

May 2021

Semester description for: 3rd semester, Master in Science in Medicine with Industrial Specialisation - Fall 2021

Semester details

The study curriculum: Master in Science in Medicine with Industrial Specialisation

Semester framework theme

This should include an elaborated description in a prose form of the focus of the semester, activities implemented to fulfil the competence objectives and the thematic(s) of the semester. In other words, the semester description includes the "framework theme" that the students will be exposed to during the semester. The role of the semester and its contribution to students' academic progression should also be described.

During the second year of Master's (9th and 10th semester) students will work independently on projects outlined by a qualified supervisor. Projects can be of short duration (one semester-30 ECTS) whereby two projects are performed during the period of the final year. Alternatively, the projects can be of a long duration (two semesters-60 ECTS). During this period of time, the student will work on the research project outlined with adequate supervision from their supervisor. All projects have to be approved by the supervisor and the study leader. The Master students will be building on acquired knowledge and skills that has been obtained throughout the earlier semesters. Master students are allowed to collaborate with industry and require an internal contact person and University supervisor, the formality is such that an official agreement is made and approved before project start. Upon completion of the Masters project, the student should be at a level to enter the academic / industrial market.

Semester organisation and time schedule

This must be a short description the of the different activities of the semester, their mutual connections and the way in which they support each other and also support students in reaching their goals; such activities may be study trips, internship periods, project modules course modules, including laboratory activities, cooperation with external stakeholders, possible cross-disciplinary cooperation relations, any guest lectures and other events.

The 9th and 10th semester consists of either one long project that runs over the 2 semesters or two short projects. These are assessed in the form of a written report that is examined by oral examination with external censors. No courses are planned during this period. A status seminar will be held in the spring in the form of a progress report.

Semester coordinator and secretariat assistance

Names of anchorperson (teaching staff), course coordinator, semester coordinator (or similar title) and secretariat assistance provider(s).

Semester coordinator: Meg Duroux, <u>megd@hst.aau.dk</u>, Department of Health, Science and Technology Semester secretary: Dorthe Skree, <u>dsk@hst.aau.dk</u>, Department of Health, Science and Technology Student representative: Please check semester details on Moodle.

Module description (description of each module)

Module title, ECTS credits (and possibly STADS code)

Profile: BM,TM,MMA Master's Thesis / Kandidatspeciale 30 ECTS project module

Location

Master, Science in Medicine with Industrial Specialisation, 3rd Semester Study Board for Medicine

Module coordinator

The academic staff member responsible for the organisation and execution of the module. The module leader may be the same person as the semester coordinator. If a person responsible for exam is pointed out, please state name and e-mail address here.

Meg Duroux, <u>megd@hst.aau.dk</u>, Department of Health, Science and Technology.

Type and language

Module type (e.g. study subject module, course module, project module etc.) Language of instruction.

The projects should preferably be written in English, although Danish is allowed in agreement with the supervisor.

Objectives

Description of the content and objectives of the course as regards learning objectives of the students in the module. This comprises a transcript of the knowledge, skills and competences described in the study regulations and curriculum. Reference can be made to elaborations on semester Moodle site and/or to curriculum on Study Board website (applicable for MedIS and Medicine). https://studieordninger.aau.dk/2020/23/1811

From Curriculum:

The candidate programme in Medicine with Industrial Specialisation is composed of three health related profiles: Biomedicine, Translational Medicine and Medical Marketing. After completing this project module, the student is expected to have the knowledge, skills and competences outlined for the chosen profile outlined below.

Biomedicine

Knowledge:

- Demonstrate knowledge in one or more subject areas that is based on the highest international research level
- Explain in details advanced concepts and theories of molecular and cellular biology in human pathophysiology
- Explain in detail advanced key technologies used in biomedical research
- Explain how molecular and cellular biology can be used in clinical diagnostics
- Describe how molecular pharmacology can help to understand the mechanism of a drug
- Understand current trends and identify challenges in cell- and molecular-based assays used in biomedical research
- Summarise how manipulations of the immune system may alleviate, stop or avoid disease processes
- Describe the principles of molecular therapy using small molecule, protein based drugs or gene therapy
- Understand the translational similarities and differences between animal models of major diseases and human pathophysiology
- Describe how molecular pharmacology can help understanding how drugs works against a pathogenesis

- Explain how different regenerative and tissue engineering approaches can be used to treat human diseases
- Explain how precision and personalised medicine approaches can be used to optimise diagnostics and treatment of human diseases

Skills:

- Investigate and critically assess relevant scientific literature
- Understand and reflect on new knowledge and identify scientific problems
- Understand and reflect on the regulations, guidelines and ethical requirements of preclinical and clinical studies (including concepts of data and sample collection, biobanking, data handling and reporting)
- Design an experimental study to address a scientific problem
- Evaluate and select molecular methods to solve a scientific problem
- Qualitatively and quantitatively analyse and interpret results from molecular experiments
- Communicate research-based knowledge and discuss scientific problems with both peers and nonspecialists
- Present ideas and results of experiments clearly to a specific audience in both oral and written form
- Identify appropriate sources of materials and interpret the corresponding specification datasheets to design experimental protocols

Competences:

- Manage a scientific project
- Collaborate to solve complex scientific problems
- Independently initiate and implement discipline-specific and interdisciplinary cooperations
- Independently take responsibility for own professional development and specialisation
- Suggest likely targets for molecular therapy based on genetic, proteotypic or phenotypic manifestations
- Combine the theoretical knowledge about genomes, proteomes and metabolomes with the ability to perform laboratory experiments in order to design a diagnostic or analytical protocol
- Analyse and interpret molecular data such as DNA sequences, mRNA and proteins using bioinformatic tools
- Compare and suggest suitable forms of protein, immunotherapy, stem cell therapy, regenerative medicine and precision medicine for a series of typical patients
- Analyse disease processes or responsiveness to treatment using relevant methods

Translational Medicine

Knowledge:

- Demonstrate knowledge of core principles of translational research principles applied in research and drug/devise development
- Describe the legal and organisational framework of translational medicine
- Understand and scientifically reflect over the relevant knowledge and identify scientific problems in translational research
- Demonstrate knowledge of core principles of research pharmacology based on the highest international knowledge in modern pharmacology
- Understand scientific problems and challenges in translational research and drug development and how to reflect on scientific and statistical challenges
- Have an in depth understanding of different steps for planning, practical execution, completion and evaluating clinical trials
- On a scientific, analytical and ethical basis, reflect over the relevant knowledge and identify scientific problems
- Demonstrate an in depth understanding of different translational models and approaches from a multi- and interdisciplinary perspective
- Understanding scientific problems and challenges in translational research
- Understand how to transfer laboratory discoveries into new methods for diagnosis, preventing and treating diseases plus testing these methods in humans

Skills:

- Formulate and analyse all documents and regulations involved in planning, practical execution, completion and evaluating clinical trials
- Suggest how Good Clinical Practice and Good Manufacturing Practice can be implemented and maintained
- Suggest submission processes in relation to EMA and FDA
- Apply methods and tools to analyse current pharmacology research projects, to evaluate obtained data, to predict or interpret findings and to communicate these by scientific presentations
- Suggest relevant biomarkers to be applied in translational research
- Develop new biomarkers as proxies for specific mechanisms and diseases
- Analyse, compare and discuss critically and systematically different forms of clinical trials concerning design and statistical models
- Explain topics essential for translational medicine and drug/medical device development
- Apply a set of principles and methods at any stage from design to conduction and reporting a clinical trial at any phase from phase I to phase IV
- Apply rules and guidelines to conduct and monitor a trial, report of post-marketing drug surveillance, adverse reactions, pharmacovigilance and the health economical perspectives
- Explain topics essential for translational medicine and drug/devise development
- Assess or predict mechanisms of action or potential side-effects of drugs/devices for a certain disorder or condition
- Write research and clinical trial protocols for research in translational medicine and choose suitable methodology and apply appropriate statistics and data handling principles
- Apply research questions to translational biomedical research
- Investigate and critically assess relevant scientific literature

Competences:

- Formulate and execute translational research projects
- Formulate research proposals to identify mechanisms of action or potential side-effects of new drugs/devises for a certain disorder or condition
- Analyse analytically and statistically clinical trial data
- Design clinical trials utilising translational knowledge and biomarkers
- Plan research project concerning approval, conduct ethical considerations and relate relevant aspects of translational medicine with advanced concepts in biomedicine
- Assess safety and efficacy of drugs/medical devices considering global benefits to people and economies utilising
- guidelines, standards, tools and approaches
- Scientifically reflect over the relevant knowledge and identify scientific problems in translational research
- Critically evaluate the importance of basic research into a translational context
- Being able to participate into translational science discussions, which explore a variety of approaches in order to solve big real-world problems

Medical Market Access

Knowledge

- Understand scientific problems within medical market access
- Demonstrate an in-depth understanding of different health economic analysis and approaches from a multi- and interdisciplinary perspective
- Describe basic marketing theories and strategies with a focus on application within the health sector
- Outline the health care system's organisation and financing, including the central differences between different health systems
- Demonstrate an in-depth understanding of quality in healthcare
- Identify a company's need for information on key market conditions

Skills

- Investigate and critically assess relevant scientific literature
- Design a health economic analysis, including the collection of both patient-specific data and registerbased data
- Design a market analysis for a topic related to the health care system, including the collection of both qualitative and quantitative data

- Analyse and interpret a health economic analysis, including sensitivity analysis and budget expenditures
- Analyse problems in relation to quality and discuss potential solutions for quality improvements in healthcare
- Discuss the potential consequences of changes to the organisation and financing of the health system, including prioritisation

Competences

- Scientifically reflect over the relevant knowledge and identify scientific problems in medical market access
- Being able to participate in health economic and market access discussions, which explores a variety of approaches to solving real-world problems
- Critically appraise results from the highest international research relevant to a scientific medical problem
- Critically assess existing economic analysis and alternative models of financing and organising in the health sector
- Contribute to planning and evaluation of projects and strategies for improving economic and quality problems in healthcare
- Create a decision-analytic model to support decision making in healthcare
- Develop advanced health economic analysis, including economic evaluations (cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis etc.), budget analysis, cost-of-illness analysis, HTA reports

Academic content and conjunction with other modules/semesters

A brief and general description of the academic content of the module as well as the basis and motivation for the module; i.e. a brief review of the content and foundation of the module. The intention is to provide students with an overview of each module and to create understanding of the

module in relation to the semester and the entire program.

The 9th and 10th semester requires the student to use the skills and knowledge acquired from their bachelor and the first 2 semesters of their Masters. New skills and techniques are often introduced during this time period.

Scope and expected performance

The expected scope of the module in terms of ECTS load. This comprises number of teaching hours, exercises, preparation time, travel activity (if applicable) etc.

Participants

Indication of the participants in the module, particularly if they include several year groups, programmes or another type of co-teaching.

Students on the 9th and 10th semester Medicine with Industrial Specialisation (MedIS)

- Biomedicine
- Translational Medicine
- Medical Market Access

Prerequisites for participation

Description of the prerequisites for students' participation in the course, i.e. previous modules/courses in other semesters etc. The overall intention is to emphasise the coherence of the programme. This may be a transcript of the text in the study regulations and curriculum.

A completed Bachelor's degree (B.Sc.) in Medicine, Biotechnology, Molecular Medicine, MedIS or similar.

Module activities (course sessions etc.)

The 9th and 10th semester does not include any courses. The student is expected to work fulltime with the help and guidance of their supervisor to achieve the research aims outlined in the project description. There is no delimitation to the project theme and this should encompass the knowledge, competences and skills outlined for the specific profile.

Examination

Eksamen

1. The exam will take the form of an oral exam based on the project learning outcomes and content.

2. The project will be delivered digitally (DE)

3. Project exam will be conducted in the presence of internal supervisor (external supervisor if part of cosupervision -external to AAU or campany) and external censor.

4. The oral project exam will start with a presentation of the project work and will be followed by questions.

We refer to the webpage concerning exams https://www.hst.aau.dk/uddannelser/Undervisning+og+eksamen/

Desciption of group based project exams: https://www.hst.aau.dk/uddannelser/Regler+og+formularer/Gruppebaseret+projekteksamen/

Link to digital exams: Digital Eksamen (DE)