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# International Master in Pharmaceutical Medicine

*Excellence in education for the medicine of the future*

6 April 2020 - 15 March 2021

ISTITUTO DI RICERCHE
FARMACOLOGICHE
MARIO NEGRI · IRCCS

# INTERNATIONAL MASTER IN PHARMACEUTICAL MEDICINE

Interactions between academia, the pharmaceutical industry and regulatory authorities are of paramount importance to ensure an appropriate understanding of the efficacy and safety of drugs and consequently their appropriate clinical use.

The foundation for a successful career in clinical pharmacology and biopharma research encompasses strong scientific training and broad technical skills. While a rigorous, critical, and thorough approach to science is always important, it nonetheless should be emphasized that a strong scientific background enables one to think broadly and creatively about scientific problems / opportunity ties which is essential to the successful development of new therapeutics. Since the activities of members of a clinical pharmacology project team are interconnected, it is important to be able to understand not only one's own area of clinical research but also those of the other members, and the value a team working effectively can add. As such, multi-disciplinary training is required to provide the ability to think about all aspects of a drug discovery program and clinical development of drugs. An understanding of the clinical development process for new therapeutics is necessary to conduct the most robust and effective drug discovery research possible, and to ensure clinical data and chances of clinical development success are properly leveraged.

This will help prepare postgraduate trainees for a career in clinical pharmacology research both in the academia and the biopharma industry, with the objective of balancing public needs with the legitimate commercial aims and ensuring effective drug evaluation by regulatory authorities, and ultimately appropriate clinical use.

# OBJECTIVES

The course will provide a multi-disciplinary approach to the planning of clinical development programs, including trial design and conduct, data management, pharmacovigilance and regulatory affairs.

The main objectives are:

- Understand modern pharmacological principles and their clinical application
- Apply an integrative and multidisciplinary approach to clinical research investi gation
- Design and implement clinical development plans
- Design, implement and report individual research protocols
- Interact with regulatory bodies and understand fundamental rules to apply for research projects
- Apply the correct procedures for coordinatiing and monito ring a clinical study
- Understand the principles of pharmacovigilance and apply the correct procedures for the surveillance of the safety of medicinal products
- Understand the processes of production of the investigational medicinal product (IMP)
- Critically appraise research methods and experimental results
- Communicate research results and clinical implications to a wide scientific and lay audience

International Master
in Pharmaceutical Medicine 2018

# INTENDED AUDIENCE

The Master's degree program in Pharmaceutical Medicine prepares individuals to perform valid, credible patient-based research in academia, industry, research institutes, and health and regulatory agencies. Linking the academic and professional scientific communities, the master is reserved to:

- LM-41 Medicine and surgery
- LM-06 Biology
- LM-13 Pharmacy and industrial pharmacy
- LM/SNT1 Nursing and midwifery sciences
- LM-9 Medical, veterinary, and pharmaceutical biotechnologies
- LM-54 Chemical sciences

# CAREER OPPORTUNITIES

Careers in pharmaceutical medicine are very varied and can be challenging, exciting, fulfilling and rewarding. Pharmaceutical medicine offers a challenging multidisciplinary environment and one of great complexity. The proposed Master's degree program in Pharmaceutical Medicine may offer several career opportunities, including:

- Pharmaceutical Industries
- Clinical Research Organizations (CRO)
- Research Institutions
- Healthcare Institutions and Authorities

# PROGRAM

## Duration

The course will start in April 2020 spread over a period of one year and comprises seven modules plus a 450-hour training internship in structures of excellence in research and development of new drugs: AstraZeneca, Italfarmaco, Novartis, Pfizer, or Zambon S.p.A., which confirm with their support of this initiative a far-sighted commitment to enhance young talent in bioscience and promote new business models thanks to the synergy between academy, industry, non-profit, institutions and investors.

## Schedule

The program is based on the general concept of "on the job training", meaning that there will be mainly practical activities related to all aspects of clinical research trial.
Thus, the bulk of the training involves practical work with the different teams involved in a multi-disciplinary approach to clinical research. The research activity takes place daily under the guidance of a tutor who will supervise the participants during their training. In fact, participants are assigned to a research group in which they will collaborate with the objective of learning about the group's working approach and methodology.
Participants are also expected to attend lessons, seminars, courses and congresses organized by the partners Institutions.

The course is divided into seven macro-modules:
• Theory, research practice and innovation in pharmacology
• Ethical and legal requirements for clinical research programs
• Clinical studies in practices: project management and coordination
• Statistical methods in pharmacological research
• Scientific communication
• Legal Regulation of Drugs
• Drug discovery and development process, regulatory and commercial aspects of management in the pharmaceutical industry

## Macro-module 1: Theory, research practice and innovation in pharmacology

### Introduction to Clinical Research

**Aim:** To provide an in-depth and comprehensive understanding of the principles and practice of clinical research.

This module provides a thorough understanding of the history and evolution of clinical research, including the principles and organization of global clinical research, the future direction of health economics, innovation in Research and Development (R&D). The participants will examine the context in which research is undertaken (from molecular screening to Proof of Concept (PoC) and from PoC to Full Development) and consider types of studies, objectives and outcomes, definition and phases of protocols, and the roles and responsibilities of the clinical research team and study sponsors.

## Macro-module 2: Ethical and legal requirements for clinical research programs

### Ethical, Legal, Regulatory and Financial Considerations in Clinical Investigations

**Aim:** To provide an in-depth understanding of the ethical, legal, regulatory and financial dimensions of clinical research.

Subjects include recruitment and protection of subjects, diversity and vulnerability of populations, informed consent, privacy/confidentiality, and the role of Institutional Review Boards (IRBs) and Independent Ethics Committees (IECs). Participants will also explore international research, relationships with industry, conflict of interest, intellectual property, and publications and authorship. Budget: how to estimate the study costs; how to keep budget under control. Grant: how to write a grant application.

Macro-module 3: Clinical studies in practices: project management and coordination

## Design and Conduct of the Clinical Protocol

**Aim:** To provide a systematic understanding and critical awareness of clinical trial protocol requirements.

This module will cover all aspects of research design, including methods, objectives and hypothesis, specification of the study population, outcome measures, reliability and validity, randomization, documentation requirements, outsourcing and multi-centre trials. The trainee will participates in carrying out specific ongoing clinical trials at the Clinical Research Centre of the Mario Negri Institute. Specific issues regarding the design and conducts of studies with "cells and gene" therapies will also be discussed extensively, including the new ethical challenges (e.g. lack of preclinical data; long-term safety in patients, the "donor and patient journeys", etc).

## Good Clinical Practice (GCP) in Managing and Monitoring Clinical Trials

**Aim**: To critically examine requirements of good clinical practice and to understand correct strategies and plans in developing risk-based monitoring for investigational studies.

Topics include Standard Operating Procedures (SOPs), recruitment, quality assurance, data safety monitoring boards (DSMBs), multi-centre/large-scale trials, protocol management and amendments, audits, and reporting.

## Information and Data Management

**Aim**: To provide a critical understanding of the issues surrounding efficiency and security in the context of data management in clinical research.

Participants will examine the importance of information systems and information technology in increasing efficiencies in the management of clinical research data. It will consider the application of legal and ethical principles to the development of a data collection and management plan and the issues of confidentiality, security of information systems and electronic remote data capture (e-RDC). The value of in-stream data review and of "data analytics" models to detect safety signals or suboptimal data quality will also be addressed.

### Pharmacovigilance and Investigational Medicinal Product (IMP) Management

**Aim**: To provide an understanding of the relevance and importance of the proper monitoring of the study drug safety.

This module will cover all aspects of pharmacovigilance in clinical research: identification, recording, reporting and analysis of safety information to ensure that any safety signals are quickly identified and acted upon. Moreover, it will consider the steps of production, distribution and disposal of the investigational medicinal product according to international good manufacturing practices.

## Macro-module 4: Statistical methods in pharmacological research

### Biostatistics

**Aim:** To provide an understanding of the relevance and importance of statistics in clinical research.

This topic addresses the role of biostatistics in clinical research, including descriptive methodologies, statistical tests, and confidence intervals. Participants will examine basic concepts of data collection and analysis. The module also covers development of the Statistical Analysis Plan (SAP), preparation of the statistical report, and integration in the Clinical Study Report (CSR).

## Macro-module 5: Scientific communication

### Write Reports and Scientific Manuscripts

**Aim:** To provide an understanding of how to read the results of clinical research and how to write a scientific paper.

The participant will experience the tools necessary to complete all phases of drafting a research paper for publication, succeed in publishing scientific papers in top international journals and gain an in-depth understanding of scientific peer-review publishing and how to best present their work.

### Patient Advocacy and Relations

**Aim:** To understand the role of a patient in clinical research from a passive one (patient is a data point) to an active one (patient is a researcher)

This topic will explore the activities of the patients' associations to support the problems faced daily by patients and their relatives, and the role of the associations in representing and informing patients. Participants will also examine increasing collaboration between patients, patient advocacy groups and academia and pharmaceutical industry in facilitating clinical trial design and patient recruitment, as well as in funding new therapies and how these relationships are having an

## Macro-module 6: National and supranational health legislation

### The legal and regulatory framework governing medicinal products for human use

**Aim**: module will provide an overview on mechanisms and regulatory processes for medicines registration and the "drug cycle".

This module will allow the achievement of high skills in legal and regulatory matters, by examining the common rules for: the conduct of clinical trials, Authorisation procedures, Medicinal products for rare diseases ('Orphan medicines'), Medicinal products for children, Advanced therapy medicinal products, advertising, pharmacovigilance and collection, testing, processing, storage and distribution of human blood and blood components.

### Relations between the industry, scientific & healthcare sectors and patient association

Aim: to provide a systematic understanding of the provisions of statute law and the rules laid down by the Codes of Conduct of European and international federations of the pharmaceutical industry (EFPIA and IFPMA).

This module will cover all aspects of compliance with the relevant legal and ethical provisions such as antitrust law, law on privacy, corporate law, informed consent and conflict of interest with healthcare structures, physicians and university institutes.

### Contracts and Agreements

Aim: provide the tools necessary to understand the most used contractual forms in the pharmaceutical sector.

The module provides a thorough understanding of the contracts stipulated between the physician and the pharmaceutical company; contract drawn up between the sponsoring company and the entities involved in the clinical study; contract between the company and the Institute/Organisation (ASL, Universities, hospitals and institutions IRCCS) or Patient association.

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Macro-module 7: Drug discovery, development process and commercial aspects of management in the pharmaceutical industry

## Integrated Product Development, Healthcare Marketplace and Marketing

**Aim**: Integrated Product Development, Healthcare Marketplace and Marketing
Aim: To understand the principles and the practice of the quality system of drug lifecycle activities.

This module will focus on principles of project and portfolio management and decision-making in clinical research. Ethical and legal principles of market introduction of a drug; Good Promotional Practices. Overview of health economics and health technology assessment (HTA). Management of cross-functional teams, team work and performance assessment.

## Roles and Responsibilities in the Enterprise

**Aim**: To acquire an understanding of how enterprises are organized, who the main internal stakeholders are, how to manage a matrix organization, principles of leading oneself and leading a team.

This module will offer an overview on organizational structure, the main roles and responsibilities, principles of matrix management and influencing, principles of leadership, principles of: time management, facilitation skills, negotiation skills, how to build a high performing team.

## Coordinators

Piergiorgio Messa
*Professor of Nephrology, University of Milan – Italy*

Giuseppe Remuzzi
*Director, Mario Negri Institute – Italy*

## General information

### Course Location:

• Istituto di Ricerche Farmacologiche Mario Negri IRCCS. Via Mario Negri, 2, 20156 Milan (MI)
• Clinical Research Centre for Rare Diseases "Aldo e Cele Dacco". Via G. Camozzi, 3 24020 Ranica (BG)

Students will have the opportunity to be hosted at the guesthouse of the Clinical Research Centre for Rare Diseases "Aldo e Cele Daccò" (Ranica, Bergamo) where the main activities of the Master will be performed.

### Campus

Each student will undertake a major individual research project over the remainder of the course in one of the primary research areas in academia or the industry. The research will be supervised by senior staff. Based on the research project assigned to each student, an internship lasting approximately 4 months will be done at one of the following sites:

• Novartis Farma S.p.A
• Pfizer Italia S.r.l.
• Italfarmaco S.p.A.
• Zambon S.p.A.
• AstraZeneca S.p.A.

### Publication of the notice
(www.unimi.it/studenti/master)

### Deadline application
10 March 2020

### Number of participants
The Master will be activated for 14 students

### Start date
6 April 2020

### End date
15 March 2021

### Credits
60 CFU

### Registration fee
4500€

For all information relating to administrative procedures regarding selection, registration, payments and certification of students please refer to the Office of Doctoral and Master university:

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