TRANSLATING STEM CELL RESEARCH FROM BENCH TO BED (AB000007)

1. language

English

2. course contents

Coordinator: Prof. Antonio Oliva
Year Course: 1° year
Semester: 2° semester
UFC: 10
Modules and lecturers:
- BASICS OF APPLIED ECONOMICS (AB000055) - 2 UFC - SSD SECS-P/06
Prof. Alessandro Campana
- INTRODUCTION TO ETHICS IN CLINICAL TRIALS: ETHICAL COMMITTEES (AB000058) - 2 UFC - SSD MED/43
Proff. Antonio Oliva, Francesca Cazzato
- REGULATORY ASPECTS IN ATMPS AND BEYOND (AB000059) - 2 UFC - SSD IUS/14
Prof. Cristina Longinotti
- TECHNOLOGY TRANSFER IN BIOTECHNOLOGY (AB000057) - 2 UFC - SSD SECS-P/06
Prof. Davide Ederle
- TRANSLATING INTO THE CLINICS: RESEARCH PROCESSES AND PHASES OF CLINICAL TRIALS (AB000053) - 2 UFC - SSD IUS/14
Prof. Ilja Richard Pavone

3. BIBLIOGRAPHY

Introduction To Ethics In Clinical Trials: Ethical Committees

Updated scientific articles, journals, and protocols will be provided to students during the course.
The following textbooks may be used for support/consultation on basic topics:

- Chapter: "Ethical Issues" In: L.M. Friedman, C.D. Furberg, D.L. DeMets, D.M. Reboussin, C.B. Granger, Fundamentals of Clinical Trials, Springer International Publishing, Cham, 2015.
- E. Furlan, Comitati etici in sanità. Storia, funzioni, questioni filosofiche., 2015.
- The Oxford Textbook of Clinical Research Ethics edited by Ezekiel J. Emanuel, Christine C. Grady, Robert A. Crouch, Reidar K. Lie, Franklin G. Miller, and David D. Wendler

Regulatory Aspects In Atmps And Beyond

Optional book:

- QIU T e TOUMI M. Regenerative Medicine: Unlocking Patient Access and Commercial Potential. CRC Press 2023 - Chapter 1 – Regulation of RMs in globally

Other bibliography:

- EDUCATIONAL READING MATERIALS from EMA WEBSITE: Regulation EC 1394/2007. Legal Framework. EMA website. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000295.jsp
- EU Medicinal Products Directive, 2001/83/EC. EMA website. http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004481.pdf
- Reflection paper on classification of advanced therapy medicinal products, EMA/CAT/600280/2010 rev.1. EMA website. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/06/WC500187744.pdf
- Committee for Advanced Therapies (CAT). EMA website. http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000266.jsp
- Guidelines Relevant for Advanced Therapy Medicinal Products. EMA website http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000298.jsp&mid=WC0b01ac05800862bd

Basics Of Applied Economics

Updated scientific articles, textbooks and journals will be provided to students during the course.
Optional book:

- ROBERT E. HALL, MARC LIEBERMAN. Microeconomics : Principles & Applications. South-Western Pub; 6th Edition (16 February 2012)

Other bibliography:

- JEROEN KEMPERMAN, JEROEN GEELHOED, JENNIFER OP'T HOOG. Brillant Business Models in Health care. Springer (2017)
- THOMAS SOWELL. Applied Economics. Thinking Beyond Stage One: Second Edition. Basic Books (2008)

Technology Transfer In Biotechnology

Updated scientific articles, textbooks and journals will be provided to students during the course. Different IT tools will be used during the course. Participation in the lessons will therefore require the use of a computer connected to the internet and the activation of (free) asana.com and miro.com accounts.

Translating Into The Clinics: Research Processes And Phases Of Clinical Trials

Updated scientific articles, textbooks and journals will be provided to students during the course. The following textbooks and articles may be used for support/consultation on basic topics

T.L. Beauchamp, J.F. Childress, "Principles of Biomedical Ethics", Oxford University Press (2001); G. Rasi, A. Mugello, "European Union Regulation on clinical trials and Regulation on medical devices: A common soil for future development", Frontiers in Drug Safety and Regulation (2022):

pp. 1-5

I.R. Pavone, “Animal Experimentation and Animal Welfare in the Context of the European Union: Reflections on Directive 2010/63/EU and its Transposition in Italy”, BioLaw Journal – Rivista di biodiritto, pp. 227-249;

I.R. Pavone, “Legal responses to placebo-controlled trials in developing countries”, Global Bioethics (2016): pp. 76-90

I.R. Pavone, “Diritti fondamentali dei pazienti affetti da malattie rare nella prospettiva internazionalistica”, in Questa volta è una zebra. Etica della ricerca sulle malattie rare (a cura di E. Mancini), CNR Edizioni (2021): pp. 8-15.

Where necessary, students will be provided with supplementary teaching materials, in the form of articles, journals and protocols updated during the course, as well as the indication of appropriate and reliable telematic sources, to supplement, deepen and update the content explained in class.

4. OBJECTIVES

The integrated course aims to provide students an overview of the main aspects and innovations in stem cell research by addressing the main regulatory issues and clinical, economic and ethical implications.

Upon completion of the integrated course, the student must demonstrate that he or she has acquired the following objectives:

Knowledge and understanding of the main issues beyond clinical research, with particular reference to its economic and ethical implications and translation into the clinical setting. Moreover, through the integrated approach, the student must demonstrate to have acquired a wide knowledge of the topic, a critical view of the advantages and issues related to stem cell research and to consider economic implication and models together with the ability to translate scientific results in innovations.

Applying knowledge and understanding of how to appropriately interpret and understand the applicative aspects of stem cell research with respect to different settings proposed in each module. Considering also the implication that these models may have in the economic field.

Making judgements - Critically reviewing the scientific literature on stem cell research, discussing current regulatory aspects in Atmps, formulating an own opinion on key bioethical, clinical and economic issues, identifying cost-effective strategies, acquiring design skills to realize innovative projects.

Communication skills - Know how to unambiguously communicate, exposing the information in a coherent logical sequence, using technical language and correct terminology, in order to appropriately present the scientific results obtained from the research to the general public, potential investors and pharma companies, as well as the associated limitations and possible related clinical issues. In addition achieve an adequate skill to develop economic concepts using the adequate terminology.

Learning skills - At the end of the integrated course, the student must demonstrate a good capacity of expand his/her knowledge through scientific papers by referring online platforms and to articulate basic economic analysis, updating him/herself by attending specialized seminars, conferences, masters etc.

5. prerequisitES

Students must have previously acquired knowledge related to the basic disciplines provided in the three-year degree courses preparatory to this degree class.

6. TEACHING METHODS

The teaching methodology is based on face-to-face lectures and when scheduled, experimental activity/laboratory exercises. Teaching is based on interactive modes characterized by discussion and active learning, including "problem-based learning," "self-learning," and "case studies" strategies.
Lectures will be supported by digital material (i.e., slides) that will be explained by the lecturer.
The teaching methods are designed to enable the student to achieve the learning objectives, according with the following points:

Knowledge and understanding - Frontal teaching will systematically cover the topics of each module using digital supplementary material; the more complex aspects will be clarified in order to provide students with the tools to easy learn the integrated course syllabus.

Application of knowledge and understanding - During lectures, practical examples will be provided, and students will be invited to actively participate in collegial discussion of cases, asking questions, proposing problem-solving strategies. The frontal teaching will be sided by group work to practice the notions learned.

Making judgements - The proposed teaching methods are designed to allow the student to develop a critical view and acquire autonomy of judgement on applied cases regarding the topics covered in each module. Teams will be created which will have to autonomously understand the economic implications and identify strategies for valorizing the research results.

Communication skills - Students will be encouraged to develop their communication skills aimed at exposing the topics of the integrated course through discussion with the lecturer and colleagues. Teaching methods aim to ensure that the student at the end of the course is able to use technical terminology for unambiguous communication within the scientific community, to potential investors and industrial partners.

Learning skills- The use of international scientific articles will enable the student to study up-to-date topics and provide him/her with the tools for continuous independent learning. Students will also learn how to acquire and use economic and business information to understand the innovation potential of research results and promote their exploitation.

7. OTHER INFORMATIONS

Lecturers are available at the end of each lesson and, upon request by e-mail, to schedule appointments either face-to-face or via digital platform.
Lecturers may send communications to the class via email and/or via the BlackBoard platform.

NOTE ON STUDENTS' RESPONSIBILITY

The responsibility for learning falls increasingly on students, as they advance through the course; hence, ultimately, the commitment and the dedication to learn must come from them.

As members of the Università Cattolica S. Cuore learning community, students are expected to respect the intellectual property of course instructors. All course materials presented to students are the copyrighted property of the course instructors and are subject to the following conditions of use:

1) Students may not record nor reproduce lectures or any other classroom activities, unless differently specified by the instructor; however, they may use the recordings for their own course-related purposes only.

2) Students may not reproduce and/or post any course material provided by the instructors online or distribute them without the advance written permission of the course instructor and, if applicable, of any students whose voice or image is included in the recordings.

3) Any students violating the conditions described above may face academic disciplinary sanctions. As members of a learning community, students are expected to respect the time and efforts of their fellow classmates. Therefore, the use of social media and other electronic distractions that can disrupt the concentration of other students in the classroom is NOT allowed.

NOTE ON ACADEMIC INTEGRITY AND CHEATING POLICY

The principles of truth and honesty are fundamental to the educational process and the academic integrity of the University. All students have a right to expect fair and honest evaluation of their work. CHEATING UNDERMINES THIS EXPECTATION AND WILL NOT BE TOLERATED.

Students must avoid the following misconduct behaviors that are considered as cheating:

DO NOT exchange ID badges to collect presence among classmates who cannot attend a lecture.

DO NOT share answers of quizzes during exams.

Any student found by the instructors to be cheating will receive a failing grade for the exam or other graded work, and will be reported to the Course's Coordinator and Instructors' Committee. The instructors may, at their discretion, decide to give a failing grade for the course in severe cases of academic dishonesty.

8. learning verification methods

The examination consists of a written test with multiple-choice questions concerning the content of all course modules (the number of questions given is proportional to the number of CFUs for each module) and is aimed at ascertaining the student's understanding of the topics. The student will be able to achieve the maximum score (30/30 cum laude) by answering correctly and exhaustively all questions from all teaching modules. The objective of the examination thus organized is to assess the student's acquisition of the following skills and knowledge:

• ***Knowledge and understanding*** of the topics of each module of the integrated course. Knowledge of the theoretical concepts governing stem cell biology and research as well as the main scientific methodologies applied in the field, in order to identify innovative approach and fully comprehend their applications in regenerative medicine.
• ***Applying knowledge and understanding*** - Student has to demonstrate to have acquired an adequate knowledge and to be able to apply correctly the concepts during the examination.
• ***Making judgments*** – During the test, the student has to demonstrate the ability to make cross-cutting links on the course topics independently, developing a systematized and personalized methodological approach to the issues of stem cell research.
• ***Communication skills*** – by showing to have learnt appropriate scientific terminology.
• ***Learning skills*** - through the ability to investigate and address issues independently, using critical reasoning, developing innovative problem-solving strategies.

9. program

<Introduction To Ethics In Clinical Trials: Ethical Committees>

- Principles for Ethical Research
- Ethical issues in clinical trials (ethics training, randomization, conflict of interest, informed consent, safety and efficacy monitoring, early termination, privacy and confidentiality)
- Clinical trials in vulnerable populations
- Composition and function of ethical committees

- International and Italian regulations on ethical committees

< Regulatory Aspects In Atmps And Beyond >

- Definitions: Medicinal Product, Medical device and ATMP. ATMPs classification.
- Regulatory framework in the EU: general principles, risk-based approach, quality-related features, non-clinical and clinical development, marketing authorization, post-marketing requirements
- Examples of approved products in the EU
- Overview of ATMP regulation in non-EU countries
- The one-step approach to regenerative medicine
- The upcoming Substance of Human Origin (SoHO) regulation

< Basics Of Applied Economics >

- The economic environment: how to manage the different environments (legal, political, technical, financial, physical, economic, research and innovation) in which the companies are active
- The market : how the companies manage the supply and the demand of products and services. The competitive aspects in the innovation economy and in the health sector
- The economic – financial issues and the assets/liabilities structure of a company in a changing and innovative environment
- The organisation of a company : the need to adapt to the market changes
- Marketing : basic definition and tools

<Technology Transfer In Biotechnology>

- Definition and key elements of Technology Transfer.
- Intellectual Property management
- Business Modeling
- Project Management
- Pitching

<Translating Into The Clinics: Research Processes And Phases Of Clinical Trials>

Part I Introduction

What is the clinical trial process
Why are clinical trials necessary
What are the different phases of a clinical trial
Therapeutic and Non Therapeutic Research
Core issues regarding human subject research:
i)Respect of Patients: Informed Consent
ii) Beneficence: The Assessment of Risks and Benefits
iii) Justice: Selection of human subjects and non-discrimination

Part II The Legal Landscape

IIA History of Medical Ethics

The Nuremberg Code
Art. 7 of the International Covenant on Civil and Political Rights
The WHA Declaration of Helsinki
The Belmont Report
International Ethical Guidelines for Health-related Research Involving Humans (CIOMS)
The UNESCO Declaration on Bioethics and Human Right

IIB The European Standards

IIB1 The Council of Europe

The European Convention on Biomedicine and Human Rights
The Additional Protocol on Biomedical Research
The European Convention against Trafficking in Human Organs

IIB2 The European Union

The Right to Health in the European Union
The EU Clinical Trials Regulation
The EU Regulation on Medical Devices
The EU Regulation on Orphan Medicinal Products
The European and Developing Countries Clinical Trials Partnership (EDCTP)

Part III Specific Problems

Experiments on animals: the main scientific, ethical and legal issues
Clinical trials in developing countries and the issue of double standards
The production and the global roll out of COVID-19 Vaccines