



AALBORG UNIVERSITET

Department of Health Science and Technology

# SEMESTER DESCRIPTION

## Master of Digital Health

AALBORG

## I st semester

Autumn semester  
2025

### Study board for

Health and Technology

### Study Regulations/Curriculum:

<https://studieordninger.aau.dk/2024/48/5163>

### Semester framework theme:

This is the initial semester out of four on the master program in digital health. It consists of three modules of each 5 ECTS.

*1. Health and Social Science Research Methodologies and Communication.* The students are introduced to the cross-disciplinary methodology and information seeking techniques they are to utilize in their digital health studies.

*2. Directives, Regulations and Requirement for Digital Health Products.* The students are presented for current knowledge about regulations and directives etc. that shape the use of health IT solutions with particular attention to AI.

*3. Design, Development and Implementaion of Digital Technologies in a Healthcare Context.* The students are taught research-based theories, concepts and approaches to digital health technology with a focus on user-driven innovation.

### Semester coordinator:

Sine Agergaard ([sine@hst.aau.dk](mailto:sine@hst.aau.dk))

### Secretariat assistance:

#### Programme secretary:

Tinna Hjort ([tilu@hst.aau.dk](mailto:tilu@hst.aau.dk))

#### Study board secretary:

Berit Lund Sørensen ([blc@hst.aau.dk](mailto:blc@hst.aau.dk))

## Content:

<b>SEMESTER ORGANISATION AND TIME SCHEDULE .....</b>	<b>2</b>
<b>COURSE MODULE DESCRIPTION I .....</b>	<b>4</b>
<i>DIRECTIVES, REGULATIONS, AND REQUIREMENTS FOR DIGITAL HEALTH PRODUCTS.....</i>	<i>4</i>
<b>COURSE MODULE DESCRIPTION II .....</b>	<b>8</b>
<i>DESIGN, DEVELOPMENT AND IMPLEMENTATION OF DIGITAL TECHNOLOGIES IN A HEALTHCARE CONTEXT .....</i>	<i>8</i>
<b>COURSE MODULE DESCRIPTION III .....</b>	<b>12</b>
<i>HEALTH AND SOCIAL SCIENCE RESEARCH METHODOLOGIES AND COMMUNICATION.....</i>	<i>12</i>

## Semester organisation and time schedule

This semester consists of the following project and course modules:

<https://studieordninger.aau.dk/2024/48/5163>

Module type	Title	Module coordinator:	ECTS	Assessment
Course module	<a href="#">Directives, Regulations and Requirements for Digital Health Products</a>	<a href="#">Ulrike Sabine Pielmeier</a>	5	7-point grading scale
Course module	<a href="#">Design, Development and Implementation of Digital Technologies in a Healthcare Context</a>	<a href="#">Jeppe Eriksen</a>	5	7-point grading scale
Course module	<a href="#">Health and Social Science Research Methodologies and Communication</a>	<a href="#">Sine Agergaard</a>	5	7-point grading scale

### Semester outline

The main activities during the semester are outlined here:

September/February	October/March	November/April	December/May	January/June
Semester group meeting ( <a href="#">here</a> )		Semester group meeting ( <a href="#">here</a> )		Exam ( <a href="#">find the exam plan here</a> )

### Semester evaluation

The semester is evaluated the following ways:

1. The students are invited to participate in two semester group meetings. The semester coordinator decides how the semester group meetings will be executed. The module coordinators are also invited.
2. The students will receive an electronic survey at the end of the semester in order to evaluate the semester and its activities. Time will be given to evaluate the previous semester at the beginning of the following semester.

3. Based on the above evaluations from the students, the semester coordinator will prepare a semester evaluation report which will be processed by the study board after the semester is completed.

### **Part time study**

The programme is a part time study and the students are expected to spend approximately 20 hours per week on their studies (incl. exams and exam preparations).

The average student is expected to work 30 hours per ECTS.

In this way, a course module of 5 ECTS requires 150 hours of work incl. exam and its preparation.

## Course module description I

# DIRECTIVES, REGULATIONS AND REQUIREMENTS FOR DIGITAL HEALTH PRODUCTS

FORORDNINGER, REGULATIVER OG KRAV TIL  
BRUG AF DIGITALE SUNDHEDSTEKNOLOGISKE  
PRODUKTER

ECTS: 5

### Course module coordinator:

Ulrike Pielmeier ([upiel@hst.aau.dk](mailto:upiel@hst.aau.dk)). Department of Health Science and Technology

### Exam plan

Is located here:

<https://www.hst.aau.dk/staff-and-students/for-students-and-teaching-staff#exam-plans>

**Primary teaching language:** English

**Type of exam:** Oral

**Assessment:** 7-point grading scale

**Duration of examination:** 20 minutes exam per student + 10 minutes vote

### Participants in an oral exam:

- ☒ Exam supervisor
- ☒ Lecturer
- ☒ Internal co-assessor

### Description of the practical conduct of the exam:

**The exam is conducted:** ☒ individually ☐ group based

**Exam language:** Both Danish and English

### The exam starts with a presentation from the student(s):

- ☒ Yes ☐ No ☐ Not relevant

### At an oral exam the student draws one or more question(s):

- ☒ Yes ☐ No ☐ Not relevant

### Permitted aids in the exam:

- ☒ Notes, literature, online books in offline condition, PC and calculator.

## SCOPE AND EXPECTED WORK EFFORT

Activity	Amount of hours spent on study activities in the module
Lectures	25
Workshop/group exercises	25
Exam	0,5
Exam preparation	30
Litterature study	35
Individual homework	35

## MODULE ACTIVITIES

Title	Lecturer and place of employment	Learning objectives from the programme curriculum
<b>Standards, regulatory conditions and processes in the life cycle of digital health products</b>  2 lectures,  Literature study  Group exercise  Individual homework	U. Pielmeier  AAU	<ul style="list-style-type: none"> <li>• Can account and describe the purpose of standards, regulatory conditions, documents, and organizations relevant for digital health products.</li> <li>• Can account for phases in regulatory life cycle of digital health products internationally and in Europe, including organizational, practical, timing requirements and evidence related to quality control.</li> <li>• Can describe the standardization process and can account for the relevant standardization organizations.</li> </ul>
<b>Risk classification process and rules in the EU and internationally</b>  1 lecture  Literature study  Group exercise  Individual homework	U. Pielmeier  AAU	<ul style="list-style-type: none"> <li>• Can establish the necessary documentation for approval of digital health products.</li> <li>• Can identify risk classification for a digital health product and the associated classification requirements.</li> <li>• Can identify relevant standards for a given digital health product.</li> </ul>
<b>Clinical Evaluation: Requirements, management, process, documentation and roles</b>  2 lectures,	U. Pielmeier  AAU	<ul style="list-style-type: none"> <li>• Can prepare a clinical evaluation plan, a risk management plan, and identify challenges in relation to regulatory approval of a digital health product.</li> <li>• Can identify relevant standards for a given digital health product.</li> </ul>

Literature study Individual homework		
<b>Artificial Intelligence: Special considerations for digital health products</b>  1 lecture Literature study	S. Schmidt, AAU	<ul style="list-style-type: none"> <li>• Can describe the special considerations for digital health products when based on artificial intelligence.</li> <li>• Can identify strategies for handling protection of personal data, cybersecurity, and requirements for traceability.</li> </ul>
<b>Risk Management and Quality Control</b>  1 lecture <b>Literature study</b> Individual homework	U. Pielmeier AAU	<ul style="list-style-type: none"> <li>• Can identify relevant standards for a given digital health product</li> <li>• Can prepare a clinical evaluation plan, a risk management plan, and identify challenges in relation to regulatory approval of a digital health product.</li> <li>• Can establish the necessary documentation for approval of digital health products.</li> </ul>
<b>Personal data protection, cybersecurity and requirements for traceability</b>  1 lecture Literature study Individual homework	U. Pielmeier, Jens Myrup Pedersen AAU	<ul style="list-style-type: none"> <li>• Can identify strategies for handling protection of personal data, cybersecurity, and requirements for traceability.</li> </ul>

## Litterature

Litterature list is found in Moodle.

<https://www.moodle.aau.dk/course/view.php?id=55862>



## Course module description II

# DESIGN, DEVELOPMENT AND IMPLEMENTATION OF DIGITAL TECHNOLOGIES IN A HEALTHCARE CONTEXT

PROJEKTLEDELSE AF DESIGN-, UDVIKLING- OG IMPLEMENTERINGSPROCESSER AF DIGITAL SUNDHED

ECTS: 5

## Course module coordinator:

*Jeppe Eriksen (je@plan.aau.dk). Department of Sustainability and Planning*

## Exam plan

Is located here:

<https://www.hst.aau.dk/staff-and-students/for-students-and-teaching-staff#exam-plans>

**Primary teaching language:** English

**Type of exam:** Oral

**Assessment:** 7-point grading scale

**Duration of examination:** 20 minutes

**Duration of potential preparation time:** 20 minutes

5 days prior to the oral exam the students are presented for the list with all exam questions. At the oral exam each student will draw one of these questions and have 20 minutes to prepare their initial presentation of the answers to the exam question.

## Participants in an oral exam:

- ☒ Exam supervisor
- ☒ Lecturer
- ☒ Internal co-assessor

## Description of the practical conduct of the exam:

**The exam is conducted:** ☒ individually ☐ group based

**Exam language:** Both Danish and English

## The exam starts with a presentation from the student(s):

☒ Yes ☐ No ☐ Not relevant

## At an oral exam the student draws one or more question(s):

☒ Yes ☐ No ☐ Not relevant

## Permitted aids in the exam:

☒ Everything incl. the internet (not for communication), notes, literature, online books, PC and calculator.

## SCOPE AND EXPECTED WORK EFFORT

The students are introduced to research-based theories, concepts, and approaches within and to the management of user-driven innovation processes, with an emphasis on methods for facilitating the involvement of users and stakeholders (e.g., healthcare professionals, citizens/patients/family members, as well as system developers/owners) in the design and implementation related to change and digitalisation in the healthcare sector.

The course emphasizes practical application with the aim of enabling students to participate in design, development, and implementation projects. The course will be a combination of physical attendance, online seminars and group work. The module is anchored within the Research Group for Techno-Anthropology & Participation, Department of Sustainability and Planning.

Activity	Amount of hours spent on study activities in the module
Lectures	20
Workshop/group exercises	25
Group work	25
Exam and preparation	30
Individual work	50

## MODULE ACTIVITIES

Lesson title, date, place	Lecturer(s)	Program for the day	Learning objectives (programme curriculum)
Day 1 – Introduction to design, development and implementation of digital technology in a healthcare setting 11/9 (Hybrid, SUND/Zoom)	Ditte Weber, Assistant Professor	08.30–09.15 Introduction to the course and participants 09.15–09.30 Coffee break 09.30–12.00 Introduction to PD and UIM, incl. project management skills (with 15 min break) 12.00–13.00 Lunch 13.00–14.00 Exercise: Project management – participants' experiences 14.00–16.00 Presentation and exercise with visual and tangible artefacts	Knowledge: Knowledge of project management and how they support user involvement in design, development, and implementation of digital health projects.  Skills: Identify, select, and apply project management tools for planning of design, development and implementation of project processes. Apply design-oriented and creative methods in co-creation with different actors.  Competences: Reflect on and account for how the various forms of involvement of stakeholders and design methods frame new technological design.
Day 2 – Design tools and methods I: user involvement in design and implementation of tech in health 2/10 (Online, Zoom)	Jeppe Eriksen, Associate Professor  Christian Nøhr, Professor	08.30–09.30 Project management continued 10.00–12.00 Introduction to design, development and implementation of digital technology in healthcare 12.00–13.00 Lunch 13.00–16.00 TBD	Knowledge: Explain different technological innovation theories and concepts, methods, tools, perspectives and strategies for the design, development, and implementation of digital health technologies.  Skills: Identify, select, and apply project management tools for planning of design, development and implementation of project processes. Apply design-oriented and creative methods in co-creation with different actors.  Competences: Reflect on and account for how the various forms of involvement of stakeholders and design methods frame new technological design.

<p>Day 3 – Design tools and methods 2: user involvement in design, development and implementation of tech in healthcare</p> <p>30/10 (Online, Zoom)</p>	<p>Signe Pedersen, Associate Professor</p> <p>Jens Dorland, Associate Professor</p> <p>Kristina Tornbjerg Eriksen, Assistant Professor</p>	<p>08.30–12.00 Toolbox / games &amp; case on healthcare centres + exercise</p> <p>12.00–13.00 Lunch</p> <p>13.00–16.00 Workflow analysis as participatory tool, HERO-model and robots in healthcare + exercise</p>	<p>Skills: Plan context-sensitive facilitation strategies to enhance the involvement of specific user groups in technological innovation. Apply design-oriented and creative methods in co-creation with different actors.</p> <p>Competences: Lead user involvement for design, development, or implementation of digital health innovation projects. Reflect on and account for how the various forms of involvement of stakeholders and design methods frame new technological design.</p>
<p>Day 4 – Mapping user needs and requirements in user involvement design and implementation of tech in health</p> <p>27/11 (Hybrid, SUND/Zoom)</p>	<p>Ditte Weber, Assistant Professor</p>	<p>08.30–12.00 Tools: Personas, scenarios, and Sanders' design map</p> <p>12.00–13.00 Lunch</p> <p>13.00–16.00 Participant presentations + course evaluation</p>	<p>Skills: Map user needs and user requirements for design, development, or implementation in relation to digital health innovation.</p> <p>Competences: Lead user involvement for design, development, or implementation of digital health innovation projects. Reflect on and account for how the various forms of involvement of stakeholders and design methods frame new technological design.</p>

## Course module description III

# HEALTH AND SOCIAL SCIENCE RE- SEARCH METHODOLOGIES AND COM- MUNICATION

## SUNDHEDSVIDENSKABELIGE OG SAMFUNDSDVIDENSKABELIGE METODER OG FORMIDLING

ECTS: 5

### Course module coordinator:

Sine Agergaard ([sine@hst.aau.dk](mailto:sine@hst.aau.dk)). Department of Health Science and Technology

### Exam plan

Is located here:

<https://www.hst.aau.dk/staff-and-students/for-students-and-teaching-staff#exam-plans>

**Primary teaching language:** English

**Type of exam:** Oral

**Assessment:** 7-point grading scale

**Duration of examination:** 20 minutes + 10 minutes vote

**Duration of potential preparation time:** 4 days before the oral exam the students are provided with a set of exam questions and case material asking them to prepare a presentation that is to initiate the oral exam.

### Participants in an oral exam:

- ☐ Exam supervisor
- ☒ Lecturer
- ☒ Internal co-assessor

### Description of the practical conduct of the exam:

**The exam is conducted:** ☒ individually ☐ group based

**Exam language:** Both Danish and English

### The exam starts with a presentation from the student(s):

- ☒ Yes ☐ No ☐ Not relevant

### At an oral exam the student draws one or more question(s):

- ☐ Yes ☒ No ☐ Not relevant

### Permitted aids in the exam:

- ☒ Notes, literature, online books in offline condition, PC and calculator.

## SCOPE AND EXPECTED WORK EFFORT

Activity	Amount of hours spent on study activities in the module
Lectures	24
Workshop/group exercises	24
Exam	2
Exam preparation	30
Litterature readings	35
Individual homework	35

## MODULE ACTIVITIES

Title	Lecturer and place of employment	Learning objectives from the programme curriculum
<b>12/9 (physical) morning</b>	Basic principles in research processes, e.g., evidence and innovation. Introduction to different types of research and their complexity (Sine Agergaard AAU SUND)	<ul style="list-style-type: none"> <li>- Can explain the principles of the research process in relation to the chosen scientific knowledge production method(s).</li> <li>- Can explain the possibilities and limitations of different types of study designs and methods with reference to the choices made in a study.</li> </ul>
<b>12/9 (physical) afternoon</b>	Understanding knowledge production, design and method. Quality in research process and product (Ninna Meier and Helle Sofie Wentzer, SSH, AAU)	<ul style="list-style-type: none"> <li>- Can reflect on and critically relate to the knowledge that can be produced with different social and health science designs and methods.</li> <li>- Can independently explain the possibilities and limitations of different types of study designs and methods with reference to relevant quality criteria, cf. the choices made in a study.</li> <li>- Can discuss scientific quality criteria, in general, as well as in relation to different scientific designs and methods.</li> </ul>
<b>3/10 (online) morning</b>	Descriptive research; hypothesis and quantitative method (Louise Pape-Haugaard, TECH /Jan Sørensen, SUND)	<ul style="list-style-type: none"> <li>• Can argue for and select relevant study designs for exemplified hypothesis or problem formulation.</li> <li>• Can argue for connections between hypothesis or research questions, study designs, scientific method(s), and data.</li> </ul>
<b>3/10 (online) afternoon</b>	Explanatory research; experimental design and interventions (Louise Pape-Haugaard, TECH /Jan Sørensen, SUND)	<ul style="list-style-type: none"> <li>• Can explain in detail classic study designs and methods within health sciences and social sciences research.</li> <li>• Can argue for and select relevant study designs for exemplified hypothesis or problem formulation.</li> </ul>
<b>31/10 (online) morning</b>	Interpretative research; qualitative research and the significance of context (Sine Agergaard, AAU SUND)	<ul style="list-style-type: none"> <li>• Can argue for and select relevant study designs for exemplified hypothesis or problem formulation.</li> <li>• Can discuss and critically reflect on the connection between research questions and the choice of research design and methods – in general and in relation to specific studies.</li> </ul>
<b>31/10 (online) afternoon</b>	Literature search, academic writing and critical reading (Helle Sofie Wentzer & Ninna Meier, SSH, AAU)	<ul style="list-style-type: none"> <li>• Can discuss the advantages and disadvantages of different methods for structured coverage of a research area through systematic literature search, as well as critical reading and assessment of scientific literature.</li> <li>• Can communicate own research, both orally and in writing.</li> </ul>

<b>28/11 (physical) morning</b>	Transformative research; participatory design and methods (Sine Agergaard, AAU SUND)	<ul style="list-style-type: none"> <li>• Can argue for and select relevant study designs for exemplified hypothesis or problem formulation.</li> <li>• Can reflect on and critically relate to the knowledge that can be produced with different social and health science designs and methods</li> </ul>
<b>28/11 (physical) afternoon</b>	Summing up, exam preparation and evaluation (Sine Agergaard, AAU SUND & Helle Sofie Wentzer, SSH AAU)	<ul style="list-style-type: none"> <li>• Can explain the possibilities and limitations of different types of study designs and methods with reference to the choices made in a study.</li> </ul>

## Litterature

Litterature list is found in Moodle.

<https://www.moodle.aau.dk/course/view.php?id=55864>