

CLINICAL RESEARCH: WHAT IS ALL ABOUT?

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

COURSE DIRECTORS:

Inês Zimbarra Cabrita, Ph.D.
Francisca Patuleia Figueiras, Ph.D.

SCIENTIFIC COMMITTEE:

Fausto J. Pinto, MD, Ph.D, FESC, FACC, FSCAI, FASE
Dulce Brito, MD, Ph.D, FESC
Joaquim Ferreira, MD, Ph.D
Catarina Sousa, MD
Cristina Valente, Pharm D.

DATES

May 22 and 23, 2017 1st EDITION
October 16 and 17, 2017 2nd EDITION

DAY 1 – INTERACTIVE SESSIONS & GCP TRAINING

9 am: Welcome & Reception

Session 1. Types of Studies and Research Design

1. Interventional & Non-Interventional Studies: what is all about
2. Fundamentals of Clinical Trials
3. Medical Device Studies

Session 2. Regulatory Aspects

- 2.1. Highlights of the International current guidelines
- 2.2. Portuguese specific requirements from 2014: what have changed

10:30 am: Coffee-break

Session 3. Clinical Study: the first contact with investigators and study team

- 3.1. Feasibility & Study setting up
- 3.3. Defining the right Study Team: more than expertise
- 3.4. Regulatory submission & Site Activation: ready to enroll!

Session 4. Patient-Centered Research

- 4.1. Patient Recruitment & Strategies: how to make recruitment effective
- 4.2. Patient Informed Consent and its particularities
- 4.3. Retention issues: understanding the reasons and the outcomes

1 pm - 2 pm: Lunch

Session 5. Clinical Study Ongoing Activities & Stakeholders

- 5.1. Study Procedures & Study Team Interaction
- 5.3. Case Report Form & Medical Files: walking together
- 5.4. The role of Pharmacy in Clinical Trials: not just dispensing
- 5.5. Understanding the Sponsor Role and Requests

Session 6. Pharmacovigilance

- 6.1. The Importance of Safety in Clinical Research
- 6.2. The Study Team Responsibilities
- 6.2. Documentation & Reporting

Session 7. Audits and Inspections

- 7.1. Understanding the differences
- 7.2. Demystify & Be Prepared for it!

DAY 2 – WORKSHOP & GCP EXAM

9 am: Welcome

Session 8. Workshop: Tricks & Tips for the Investigators and Study Team

- 8.1. How to combine Standard Clinical Practice and Clinical Research
- 8.2. How to maximize the study team performance
- 8.3. Practical Examples

10:30am Coffee-break

Session 9. GCP Exam & Certificate

Session 10. Closing Remarks

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).

CONTACTS

AIDFM
Av. Prof. Egas Moniz, Piso 01
1649-028 Lisboa Portugal
info@aifdm-cetera.com
Tel: +351 21 793 09 20 Fax: +351 21 793 09 21

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