

■ Clinical Development 101: General Principles

OVERVIEW

Clinical Development 101: General Principles sets the stage for the entire clinical development process. The general principles discussed include who conducts trials and their roles; how clinical trials are designed to reduce bias; why Good Clinical Practices help manage risk. Clinical Development 101 provides the foundational knowledge needed to understand the Clinical Trial Phases I-IV.

Five Takeaways:

1. Ability to explain the purpose of each clinical trial phase and list its milestone.
2. Familiarity with individuals and groups conducting a clinical trial and their roles.
3. Fluency in drug development concepts such as control groups, bias, blinding, randomization, and endpoints.
4. Knowledge of the study design criteria to reduce bias and keep patients safe.
5. Required regulatory studies and the data collected to enable follow-on studies.

AGENDA

Clinical Development Introduction

- Drug development milestones
- Clinical research and clinical studies
- Streamlining development in evidence-based medicine, translational medicine, and patient centric trials

Conducting Clinical Trials

- Inclusion and exclusion criteria
- Ethics committees and institutional review boards
- Clinical trial data management and reporting

Clinical Trials: Basic Principles

- Core principals of good clinical practices (GCP)
- Risk management in clinical trials
- Clinical trial designs

