30. CLINICAL RESEARCH ASSOCIATE[i]	
Level II	
Department of Health Sciences (DSS)	
Course coordinator	Romina Nassini
Executive Committee	Pierangelo Geppetti Domenico Pellegrini Francesco de Logu
Contact person for information regarding teaching organization, class schedule, course content	Marina Di Pirro marina.dipirro@unifi.it Phone 055 275 7216
Practical-professional profile of the course and industry sector of reference	The Clinical Research Associate Master Course aims to create a professional figure that is increasingly in demand by pharmaceutical companies, Contract Research Organizations (CRO) or other organizations that perform monitoring activities during clinical drug trials. This figure is required by Italian and European regulations, as stipulated in the standards of good clinical practice. The course has a duration of 14 months, which includes 2 months of "full immersion" residential theoretical training (at the Department of Health Sciences) and 12 months of internship at a Pharmaceutical Company, CRO, or other institution conducting clinical research. The internship, precisely because of the professionalizing nature of the Master Course, plays a key role and is based on a 12-month internship within pharmaceutical companies, CROs, or other institutions conducting clinical research. By the end of the course, learners will have acquired the full range of knowledge and skills needed to work in the field of clinical research.
Access prerequisites	Master's degree obtained in accordance with the system under Ministerial Decree No. 270/2004 (or specialist degree under Ministerial Decree No. 509/1999 equated under D.I. July 9, 2009) in one of the following classes • LM-6 Biology; • LM-8 Industrial Biotechnology • LM-9 Medical, Veterinary, and Pharmaceutical Biotechnology; • LM-13 Pharmacy and Industrial Pharmacy • LM-54 Chemical Sciences • LM/SNT1 Nursing and midwifery • LM/SNT2 Rehabilitation health professions Single-cycle degree obtained in accordance with the system under Ministerial Decree No. 270/2004 (or specialist degree under Ministerial Decree No. 509/1999 equated under D.I. July 9, 2009) earned in one of the following classes: • LM-41 Medicine and Surgery • LM-42 Veterinary Medicine • LM-46 Dentistry and Dental Prosthetics Degree awarded according to a system prior to Ministerial Decree No. 509/1999 in • Pharmaceutical Biotechnology • Biotechnology - Industrial biotechnology curriculum • Biotechnology - Medical biotechnology curriculum • Biotechnology - Veterinary biotechnology curriculum • Biotechnologies • Pharmaceutical chemistry and technologies • Industrial Chemistry • Chemistry

	• Pharmacy • Medicine and Surgery • Veterinary medicine • Dentistry and Dental Prosthetics • Biology Degree awarded according to a system prior to Ministerial Decree No. 509/1999 of closely related content, deemed suitable by the Executive Committee or a Commission specifically appointed by it.
How the admission procedure takes place	Interview
Duration	14 months
Teaching methods	in-person classes
Language of instruction	Italian
Attendance requirements	67%
Location of the course	Department of Health Sciences (DSS), Viale Pieraccini, 6 - 50139 Florence, Italy
Foreseen lecture schedule	November 2022 to December 2023, daily
Examinations procedures and schedule	Quiz at the end of training activities (December).
Final examination	The final examination consists of the presentation of a paper.

Available places and enrolment fees	
Full-fee students	
Minimum number	5
Maximum Number	6
Enrolment fee	€2,000
Free-of-charge supernumerary places	
UNIFI employees	1
AOU Careggi Employees	1
AOU Meyer Employees	1
Single Modules	
None planned	

Description of the activities and training objectives of the internship	The educational objective of the internship is to teach the practical aspects of the clinical research associate profession. Specifically, the student will be expected to work alongside a clinical research associate to follow all the procedures required for a clinical trial, including investigator meetings, paperwork required for approval by an ethics committee and hospital administration, monitoring visits and closing visits audits, and completion of case report forms. In order to achieve these objectives, the student will be required to work at the company where the internship will be held and also at the facilities where the various phases of the experimentation take place, including hospitals, university clinics, etc. Observational activity. 600 total hours of internship.

[i] This document is a translation of the form A.1 relating to the characteristics of the course attached to the Decree of the Deputy number 652 (record 154925) of 13th of July 2023, drafted in Italian and issued on the Master | Didattica | Università degli Studi di Firenze | UniFI and which therefore constitutes the only official document. This English translation cannot be used for legal purposes and has the sole purpose of supplying information in English on the content of the public notice.