

# 28 SEPTEMBER

# 2018

CASA DA PRELADA, PORTO

# GICD

# ACADEMY 2018

## EARLY PHASE CLINICAL TRIALS

PLANNING AND PERFORMING TO PROVIDE SAFETY DATA WITH  
THE LEAST AMOUNT OF RISK TO HUMAN SUBJECTS  
**LET'S LEARN HOW TO DO IT**

## PROGRAMME

**8H00 RECEPTION OF THE PARTICIPANTS**

**8H30 EARLY PHASE CLINICAL TRIALS – STAKEHOLDERS**  
**9H30** (COORDINATION: DR. HÉLDER MANSINHO)

- » The role of GICD in clinical research
- » Pre-clinical trials startup
- » The role of health institutions in clinical research
- » Amgen – a dedicated actor in clinical research

**9H30 TRANSLATIONAL MEDICINE**  
**10H30** (COORDINATION: PROF. LÚCIO LARA SANTOS)

- » Translational Medicine – from the lab to the clinic
- » Early phase clinical trials
- » Important statistics in early phase clinical trials
- » Flash information:
  - i) the role of nurse
  - ii) the role of pharmacist
  - iii) the role of study coordinator

**10H30 COFFEE BREAK**  
**11H00**

**11H00 EARLY PHASE CLINICAL TRIALS – ORGANIZATION**  
**13H00** (COORDINATION: PROF. LUÍS ALMEIDA)

- » Early phase clinical trials: dimension and development in oncology
- » The Phase I unit
- » Regulatory aspects
- » How to write a early phase clinical trial protocol

**13H00 LUNCH**  
**14H00**

**14H00 DEVELOPMENT OF A CLINICAL TRIAL PROJECT**  
**17H00** (COORDINATION: DR. JÚLIO OLIVEIRA)

- » Example of Phase Ib – repurposing clinical trial
- » Presentation of the developed project

**17H00 COFFEE BREAK**  
**17H30**

**17H30 VISIT TO A PHASE I UNIT**  
**18H30 CLOSING SESSION**

Pre-course: Participants are invited to attend and complete the Clinical Investigator Certificate Level (CLIC 1) included in the course.

ORGANIZATION:



SUPPORT:



SCIENTIFIC / PEDAGOGICAL  
COORDINATION:



CERTIFICATION:



associação para a formação  
profissional e investigação  
da universidade de aveiro