

CASE STUDY BASED PUZZLE

BP807 ET: COMPUTER AIDED DRUG DESIGN

TOPIC: DRUG DISCOVERY AND DEVELOPMENT

Puzzle 1: The Quest for a Novel Antidiabetic Agent

A pharmaceutical research team at “NovaThera Labs” is developing a new oral antidiabetic drug targeting a novel receptor subtype (GLUT-X). The project has successfully identified a promising hit compound from a natural product library. However, when scaling up to lead optimization, the compound shows poor oral bioavailability and high first-pass metabolism.

The management is debating whether to continue optimization or to move toward a prodrug strategy to improve pharmacokinetic properties.



1. Identify the current stage of drug discovery the team is in, and explain the key goals of this stage.
2. Discuss two rational approaches that could be applied to improve bioavailability before entering preclinical development.

Puzzle 2: Clinical Development Dilemma

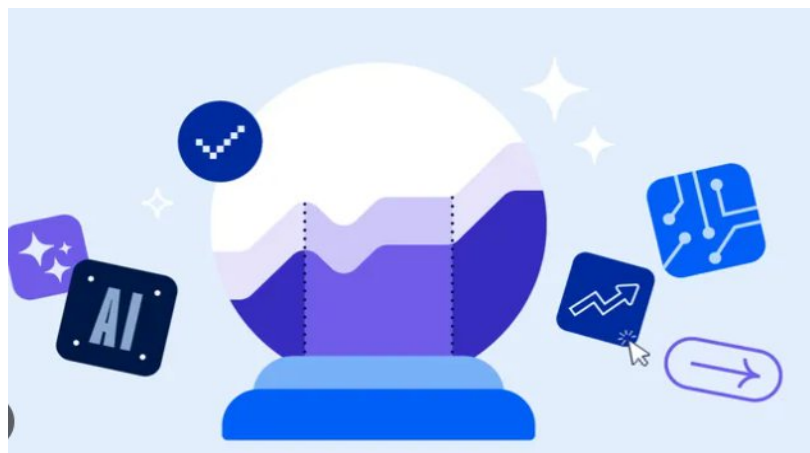
After successful preclinical safety studies, “NovaThera Labs” plans to start Phase I clinical trials for their optimized antidiabetic lead. However, during regulatory review, the agency raises concerns about insufficient toxicokinetic data in animal models and requests additional studies.



1. Explain the main purpose of Phase I trials and what type of data regulators expect before approval.
2. Propose how the research team can bridge the regulatory gap efficiently without delaying development excessively.

Puzzle 3: Market Launch Challenge

After Phase III success, the drug “Glutarex” receives approval. Post-marketing surveillance reveals rare cases of hepatotoxicity not detected in earlier trials.



1. Identify the stage of drug development this issue falls under and explain its importance.
2. Suggest how pharmacovigilance data can guide the company’s risk management plan and possible formulation adjustments.