

Clinical Development 201: Phase I

50-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITE: CLINICAL DEVELOPMENT 101

OVERVIEW

Clinical Development 201: Phase I explores the prerequisites, purpose, design, and conduct of Phase I trials. Topics such as bioequivalence, pharmacokinetics, pharmacodynamics, endpoints, selection of dose, and more are explained in detail.

Five Takeaways:

1. Requirements for and maintenance of an Investigational New Drug (IND) application and a Clinical Trials Application (CTA).
2. Purpose of, and characteristics of Phase 0 and Phase I clinical 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 to take at the conclusion of the Phase I clinical study.

AGENDA

- **Clinical Trial Prerequisites** identifies the CMC, preclinical safety, and pharmacology prerequisites for entering early phase clinical trials. Learn the requirements needed for the IND application and how ethics committees and Institutional Review Boards (IRBs) must review the protocols prior to a drug entering humans for the first time.
- **Phase 0/I Study Designs and Objectives** describes the purpose of, and characteristics of Phase 0 and Phase I clinical trials and the general approach associated with bioequivalence studies. Compares and contrasts the expectations related to clinical benefit in early clinical trials.
- **Phase I Conducting the Clinical Study** explains how dosage is determined using maximum tolerated dose (MTD), single ascending dose (SAD), and multiple ascending dose (MAD), pharmacokinetics, and pharmacodynamics data. Discusses typical endpoints assessed in Phase I clinical trials and how and why clinical trial phases are sometimes combined. This section also describes the requirements for Clinical Trial Safety Reports associated with adverse events and what steps take place at the conclusion of the clinical study.