ON-DEMAND, SHORT CLASS | LEVEL TWO | 50-MINUTES

SUGGESTED PREREQUISITE: CLINICAL DEVELOPMENT 101

biotechPrimer
Life Science Training From Industry Experts

Clinical Development 201: Phase I

OVERVIEW

Clinical Development 201: Phase I explains the purpose of Phase I and the regulatory roles of the FDA, IRB, and EMA. Class highlights include how data from bioequivalence, pharmacokinetics, and pharmacodynamics studies are used to assess the success of Phase I endpoints. The last section explores how the single ascending dose and multiple ascending dose protocols help refine patient dosage schedules.

Five Takeaways:

1. Requirements for and maintenance of an Investigational New Drug (IND) application and a Clinical Trials Application (CTA).
2. Purpose of Phase 0 and Phase I clinical trials and the regulatory agencies that oversee the trials.
3. Expectations related to clinical benefit in early clinical trials for standard development programs, and development of treatments for conditions associated with serious unmet medical needs.
4. Typical endpoints assessed in Phase I clinical trials.
5. Steps sponsors take after Phase I is completed.

AGENDA

Clinical Trial Prerequisites

- Preclinical to Phase I clinical trials
- Clinical trial sequencing
- IRB, IB, IND, and CTA requirements

Phase 0/I Study Designs and Objectives

- Phase 0 and Phase I clinical trials
- Bioequivalence studies

Phase I Conducting the Clinical Study

- Maximum tolerated dose (MTD), single ascending dose (SAD), multiple ascending dose (MAD), pharmacokinetics, and pharmacodynamics data
- Endpoints assessed in Phase I clinical trials
- Clinical trial safety reports