

CLINICAL RESEARCH: WHAT'S IT ALL ABOUT?

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

10th EDITION [ONLINE] | November 21 and 22, 2022

DAY 1

09:00 – 09:10: **Opening presentation** - Inês Zimbarra Cabrita and Francisca Patuleia Figueiras

09:10 – 10:00: **Session 1.** Types of Studies and Research Design – Pedro Carrilho Ferreira

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

10:00 – 10:45: **Session 2.** Regulatory Aspects - Inês Zimbarra Cabrita

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

10:45- 11:15 : Coffee break

11:15 – 12:30 : **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!

12:30 - 13:00 : **Session 4.** Patient-Centered Research – Cecília Gomes

13:00- 14:00 : Lunch break

14:00 - 17:00 : **Session 5.** Interactive Workshop

DAY 2

09:00 - 10:00 : **Session 6.** The Physician as Clinician and Principal Investigator – Dulce Brito

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

7.1. Study Procedures & Study Team Interaction

7.2. Case Report Form & Medical Files: walking together

11:00 - 11:30 :Coffee-break

11:30 - 12:30 : **Session 7.** Clinical Study Ongoing Activities & Stakeholders (Part II) – Cristina Valente

7.3. The role of Pharmacy in Clinical Trials: not just dispensing

7.4. Understanding the Sponsor role and requests

12:30 - 13:00 : **Session 8.** Audits & Inspections – Inês Zimbarra Cabrita

8.1. Understanding the differences

8.2. Demystify & Be prepared for it

13:00 - 14:00: Lunch break

14:00- 16:00 : **Session 9.** Pharmacovigilance Workshop – Catarina Sousa

9.1. The importance of Safety in Clinical Research

9.2. The Study Team Responsibilities

9.3. Documentation & Reporting

16:00 - 17:00 : **Final Exam**

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IN COLLABORATION WITH:



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