

Regenerative Medicine and Tissue Engineering

**Ma
ste
r** Cattolica

Due to the COVID-19 pandemic, the entire course will be held online (virtual).
There will be no face-to-face lectures or networking activities.
Registration fees have been significantly reduced.

FACOLTÀ DI MEDICINA E CHIRURGIA "A. GEMELLI"
Academic Year 2020/21 - 1st edition
Rome, April 2021 - March 2022

Master of Advanced Study

Gemelli

Fondazione Policlinico Universitario Agostino Gemelli IRCCS
Università Cattolica del Sacro Cuore



**UNIVERSITÀ
CATTOLICA
del Sacro Cuore**



Overview

The aim of the Master's program is to provide a multidisciplinary post-graduate training in regenerative medicine and tissue engineering, representing a unique opportunity for in-depth research on innovative and specialized areas of stem cell research and tissue engineering technology. The advanced level of the course aims to give the basis for the development of a critical scientific approach towards the treated topics. Lectures will be given by over 40 internationally renowned, European and extra-European scientists from the most relevant and distinguished Universities and Research Centres in the field of regenerative medicine worldwide.

Admission

Applicants should hold any academic qualification recognized as equivalent to the Italian "Laurea Specialistica or Laurea Magistrale" degrees in: Biology, Medicine and Surgery, Biotechnology, Pharmaceutical Sciences, Veterinary Medicine, Biomedical Engineering, Material Engineering, Dentistry, and Chemistry. Additional requirements: good English, good knowledge of the Master's topic basics. To be admitted to the Master of Advanced Study in "Regenerative Medicine and Tissue Engineering" the candidates will be selected based on their Curriculum Vitae and will have to pass an entrance exam consisting of an interview during which skills and motivations will be assessed. Interviews will be held entirely online.

Learning Objectives

The training program is divided in 11 modules covering a wide range of topics focusing on recent advances in:

- fundamentals of regenerative medicine
- stem cell research, from in vitro and pre-clinical models to clinical applications
- novel technologies in tissue engineering and biomaterials
- ethics and safety issues
- principles of advanced therapy medicinal products (ATMPs) regulation
- market access and business opportunities

Lectures are accompanied by workshops and panel/roundtable discussions with lecturers, allowing for professional networking in both formal and informal settings (lunch/dinner/cocktails with the experts), and favoring an update on the "hot topics" in the field. Internship programs are included to improve practical skills.

Program

The advanced level University Master lasts one year for a total of 60 credits. Lessons are divided into 3 sessions, each session has a 1-week duration (June 22-27, 2021; August 30-September 4, 2021; January 26-30, 2022). In addition, participants will be invited to attend an international workshop/meeting in the area of interest. An internship program of 700 hours is mandatory. The internship will be on a topic relevant to the Master program and can be held in any Institute. The internship must be approved by the Board prior to commencement.

Due to the COVID-19 pandemic, the entire course will be held online (virtual). There will be no face-to-face lectures or networking activities. Registration fees have been significantly reduced.



Introduction

A live streaming commencement ceremony of the Master's course, a quick glance at the lectures, the topics and modules included, the lecturers, and the internship program

Fundamentals of Regenerative Medicine

Introduction to the course, discussion of aims and expectations
(Ornella Parolini, course organizers and attendees)

The history of regenerative medicine
(Ranieri Cancedda, Università degli Studi di Genova, Genoa, Italy)

Regenerative medicine: Pandora's box
(Silvio Garattini, Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Milan, Italy)

Biology and properties of stem cells: embryonic, adult and induced pluripotent
(Maddalena Mastrogiacomo, Università degli Studi di Genova, Genoa, Italy)

Regenerative medicine and its cultural and anthropological outcomes
(Mons. Tomasz Trafny, Pontifical Council for Culture)

Regeneration from the salamander's point of view: understanding key players
(Ken Muneoka, Texas A&M University, College Station, Texas, USA)

Module 1**Advanced Stem Cell Concepts**

Hematopoietic stem cells: milestones in umbilical cord blood transplantation
(Annalisa Ruggeri, IRCCS San Raffaele Scientific Institute, Milan, Italy)

Hematopoietic stem cells for cerebral palsy
(Joanne Kurtzberg, Duke University School of Medicine, Durham, North Carolina, USA)

Bone marrow as a multifunctional stem cell niche: the key players
(Diego Correa, University of Miami, Miller School of Medicine, Miami, Florida, USA)

Mesenchymal stromal cells: from the 2006 MSC consensus to current views
(Massimo Dominici, Università degli Studi di Modena e Reggio Emilia, Modena, Italy)

Use of induced pluripotent stem cells and tissue engineering to model brain and liver disease
(Catherine Verfaillie, KU Leuven, Leuven, Belgium)

Panel debate with experts working with different MSC sources (bone marrow, adipose tissue, perinatal tissues): nomenclature, specific features and properties, the handling protocols' dilemma
(Massimo Dominici, Università degli Studi di Modena e Reggio Emilia, Modena, Italy; Ornella Parolini, Università Cattolica del Sacro Cuore, Rome, Italy; Laura de Girolamo, IRCCS Istituto Ortopedico Galeazzi, Milan, Italy)

Multilineage differentiating stress enduring (Muse) cells
(Mari Dezawa, Tohoku University Graduate School of Medicine, Sendai, Japan)

Module 2**Modern Era of Regenerative Medicine**

Relevance of inflammation in disease and tissue regeneration
(Silvano Sozzani, Sapienza Università di Roma, Rome, Italy)

Regeneration of Neuronal Network
(Zaal Kokaia, Lund University, Stem Cell Center, Lund, Sweden)

The brain and the immune system: regenerating the injured brain
(Elisa R Zanier, Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Milan, Italy)

Cell therapy for muscular dystrophy
(Giulio Cossu, University of Manchester, Manchester, UK)

Extracellular vesicles in cardiac regeneration
(Sveva Bollini, Università degli Studi di Genova, Genoa, Italy)

Discussion: Cell replacement versus paracrine effects
(Ornella Parolini, Università Cattolica del Sacro Cuore, Rome, Italy)

Working Groups with tutors and experts on specific issues/criticisms/controversies related to module topics

Module 3

Tissue Engineering and Biomaterials

Nature inspires chemical engineers to develop smart devices for regenerative medicine & nanomedicine
(Anna Tampieri, National Research Council - CNR, Faenza, Italy)

Biomimicry at nanoscale level: a step forward towards tissue integration and regeneration
(Matteo Santin, University of Brighton, Brighton, UK)

Biomimetic chemistry and biomechanics in bone scaffold design
(Anna Tampieri, National Research Council - CNR, Faenza, Italy)

3D printing and bioprinting techniques: towards new frontiers
(Ilaria Cacciotti, University of Rome "Niccolò Cusano", Rome, Italy)

The multi-faceted application of graphene-based materials
(Massimiliano Papi, Università Cattolica del Sacro Cuore, Rome, Italy)

Fibrous membranes as promising platforms for guided regenerative medicine
(Ilaria Cacciotti, University of Rome "Niccolò Cusano", Rome, Italy)

Module 4

Modelling Diseases from Cells to Organisms

Static vs. dynamic culture systems: addressing biomimicry with bioreactors
(Ivan Martin, University of Basel, Basel, Switzerland)

Organoids and organs on chip
(Uwe Marx, TissUse GmbH, Berlin, Germany)

Regulatory testing requirements: an overview for human medicinal products and 3R testing approach (replacement, reduction, refinement)
(To be determined)

Pre-clinical animal models for regenerative medicine applications
(Peter Ponsaerts, University of Antwerp, Antwerp, Belgium)

Module 5

Veterinary Medicine Applications of Regenerative Medicine

Emerging challenges in Veterinary medicine applications
(Offer Zeira, San Michele Veterinary Hospital, Tavazzano con Villavesco, Lodi, Italy)

Experimental and clinical tissue engineering of bone and osteochondral tissue
(Antonio Crovace, Università di Bari Aldo Moro, Bari, Italy)

Novel cell-based strategies for tendon regeneration
(Valentina Russo, Università di Teramo, Teramo, Italy)

Stem cells for feline and canine cardiomyopathies
(Jayesh Dudhia, Royal Veterinary College, University of London, London, UK)

Equine amniotic cells and their potential application in veterinary regenerative medicine: in vitro and preclinical studies
(Anna Lange-Consiglio, Università degli Studi di Milano, Milan, Italy)

Module 6

Roadmap to Clinical Translation

Mesenchymal Stem Cells to induce tolerance to organ transplant
(Giuseppe Remuzzi, Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Bergamo, Italy)

The role of regulatory bodies in translational research: from basic science to clinical trials
(Maria Cristina Galli, Istituto Superiore di Sanità, Rome, Italy)

Update on clinical trials with mesenchymal stromal cells
(Martino Introna, Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII, Bergamo, Italy)

Advanced therapy medicinal products, the road to the clinic
(Graziella Pellegrini, Università di Modena e Reggio Emilia, Modena, Italy)

Update on clinical trials with hematopoietic stem cells
(Maria Ester Bernardo, San Raffaele-Telethon Institute for Gene Therapy (SR-TIGET), IRCCS San Raffaele Scientific Institute, Milan, Italy)

Update on clinical trials with induced pluripotent stem cells
(Marius Wernig, Stanford University School of Medicine, Stanford, CA, USA)

Working Groups with tutors and experts on specific issues/criticisms/controversies related to module topics

Module 7



From a Research Project to a Translational Product

Module 8

Grant writing: European vs. American calls for grants
(Chiara Gabbi, Independent Scholar, Reggio Emilia, Italy)

A practical session: writing grants and establishing collaborations
(Chiara Gabbi, Independent Scholar, Reggio Emilia, Italy; Laura Motta, Università Cattolica del Sacro Cuore, Rome, Italy)

Technology transfer and intellectual property
(Filippo Leone, Università Cattolica del Sacro Cuore, Rome, Italy)

From Research to Clinic: A Dialogue Between Research Laboratories and Competent Authorities

Module 9

Experience with the regulatory board: from inspection to certification
(Representative of national and international biotech and pharmaceutical companies in the field of Regenerative Medicine and Tissue Engineering)

Classification of biological products and Advanced Therapy Medicinal Products (ATMPs): an international overview
(Maria Cristina Galli, Istituto Superiore di Sanità, Rome, Italy; Other Regulatory Institution Representatives)

Good Laboratory Practice (GLP) in preclinical research
(To be determined)

"From discovery to therapy": simulations of practical approaches to comply with regulatory requirements
(Maria Cristina Galli, Istituto Superiore di Sanità, Rome, Italy)

GMP requirements for Advanced Therapy Medicinal Products
(Simona Russo, Agenzia Italiana del Farmaco – AIFA, Rome, Italy) (To be confirmed)

Good Clinical Practice (GCP)
(Angela Del Vecchio, Agenzia Italiana del Farmaco – AIFA, Rome, Italy) (To be confirmed)

An introduction to regulatory affairs in pharmaceutical sector and presentation of a medicinal product certification scheme
(Giuseppa Pistrutto, Agenzia Italiana del Farmaco – AIFA, Rome, Italy) (To be confirmed)

Regenerative Medicine: Market Access and Business Opportunities

Module 10

Market access strategies
(Americo Cicchetti, Università Cattolica del Sacro Cuore, Rome, Italy)

Commercialization of cell-based products, the experience of companies
(Representative of industries and biotech companies)

Biotech industries and companies in the regenerative medicine scenario
(Representative of national and international industries and biotech companies)

Conclusive remarks, take-home messages, SWAP analysis of course content and outcomes

Module 11

Workshop

The attendees will be invited to attend an international workshop/meeting in regenerative medicine
(To be defined)

Update

A live streaming closing ceremony of the Master's course in order to provide the students with the opportunity to discuss their internship and provide feedback on the course





Director of Master program:

Prof. Ornella Parolini

Scientific Board

Prof. Ornella Parolini

Prof. Wanda Lattanzi

Prof. Luciana Teofili

Dr. Antonietta Rosa Sillini

Management Board:

Dr. Marta Barba

Dr. Lorena Di Pietro

Dr. Andrea Papait

Dr. Daniela Gallo

Dr. Francesca Romana Stefani

The deadline for applications is March 15, 2021

INFORMATION

www.unicatt.it/offerta-formativa-master-universitari

Email: Master.RegenerativeMedicine@unicatt.it



UNIVERSITÀ
CATTOLICA
del Sacro Cuore

www.unicatt.it