



UNIVERSITÀ
DEGLI STUDI
DI PERUGIA



ADVANCED COURSE IN PRE-CLINICAL AND CLINICAL RESEARCH

Academic year 2018-2019

COORDINATOR

Prof. Susanna Esposito
*Full Professor of Pediatrics
Department of Surgical and
Biomedical Sciences
University of Perugia, Perugia
Italy*

**SCHOOL OF MEDICINE,
UNIVERSITY OF PERUGIA**

*Building Ellisse B, Piazza Lucio Severi 1,
Loc. S. Andrea delle Fratte
06132 Perugia, Italy*

PROFESSORS AND TEACHERS

DEPARTMENT OF SURGICAL AND BIOMEDICAL SCIENCES

University of Perugia, Perugia

Prof. Susanna Esposito
Full Professor of Paediatrics

Prof. Mauro Bacci
Full Professor of Legal Medicine

Prof. Giampietro Ricci
Associate Professor of Otorhinolaryngology

Jacopo Vannucci
Researcher of Thoracic Surgery

DEPARTMENT OF EXPERIMENTAL MEDICINE

University of Perugia, Perugia

Prof. Paolo Puccetti
Full Professor of Pharmacology

Prof. Luigina Romani
Full Professor of General Pathology

Francesca Fallarino
Associate Professor of Pharmacology

Chiara De Waure
Associate Professor of Public Health

Ciriana Orabona
Researcher in Pharmacology

DEPARTMENT OF MEDICINE

University of Perugia, Perugia

Maria Paola Martelli
Associate Professor of Blood Diseases

Carmelinda Ruggiero
Associate Professor of Gerontology and Geriatrics

Virginia Bocciardi
Researcher of Gerontology and Geriatrics

ADMINISTRATIVE CENTER FOR SUPPORT TO RESEARCH

University of Perugia, Perugia

Piera Pandolfi

Gina Olsen

Elisabetta Rossini

Giovanni Checcucci Lisi
Medical Director Sanofi, Rome

Umberto Filibeck
*Former Director, GCP Promotion and Inspection Office
e Pharmacovigilance inspections
Italian Drug Agency, Rome*

Stefano Lagravinese
ClinOpsHub srls Mesagne (BR)

Josè Lapinet
Medical Director GSK, Verona

Davide Matino
McMaster University, Hamilton, ON, Canada

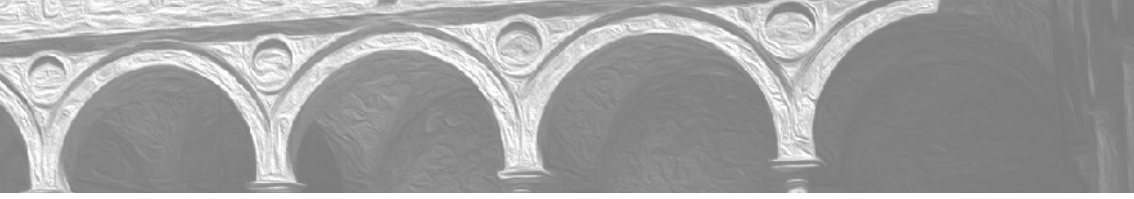
Virginio Oldani
Medical Director Novartis, Origgio (VA)

Stefano Valente
Medical Director MSD, Roma

EXTERNAL TEACHERS

Alberto Argentiero
*Research grant holder
University of Milan, Milan*

Giampaolo Bucaneve
*Regional Pharmacovigilance Center
Umbria Region, Perugia*



CALL FOR APPLICATIONS: 15th October 2018

CALL DEADLINE: 30th November 2018

<https://www.unipg.it/didattica/accesso-corsi-numero-programmato/corsi-di-perfezionamento?layout=concorso&idConcorso=13676>

MODULE 1

Day 1 • March 14th, 2019

PRINCIPLES OF PRE-CLINICAL RESEARCH

(Coordinator: P. Puccetti Professors: L. Romani, F. Fallarino, M.P. Martelli, C. Orabona, J. Vannucci)

9.00 am - 11.00 am From the animal model to the clinical practice

11.00 am - 1.00 pm From metagenomics to clinical practice

2.00 pm - 4.00 pm Pharmacokinetics, pharmacogenetics and pharmacogenomics

4.00 pm - 6.00 pm Biomarkers and new therapies

Day 2 • March 15th, 2019

9.00 am - 11.00 am Drug design and development of new pharmaceutical formulations

11.00 am - 1.00 pm Advanced therapies: gene therapy, cell therapy and tissue engineering

2.00 pm - 4.00 pm The phases of pre-clinical research

4.00 pm - 6.00 pm How to determine the value of a drug and the degree of innovation

Day 3 • March 16th, 2019

9.00 am - 1.00 pm **Laboratory exercises**

● **MODULE 2** ●

Day 4 • April 11th, 2019

PRINCIPLES OF CLINICAL RESEARCH

(Coordinator: S. Esposito; Professors: C. Ruggiero, V. Bocciardi, A. Argentiero, J. Lapinet, S. Lagravinese)

9.00 am - 11.00 am Methodology and phases of clinical research: special focus on phase 1

11.00 am - 1.00 pm Good Clinical Practice

2.00 pm - 4.00 pm How to set up a non-profit clinical trial

4.00 pm - 6.00 pm How to participate in a profit experimentation

Day 5 • April 12th, 2019

9.00 am - 11.00 am Collection, management and data quality

11.00 am - 1.00 pm Monitoring in clinical trials

2.00 pm - 4.00 pm Child is not a small adult

4.00 pm - 6.00 pm The importance of networks and networks in clinical research

Day 6 • April 13th, 2019

9.00 am - 1.00 pm Role playing: the actors of clinical research

MODULE 3

Day 7 • April 16th, 2019

PHARMACOVIGILANCE

(Coordinator: S. Esposito; Professors: P. Puccetti, G. Ricci, A. Argentiero, G. Bucaneve, G. Checcucci Lisi, S. Lagravinese)

- 9.00 am - 11.00 am Equivalent drugs, biotech and biosimilars
- 11.00 am - 1.00 pm The roles of professional figures and health structures: general practitioner, hospital doctor, pharmacist, hospital pharmacist, Health Local Authorities, regional centers and AIFA (Italian Drug Agency) / EMA (European Medicines Agency)
- 2.00 pm - 4.00 pm Pharmacovigilance of drugs, vaccines, devices and phytotherapics
- 4.00 pm - 6.00 pm The spontaneous reports and the role of the CRO and of the Pharmaceutical Company in the management of adverse events

Day 8 • May 17th, 2019

- 9.00 am - 11.00 am Medication errors and populations at risk of adverse reactions
- 11.00 am - 1.00 pm The Anti-Poison Center
- 2.00 pm - 4.00 pm Clinical trial and reimbursement of drugs
- 4.00 pm - 6.00 pm Accelerated procedures for access to medicines

Day 9 • May 18th, 2019

- 9.00 am - 1.00 pm
How to report an adverse event: practical exercises

● **MODULE 4** ●

Day 10 • June 13th, 2019

REGULATORY AND BIOETHIC ASPECTS

(Coordinator: S. Esposito; Professors: P. Puccetti, M. Bacci, F. Fallarino, A. Argentiero, G. Bucaneve, U. Filibeck, V. Oldani)

9.00 am - 11.00 am The new legislation on animal and clinical trials: interpretation and application criteria

11.00 am - 1.00 pm Registration processes and IMP management

2.00 pm - 4.00 pm The Ethics Committees: role and functions

4.00 pm - 6.00 pm How to draw up a protocol and submit it to the Ethics Committee

Day 11 • June 14th, 2019

9.00 am - 11.00 am Legal aspects: contracts, privacy and data ownership

11.00 am - 1.00 pm Patents in the pharmaceutical sector

2.00 pm - 4.00 pm Principles of bioethics

4.00 pm - 6.00 pm Informed consent and legislative criticalities in clinical research

Day 12 • June 15th, 2019

9.00 am - 1.00 pm Role playing on how to present an informed consent

• **MODULE 5** •

Day 13 • July 8th, 2019

DATA ANALYSIS AND PUBLICATION OF A SCIENTIFIC WORK

(Coordinator: P. Puccetti; Professors: C. De Waure, D. Matino)

9.00 am - 11.00 am Basics of biostatistics

11.00 am - 1.00 pm Design, sampling and data analysis

2.00 pm - 4.00 pm Bases of pharmacoeconomics

4.00 pm - 6.00 pm Health Technology Assessment

Day 14 • July 9th, 2019

9.00 am - 11.00 am Bibliographic research

11.00 am - 1.00 pm From the protocol to the publication of a scientific article

2.00 pm - 4.00 pm Systematic reviews of the literature and meta-analysis

4.00 pm - 6.00 pm The GRADE method and the evaluation of the quality of the evidence

● **MODULE 6** ●

Day 15 • July 11th, 2019

PECULIAR ASPECTS OF CLINICAL RESEARCH

(**Coordinator:** P. Puccetti; **Professors:** L. Romani, S. Esposito, M.P. Martelli, A. Argentiero, P. Pandolfi, G. Olsen, E. Rossini)

9.00 am - 11.00 am How to access national research funds

11.00 am - 1.00 pm How to access European and international research funds

2.00 pm - 4.00 pm Bio-banks

4.00 pm - 6.00 pm Sample use and re-call of patients for studies other than those initially planned

Day 16 • July 12th, 2019

9.00 am - 11.00 am The role of patients and their associations

11.00 am - 1.00 pm University and Spin-off

2.00 pm - 6.00 pm Practical exercises on how to set up a scientific work: the tricks of the trade and the mistakes to be avoided

GENERAL INFORMATION

CERTIFICATION ISSUED:

Certificate of attendance

PROPOSING STRUCTURE:

Department of Surgical and Biomedical Sciences

DURATION:

6 months

TEACHING PROVISION:

Frontal teaching

COST:

2.500,00 euro

START AND END OF REGISTRATION:

From 14th January to 15th February 2019

PERIOD OF DEVELOPMENT:

From 14th March to 13th September, 2019

ACCESS TITLES

Access to the course is reserved as a priority for holders of:

- Bachelor's degree in Medicine and Surgery, Pharmacy, Chemistry and Pharmaceutical Technologies, Veterinary Medicine, Dentistry and Dental Prosthesis; - Master's Degree in Biotechnology, Biological Sciences, Chemical Sciences, Physics, Agricultural Sciences and Technologies, Computer Science, Mathematics, Engineering, Food Science and Technology, Economics and Business Sciences, Jurisprudence.

THE HOLDERS OF THE FOLLOWING SPECIALIST DEGREE COURSES CAN ACCESS THE COURSE:

- Medicine and Surgery, Veterinary Medicine, Pharmacy and Industrial Pharmacy, Agricultural Biotechnology, Industrial Biotechnology, Medical, Veterinary and Pharmaceutical Biotechnologies, Industrial Biotechnology, Medical, Veterinary and Pharmaceutical Biotechnology, Biology, Human Nutrition Sciences, Chemical Sciences, Physics, Agricultural Sciences and Technologies, Agri-Food Sciences and Technologies, Computer Science, Mathematics, Biomedical Engineering, Science of the Economy, Economics and Business Sciences, Jurisprudence.

COORDINATOR

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