413
- ICH M3(R2), ICH S7A / S7B
- Global regulatory expectations (FDA, EMA, PMDA, MHRA, TGA, NDCT, ANVISA etc.)

| GLP-compliant execution with regulatory-ready reporting

Strategic Outcomes

- Determination of **NOAEL / LOAEL**
- Identification of **target organ toxicity**
- Assessment of **dose-response relationships**
- Evaluation of **reversibility of toxic effects**

These insights directly support:

- IND / CTA submissions
- First-in-human (FIH) dose selection
- Clinical risk mitigation strategies

Why Veeda Lifesciences

- Proven expertise in nonclinical safety evaluation
- Integrated approach across **toxicology and bioanalysis**
- Successful Global Regulatory Acceptance
- Strong track record of **27,500 GLP studies**

Partner with Confidence

Delivering high-quality, compliant, and insight-driven sub-chronic toxicity studies to accelerate your development journey.

India: +91 79677 73000
Europe: +30 210 699 7247

info@veedalifesciences.com

www.veedalifesciences.com

Excellence In Everything