Clinical Trials Boot Camp Pilot Agenda

October 20-24, 2025 | 8:30 AM – 4:30 PM Daily

Lilly Corporate Center

Day 1: Overview of Drug Development at Lilly Monday, October 20, 2025
Introduction
Lifecycle Overview
Organizational Structure
Introduction to Key Functions (Panel)
Bioethics
Milestones & Governance
Data Management 101
Steering Committees

Day 2: Fundamentals Tuesday, October 21, 2025
Regulatory 101
Safety 101
Statistics 101
Study Design
Study Set Up
Quality 101

Day 3: Phase 1 & 2 Trial Design and Execution Wednesday, October 22, 2025
Phase 1 to Phase 2 Transition
Therapeutic Area Considerations (Panel)
Phase 1 Special Studies
Case Study: A Phase 1 Dose Escalation Study
Phase 2 Study Design
Phase 2 Interim Analysis
Regulatory Interaction in Phase 2
Safety case study

Day 4: Phase 3 Trial Design & Execution Thursday, October 23, 2025
Phase 2 to Phase 3 Transition
Phase 3 Study Design
Endpoints and the Label
Study Close-Out
Clinical Trial Operations
Clinical Trial Management
Medical Affairs

Day 5: End of Phase 3 & Lifecycle Management Friday, October 24, 2025
Phase 3 Regulatory – The Electronic Common Technical Document (eCTD)
Medical & Safety Monitoring
Issue Management
Phase 4 Overview
Integrated Evidence Generation
Accelerate Reach & Scale
Session Close

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