



Organizers:
Paulo J Oliveira
(Coimbra, Portugal)
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Coimbra, Portugal, 22-24 May 2019



Pre-congress course | How to set up an Investigator-Initiated Clinical Trial?

Organizer: João Sargento Freitas (Centro Hospitalar e Universitário de Coimbra, Coimbra, Portugal)

Day: Wednesday 22 May, 9.30-11.00

Meeting room: Meeting room Copelia+Giselle, Hotel Vila Gale (Congress venue 1)

Admission: Limited seats to 30.

Pre-registration is required through the official congress registration form

Admissions open to all those interested in clinical research, from all areas of health care (physicians, pharmacists, nurses, study coordinators, biologists, biochemists, biomedical engineers...)

Wednesday, 22 May

9.30-11.00 Session 1 : How to set up an Investigator Initiated clinical Trial?

Chairs : Catarina Oliveira (Coimbra, Portugal)

João Sargento Freitas (Coimbra, Portugal)

9:30 **What is a clinical trial? – Definition, phases and classification.** Rui Baptista, (Coimbra, Portugal)

9:45 **What is needed from preclinical research to set up a clinical trial?** Miguel Lino, (Cantanhede, Portugal)

10:00 **Statistical design – sample size calculation and analysis of results.** TBD

10:15 **Ethical requirements,** Isabel Santana (Coimbra, Portugal)

10:30 **Submission check-list.** Catarina Madeira (Lisbon, Portugal)

10:45 **Discussion**