AIDFM CETERA
ACADEMIC CONSULTING RESEARCH ORGANIZATION

CLINICAL RESEARCH:
WHAT'S IT ALL ABOUT ?

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

9th EDITION [ONLINE] | June 17 and 18, 2021

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 – 11:15 : **Session 2.** Regulatory Aspects - Tiago Martins

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

11:15- 11:30 : Coffee break

11:30 – 13:00 : **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!

13:00- 14:00 : Lunch break

14:00 - 14:45 : **Session 4.** Patient-Centered Research – Cecília Gomes

14:45 - 17:00 : **Session 5.** Interactive Workshop

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

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 - 11:15 : Coffee-break

11:15 - 12:00 : **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

12:00 - 12:45 : **Session 8.** Audits & Inspections – Inês Zimbarra Cabrita

8.1. Understanding the differences

8.2. Demystify & Be prepared for it

12:45 - 13:45: Lunch break

13:45 - 15:15 : **Session 9.** Pharmacovigilance with practical session – Catarina Sousa

9.1. The importance of Safety in Clinical Research

9.2. The Study Team Responsibilities

9.3. Documentation & Reporting

15:15 - 16:15 : **Session 10.** Interactive Workshop

16:15 - 17:00 : **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:

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