

CLINICAL RESEARCH: WHAT'S IT ALL ABOUT?

...a focused training for busy investigators and study teams

7th EDITION | October 10 and 11, 2019

DAY 1

8:45 - 9:00 : Registration & Welcome

9:00 - 9:15 : Opening presentation - Inês Zimbarra Cabrita

9:15 - 10:15 : **Session 1.** Types of Studies and Research Design - Pedro Carrilho Ferreira

- 1.1. Interventional & Non-Interventional Studies: what is all about?
- 1.2. Phases of Clinical Trials
- 1.3. Medical Device Studies

10:15 - 11:00 : **Session 2.** Regulatory Aspects - Cristina Valente

- 2.1. Highlights of the International current guidelines
- 2.2. Regulatory requirements

11:00 - 11:15 : Coffee-break

11:15 - 12:45 : **Session 3.** Clinical Study : the first contact with investigators and study team - Francisca Patuleia Figueiras

- 3.1. Feasibility & Study setting up
- 3.2. Defining the right Study Team: more than expertise
- 3.3. Regulatory submission & Site Activation: ready to enroll!

12:45 - 14:00 : Lunch

14:00 - 15:30 : **Session 4.** Clinical Study Ongoing Activities & Stakeholders – Cristina Valente

- 4.1. Study Procedures & Study Team Interaction
- 4.2. Case Report Form & Medical Files: walking together
- 4.3. The role of Pharmacy in Clinical Trials: not just dispensing
- 4.4. Understanding the Sponsor role and requests

15:30 - 17:00 : **Session 5.** Interactive Workshop- Inês Zimbarra Cabrita

DAY 2

9:00 - 10:00 : **Session 6.** The Physician as Clinician and Principal Investigator – Dulce Brito

10:00 - 10:45 : **Session 7.** Patient-Centered Research – Inês Zimbarra Cabrita

- 7.1. Patient Recruitment & Strategies: How to make recruitment effective
- 7.2. Patient Informed Consent and its particularities
- 7.3. Retention issues: understanding the reasons and the outcomes

10:45 - 11:00 : Coffee-break

11:00 - 12:30 : **Session 8.** Pharmacovigilance – Catarina Sousa

- 8.1. The importance of Safety in Clinical Research
- 8.2. The Study Team Responsibilities
- 8.3. Documentation & Reporting

12:30 - 13:00 : **Session 9.** Audits & Inspections – Inês Zimbarra Cabrita

- 9.1. Understanding the differences
- 9.2. Demystify & Be prepared for it

13:00 - 14:00 : Lunch

14:00 - 15:45 : **Session 10.** Interactive Workshop- Inês Zimbarra Cabrita

15:45 - 16:00 : Lunch

16:00 - 17:00 : Final exam



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