Januar 2020

Semester description for:
2nd semester, Master in Science in Medicine with Industrial Specialisation - Spring 2020

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.

The programme is structured into three profiles: Biomedicine (BM), Translational Medicine (TM), and Medical Market Access (MMA). Biomedicine focuses on the understanding of causes and treatment of disease at the molecular and cellular level. Students will learn human pathophysiology and how to identify new targets for treatment. Translational medicine is driven by the objective of improving clinical outcomes by efficiently moving results from basic science to clinical application. Clinical trials considering all aspects is the focus of this semaster for TM students. BM and TM students also have a common course in which aspects of molecular therapy will be covered that can be beneficial from molecular levels for BM students and at the applicability in clinical trials for TM students. Medical Market Access is driven by the objective to improve market access of industry within the biotechnological, pharmaceutical and medical devices markets. Students will focus on Economics of Health Technologies and Technology Assessment and Non-Experimental Research Design and Analysis. All students will also learn Regulatory and Ethical Aspects of Clinical Research at a general level applicable for BM, TM and MMA.

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.

Definitions of course activities
The semester applies a combination of academic, problem-oriented and interdisciplinary approaches and organised based on the following work and evaluation methods that combine skills and reflection (depends on the course and topic). See below list. All forms are included in this semester.

Lecture – a 45-90 minutes presentation by teacher
Workshop/Exercise – a scheduled activity allowing students to solve and discuss problems in small groups with the option of feedback from teachers
Discussion – a scheduled time-slot for discussion of specific subjects among students and teacher(s) **Student presentation** – lectures prepared by students typically presenting how they have solved a specific problem
Problem solving – students solve problems defined by the teacher and related to a subject
Self-Study – Student is responsible for reading up on a selected topic of interest that is not covered during lectures that will assist them in their case presentations.
Case exercises – Question-driven discussions and evaluation of content for selected readings, including journal articles and patient case examples.
Case presentations – Presentation of a journal article or patient case example
Seminar - scheduled study activity in which students present the task they are doing, in order to feedback from teachers and fellow students.
Mini Project - students prepare in small groups a project - a self-chosen task, which allows them to train skills in project management.

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

Semester coordinator(s): Parisa Gazerani, gazerani@hst.aau.dk , and Tue Bjerg Bennike tbe@hst.aau.dk, Department of Health, Science and Technology
Semester secretary: Dorthe Skree, dsk@hst.aau.dk , School of Medicine and Health Student representative: Please check semester details on Moodle.

Module description (description of each module)

Module title, ECTS credits (and possibly STADS code)
Profile: TM, BM and MMA
Regulatory and Ethical Aspects of Clinical Research / Regulatoriske og etiske aspekter iklinisk forskning
5 ECTS course module

Location
Master, Science in Medicine with Industrial Specialisation, 2nd semester
Board of Studies 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.

Parisa Gazerani, gazerani@hst.aau.dk, Department of Health science and Technology

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

This course consists of formal lectures and in-class activities, for further practice and will be delivered in English.

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).

From The Study Curriculum:

After attending this course, the student is expected to:

Knowledge
- Describe the legal framework of translational medicine
- Describe the regulatory process, including Good Clinical Practice, Good Laboratory Practice and Good Distribution Practice (GCP, GLP, GDP)
- Discuss the institutions and factors governing the conduct of research (legislation, boards, and guidelines)
- Explain the Danish requirements for and process of obtaining approval of experiments with animals and with humans, in particular relating to drug testing
- Discuss the interests and needs of healthy and ill subjects in research
- Reflect on the concept “conflicts of interests” in terms of researchers and other actors (e.g. manufacturing companies, contract research companies, and patient organisations)
- Discuss the issue of access to research results and research data
- Discuss the concept “scientific fraud” and the related institutions in public and private research

Skills
- Explain the role of the end user
- Identify actors and their driving forces in research
- Suggest how Good Clinical Practice, Good Laboratory Practice, Good Distribution Practice can be implemented in a specific experiment/research project or manufacturing process
- Relate Good Manufacturing Practice to the work with research
- Discuss the importance of following

Competences

- Provisionally plan a (small) research project concerning approval, conduct and ethical considerations
  Analyze case studies of clinical trials

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 programme.

The purpose of this module is to prepare students with current knowledge on ethical requirements and regulations for conduct of human research. It also gives a short refresher to animal ethics for translational studies purposes. Students will gain hands on cases and will practice to gain skills for writing protocols, and apply for approvals and will be familiar to use good practices in research, lab, clinic, and drug production and distribution. In this module, students will also gain competences to discuss diverse aspects of course topics within the framework of their own track with examples and cases and this has been well balanced among tracks of BM, TM, and MMA to provide similar level of benefit from the content of the course. It is arranged in line with 3 different tracks of within the area of health care system for the entire semester

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.

The module comprises lectures and classroom activities on various theoretical subjects, discussion of papers, work with study problems, presentations by students, and lectures by experts in drug and medical device development in terms of ethical aspects and regulation. Students are required to actively participate in module and to write a "mini project".

Since active participation from students in lectures, discussions, and work on study problems during the module is expected, attendance will be recorded. Workload will correspond to the 5 ECTS credits (i.e. 150 hours) provided by the course and the workload is described as follow:

There are 11 actual in person sessions, one e-learning, one pharmacy tour, and one self-study session, each considered as number of 45 min (could be from 2 to 9, please see the table below) that include lectures and practices in form of exercises, cases (work with literature and study problems at class-room), student presentations, and discussion. This makes 45 hours in total. There are 3-4 hours workload of home reading and preparations before or after each session (in total 60 hours). Additionally, in order for students to pass the module, a mini-project with an expected work load of approximately 45 hours should be prepared (consisting self-study, development and writing on a topic related to the module) to be submitted for the final exam. This makes it total of 150 hours for the entire module.

Participants

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

Master students in the second semester of the MedIS master program (MedIS 8).

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.
Participation in all exams of the 1. Semester. In other words, students are expected to have passed first semester in MedIS master.

Recommended literature:

This course covers rules and regulations and is heavily based on authorities' webpages, links, and suggested materials that will be posted by lecturers. There is no one single book to be offered for this course. Lecturers may suggest or offer book or book chapters related to own sessions. Students are encouraged to follow the lectures, lecture notes and literature proposed by each teacher. For each lecture, or session, the points from the study curriculum will be presented and extended learning objective expected from each lecture-session will be added for further and deeper details, in which eh students can find where to put emphasize to fulfill the learning objectives.

Module activities (course sessions etc.)

Level 1

Activity - type and title	**Planned instructor***	**Learning goals from curriculum**	**Time consumption**
Course introduction	Parisa Gazerani, HST	Describe the legal frame-work Describe the regulatory process, including Good Practices in general Discuss the legislation, boards,and Guidelines including the Danish requirements	E-learning, posted materials introduction to module + module structure, activities and mini project
Ethical theory basis for conduct of human research	Jes Lynning Harfeld, Institute for culture and learning	Discuss ethical and legal issues, and concerns of phi-losophers, lawyers, policy- makers, and scientists. Discuss the differences between values morals and ethics. Discuss why research with human participants requires ethical approval. Discuss the interests and needs of healthy and ill sub- jects in research Reflect on the concept “conflicts of interests” Discuss the issue of access to research results and re- search data Discuss the concept “scientific fraud”	6x45 min lecture (4x45 min) + discussion of practical tasks about conduct of human research (self-learning)
How to prepare an ethics protocol	Lone Schødt Andersen, HST	Explain the Danish requirements for and process of obtaining approval of experiments with humans, in par- ticular relating to drug testing	2x45 min lecture + 90 min self- study practice

	GMP	Anne Estrup Olesen (Clinical Institute) or Jeanette Prangsgaard (HST)	Describe the regulatory pro- cess of Good Practice of GMP Relate Good Manufacturing Practice to the work with re- search	2x45 min lecture + 2x45 min self-study practice on cases, and examples
	Drug Management	Hanne Plet, Hospital Pharmacy, Region North	Explain the role of the end user Identify actors and their driving forces in drug research	4x45 min lectures
	GDP	Hanne Plet, Hospital Pharmacy, Region North	Describe the regulatory pro- cess, including Good Prac- tice in Distribution, GDP + Discuss the importance of this	4x45 min lectures
	Biobanking	Parisa Gazerani, HST	Good Laboratory Practice and institutions and factors governing the conduct of research Discuss the importance of the above	2x45 min lecture + 2x45 self-reflection and self-study on bi- obanking and personal data handling, data security
	GCP I, II	GCP unit, Aalborg and Aarhus Uni- versitet hospitals, Sanne Andersen, and Birgitte Olrik Schlemmer (Aarhus)	Describe the regulatory pro- cess, Good Clinical Practice Discuss the importance of the above	9x45 min lectures + classroom activities for reflections on learning
	Ethical aspects from a Medical Market perspective	Louise Hansen or related colleagues, Clinical Institute, Center for Health Economy	Identify actors and their driving forces in research Reflect on the concept “conflicts of interests” in terms of researchers and other ac- tors (e.g. manufacturing companies, contract research compa nies, and patient organisations)	4x45 min lectures
	Medical device development and regulations	Federico Gabriel Arguissain, HST or Romulus Lontis, HST	Analyze case studies of clinical trials of medical devices Relate Good Manufacturing Practice to the work with re- search Discuss the importance of this Explain the role of the end user Describe the legal framework	4x45 min lecture + 2x45 min discussion in students groups (in class room activity and presentation)

Animal research ethical regulations	Winnie Jensen, HST	Explain the Danish require- ments for and process of obtaining approval of exper- iments with animals in par- ticular relating to drug test- ing	4x45 lecture or posted for flipped class room
Mini project activities	Self-study	Analyze case studies of clinical trials	4x45 self-study on the mini project case
Hospital pharmacy tour*	Hanne Plet, Hospital Pharmacy, Region North	Process of drug production and distribution	2x45 min tour Hospital pharmacy tour (*optional)

** All rights reserved for changes during the semester due to e.g. illness, cancellations etc.*

Examination

Exam plan: https://www.hst.aau.dk/uddannelser/Undervisning+og+eksamen/

Type of examination: DE with requirement of eligibility (active attendance (50% of the course time)) and writing a "mini project" for submission to DE as final evaluation of the course, with all types of helps available:

1. Attendance: The students are expected to attend at least half of the sessions of the module. Self- studies and flipped classrooms, tours and similar are not included.
2. The final examination of the module will take place like this: Each student will have to personally write a "Mini project". The mini project will be introduced to the students at the beginning of the course. The students must upload the personal mini project into the AAU digital exam system before the given deadline.
3. The written mini project will reveal if the students have obtained the competences described in the curricu- lum. These competences is being taught during the session through lectures (live and posted), self-study on cases, and group work at classroom, presentations and discussions.
4. The mini project will be evaluated using the 7-step grade system and one grade will be given.

We refer to webpage concerning exams at Digital Eksamen (DE).

Module description (description of each module)

Module title, ECTS credits (and possibly STADS code)
Immuno- and Molecular Therapy / Immun- og molekylærterapi
5 ECTS course module

Location
Master of Science in Medicine with Industrial Specialisation, 2nd 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.

Ralf Agger, agger@hst.aau.dk
Department of Health Science and Technology

(Ralf Agger organizes the immunotherapy part of the course, Maj Schneider Thomsen organizes the molecular therapy part of the course)

Responsible for the exam:

Ralf Agger, agger@hst.aau.dk
Department of Health Science and Technology

Maj Schneider Thomsen, mst@hst.aau.dk
Department of Health Science and Technology

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

English. All written materials will be in English. The course is based on sessions which include lectures and work with study problems and discussion in plenum.

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).

From Curriculum:

After attending this course, the student is expected to:

Knowledge
- Summarize how manipulations of the immune system may alleviate, stop or avoid disease processes
- Argue how proteins and products of the immune system (antibodies, cytokines and cells) can be utilized as therapeutic agents either as such or in conjugation with drug-encapsulated carriers

Skills
- Summarize the mechanisms of action of different forms of protein and immunotherapy
- Design experiments in protein and immunotherapy

Competences
Compare and suggest suitable forms of protein and immunotherapy for a series of typical patients and give reasons for the choices.

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 programme.

The course builds on the qualifications in biochemistry, cell biology, pathology, and immunology acquired in the bachelor program of Medicine with Industrial Specialization or in similar bachelor programs. Furthermore, the course draws on the course on molecular and cellular methods in biomedicine taught on the 1st semester of the master programme in Medicine with Industrial Specialization.

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.
The module is divided in two: The first five sessions will be on immunotherapy and the following five sessions will be primarily related to molecular therapy. The course comprises lectures on various theoretical subjects, discussion of papers, work with study problems, presentations by students, and lectures by clinicians.

The total load of 5 ECTS (150 hours) is distributed between:
The course consist of 9 sessions with the following activities:

- **Lecture**: Two lectures per session 1-9 (90 min (approximately) = total 13.5 hours)

- **Workshop/Exercise:** The remaining time after lectures (session 1-9, 90 min (approximately): 13.5 hours; session 10, 180 min: 3 hours = Total 16.5 hours) will be used for practices in form of exercises, cases (work with literature and study problems), student presentations and discussion in plenum with feedback from the course organiser.

- **Self-Study** – Student are expected to prepare for each session 9hours
- **Preparation for exam** 30 hours

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

Biomedicine and translational medicine students (BM/TM)

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.

Passed course in basic immunology (module 2.3 of the AAU medicine/medIS bachelor programme or equivalent). Passed course on proteomic and genomics ("Proteomics and Genomics in Diagnostics and Disease" on the AAU medIS master programme or equivalent).

Module activities (course sessions etc.)

Level 1

Activity - type and title	**Lecturer including department affiliation***	**Learning goals from curriculum**
Immunotherapy session 1. Lecture: "Transplantation immunology and immunosuppressive drugs - with an introduction to immunotherapy" Clinical lecture: "Kidney transplantation and how to avoid rejection" (Titles of lectures are preliminary) Work with study problems and discussion in plenum	Ralf Agger, HST, AAU (Maj Schneider Thomsen, HST, AAU: introduction to molecular therapy) Birgitte Bang Pedersen, consultant, Dept. of Nephrology, Aalborg University Hospital.	**Knowledge** • Summarize how manipulations of the immune system may alleviate, stop or avoid disease processes • Argue how proteins and products of the immune system (antibodies, cytokines and cells) can be utilized as therapeutic agents either as such or in conjugation with drug-encapsulated carriers **Skills** • Summarize the mechanisms of action of different forms of protein and immunotherapy • Design experiments in protein and immunotherapy **Competences** • Compare and suggest suitable forms of protein and immunotherapy for a series of typical patients and give reasons for the choices.
Immunotherapy session 2. **Lecture:** "Immunostimulatory and immunomodulatory drugs (-imex and -imod)" **Clinical lecture:** "Immune therapy in MS" (Titles of lectures are preliminary)" Work with study problems and discussion in plenum	Emil Kofod-Olsen, HST, AAU Claudia Pfleger, Dept. of Neurology, Aalborg University Hospital.	**Knowledge** • Summarize how manipulations of the immune system may alleviate, stop or avoid disease processes • Argue how proteins and products of the immune system (antibodies, cytokines and cells) can be utilized as therapeutic agents either as such or in conjugation with drug-encapsulated carriers **Skills** • Summarize the mechanisms of action of different forms of protein and immunotherapy • Design experiments in protein and

		immunotherapy **Competences** • Compare and suggest suitable forms of protein and immuno therapy for a series of typical patients and give reasons for the choices.
Immunotherapy session 3. **Lecture:** "New and experimental forms of immunotherapy in cancer" **Clinical lecture:** "Immune checkpoint blockade as a treatment for cancer" (Titles of lectures are preliminary)" Work with study problems and discussion in plenum	Ralf Agger, HST, AAU Andreas Carus, Dept. of Oncology, Aalborg University Hospital	**Knowledge** • Summarize how manipulations of the immune system may alleviate, stop or avoid disease processes • Argue how proteins and products of the immune system (antibodies, cytokines and cells) can be utilized as therapeutic agents either as such or in conjugation with drug-encapsulated carriers **Skills** • Summarize the mechanisms of action of different forms of protein and immunotherapy • Design experiments in protein and immunotherapy **Competences** • Compare and suggest suitable forms of protein and immuno therapy for a series of typical patients and give reasons for the choices.
Immunotherapy session 4. **Lecture:** "Tissue damage induced by the immune system" **Clinical lecture:** "Biologic treatment in rheumatoid arthritis" (Titles of lectures are preliminary)" Work with study problems and discussion in plenum	Emil Kofod-Olsen, HST, AAU Line Uhrenholt, Dept. of Rheumatology, Aalborg University Hospital	**Knowledge** • Summarize how manipulations of the immune system may alleviate, stop or avoid disease processes • Argue how proteins and products of the immune system (antibodies, cytokines and cells) can be utilized as therapeutic agents either as such or in conjugation with drug-encapsulated carriers **Skills** • Summarize the mechanisms of action of different forms of protein and immunotherapy • Design experiments in protein and immunotherapy **Competences** • Compare and suggest suitable forms of protein and immuno therapy for a series of typical patients and give reasons for the choices.
Immunotherapy session 5. **Lecture:** "Tolerance and autoimmunity" **Clinical lecture:** "Autoimmune diseases with focus on SLE and ANCA-associated vasculitis" (Titles	Ralf Agger, HST, AAU Jon Waarst Gregersen, Dept. of Nephrology, Aalborg University Hospital.	**Knowledge** • Summarize how manipulations of the immune system may alleviate, stop or avoid disease processes • Argue how proteins and products of the immune system (antibodies, cytokines and cells) can be utilized as therapeutic agents either as such or in conjugation with drug-

of lectures are preliminary)" Work with study problems and discussion in plenum		encapsulated carriers **Skills** • Summarize the mechanisms of action of different forms of protein and immunotherapy • Design experiments in protein and immunotherapy **Competences** • Compare and suggest suitable forms of protein and immuno therapy for a series of typical patients and give reasons for the choices.
Molecular therapy session 1 - Peptide and protein therapeutics Lecture 1: "Introduction to the module: Immuno- and Molecular Therapy" Lecture 2: "Peptide and protein therapeutics" Lecture 3: "TBA"	Maj Schneider Thomsen, HST, AAU TBA	**Knowledge** • Argue how proteins and products of the immune system (anti- bodies, cytokines and cells) can be utilized as therapeutic agents either as such or in conjugation with drugencapsulated carriers **Skills** • Summarize the mechanisms of action of different forms of protein and immunotherapy • Design experiments in protein and immunotherapy **Competences** • Compare and suggest suitable forms of protein and immuno therapy for a series of typical patients and give reasons for the choices.
Molecular therapy session 2 – Gene therapy Lecture 1 and 2: "Viral and Non-viral drug delivery" Work with study problems and discussion in plenum	Annette Burkhart Larsen, HST, AAU Charlotte L. M. Rasmussen, HST, AAU	**Knowledge** • Argue how proteins and products of the immune system (anti- bodies, cytokines and cells) can be utilized as therapeutic agents either as such or in conjugation with drug-encapsulated carriers **Skills** • Summarize the mechanisms of action of different forms of protein and immunotherapy • Design experiments in protein and immunotherapy **Competences** • Compare and suggest suitable forms of protein and immuno therapy for a series of typical patients and give reasons for the choices.
Molecular therapy session 3 – Targeted theapy Lecture 1: "Targeted delivery"	Maj Schneider Thomsen, HST, AAU Torben Moos, HST, AAU	**Knowledge** • Argue how proteins and products of the immune system (anti- bodies, cytokines and cells) can be utilized as therapeutic agents either as such or in conjugation with drug-encapsulated carriers

Lecture 2: "Macromolecular drug transport into the brain using targeted therapy" Work with study problems and discussion in plenum		**Skills** • Summarize the mechanisms of action of different forms of protein and immunotherapy • Design experiments in protein and immunotherapy **Competences** • Compare and suggest suitable forms of protein and immuno therapy for a series of typical patients and give reasons for the choices.
Molecular therapy session 4 – Nano carriers and their formulation Lecture 1 and 2: "Multifunctional Nanocarrier systems, their formulations and clinical value" Work with study problems and discussion in plenum	TBA Kasper Bendix Johnsen, DTU Health Tech	**Knowledge** • Argue how proteins and products of the immune system (anti- bodies, cytokines and cells) can be utilized as therapeutic agents either as such or in conjugation with drug-encapsulated carriers **Skills** • Summarize the mechanisms of action of different forms of protein and immunotherapy • Design experiments in protein and immunotherapy **Competences** • Compare and suggest suitable forms of protein and immuno therapy for a series of typical patients and give reasons for the choices.
Molecular therapy session 5 – Follow up. Student presentations and discussion in plenum.	Maj Schneider Thomsen, HST, AAU	**Skills** • Summarize the mechanisms of action of different forms of protein and immunotherapy • Design experiments in protein and immunotherapy **Competences** • Compare and suggest suitable forms of protein and immuno therapy for a series of typical patients and give reasons for the choices.

Examination

1. Written exam and Digital Exam (www.de.aau.dk) will be used.

2. The students will be tested in their knowledge, skills, and competences obtained through the module by answering multiple choices, short and long assay questions, and cases.

3. The exam:
    a. Duration: 2 hours
    b. Remember to bring your student identification card
    c. Please make sure to install the program ITX-Flex. AAU takes no liability if there arise problems with your electronic equipment Dataset and written materials.

d. Digital Exam Questions are in English (NB! There will be no dictionaries available).
e. The answers may be in English or Danish
f. No form of communication with other examinees is allowed
g. No aids of any kind are allowed

For further information about examination, we refer to: Digital Eksamen (DE)

Module description (description of each module)

Module title, ECTS credits
Profile: BM
Regenerative Medicine / Regenerativ medicin
5 ECTS course module

Location
Master, Science in Medicine with Industrial Specialisation, 2nd semester
Board of Studies 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.

Vladimir Zachar, vlaz@hst.aau.dk, HST

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

Course module in English

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).

From Curriculum:

After attending this course, the student is expected to:

Knowledge
Has knowledge about engineering, developmental, molecular biological, biological, and medical concepts

Skills
- Can apply an understanding of the processes that determine at the molecular level cellular responses into schemes that aim to replace human tissues or organs, or aim at the restoration of physiological state of thereof
- Can design rational biotherapies for relevant human diseases using appropriate set of engineering and molecular biological tools
- Can assess the prospective value of proposed solutions, including medical significance and feasibility, both at the theoretical and empirical levels
- Can apply different regenerative and tissue engineering approaches to treat intractable human diseases.

Competences
- Must have insight into molecular processes that underlie cell-cell as well as cell-material interactions and must understand how knowledge of these processes can be applied for the benefit of tissue regeneration in vivo and engineering of tissues in vitro.
- Can research, synthesize, and critically appreciate knowledge available across different fields to account for treatment options that are viable from the point of currently established medical criteria

- Can evaluate and identify novel areas of interest, the theoretical and practical knowledge of is necessary, in order to accomplish a successful regenerative therapeutic paradigm.

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 programme.

The module addresses in the first part interactions between the cells and biomaterials and the properties of stem cells. In the second part, the previous knowledge is used to obtain a deeper understanding of cell-based and tissue eingineering approaches to treat pathological conditions of major organ systems.

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.

The total load of 5 ECTS is in the form of a study group and is distributed between:

Lectures – The total is 15 lectures, this gives 10 hrs per lecture of student work. Each lecture is being a 45-90 minutes introduction into the theme.

Problem solving – With each lecture students solve problems defined by the teacher and related to a subject for 90 – 135 min. Solutions to the problems are presented by students and discussed at the end of this period.

Self-Study – Student is responsible for reading up on a selected topic of interest that is not covered during lectures that will assist them in their case presentations. Takes 5 hrs per lecture.

Preparation for exam – 1hr per lecture

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

MedIS students

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.

Participation in exams on 1st semester

Module activities (course sessions etc.)

Activity - type and title	Planned instructor*	Learning goals from curriculum	Time consumption
Lecture: Cell fate	V. Zachar, HST	• Basic cell responses Reg. medicine intro, signal transduction, cell survival	125 min combined lecture and group work + preparation for lecture

Lecture: Extracellular matrix and environment	C.P. Pennisi, HST	• Basic cell responses Extracellular molecules, cell responses to environment	125 min combined lecture and group work + preparation for lecture
Lecture: Biomaterials and biocompatibility	C.P. Pennisi, HST	• Cell-material interactions Chemistry of biomaterials, surface topography and physical properties	125 min combined lecture and group work + preparation for lecture
Lecture: Tailoring biomaterials	C.P. Pennisi, HST	• Cell-material interactions Cell responses to 2- and 3- dimensional matrices, manufacturing of scaffolds	125 min combined lecture and group work + preparation for lecture
Lecture: Pluripotent stem cells	V. Zachar, HST	• Cell and molecular responses Types and biology of pluripotent stem cells, differentiation stratagies, therap. applications	125 min combined lecture and group work + preparation for lecture
Lecture: Somatic stem cells	H. Alipour, HST	• Cell and molecular responses Types and biology of somatic stem cells, differentiation stratagies, therap. applications	125 min combined lecture and group work + preparation for lecture
Lecture: Neural regeneration	F. Febbraro, HST	• Specific regenerative approach Structure of nervous system, regeneration of CNS and PNS	125 125 min combined lecture and group work + preparation for lecture
Lecture: Cartilage regeneration	V. Zachar, HST	• Specific regenerative approach Structure of cartilage, approaches to regenerate cartilage	125 min combined lecture and group work + preparation for lecture
Lecture: Bone regeneration	T. Fink, HST	• Specific regenerative approach Structure of bone, approaches to regenerate bone	125 min combined lecture and group work + preparation for lecture

Lecture: Skeletal muscle regeneration	C.P. Pennisi, HST	• Specific regenerative approach Structure of skeletal muscle, approaches to regenerate skeletal muscle	125 min combined lecture and group work + preparation for lecture
Lecture: Smooth muscle regeneration	J. Emmersen, HST	• Specific regenerative approach Structure of smooth muscle, approaches to regenerate smooth muscle	125 min combined lecture and group work + preparation for lecture
Lecture: Corneal regeneration	L. Liu, NovoNordisk	• Specific regenerative approach Structure and physiology of corneal limbus, approaches to regenerate cornea	125 min combined lecture and group work + preparation for lecture
Lecture: Cell-based therapies for wound healing	S. E. Riis, HST	• Specific regenerative approach Pathophysiology of chronic wounds, approaches to treat chronic wounds	125 min combined lecture and group work + preparation for lecture
Lecture: Regeneration of heart	F. Dardmeh, HST	• Specific regenerative approach Cell-based therapy of heart from a clinical perspective	125 min combined lecture and group work + preparation for lecture

Examination

Will be in Digital Exam (www.de.aau.dk)
Will be in written format for 2 hours.
Evaluation form: 7-grade scale
Exam responsible: Vladimir Zachar
Important information:

Remember to bring your student identification card
Meet one hour before the start of the exam
Program Exam Monitor should be installed on your PC https://aau.exammonitor.dk
School/AAU takes no liability if there arise problems with your electronic equipment
Dataset and written materials are provided by Digital Exam www.de.aau.dk
Answers are done in Digital Exam
Questions are in English (NB! There will be no dictionaries available)
The answers may be in English or Danish
Any communication or attempt to communicate by examinees´ electronic devices during the exam with unauthorized equipment will be qualified as cheating
No form of communication with other examinees is allowed
***No aids are allowed

We refer to webpage concerning exams at DE. Exam plan can be found here:
https://www.hst.aau.dk/uddannelser/Regler+og+formularer/Eksamensplaner/

Module description (description of each module)

Module title, ECTS credits (and possibly STADS code)
Profile: BM
Personalised Medicine / Individualiseret medicin
15 ECTS project module

Location
Master, Science in Medicine with Industrial Specialisation, 2nd semester
Board of Studies 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.

Maj Schneider Thomsen, mst@hst.aau.dk, Department of Health Science and Technology

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

Projects can be written in Danish or English.

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).

From Curriculum:

After completing this module, the student is expected to:

Knowledge
- Explain the concepts and problems related to personalized medicine

Skills
- Apply theoretical knowledge relevant to the biological system of interest
- Design a proper experimental study
- Compare and choose relevant experimental methods

Competences
- Formulate a working hypothesis and teach the students how to test these hypotheses using relevant methods in order to obtain control of a disease process
- Integrate core knowledge and skills related to personalized medicine
- Critically demonstrate an understanding at the theoretical and practical level on relevant methodology used for testing biomedical hypotheses.

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 programme.

Project theme in BM profile is “Personalised Medicine”. The project is supposed to cover concepts and problems related to personalized medicine. It is highly important that the project includes experiments to allow the students to work in depth on the topic.

Scope and expected performance

The project is planned to encompass 15 ECTS/450 hours/half of the semester. The students are supposed to do intitial theoretical preparations (est. 50 hours) followed by the practical work (est. 300 hours), report writing (est. 75 hours) and reading and preparations to the exam (est. 25 hours) the practical work in the laboratory and meetings with the supervisor.

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

Students who have passed the first semester of the profile Biomedicine can write project in this semester. Since there are some BM/TM projects, it can be extended to some aspects of TM profile in case of the BM/TM definition in the project.

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.

Students are expected to be able to explain the concepts and problems related to personalized medicine.

Module activities

Students are supposed to formulate a working hypothesis with the aid of supervisors and to come up with methods on how to test these hypotheses using relevant methodological considerations. In the project work and report, the students are assumed to integrate core knowledge and skills related to personalized medicine and to be able to demonstrate theoretical and practical level on relevant methodology used for testing biomedical hypotheses.

Examination

The exam will be an oral group exam based on the submitted project.
During the exam, the students will be assessed on the progression of their knowledge, skills and competences as described in the curriculum.
The oral examination form was chosen to facilitate the evaluation of their abilities to work problem-based with a specific topic and to demonstrate their abilities to discuss an academic topic on an appropriately scientific level.
Present at the exam will be the students, the internal supervisor, potential co-supervisors, and an external censor. The exam will be evaluated by the internal supervisor and the external censor. The exam with be assessed using the 7 point scale.
The students are expected to give a short presentation (10 min per student) of the project at the beginning of the oral exam. The length of the exam will be 45 minutes per student.
Aids (the project report and notes) will be allowed
The project report should be handed in using digital exam (www.de.aau.dk)

If the exam format is changed before the reexam, this will be announced no later than 14 days before.
For more information please consult

- The exam plan on https://www.hst.aau.dk/uddannelser/Regler+og+formularer/Eksamensplaner/
- Digital Exam www.de.aau.dk

AALBORG UNIVERSITET

Module description (description of each module)

Module title, ECTS credits (and possibly STADS code)
Profile: TM
Perspectives of Clinical Trials in Drug and Medical Device Development / Kliniske undersøgelser ved udvikling af medicin og medicinsk udstyr
5 ECTS course module

Location
Master, Science in Medicine with Industrial Specialisation, 2nd semester
Board of Studies 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.

Parisa Gazerani, gazerani@hst.aau.dk, Department of Health science and Technology

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

This course is delivered in English

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).

From Curriculum:

Students who complete this course are expected to:

Knowledge
- Have an in depth understanding of different steps for planning, practical execution and completion of a clinical trial.

Skills
- Analyze, compare and discuss critically and systematically different forms of clinical trials concerning design and statistical models.
- Identify, formulate, discuss and evaluate issues, rules and responsibilities in clinical trial activities.
- Choose relevant problem-solving techniques in the design and analysis of clinical trials
- Apply gained knowledge and skills to design a clinical trial following regulations and requirements and analyze it.

Competences
- Assess product safety and efficacy utilizing monitoring tools, standards, and approaches while considering global benefits to people and economies.
- Instruction: This course consists of formal lectures given by mentors and experts, with extensive background in clinical trials, who will guide students through the learning process.

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 programme.

The module addresses important aspects of clinical trials for drug and medical device development. Firstly, students will learn what are clinical trials and the purpose of each phase and how it is conducted and the they go deeper into several issues and challenges in designing, performing and handling data coming out of trials.

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.

The module comprises lectures and classroom activities on various topics related to clinical trials in a broad spectrum, discussion of papers, work with study problems, presentations by students, and classroom dis-cussions on a given exercise-assignment. Students are required to actively participate in module.

Workload will correspond to the 5 ECTS credits (i.e. 150 hours) provided by the course and the workload is described as follow:

There are 14 actual sessions and one seminar each considered as number of 45 min (from 2 to 6 45 min) that include lectures and practices in form of exercises, cases (work with literature and study problems), student presentations, and indepth discussion. This makes 45 hours.There are also 45 to 50 hours workload required of home reading and preparations before/after each session. For seminar and presentation preparation, 20 additional hours have been allocated. Additionally, in order for students to prepare for the exam and attending, approximately 30 hours are required.

In total 150 hours (max) will be spent for this module.

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

MedIS students

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.

1st semester Master of Science in Medicine with Industrial Specialization

Module activities (course sessions etc.)

Activity - type and title	**Planned instructor***	**Learning goals from curriculum**	**Time consumption**
Introduction to Clini-cal Research	Parisa Gazerani, HST	Have an in depth understanding of different steps for planning, practical execution and completion of a clini- cal trial	4x45 min
Clinical trials: phases	Parisa Gazerani, HST	Clinical trial phases I, II, III *Detailes:* There are four phases of clinical trials (I, II, III and IV) and the goal of this session is to expose students to essential ele-ments of these phases.	4x45 min lecture com-bined with group work

Clinical trials: design and conduct + examples	Parisa Gazerani, HST	Design of clinical trials I,II, III *Detailes:* Clinical trial phases design: different types of clinical trial design, objectives and outcomes in clinical trials will be discussed through examples in different study design	4x45 min lecture combined with group work
Post marketing	Parisa Gazerani, HST	Phase IV and post-marketing drug surveillance *Detailes:* Phse IV purpose and examples in post-marketing drug sur- veillance	4x45 min lecture com- bined with group work
Pharmacovigilance	Parisa Gazerani, HST	Concept of vigilance *Detailes:* Pharmacovigilance: Rules and guidelines to safeguard the reliability of trials, policy deci- sions, roles of stakeholders, reporting and monitoring adverse re- actions, drug use in community, role of media and pharmacoeconomics.	4x45 min lecture com- bined with group work
Drug Withdrawals and label revision	Parisa Gazerani, HST	Challenges in clinical trials *Detailes:* Drug widrawals, block box warning and examples in policy de- cisions, roles of stakeholders includ- ing pharmaceutical firms, commercial in- fluence on clinical trials	4x45 min lecture combined with group work and presentation of ex- amples
Translational biomarkers	Parisa Gazerani, HST	Application of biomarkers in clinical trials *Detailes:* Translational biomarkers	4x45 min lecture com- bined with group work and presentation of examples
Clinical trials in special population (elderly, pediatric and geriatrics, renal and liver impaired)	Parisa Gazerani, HST	clinical trials conducted for special population Design and challenges in special population for drug testing , eg pedi- atrics	4x45 min lecture combined with group work and presentation of ex- amples
Patients recruitment and retention challenges	Rasmus Hogreffe, external Company, virtual clinical trials	Challenges in clinical trial conduct *Detailes:* How to predict retention and avoid it and aslo how to plan to recruit successfully	4x45 min lecture com- bined with group work
Clinical trials for medical devices	Lotte N.S. Andreasen Struijk, HST	An example of medical device devel- opment, its design and challenges *Detailes:* Medical device development, special needs, Rules and guidelines	2x45 min lecture combined class room discussion

Statistics in clinical trials I	Carsten Dahl Mørch, HST	Data handling in clinical trials *Detailes:* How to analyze clinical data, prevention and treatment of missing data in clinical trials through changes in study design and use of appropriate statistical methods	4x45 min lecture com- bined with group work
Statistics in clinical trials II	Carsten Dahl Mørch, HST	Data handling in clinical trials *Detailes:* How to analyze clinical data, prevention and treatment of missing data in clinical trials through changes in study design and use of appropriate statistical methods	4x45 min lecture com- bined with group work
Quality assurance in clinical trials	Mathias Madsen, external comany (globalaes.com)	QA role in a CRO based environment for clinical trials *Detailes:* How to ensure quality of a clinical trial to safeguard the reliabil- ity of trials	2x45 min lecture combined class room discussion
Industry meets academia	Louise Bornebusch Lund, AAU Innovation	Interfaces between industry and academia *Detailes:* Rules, rights in the interface of academia and industry, pol- icy decisions, roles of stakeholders including pharmaceutical firms, commercial influence on clinical trials, patenting	2x45 min lecture combined class room discussion
Seminar	Seminar, hosted by Parisa Gazerani, HST	Student and senior presentation on clinical trials topics *Detailes:* How to present aspects of clinical trial related to the course top- ics	Full day seminar with invited speakers and students presentation

** All rights reserved for changes during the semester due to e.g. illness, cancellations etc.*

Examination

- The exam format will be an individual written exam of 2 hour duration.
- The exam will contain both short answer questions and essay questions.
- This format was chosen to ensure that both knowledge, skills and competences are tested.
- The assessment is on 7-scale. This will be assessed by the module coordinator.
- The exam will be distributed at the day of exam and should be handed in using Digital Exam.
- During the exam it will be allowed to use aids, but only notes are allowed in the form of books or in paper form without the use of the Internet.
- Be aware that any communication is not allowed during the exam. It is the student's responsibility to ensure this.
- If the exam format is changed before the reexam, this will be announced no later than 14 days be- fore.
- For more information please consult:
  - The exam plan on https://www.hst.aau.dk/uddannelser/Regler+og+formularer/Eksamensplaner/
  - Digital Exam (www.de.aau.dk)

Module description (description of each module)

Module title, ECTS credits (and possibly STADS code)
Profile: TM
Clinical Trials/Kliniske forsøg
15 ECTS project module

Location
Master, Science in Medicine with Industrial Specialisation, 2nd semester
Board of Studies 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.

Parisa Gazerani, gazerani@hst.aau.dk, Department of Health, Science and Technology.

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

Projects can be written in Danish or English.

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).

From Curriculum:

After completing this module, the student is expected to:

Knowledge
- Understand theoretical and practical issues relating to clinical trials essential for translational medicine and drug/medical device development

Skills
- 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.
- Obtain experience in any relevant area within the concept of clinical trials such as design, setting outcomes, use of appropriate statistical methods, application of rules and guidelines to conduct and monitor a trial, report of post-marketing drug surveillance, adverse reactions, pharmacovigilance, and the role of media and pharmacoeconomics.

Competences
- Select methodology appropriate to the chosen field and problem within translational medicine
- Collect, critically analyze and interpret data.
- Utilize guidelines, standards, tools, and approaches for assessing safety and efficacy of drugs/medical devices considering global benefits to people and economies.

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 programme.

The theme of the TM project is ”clinical Trials” and this theme is highly broad spectrum and can cover topics like design of a clinical trial, conduction, data analysis, or data mining, or topics related to drug safety, questionnare assays, challenges of clinical trials and similar. Drugs and device development are both equally

important and related to the project topics. Topics related to monitoring a trial, reporting of post-marketing drug surveillance, or adverse reactions and pharmacovigilance, role of media and pharmacoeconomics are also encouraged in projects.

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.

During the project period (15 ECTS) it is expected that the students work full time on the project unless they are participating in other courses. Project work includes reading scientific literature, applying methods obtained from the courses that are relevant for their project, writing, analysing, etc.

In total, the project should be allocated to approximately 150 hours of work per student, of which 125 shold be used in preparing the written report, and 25 hours should be used for preparation and examination.

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

MedIS students in TM (or candidates with a competence in clinical trial and human research in medicice and health area). Since there are some BM/TM projects, it can be extended to some aspects of BM profile in case of the BM/TM definition in the project.

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.

1st semester, Master of Science in Medicine with Industrial Specialization

Module activities (course sessions etc.)

Students are expected to write a project within the area of "clinical trials". The goal is to apply their knowledge and skills in any aspects of clinical trials for development of a drug or medical device and reach to competency of design, conduct, data handling, analysis or problem solving in clinical trial challenges, application of rules and guidelines in a trial, reports of e.g. adverse reactions, and the concept and action s related to the pharmacovigilance.

Students are encouraged to form groups of max 4. They are expected to apply the techniques, regulations, etc. learned from courses taught. Furthermore, they should have a general understanding of the clinical trials and associated areas.

Methods that are highly relevant to use are including but not limited to preparation of ethical approval for a clinical trial, retrospective studies and data mining of already conducted clinical trials, analyzing collected data from clinical trials (phases 1-4), conduction of pilot test for optimization of methods and parameters applied in a clinical trials, and similar.

The supervisors are affiliated to mainly (but not limited to) department of health science technology, Aalborh university hospital, clinics, apotek, health sector, and similar.

The students are entitled to a minimum of three meetings with their supervisor(s) during the project period.

Examination

The exam will be an oral group exam based on the submitted project.
During the exam, the students will be assessed on the progression of their knowledge, skills and competences as described in the curriculum.

The oral examination form was chosen to facilitate the evaluation of their abilities to work problem-based with a specific topic and to demonstrate their abilities to discuss an academic topic on an appropriately sci- entific level.
Present at the exam will be the students, the internal supervisor, potential co-supervisors, and an external censor. The exam will be evaluated by the internal supervisor and the external censor. The exam with be as- sessed using the 7 point scale.
The students are expected to give a short presentation (10 min per student) of the project at the beginning of the oral exam. The length of the exam will be 45 minutes per student.
Aids (the project report and notes) will be allowed
The project report should be handed in using digital exam (www.de.aau.dk)

If the exam format is changed before the reexam, this will be announced no later than 14 days before.
For more information please consult

- The exam plan on https://www.hst.aau.dk/uddannelser/Regler+og+formularer/Eksamensplaner/Medis-Medicin-e2019/
- Digital Exam (www.de.aau.dk)

Module description (description of each module)

Module title, ECTS credits (and possibly STADS code)
Profile: MMA
Economics of Health Technologies and Technology Assessment / Økonomi i sundhedsteknologi og teknologivurdering
5 ECTS course module

Location
Master, Science in Medicine with Industrial Specialisation, 2nd semester
Board of Studies 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.

Louise Hansen, lhan@business.aau.dk, Clinical Institute, Center for Health Economy, AAU

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

The course will be held in English.

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).

From Curriculum:

After attending this course, the student is expected to:

Knowledge

- Knowledge of the construction and use of models for analysis of the costs and effects of new medical technologies (including new medicines and medical devices)
- Knowledge of the use of patient-specific data from clinical trials as well as register-based data for analysis of costs and effects of new medical technology, including subgroup analyses.

Skills

- Can use the methods of the field to analyse economic and clinical effects for current issues in the health sector
- Can structure and present results from advanced health economic models and analyses of costeffectiveness, budget impact and cost-of-illness analyses

Competences

- Can develop advanced health economic analyses, including economic evaluations (cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis, etc.), budget analyses, cost-of-illness analyses, MTV reports, etc.
- Can critically assess methods and results from health economic calculations
- Can be part of a health economic team in a company/organisation that performs and/or uses health economic analyses of new medical technology

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 programme.

The course is an introduction to decision analytic modelling. It builds upon the 1. Semester course "The Economics of Health and Health Care" where the basic principles of economic evaluation was introduced. The course provides the students with hands-on knowledge of how to construct evidence-based decision analytic models in relevant software programs such as TreeAge and Excel. Furthermore, the advanced methods of economic evaluation is taught and discussed. In short, the students learn how to make the different kinds of economic models and analyses that are used today in research and business with a special emphasis on medical market access.

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.

The course is 5 ECTS and the students can expect a workload of approx. 150 hours. The course is offered as 7 sessions of 6 hours. Besides these 42 hours in the classroom the student should expect approx 78 hours for preparations (especially reading, but also for exercises/home work) and 30 hours for the examination.

Participants

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

The course is part of MMA master programme but is also offered to students in other educations e.g. Clinical Science and Technology (KVT). The course build on the 1. Semester course "The Economics of Health and Health Care", and students from other educations should not participate without a basic understanding of health economic evaluation from similar courses.

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.

The prerequisite for participation in this course is participation in MMA courses and project exams in the 1th Semester or other similar courses providing a basic knowledge of health economics.

Module activities

Level 1			
Activity - type and title	**Planned instructor***	**Learning goals from curriculum**	**Time consumption**
Lecture 1 – Introduction to decision analytic modelling and decision theory	*Anne Sig Sørensen, AAU*	*Knowledge of the construction and use of models for analysis of the costs and effects of new medical technologies (including new medicines and medical devices)* *Can use the methods of the field to analyse economic and clinical effects for current issues in the health sector* *Can develop advanced health economic analyses, including economic evaluations (cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis, etc.), budget analyses, cost-of-illness analyses, MTV reports, etc.*	*6 * 45 minutes*
Lecture 2 – Probabilistic sensitivity analysis	*Anne Sig Sørensen, AAU*	*Can develop advanced health economic analyses, including economic evaluations (cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis, etc.), budget analyses, cost-of-illness analyses, MTV reports, etc.* *Can critically assess methods and results from health economic calculations*	*6 * 45 minutes*
Lecture 3 – Introduction to Markov models	*Lars Ehlers/Anne Sig Sørensen,AAU*	*Knowledge of the construction and use of models for analysis of the costs and effects of new medical technologies (including new medicines and medical devices)* *Can critically assess methods and results from health economic calculations* *Can use the methods of the field to analyse economic and clinical effects for current issues in the health sector* *Can develop advanced health economic analyses, including economic evaluations (cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis, etc.), budget analyses, cost-of-illness analyses, MTV reports, etc.* *Can structure and present results from advanced health economic models and analyses of costeffectiveness, budget impact and cost-of-illness analyses*	*6 * 45 minutes*
Lecture 4 – Advanced modelling issues	*Lars Ehlers/Anne Sig Sørensen, AAU*	*Can structure and present results from advanced health economic models and analyses of costeffectiveness, budget impact and cost-of-illness analyses.* *Can develop advanced health economic analyses, including economic evaluations (cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis, etc.), budget analyses, cost-of-illness analyses, MTV reports, etc.* *Can be part of a health economic team in a company/organisation that performs and/or uses health economic analyses of new medical technology.*	*6 * 45 minutes*
Lecture 5 – Practical introduction to decision analytic modelling	*Anne Sig Sørensen, AAU*	*Can structure and present results from advanced health economic models and analyses of costeffectiveness, budget impact and cost-of-illness analyses.* *Can develop advanced health economic analyses, including economic evaluations (cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis, etc.), budget analyses, cost-of-illness analyses, MTV reports, etc.* *Can be part of a health economic team in a company/organisation that performs and/or uses health economic analyses of new medical technology.*	*6 * 45 minutes*

Lecture 5 – Economic evaluation alongside clinical trials	*Lars Ehlers/Sabrina Storgaard Sørensen, AAU*	*Knowledge of the construction and use of models for analysis of the costs and effects of new medical technologies (including new medicines and medical devices)* *Knowledge of the use of patient-specific data from clinical trials as well as register-based data for analysis of costs and effects of new medical technology, including subgroup analyses.* *Can critically assess methods and results from health economic calculations*	*6 * 45 minutes*
Lecture 6 – Advanced methods for elicitation of effect measures within health economics	*Cathrine Elgaard Jensen/Sabrina Storgaard Sørensen, AAU*	*Can use the methods of the field to analyse economic and clinical effects for current issues in the health sector.* *Can be part of a health economic team in a company/organisation that performs and/or uses health economic analyses of new medical technology.* *Can critically assess methods and results from health economic calculations*	*6 * 45 minutes*

** All rights reserved for changes during the semester due to e.g. illness, cancellations etc.*

Examination

- The exam format will be an individual written exam of 2 hour duration.
- 72 hours before the start of the exam, an article or other written material will be distributed. This will form the basis for some of the questions in the written exam.
- The exam will contain both short answer questions and essay questions.
- This format was chosen to ensure that both knowledge, skills and competences are tested.
- The assessment is pass/fail. This will be assessed by the module coordinator and an internal censor.
- The exam will be distributed and should be handed in using Digital Exam.
- During the exam it will be allowed to use aids, but only notes are allowed in the form of books or in paper form without the use of the Internet.
- Be aware that any communication is not allowed during the exam. It is the student's responsibility to ensure this.
- If the exam format is changed before the reexam, this will be announced no later than 14 days before.
- For more information please consult:
  - The exam plan on https://www.hst.aau.dk/uddannelser/Regler+og+formularer/Eksamensplaner/
  - Digital Exam (www.de.aau.dk)

Module description (description of each module)

Module title, ECTS credits (and possibly STADS code)
Profile: MMA
Non-Experimental Research Design and Analysis / Teoretisk forskningsdesign og –analyse
5 ECTS course module

Location
Master, Science in Medicine with Industrial Specialisation, 2nd semester
Board of Studies 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.

Louise Hansen, lhan@business.aau.dk, Clinical Institute, Center for Health Economy, AAU

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

The course will be held in English.

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).

From Curriculum:

After attending this course, the student is expected to:

Skills
- Can design and implement a market analysis
- Can plan, collect, analyse, and present data from e.g. a quantitative study (such as a survey or register-based study), as well as a qualitative study
- Can understand and explain the steps in a "good" regression analysis, including the relationship between purpose and methodology, inclusion of theory/evidence and put forth hypotheses, examination of data, use statistical tools in model specification, risk of bias and a loss of efficiency, etc.
- Can use the guidelines on a "good method of analysis" for a given issue, including assessing the possibilities for conducting a ceteris paribus cause-effect analysis based on a data set with nonrandomized data
- Can critically assess articles/reports that use regression analysis/statistical analysis of register-based data or questionnaire data
- Can use and combine methods in the prerequisite subjects overall to design and develop a market analysis for a topic related to the health care system
- Can work with qualitative data and quantitative surveys simultaneously. Can specifically handle/evaluate how the company can obtain knowledge on a topic by means of a non-experimental study.

Competences
- Can design market studies
- Can be part of a medical market access/marketing team in a company, including constructively assessing and participating in marketing activities (including critiquing the activities of competitors)

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 programme.

This course module is designed to give the students a thorough understanding of the underlying data analyses used in market analysis. It will include both qualitative and quantitative methodologies and analyses, that will enhance the students skills for conducting market analysis. This module builds on the existing knowledge from the previous semester and will enable students to analyse non-experimental data sources, as compared to the other MMA module (Economics of Health Technology and Technology Assessment) of this semester which will focus on experimental data analysis and economic evaluations.

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.

The course is 5 ECTS and the students can expect a workload of 150 hours. The course is offered as 8 lectures and 7 exercise sessions. This is equivalent to 52 hours of confrontation time
in the classroom. Besides this, the students should expect to use 68 hours for preparations and 30 hours for examination.

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

Participants include students on the 2nd semester of the master 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.

Students are required to have a basic understanding of health economics, marketing and quality improvement equivalent to participation in MMA courses and project exam in the 1st semester.

Module activities

Level 1

Activity - type and title	**Planned instructor***	**Learning goals from curriculum**	**Time consumption**
Lecture 1 *Introduction to the course*	*Louise Hansen, AAU*	*Can understand and explain the steps in a "good" regression analysis, including the relationship between purpose and methodology, inclusion of theory/evidence and put forth hypotheses, examination of data, use statistical tools in model specification, risk of bias and a loss of efficiency, etc.*	*2 * 90 minutes*
Exercise 1	*Louise Hansen, AAU*	*Can understand and explain the steps in a "good" regression analysis, including the relationship between purpose and methodology, inclusion of theory/evidence and put forth hypotheses, examination of data, use statistical tools in model specification, risk of bias and a loss of efficiency, etc.*	*90 minutes*
Lecture 2 *Data collection for qualitative research*	*Kristine Glavind, AAU*	*Can plan, collect, analyze, and present data from e.g. a quantitative study (such as a survey or register-based study), as well as a qualitative study* *Can use the guidelines on a "good method of analysis" for a given issue, including assessing the possibilities for conducting a ceteris paribus cause-effect analysis based on a data set with non-randomized data*	*2 * 90 minutes*
Lecture 3 *Moving from data to interpretation: some techniques*	*Kristine Glavind, AAU*	*Can plan, collect, analyze, and present data from e.g. a quantitative study (such as a survey or register-based study), as well as a qualitative study* *Can use the guidelines on a "good method of analysis" for a given issue, including assessing the possibilities for conducting a ceteris paribus cause-effect analysis based on a data set with non-randomized data*	*2 * 90 minutes*
Lecture 4 *Qualitative research designs*	*Kristine Glavind, AAU*	*Can plan, collect, analyze, and present data from e.g. a quantitative study (such as a survey or register-based study), as well as a qualitative study* *Can use the guidelines on a "good method of analysis" for a given issue, including assessing the possibilities for conducting a ceteris paribus cause-effect analysis based on a data set with non-randomized data*	*2 * 90 minutes*
Lecture 5 *Self-completion questionnaires*	*Annette Willemoes Holst-Kristensen, AAU*	*Can plan, collect, analyze, and present data from e.g. a quantitative study (such as a survey or register-based study), as well as a qualitative study*	*2 * 90 minutes*
Exercise 2 *Development of questionnaires*	*Annette Willemoes Holst-*	*Can plan, collect, analyze, and present data from e.g. a quantitative study (such as a survey or register-based study), as well as a qualitative study*	*2 * 90 minutes*

	Kristensen, AAU	*Can design market studies*	
Lecture 6 *Regression analysis*	*Louise Hansen, AAU*	*Can understand and explain the steps in a "good" regression analysis, including the relationship between purpose and methodology, inclusion of theory/evidence and put forth hypotheses, examination of data, use statistical tools in model specification, risk of bias and a loss of efficiency, etc.* *Can use the guidelines on a "good method of analysis" for a given issue, including assessing the possibilities for conducting a ceteris paribus cause-effect analysis based on a data set with non-randomized data*	*2 * 90 minutes*
Exercise 3 *Regression analysis*	*Louise Hansen, AAU*	*Can understand and explain the steps in a "good" regression analysis, including the relationship between purpose and methodology, inclusion of theory/evidence and put forth hypotheses, examination of data, use statistical tools in model specification, risk of bias and a loss of efficiency, etc.* *Can use the guidelines on a "good method of analysis" for a given issue, including assessing the possibilities for conducting a ceteris paribus cause-effect analysis based on a data set with non-randomized data*	*90 minutes*
Lecture 7 *Ordinary Least Squares and Generalised Linear Models*	*Louise Hansen, AAU*	*Can understand and explain the steps in a "good" regression analysis, including the relationship between purpose and methodology, inclusion of theory/evidence and put forth hypotheses, examination of data, use statistical tools in model specification, risk of bias and a loss of efficiency, etc.*	*2 * 90 minutes*
Exercise 4 *Ordinary Least Squares and Generalised Linear Models*	*Louise Hansen, AAU*	*Can understand and explain the steps in a "good" regression analysis, including the relationship between purpose and methodology, inclusion of theory/evidence and put forth hypotheses, examination of data, use statistical tools in model specification, risk of bias and a loss of efficiency, etc.*	*90 minutes*
Lecture 8 *Logistic and Time-to-event analyses*	*Louise Hansen, AAU*	*Can understand and explain the steps in a "good" regression analysis, including the relationship between purpose and methodology, inclusion of theory/evidence and put forth hypotheses, examination of data, use statistical tools in model specification, risk of bias and a loss of efficiency, etc.*	*2 * 90 minutes*
Exercise 5 *Logistic and Time-to-event analyses*	*Louise Hansen, AAU*	*Can understand and explain the steps in a "good" regression analysis, including the relationship between purpose and methodology, inclusion of theory/evidence and put forth hypotheses, examination of data, use statistical tools in model specification, risk of bias and a loss of efficiency, etc.*	*90 minutes*
Exercise 6 *Regression models*	*Louise Hansen, AAU*	*Can critically assess articles/reports that use regression analysis/statistical analysis of register-based data or questionnaire data*	*2 * 90 minutes*
Exercises 7 *Combining qualitative and quantitative research for economic evaluation*	*Louise Hansen, AAU*	*Can use and combine methods in the prerequisite subjects overall to design and develop a market analysis for a topic related to the health care system* *Can work with qualitative data and quantitative surveys simultaneously. Can specifically handle/evaluate how the company can obtain knowledge on a topic by means of a non-experimental study* *Can design and implement a market analysis*	*2 * 90 minutes*

** All rights reserved for changes during the semester due to e.g. illness, cancellations etc.*

Examination

- The exam format will be an individual written exam of 2 hour duration.
- The exam will contain both short answer questions and essay questions.
- This format was chosen to ensure that both skills and competences are tested.
- The assessment is pass/fail. This will be assessed by the module coordinator and an internal censor.
- The exam will be distributed and should be handed in using Digital Exam
- During the exam it will be allowed to use the following aids: books, slides and notes in the form of books or in paper form without the use of the Internet. The use of internet is only allowed for down- and upload of the exam.
- If the exam format is changed before the reexam, this will be announced no later than 14 days before.
- For more information please consult:
  - The exam plan on https://www.hst.aau.dk/uddannelser/Regler+og+formularer/Eksamensplaner/
  - Digital Exam (www.de.aau.dk)

Module description (description of each module)

Module title, ECTS credits (and possibly STADS code)
Profile: MMA
Economic Evaluations and Technology Assessments / Sundhedsøkonomi og teknologivurdering
15 ECTS project module

Location
Master, Science in Medicine with Industrial Specialisation, 2nd semester
Board of Studies 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.

Louise Hansen, lhan@business.aau.dk, Clinical Institute, Center for Health Economy, AAU

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

The project can be written in either Danish or English

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).

From Curriculum:

After completing this module, the student is expected to:

Knowledge
- A basic understanding of the methods of health economics and health technology assessment provides a framework for subsequent courses.
- The understanding of economics of health and medical care in theory and practice is the foundation for the track

- To describe topics in market oriented medical care.
- To understand and apply the methods for the health economic evaluation
- To understand and apply the methods for the health technology assessment of alternative health technologies.
- To understand and apply theories of evidence based marketing.

Skills

- Apply the techniques of health economic assessment and health technology are fundamental competences for the fulfilment of job requirements in the market oriented parts of the medical industry.
- Provide a general overview of the economics of health and medical care, and cover the medical and nonmedical determinants of health; markets for health care services and health insurance,
- Analyse key players in the health care sector, and different health care systems.
- Use methods for the economic evaluation of health technologies (i.e. cost-effectiveness analyses, costutility analyses, soctbenefit analyses) that are increasingly used for reimbursement and pricing decisions in health care markets.

Competences

- Assess medical products using advanced interdisciplinary tools for. It provide the students with an understanding of the basic tools for health technology assessment as a means for political, administrative and clinical decision-making in national and international health care systems

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 programme.

The theme for projects in MMA for this semester is Economic Evaluations and Technology Assessments and the students are supposed to assess medical products using advanced interdisciplinary tools for health technology assessment by means for political, administrative and clinical decision-making in national and international health care systems.

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.

During the project period it is expected that the students work full time on the project unless they are participating in other courses. Project work includes reading scientific literature, applying methods from the courses that are relevant for their project, writing etc.

In total, the project should amount to approximately 150 hours of work per student, of which 125 shold be used in preparing the written product, 25 hours should be used preparation and examination.

Participants

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

Participant include students on the 2nd semester of the master 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.

Students are required to have a basic understanding of health economics, marketing and quality improvement equivalent to participation in MMA course and project exams in the 1st semester.

Module activities

Students are supposed to write their project in groups of approximately 4 students. They are expected to apply the techniques from one or both of the courses taught on the 2nd semester of MMA. Furthermore, they

should have a general understanding of the economics of health and medical care, and cover the medical and nonmedical determinants of health; markets for health care services and health insurance.

Methods that are highly relevant to use are cost-effectiveness analyses, cost-utility analyses, cost-benefit analyses because these are methods that are increasingly used for reimbursement and pricing decisions in health care markets.

The supervisors are affiliated to Danish Center for Healthcare Improvements at the Department of Business and Management.

The students are entitled to a minimum of three meetings with their supervisor during the project period.

Examination

The exam will be an oral group exam based on the submitted project.
During the exam, the students will be assessed on the progression of their knowledge, skills and competences as described in the curriculum.
The exam with be assessed using the 7 point scale.
The oral examination form was chosen to facilitate the evaluation of their abilities to work problem-based with a specific topic and to demonstrate their abilities to discuss an academic topic on an appropriately scientific level.
Present at the exam will be the students, the internal supervisor, potential co-supervisors, and an external censor. The exam will be evaluated by the internal supervisor and the external censor.
The students are expected to give a short presentation (max 7 minutes) of the project at the beginning of the oral exam. The length of the exam will be 45 minutes per student.
Aids (the project report and notes) will be allowed
The project report should be handed in using digital exam (www.de.aau.dk)

If the exam format is changed before the reexam, this will be announced no later than 14 days before.
For more information please consult

- The exam plan on https://www.hst.aau.dk/uddannelser/Regler+og+formularer/Eksamensplaner/
- Digital Exam (www.de.aau.dk)