

## CLINICAL RESEARCH: WHAT'S IT ALL ABOUT?

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

4th EDITION | October 11 and 12, 2018 (English version)

### DAY 1

9:00 : Welcome & Reception

9:00 – 9:15 : Opening presentation – Inês Zimbarra Cabrita & Francisca Patuleia Figueiras

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 – 10:45 : **Session 2.** Regulatory Aspects – Cristina Valente

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

10:45 - 11:00 : Coffee-break

11:00 – 11:45 : **Session 3.** Patient-Centered Research – Marta Capinha

- 3.1. Patient Recruitment & Strategies: How to make recruitment effective
- 3.2. Patient Informed Consent and its particularities
- 3.3. Retention issues: understanding the reasons and the outcomes

11:45 - 12:45 : **Session 4.** Clinical Study : the first contact with investigators and study team – Francisca Patuleia Figueiras

- 4.1. Feasibility & Study setting up
- 4.2. Defining the right Study Team: more than expertise
- 4.3. Regulatory submission & Site Activation: ready to enroll!

12:45 - 14:00 : Lunch

14:00 - 17:00 : **Session 5.** Interactive Workshop- Inês Zimbarra Cabrita, Francisca Patuleia Figueiras, Susana Silva e Marta Capinha

- 5.1. Practical Examples & Quiz
- 5.2. Practical Sessions

## DAY 2

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

10:00 - 11:00 : **Session 7.** Clinical Study Ongoing Activities & Stakeholders – Cristina Valente

- 7.1. Study Procedures & Study Team Interaction
- 7.2. Case Report Form & Medical Files: walking together
- 7.3. The role of Pharmacy in Clinical Trials: not just dispensing
- 7.4. Understanding the Sponsor role and requests

11:00 - 11:15 : Coffee-break

11:15 - 12:00 : **Session 8.** Audits & Inspections – Gaia Kiru

- 8.1. Understanding the differences
- 8.2. Demystify & Be prepared for it

12:00 - 12:45 : **Session 9.** Pharmacovigilance – Catarina Sousa

- 9.1. The importance of Safety in Clinical Research
- 9.2. The Study Team Responsibilities
- 9.3. Documentation & Reporting

12:45 - 14:00 : Lunch

14:00 - 14:40 : **Special Lecture** - Gaia Kiru

14:45 - 17:00 : **Session 10.** Interactive Workshop - Inês Zimbarra Cabrita, Francisca Patuleia Figueiras, Susana Silva e Marta Capinha

- 10.1 Practical Sessions
- 10.2. Final Exam

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