



GLP Toxicology Studies for IND Readiness

From study strategy and protocol development to GLP-compliant execution, biostatistics, SEND preparation, and final reporting, Noble Life Sciences helps sponsors generate the safety data required to support FDA IND submissions.

End-to-end preclinical safety support from study design through submission-ready reporting.

Design & Protocol
Species

GLP Implementation
In-Life

Data & SAS Stats
SAP

QA Oversight
Audits

IND Package
Final Report

Study Design and Protocol

Scientific planning aligned to development goals and regulatory expectations for safety packages.

- IND-enabling strategy & study design
- Dose range, route & species selection
- GLP protocol & amendment support
- Endpoint, sample & schedule planning

Deliverable

Approved GLP protocol and study plan.

GLP Study Implementation

In-life execution by experienced preclinical teams in FDA-inspected GLP facilities.

- Single and repeat-dose studies
- Acute, subchronic and chronic models
- Clinical observations and pathology
- Sample collection, necropsy and archiving

Deliverable

Study conduct and controlled source data.

Toxicology Capabilities

A broad GLP and non-GLP toxicology menu to characterize dose-response and adverse effects.

- General, exploratory & immunotoxicology
- Immunogenicity & toxicokinetics
- Biodistribution & local tolerance
- MTD, LD50, NOEL/NOAEL support

Deliverable

Decision-ready safety endpoints.

Biostatistics & SAS

GLP-compliant statistical support for robust interpretation of toxicology study data.

- Statistical analysis plan development
- SAS programming & statistical analysis
- Tables, listings, figures and QC
- Statistical analysis report preparation

Deliverable

GLP statistical analysis report.

QA and GLP Compliance

Quality assurance services built into the full study lifecycle to support data integrity.

- US CFR Title 21 Part 58 alignment
- SOP-driven training & quality systems
- Protocol, data and report audits
- CAPA, deviations and vendor quality

Deliverable

QA statement and inspection readiness.

IND-Ready Report Package

Integrated deliverables prepared for sponsor review & FDA IND application support.

- Final GLP toxicology report
- SEND dataset preparation support
- SAS analysis report and appendices
- Study records wrapped into IND package

Deliverable

Submission-ready safety report package.

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