ON-DEMAND, SHORT CLASS | LEVEL THREE | 55-MINUTES

SUGGESTED PREREQUISITE: CLINICAL DEVELOPMENT 101, CLINICAL DEVELOPMENT 201

biotechPrimer
Life Science Training From Industry Experts

Clinical Development 301: Phase II/III

OVERVIEW

Clinical Development 301: Phase II/III considers the purpose, design, and conduct of Phase II and III clinical trials. Learn the various trial design approaches, endpoint choices, statistical considerations, and special regulatory designations.

Five Takeaways:

1. Key differences between early stage (Phase I) and late-stage (Phase II/III) clinical trials.
2. Regulatory significance of clinical endpoint, primary endpoint, secondary endpoint, and surrogate endpoint.
3. Fluency in Phase II and Phase III clinical trial nuances.
4. Basic statistical analysis completed in late-stage trials.
5. Description of specialized and expedited development cycles for rare disease, orphan drugs, and therapies for unmet medical needs.

AGENDA

Phase II/III Introduction

- Transition from Phase I to Phases II and III
- Elements of a well controlled clinical trial
- Primary, secondary, and surrogate endpoints

Phase II/III Objective and Design

- Phase II and Phase III clinical trial characteristics and endpoints
- Pivotal study, adaptive trial, basket trial, and umbrella trial
- Data safety monitoring board function

Phase II/III Special Designations

- FDA orphan drug designations, EMA orphan drug status, and EU prime designation
- Clinical development for rare disease therapy