

CLINICAL RESEARCH: WHAT'S IT ALL ABOUT?

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

5th EDITION

October 15 and 16, 2018 (Portuguese 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 – Cristina Valente

- 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 - 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

ORGANISED BY
AIDFM-CETERA, a Portuguese Academic CRO, an autonomous department of
the Association for Research and Development of the Faculty of Medicine, founded in 2013
and based at the Lisbon Academic Medical Centre (CAML).

IN COLLABORATION WITH:



AIDFM
Av. Prof. Egas Moniz, Piso 01
1649-028 Lisboa Portugal
training.cetera@medicina.ulisboa.pt
Tel: +351 21 793 09 20



www.aidfm-cetera.com
CRO AIDFM-CETERA

