

2.5 ECTS

Postgraduate course

TRANSLATING CLINICAL RESEARCH INTO INNOVATION TO TACKLE AGE-RELATED HEALTH PROBLEMS

ONLINE

APPLICATION DEADLINE

31/10/2022

COURSE DATES

14/11/2022 - 25/11/2022

DURATION

30 hours

COORDINATION

Catarina Madeira
Researcher
CoLAB TRIALS/NMS

Ana Maria Rodrigues
Assistant Professor
NOVA Medical School

CONTACTS

+351 218 803 066

posgraduacao@nms.unl.pt

www.nms.unl.pt



COURSE PRESENTATION

Life expectancy has largely increased since the past century however, healthy life expectancy has not followed identical tendency. How can we live more years with good health? Understanding the ageing biology is as crucial as a healthy and active elderly population. Thus, ageing should be interdisciplinary addressed to increase the likelihoods of innovation. This course will cover health innovation technologies to tackle age-related health problems, as well as the innovation pathway from technology development to clinical testing.

LEARNING OUTCOMES

1. Ideate, critically, evidence-based service models and technologies to support ageing.
2. Recognize the importance of using systematic approaches in health promotion and disease management of senior citizens.
3. Identify the core steps in the development and evaluation of home-based intervention to improve self-management and promote behaviour change through digital health solutions.
4. Ensure usability and usefulness of healthcare solutions by performing technology development design involving end-users needs.
5. Understand the regulatory requirements to bringing medical devices and advanced therapies from the lab to clinical evaluation.
6. Identify constrains and opportunities to bringing Medical Devices and advanced therapies to the bedside to solve age related problems.
7. Recognize the key steps, stakeholders and procedures to design and implement a clinical trial.

TEACHING METHODOLOGIES

Analysis and discussion of case studies and practical exercises in class. The materials used in class are made available to students after class, except any documents to be reviewed during class, which will be sent prior to the respective class.

ASSESSMENT METHODS

- Group Assessment
Assessment of a brief oral presentation resulting from a group work carried out in class with interaction with the teacher.
- Individual assessment
Oral participation in class.

AUDIENCE / ENTRY REQUIREMENTS

Graduates in the field of life sciences

ADMISSION CRITERIA

Curricular analysis

COURSE ATTENDANCE REQUIREMENTS

Attend 90% of sessions and participate in group work.

TEACHING LANGUAGE

English

NUMERUS CLAUSUS

Max: 30 | Min: 10

TUITION FEE

Application fee: 51€
Registration fee: 35€
Frequência | Course fee: 600 €

COURSE DATES

14/11/2022 - 25/11/2022

COURSE SCHEDULE

4 pm to 7 pm (WET)

PROGRAM

MODULE 1

Gerontech and anti-ageing biomedtech

- Public Health & Gerontology.
- Gerontech - new service models.
- Overview of anti-ageing technology: stem cell therapy, gene therapy / editing, and cybernetics. Nanotechnology, cell regeneration, and digital twins.

MODULE 2

Promoting health-related behaviours and disease self-management for older adults through digital technologies

- Methodologies used to develop and validate digital technologies improving disease self-management and health related behaviours.
- Showcase of various digital interventions targeting long lasting health-related behaviours and disease management for older adults.
- The role of behavioural science and a multidisciplinary approach in the development of effective health behaviour change interventions.
- Challenges and opportunities for advancing research and implementation in the real world of these interventions.

MODULE 3

User innovation in Healthcare

- Introduction to innovation process by patients to cope for their own unmet needs.
- Showcase of healthcare solutions developed by caregivers and patients + Q&A session.
- Practical exercise to identify relevant needs and develop key enabling technologies and value chain to deploy a healthcare product project.

MODULE 4

Medical Devices from bench to bedside: regulatory requirements

- Overview of the regulatory pathway for clinical evaluation of Medical Devices (MD) and In Vitro Diagnostics (IVD) for conformity assessment will be presented.

- Practical exercise for planning a pilot clinical study based on pre-clinical/analytical data.
- Case studies with MD and IVD clinical evaluation specific to aging-related diseases.

MODULE 5

Translation of advanced therapies to clinical trials in age-related diseases

- The regulatory pathway for clinical evaluation of advanced therapies.
- Practical exercises for planning early phase clinical studies based on pre-clinical data.
- Case studies related to the translation of advanced therapies specific to aging-related diseases to the bedside.

MODULE 6

Clinical trials in age-related diseases: The pathway from an idea to regulatory requirements

- Overview of how we can transform an idea into a clinical trial protocol.
- Regulatory requirements for clinical trials according to the international legislation.

MODULE 7

Clinical trials in age-related diseases: Study design

- From early to late phase clinical trials.
- Overview of the study designs, considering the specific objectives and the target population.

MODULE 8

Time-to-action: Implementation and Management of clinical trials

- The different stakeholders involved in implementing and managing clinical trials.
- The steps to set up and conduct a clinical trial in the clinical context, from the planning to collecting data.
- The monitoring activities according to the Good Clinical Practice (ICH E6 (R2)).

MODULE 9

Group Work

MODULE 10

Course evaluation

TEACHING STAFF

- **Ana Maria Rodrigues, MD, PhD**
CHRC; NOVA Medical School
- **Catarina Madeira, PhD**
CoLAB Trials; NOVA Medical School
- **Jaime da Cunha Branco, MD, PhD**
NOVA Medical School
- **Lúcia Domingues, PhD**
NOVA-CRU; NOVA Medical School
- **Maria João Jacinto, PhD**
Patient Innovation
- **Marta Marques, PhD**
CHRC; NOVA Medical School
- **Nélia Gouveia, MD PhD**
NOVA-CRU; NOVA Medical School
- **Ricardo Leitão, MD PhD**
NOVA Medical School

COURSE EVALUATION

An anonymous evaluation questionnaire will be distributed to the students at the end of the course.

This questionnaire will assess several topics of the course such as its objectives and syllabus, the teaching and assessment methodologies and the Faculty.



REGISTRATION LINK

<https://bit.ly/3CC40R3>

CONTACTS

+351 218 803 066
posgraduacao@nms.unl.pt
www.nms.unl.pt