CLINICAL RESEARCH TRAINING PROGRAM

"Medical Devices: from regulation to practice" (1st edition)

DESCRIPTION: the medical devices are "(...) any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: (i) diagnosis, prevention, monitoring, treatment or alleviation of disease; (ii) diagnosis, monitoring, treatment, alleviation of o compensation for an injury or handicap; (iii) investigation, replacement or modification of the anatomy or of a physiological process; (iv) control of conception (…).(art. 3, t, DL nº 145/2009).

FOR: Clinical Researchers and Startups

GOAL: Provide knowledge to the graduates that enable to develop, implement and submit clinical studies with medical devices for placing on the market

PARTICIPANTS (maximum): 15

DATE: 28 April 2017

LOCAL: Escola de Medicina – Universidade do Minho (EMUM)

SCHEDULE:

08h30:	Good Clinical Practice (GCP) for Clinical Research – Mónica Gonçalves (2CA-Braga / EMUM)
09h30:	Medical Devices Regulation – Mónica Gonçalves (2CA-Braga / EMUM)
10h30:	Submission the Process to Competent Authorities – Mónica Gonçalves (2CA-Braga / EMUM)
11h00	Break
11h30:	Design of Clinical Studies for Medical Devices – Patrício Costa (EMUM)
12h30:	Applied Biostatistics – Patrício Costa (EMUM)
13h30:	Lunch Break
14h30:	CE Marking: Manufacturer Experience – João Pedro Ribeiro (PeekMed)
15h30:	Medical Device Product: Commercial Experience – João Pedro Ribeiro (PeekMed)
16h30	Workshop End

REGISTRATION: www.ccabraga.org

FEE: 50,00 € (2CA-Braga partners) or 150,00 € (others participants)

OTHERS INFORMATIONS: (+ 351) 253 027 249 or 2ca@ccabraga.org