

Preclinical Development – Submodules

Overview of Preclinical Development

Role of preclinical studies before human trials. Regulatory expectations from FDA, EMA, and ICH guidelines.

Pharmacology Studies

• Primary pharmacodynamics: mechanism of action, efficacy in models. • Secondary pharmacodynamics: off-target effects. • Safety pharmacology: evaluation of CNS, cardiovascular, and respiratory systems.

Toxicology Studies

• Acute toxicity. • Sub-acute and chronic toxicity. • Reproductive and developmental toxicity. • Carcinogenicity studies.

Pharmacokinetics & ADME

• Absorption, Distribution, Metabolism, Excretion. • Bioavailability studies. • Dose-response relationship.

Formulation Development

• Drug substance characterization. • Pre-formulation studies (solubility, stability, compatibility). • Selection of dosage form for first-in-human trials.

In Vitro & In Vivo Models

• Cell-based assays and organ-on-chip models. • Small and large animal studies. • Species selection rationale.

Safety & Regulatory Requirements

• Good Laboratory Practice (GLP) compliance. • IND-enabling toxicology packages. • Reporting standards (ICH M3, OECD guidelines).

Translational Considerations

• Bridging preclinical results to human dosing (NOAEL, MABEL). • Biomarkers for efficacy and toxicity prediction.