AIDFM CETERA
ACADEMIC CONSULTING RESEARCH ORGANIZATION

CLINICAL RESEARCH:
WHAT'S IT ALL ABOUT ?

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

8th EDITION October 15 and 16, 2020

DAY 1

9:00 - 9:10: **Opening presentation -** Inês Zimbarra Cabrita and Francisca Patuleia Figueiras

9:10 – 10:00: **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

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

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 – Inês Zimbarra Cabrita

14:45 - 17:00 : **Session 5.** Interactive Workshop - Cecília Gomes, Susana Silva

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 (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 – Cristina Valente

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 - Cecília Gomes, Susana Silva

16:15 - 17:00: **Final Exam**

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12 CME credits

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ORGANISED BY
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