

Module name	Fundamentals of scientific working
Module number	M0
Module supervisors	Dr. Michael Beithe
Content and learning objectives	<p><u>Content:</u></p> <ul style="list-style-type: none"> • Fundamentals of “Scientific Working” <ul style="list-style-type: none"> ○ Research process ○ Evaluation of scientific work • Research areas <ul style="list-style-type: none"> ○ Qualitative social research ○ Quantitative social research • Statistics <ul style="list-style-type: none"> ○ Fundamentals of statistics ○ Descriptive statistics ○ Probability theory ○ Inductive statistics ○ Data preparation • Fundamentals of literature research <ul style="list-style-type: none"> ○ Independent definition of a research topic ○ Structure of seminar papers ○ Preparation for literature searches ○ Searching library catalogues and scientific search engines ○ Evaluation of results ○ Presentation of seminar papers <p><u>Learning objectives:</u> Students will:</p> <ul style="list-style-type: none"> • demonstrate basic methodological knowledge of scientific theory and research methods • apply skills in social science data analysis, particularly in statistics • describe and apply their knowledge of fundamental research models and their areas of application • evaluate scientific work and analyse its significance for practical application.
Teaching format	The content is taught through synchronous (physically on-site and online in groups) and asynchronous (individual, guided, time- and location-independent knowledge acquisition) study (approximately 25% each). Synchronous study time takes the form of courses, face-to-face workshops (block seminars), practical exercises/work shadowing, webinars/consultations with a high level of interaction between students and lecturers, discussions, presentations, and teamwork in small groups.
Prerequisites	The general admission requirements set out in the examination regulations must be met. In preparation for face-to-face events, literature recommendations may be provided, the content of which is then assumed to be known in advance or which should be acquired during the module.
Credit points and grades	<p>Students who successfully complete the module will be awarded 5 ECTS points (credit points).</p> <p>The credit points are awarded if the module examination is passed. The module examination (portfolio format) consists of the following:</p> <ul style="list-style-type: none"> - Seminar paper (5-8 pages) + presentation (10 min) <p>The portfolio exam grade is composed of 2/3 from the seminar paper and 1/3 from the presentation (grade ratio 2:1). All parts of the exam must be passed with a grade of at least 4.0.</p>

	Depending on the number of participants, the examination will be conducted as an individual or group assignment. This will be communicated at the beginning of the semester.
Usability and frequency	The module is offered as part of the master's program "AI, Regulatory Affairs and Transformation in Medical Technology" and usually takes place once a year.
Workload	The total effort is 125 working hours for the in-person classes, self-study, feedback rounds, and the completion of the examinations.
Duration of the module	The module has a duration of one semester.

Module name	New skillsets for leadership in digital healthcare delivery and digital medical product development
Module number	M1
Module supervisors	Dr. Erika Schuettfort
Content and learning objectives	<p><u>Content:</u></p> <p>The accelerating pace of technological change demands a redefinition of leadership principles. Leadership, distinct from management, is not merely the administration of processes but the ability to inspire, guide, and transform organizations toward future-oriented goals. While management focuses on stability and efficiency, leadership emphasizes vision, adaptability, and innovation. Tools such as Objectives and Key Results (OKRs) and agile methods have become essential instruments for aligning teams with strategic priorities in dynamic environments.</p> <p>Modern leadership approaches must integrate flexibility with clarity. Transformational leadership styles, which prioritize empowerment and collaboration, are particularly suited to digital initiatives. Leading transformations requires not only technical understanding but also the capacity to manage uncertainty and foster trust within diverse teams. Theories in digital transformation highlight systemic design issues, such as the interplay between technology adoption and organizational culture, which leaders must navigate to ensure sustainable change.</p> <p>However, challenges persist. Leaders face resistance to change, fragmented digital capabilities, and the complexity of integrating artificial intelligence into existing structures. These obstacles underscore the need for continuous learning and strategic foresight to maintain competitiveness in an era defined by disruption.</p> <p><u>Learning objectives:</u></p> <p>The students will</p> <ul style="list-style-type: none"> - develop a comprehensive understanding of the theoretical foundations, core concepts, and applied methods of leadership, and translate this knowledge into actionable practices within the evolving digital business environment. - critically assess their current leadership style and benchmark it against the competencies required to successfully drive transformation initiatives. - identify the essential capabilities for leading in the digital era, determine pathways for acquiring these skills, and recognize the corresponding requirements for team performance and organizational structures. - formulate structured approaches for guiding strategic initiatives and for designing and executing coherent strategies in complex digital contexts. - demonstrate the ability to craft robust digital strategies grounded in evidence-based foresight, effectively distinguishing between speculative hype and practical realities.
Teaching format	The content is taught through synchronous (physically on-site and online in groups) and asynchronous (individual, guided, time- and location-independent knowledge acquisition) study (approximately 25% for asynchronous study and 75% for synchronous study). Synchronous study time takes the form of courses, face-to-face workshops (block seminars), practical exercises/work shadowing,

	webinars/consultations with a high level of interaction between students and lecturers, discussions, presentations, and teamwork in small groups.
Prerequisites	The general admission requirements set out in the examination regulations must be met. In preparation for face-to-face events, literature recommendations may be provided, the content of which is then assumed to be known in advance or which should be acquired during the module.
Credit points and grades	<p>Students who successfully complete the module will be awarded 5 ECTS points (credit points). The credit points are awarded if the module examination is passed.</p> <p><i>Coursework (preliminary examination requirement):</i> self-reflection sheet to be completed throughout the module; assessment: pass/fail. Prerequisite for admission to the module examination.</p> <p><i>The module examination (portfolio format) consists of the following:</i> - written paper deliverable before each sub-theme - interactive presentation of complete module & following Q&A (15 min) Both interactive presentation & Q&A assess the deep integrative understanding of themes and depth of personal understanding.</p> <p>The portfolio exam grade is composed of 1/2 from the written paper and 1/2 from the interactive presentation (grade ratio 1:1). All parts of the exam must be passed with a grade of at least 4.0.</p>
Usability and frequency	The module is offered as part of the master's program "AI, Regulatory Affairs and Transformation in Medical Technology" and usually takes place once a year.
Workload	The total effort is 125 working hours for the in-person classes, self-study, feedback rounds, and the completion of the examinations.
Duration of the module	The module has a duration of one semester.

Module name	Current models of technology in healthcare delivery
Module number	M2
Module supervisors	Anett Schönfelder
Content and learning objectives	<p><u>Content:</u></p> <p>The aim of this module is to provide students with essential insight into how healthcare systems are organised, how workflows function, and how technology integrates into these structures. The process of healthcare digital transformation in European health systems depends on the effective combination of established clinical workflows with emerging digital tools, and the reshaping of those workflows alongside innovations. Most current systems are only partially digitised. This module will provide a clear understanding of the landscape of European health system digitisation, looking at opportunities, barriers and. It will also consider advantages and disadvantages of digital transformation in EU health systems.</p> <p>Aspects of digitalisation/digital transformation which will be explored include electronic health records, telemedicine, AI-driven clinical decision support, and the impact of wearable health devices. In combination these approaches have the potential to enhance care coordination, improve efficiency, and support better patient outcomes. However, their uptake is influenced by cost pressures, fragmented infrastructures, interoperability challenges, and resistance to change within clinical environments and from stakeholders. There is no one correct vision of what future healthcare systems should be structured – including they use of digital technologies. By comparing digital maturity varies across care settings (minimally, typically, and highly digitised systems), this module will explore how digitalisation transformation can be carried out, its effects, advantages, downsides and implications for all stakeholders.</p> <p>A further focus of the module is the examination of barriers to digital health adoption. Students consider the limitations of digital-first care models, ethical questions related to AI use, and the common gap between successful pilot projects and sustainable large-scale deployment. Economic factors—including reimbursement structures, health technology assessment, and incentives for investment—provide important context for understanding why digital transformation can be slow and uneven and why it is a political and societal change question as much as a technology or clinical science one. Understanding will be informed through a range of stakeholder perspectives: policymakers, patient, citizen, clinician, managerial, and industry perspectives contribute to a multi-dimensional understanding of how health and digital care provision are experienced, implemented, and governed. International comparisons will highlight differences in digital readiness and regulatory environments.</p> <p><u>Learning objectives:</u></p> <p>By the end of this module, students will:</p> <ul style="list-style-type: none"> - develop a foundational understanding of healthcare system organisation, workflows, and the integration of digital technologies across varying levels of digitalisation. - analyse the current landscape of digital healthcare tools, including EHRs, telemedicine, AI-driven systems, and wearable technologies, and evaluate their benefits and limitations; - critically assess the barriers to digital transformation, including ethical issues, organisational constraints, reimbursement models, and infrastructure

	<p>limitations;</p> <ul style="list-style-type: none"> - evaluate real-world examples of minimally, typically, and highly digitised healthcare systems to understand how context affects implementation success; examine diverse stakeholder perspectives, including those of policymakers, patients, clinicians, managers, industry, and startups; and - gain a balanced understanding of how technology is shaping EU healthcare systems, even in environments where digitalisation remains partial or uneven.
Teaching format	<p>The content is taught through synchronous (physically on-site and online in groups) and asynchronous (individual, guided, time- and location-independent knowledge acquisition) study (approximately 25% for asynchronous study and 75% for synchronous study). Synchronous study time takes the form of courses, face-to-face workshops (block seminars), practical exercises/work shadowing, webinars/consultations with a high level of interaction between students and lecturers, discussions, presentations, and teamwork in small groups.</p>
Prerequisites	<p>The general admission requirements set out in the examination regulations must be met. In preparation for face-to-face events, literature recommendations may be provided, the content of which is then assumed to be known in advance or which should be acquired during the module.</p>
Credit points and grades	<p>Students who successfully complete the module will be awarded 5 ECTS points (credit points). The credit points are awarded if the module examination is passed.</p> <p>The module examination consists of the following portfolio examination:</p> <ul style="list-style-type: none"> - (broad themed) term paper, approx. 15 pages on "The current usage of digital and AI technologies in healthcare delivery in the EU, with an international comparison") - interactive presentation & Q&A (15 min) <p>Both interactive presentation & Q&A assess the deep integrative understanding of themes and depth of personal understanding related to the submitted written work.</p> <p>The portfolio exam grade is composed of 1/2 from the term paper and 1/2 from the interactive presentation (grade ratio 1:1). All parts of the exam must be passed with a grade of at least 4.0.</p>
Usability and frequency	<p>The module is offered as part of the master's program "AI, Regulatory Affairs and Transformation in Medical Technology" and usually takes place once every two years.</p>
Workload	<p>The total effort is 125 working hours for the in-person classes, self-study, feedback rounds, and the completion of the examinations.</p>
Duration of the module	<p>The module has a duration of one semester.</p>

Module name	Current models of medical technology development
Module number	M3
Module supervisors	Rebecca Mathias
Content and learning objectives	<p><u>Content:</u></p> <p>The aim of this module is to give students a clear understanding of how innovative medical technologies progress from early research concepts to clinical use, highlighting the processes and frameworks that structure this journey. As healthcare increasingly adopts digital, data-driven, and highly integrated technological systems, the development of medical devices requires coordinated innovation across engineering, clinical science, regulatory affairs, and quality management. This module provides foundational insight into these interconnected processes, focusing on how products are designed, validated, approved, and prepared for adoption in health systems.</p> <p>Students will explore a broad spectrum of emerging technologies—from diagnostics, AI approaches interpreting in vitro tests, and software as a medical device (SaMD) enabled digital/AI wellness/lifestyle, predictive, (pre-/) diagnostics tools, therapeutics, disease management apps, next generation companion applications to medicines, disease management apps and outcomes/value-based care tracking applications. The technologies for remote/home monitoring and wearable health technologies will be described in detail.</p> <p>These innovations are often part of larger technological ecosystems, interacting with patient data, clinical workflows, and external digital platforms. Through case studies, learners learn about these ecosystems, their technological underpinnings and will assess the technological, clinical, and commercial factors that determine why some innovations succeed and others stall, with particular attention to ethical, economic, and regulatory considerations. Addressing why a particular digital care model is being proposed, its advantages and disadvantages, and its implications will be a key consideration,</p> <p>As well exploring ‘low risk’ digital health monitoring technologies, this module also examines the development of in-hospital highly complex and safety-critical technologies, such as radiotherapy (particularly proton therapy) and MR-linac systems, and AI decision support, where engineering decisions are deeply interwoven with the local tertiary hospital application of regulatory and quality management and risk-management frameworks.</p> <p>Human-factors engineering is introduced as an essential dimension of designing digital and AI-enabled medical devices, ensuring that safety, usability, and clinical effectiveness remain central throughout development. The module also explores frontier themes shaping the future of healthcare technology, including brain-computer interfaces, AI-enabled robotic surgery systems, agentic medical AI models, and the shift towards hospital-at-home care supported by advanced digital tools. By studying these examples, students gain insight into how innovation evolves at the intersection of biotechnology, engineering, and digital health, and how these advances align with pathways to approval, reimbursement, and adoption.</p> <p><u>Learning objectives:</u></p> <p>By the end of the module, students will:</p>

	<ul style="list-style-type: none"> - have a solid grounding in basic digital technologies, trends, and their effects; - understand these technologies are increasingly being built together into interacting systems and explore the different models through which this is being done. - understand the interlinking and interoperability questions between digital health technologies; - understand the challenges in implementing 'high-risk' highly novel clinical systems in a tertiary hospital setting. - be aware of emerging frontier technologies and the impact these will have and be able to design technology development strategies linked to regulatory strategy development
Teaching format	The content is taught through synchronous (physically on-site and online in groups) and asynchronous (individual, guided, time- and location-independent knowledge acquisition) study (approximately 25% for asynchronous study and 75% for synchronous study). Synchronous study time takes the form of courses, face-to-face workshops (block seminars), practical exercises/work shadowing, webinars/consultations with a high level of interaction between students and lecturers, discussions, presentations, and teamwork in small groups.
Prerequisites	The general admission requirements set out in the examination regulations must be met. In preparation for face-to-face events, literature recommendations may be provided, the content of which is then assumed to be known in advance or which should be acquired during the module.
Credit points and grades	<p>Students who successfully complete the module will be awarded 5 ECTS points (credit points). The credit points are awarded if the module examination is passed.</p> <p>The module examination consists of the following portfolio examination:</p> <ul style="list-style-type: none"> - written (focused) description of a chosen sub-theme of development of an area of highly innovative, digital and AI technologies for healthcare in the EU (5-8 pages) - interactive presentation & Q&A (15 min) <p>Both interactive presentation & Q&A assess the deep integrative understanding of themes and depth of personal understanding related to the submitted written work.</p> <p>The portfolio exam grade is composed of 1/2 from the written description and 1/2 from the interactive presentation (grade ratio 1:1). All parts of the exam must be passed with a grade of at least 4.0.</p>
Usability and frequency	The module is offered as part of the master's program "AI, Regulatory Affairs and Transformation in Medical Technology" and usually takes place once every two years.
Workload	The total effort is 125 working hours for the in-person classes, self-study, feedback rounds, and the completion of the examinations.
Duration of the module	The module has a duration of one semester.

Module name	Current medical device regulatory processes
Module number	M4
Module supervisors	Juliane Wober
Content and learning objectives	<p><u>Content:</u></p> <p>The aim of this module is to provide students with a clear and applied understanding of the regulatory frameworks governing the development, evaluation, and use of medical devices. With a primary focus on the European Union—specifically the Medical Device Regulation (MDR), the In Vitro Diagnostic Regulation (IVDR), and the AI Act. The module explains how these regulations are structured, (broadly) what they require, and their impacts on technological innovation in healthcare. Students learn how regulatory strategies, regulatory affairs and quality management departments are structured in companies. The module links regulatory science with practical regulatory affairs product-development processes and the real demands of clinical evidence generation. While the core purpose of these regulatory systems is to ensure the safety, performance, and clinical benefit of medical technologies, the module also critically examines the challenges and weaknesses of current frameworks and laws.</p> <p>Topics include the increasing administrative and documentation burden, the resultant strain on competitiveness of EU companies, and the practical barriers these frameworks create for digitalisation and AI-enabled innovation in the health system (including for ‘in-house’ development. A comparative perspective highlights how regulation differs in other global regions, particularly examining the U.S. FDA’s framework. This provides insight into international regulatory policy, standards, and harmonisation and encourages critical thinking about how regulation could be done better, both at a national level, and in the systems developed in individual companies</p> <p>Students explore the essential concepts of medical device regulatory affairs, including classification, conformity assessment, clinical evaluation, and evidence requirements. This will include the role of standards and guidance documents and examination of how quality management systems and risk-assessment methodologies structure development across all device categories—hardware, software, diagnostics, and emerging AI systems. Special emphasis is placed on software life-cycle processes, benefit-risk analysis, and the unique regulatory considerations of in-house development and complex, high-risk technologies.</p> <p>The module also investigates the broader international environment, including current harmonisation and reliance efforts, global policy trends, and the perspectives of startups and innovators who often experience regulation as a significant barrier to market entry. Through comparative case studies and structured discussion, students gain a nuanced understanding of how regulation both enables and constrains innovation, offering a realistic view of the global medical device regulatory landscape.</p> <p><u>Learning objectives</u></p> <p>By the end of the module, students will:</p> <ul style="list-style-type: none"> - be familiar with EU laws, guidance and important standards, their implications and their challenges; - understand the nuances of the many moving parts and connected elements of the EU regulatory framework as it impacts company and product development

	<p>strategy</p> <ul style="list-style-type: none"> - have a deep understanding of the implications of the EU regulatory framework for innovative technologies and be able to critically assess new approaches and frameworks - know the international interlinking between regulatory systems, how this is developing and the barriers to further harmonisation - develop a concrete program for implementation in the company based on a technology and business strategy.
Teaching format	<p>The content is taught through synchronous (physically on-site and online in groups) and asynchronous (individual, guided, time- and location-independent knowledge acquisition) study (approximately 25% for asynchronous study and 75% for synchronous study). Synchronous study time takes the form of courses, face-to-face workshops (block seminars), practical exercises/work shadowing, webinars/consultations with a high level of interaction between students and lecturers, discussions, presentations, and teamwork in small groups.</p>
Prerequisites	<p>The general admission requirements set out in the examination regulations must be met. In preparation for face-to-face events, literature recommendations may be provided, the content of which is then assumed to be known in advance or which should be acquired during the module.</p>
Credit points and grades	<p>Students who successfully complete the module will be awarded 5 ECTS points (credit points). The credit points are awarded if the module examination is passed.</p> <p>The module examination consists of the following portfolio examination:</p> <ul style="list-style-type: none"> -(broad themed) term paper, approx. 15 pages on "Current medical device regulatory processes in the EU, with an international comparison") - interactive presentation & Q&A (15 min) <p>Both interactive presentation & Q&A assess the deep integrative understanding of themes and depth of personal understanding related to the submitted written work.</p> <p>The portfolio exam grade is composed of 1/2 from the term paper and 1/2 from the interactive presentation (grade ratio 1:1). All parts of the exam must be passed with a grade of at least 4.0.</p>
Usability and frequency	<p>The module is offered as part of the master's program "AI, Regulatory Affairs and Transformation in Medical Technology" and usually takes place once every two years.</p>
Workload	<p>The total effort is 125 working hours for the in-person classes, self-study, feedback rounds, and the completion of the examinations.</p>
Duration of the module	<p>The module has a duration of one semester.</p>

Module name	Managing digital and AI-enabled transformation in healthcare delivery
Module number	M5
Module supervisors	Prof. Dr. Stephen Gilbert
Content and learning objectives	<p><u>Content:</u></p> <p>The aim of this module is to provide students with a clear understanding of how digital and AI-enabled technologies are beginning to reshape healthcare delivery, highlighting both the opportunities they create and the constraints that influence their adoption. As telemedicine, predictive analytics, AI-assisted diagnostics, and emerging capabilities such as large language models and agentic AI advance, healthcare systems are exploring new models of care that emphasise personalisation, efficiency, and proactive intervention. Through real-world examples, students examine how these tools are being integrated into hospital operations, home-based care, and broader population-health strategies.</p> <p>The module explores how AI is currently implemented in clinical decision support, documentation, imaging, and hospital informatics. It will explore the impacts of emerging broad generalist AI technologies and agentic systems alongside the consideration of the how suited, technology enabled, collaborative and ethically aligned AI frameworks can be developed. Students will analyse applications ranging from ambient clinical scribes and multimodal diagnostic models to digital-twin technologies, virtual patients, wearables, and telemedicine ecosystems. Special attention is given to FemTech, mental-health technologies, and digital tools that shift elements of care into the home environment, illustrating how digital health innovations can support more joined-up care pathways and improve patient engagement.</p> <p>An important part of the module is the assessment of risks and unintended consequences of these new technologies (for patients, healthcare workers and healthcare systems and broader society). Topics include patient privacy and data protection, algorithmic bias, clinician workload, challenges to professional autonomy, and the safety considerations that must guide AI deployment. Students also study the regulatory and oversight approaches emerging to address these concerns, including AI-driven quality monitoring, data-analytics-based performance metrics, and the integration of medical-quality functions into digital-health organisations.</p> <p>The module additionally examines how value, evidence, and reimbursement shape implementation. Discussions address health technology assessment, return-on-investment considerations, and the tension between commercial narratives and robust clinical evidence. By evaluating both the promise and limits of AI-enabled care, and the practical obstacles such as interoperability, data governance, and ethical constraints, students will develop a grounded, realistic understanding of how digital transformation may evolve across different healthcare systems.</p> <p><u>Learning objectives:</u></p> <p>By the end of the module, students will:</p> <ul style="list-style-type: none"> - understand the likely opportunities impacts, challenges of broad AI technologies, including agentic systems, in healthcare - have a deep understanding of how appropriate, technology-enabled, collaborative and ethically aligned AI frameworks can be developed for the oversight of broad AI technologies, including agentic systems, in healthcare - will have a deep understanding of the impact of safety, data privacy, HTA, reimbursement legislation and frameworks on these technologies and be able

	to describe the possible impacts of these technologies on the development and evaluation of regulatory frameworks.
Teaching format	The content is taught through synchronous (physically on-site and online in groups) and asynchronous (individual, guided, time- and location-independent knowledge acquisition) study (approximately 25% for asynchronous study and 75% for synchronous study). Synchronous study time takes the form of courses, face-to-face workshops (block seminars), practical exercises/work shadowing, webinars/consultations with a high level of interaction between students and lecturers, discussions, presentations, and teamwork in small groups.
Prerequisites	The general admission requirements set out in the examination regulations must be met. In preparation for face-to-face events, literature recommendations may be provided, the content of which is then assumed to be known in advance, or which should be acquired during the module.
Credit points and grades	<p>Students who successfully complete the module will be awarded 5 ECTS points (credit points). The credit points are awarded if the module examination is passed.</p> <p>The module examination consists of the following portfolio examination:</p> <ul style="list-style-type: none"> - written (focused) description of a chosen sub-theme of medical device regulatory processes in the EU (5-8 pages) - interactive presentation & Q&A (15 min) <p>Both interactive presentation & Q&A assess the deep integrative understanding of themes and depth of personal understanding related to the submitted written work.</p> <p>The portfolio exam grade is composed of 1/2 from the written description and 1/2 from the interactive presentation (grade ratio 1:1). All parts of the exam must be passed with a grade of at least 4.0.</p>
Usability and frequency	The module is offered as part of the master's program "AI, Regulatory Affairs and Transformation in Medical Technology" and usually takes place once every two years.
Workload	The total effort is 125 working hours for the in-person classes, self-study, feedback rounds, and the completion of the examinations.
Duration of the module	The module has a duration of one semester.

Module name	Managing digital and AI-enabled transformation of medical technology development
Module number	M6
Module supervisors	Prof. Dr. Stephen Gilbert
Content and learning objectives	<p><u>Content:</u></p> <p>The aim of this module is to give students a clear understanding of how digital and AI-driven technologies are reshaping medical device development, enabling faster, more data-driven, and increasingly automated processes. As AI becomes central to device design, simulation, testing, and lifecycle management, development workflows are evolving toward more connected and responsive models. Students explore how these technologies support efficiency and innovation while also introducing new regulatory, quality, and safety considerations.</p> <p>The module introduces the practical implications of LLM-assisted coding, low-code and no-code development environments, and their potential future role in medical device software development. By examining how traditional software life-cycle expectations—such as documentation, verification, and testing—interact with AI-assisted coding approaches, students gain insight into the opportunities and limitations of these tools within regulated frameworks. Real-world examples illustrate how AI-enabled devices and LLM-based systems are developed under quality-management and risk-assessment processes, including the emerging concept of pre-determined change plans (PCPs) for adaptive AI.</p> <p>Students also examine clinical evidence generation and post-market activities that rely increasingly on digital technologies. Topics include enabling vigilance and real-time data collection within devices, the design of fully digitally/remotely delivered clinical studies, and novel approaches such as embedded randomised trials and placebo-device methodologies. The role of AI oversight—supported by algorithmic audit mechanisms, Article 14 of the EU AI Act, and interoperable monitoring platforms—is explored as a core element of ensuring safety and accountability throughout a device’s lifecycle.</p> <p>A further component of the module is the study of “living labs” and other real-world environments used to evaluate AI-enabled medical devices in practice. Through case studies and structured discussions, students assess both the promise and challenges of a more digitally integrated development ecosystem, gaining a realistic understanding of how AI is transforming medical technology from concept to post-market performance.</p> <p><u>Learning objectives:</u></p> <p>By the end of the module, students will:</p> <ul style="list-style-type: none"> have a broad knowledge and perspective of the likely impacts of digital and AI-driven technologies on reshaping medical device development and the regulatory implications/constraints on these changes. have a nuanced understanding of the current and potential future impacts of coding copilots, low-code and no-code approaches and the likely regulatory strategies for these approaches and constraints on the use of these approaches be able to comprehensively describe and design fully digital remote clinical studies for digital or AI-based technologies and understand the regulatory constraints on these

	have a deep knowledge of the potential and limitations of “living lab” approaches for innovative medical device development and evidence generation
Teaching format	The content is taught through synchronous (physically on-site and online in groups) and asynchronous (individual, guided, time- and location-independent knowledge acquisition) study (approximately 25% for asynchronous study and 75% for synchronous study). Synchronous study time takes the form of courses, face-to-face workshops (block seminars), practical exercises/work shadowing, webinars/consultations with a high level of interaction between students and lecturers, discussions, presentations, and teamwork in small groups.
Prerequisites	The general admission requirements set out in the examination regulations must be met. In preparation for face-to-face events, literature recommendations may be provided, the content of which is then assumed to be known in advance, or which should be acquired during the module.
Credit points and grades	<p>Students who successfully complete the module will be awarded 5 ECTS points (credit points). The credit points are awarded if the module examination is passed.</p> <p>The module examination consists of the following portfolio examination:</p> <ul style="list-style-type: none"> - (broad themed) term paper, approx. 15 pages on “Digital and AI-enabled transformation of medical technology development in the EU, with an international comparison”) - interactive presentation & Q&A (15 min) <p>Both interactive presentation & Q&A assess the deep integrative understating of themes and depth of personal understanding related to the submitted written work.</p> <p>The portfolio exam grade is composed of 1/2 from the term paper and 1/2 from the interactive presentation (grade ratio 1:1). All parts of the exam must be passed with a grade of at least 4.0.</p>
Usability and frequency	The module is offered as part of the master’s program “AI, Regulatory Affairs and Transformation in Medical Technology” and usually takes place once every two years.
Workload	The total effort is 125 working hours for the in-person classes, self-study, feedback rounds, and the completion of the examinations.
Duration of the module	The module has a duration of one semester.

Module name	Managing digital and AI-enabled transformation of medical device regulatory processes
Module number	M7
Module supervisors	Prof. Dr. Stephen Gilbert
Content and learning objectives	<p><u>Content:</u></p> <p>The aim of this module is to provide students with a clear understanding of how digital and AI technologies are beginning to transform regulatory and quality-management processes for medical devices. This is a response to: (i) every-increasing regulatory and quality management burdens; (ii) new challenges of regulatory oversight of innovative technologies; and, (iii) to new potentials of new technologies to help with the delivery of regulatory and quality management responsibilities.</p> <p>Digital and AI-enabled tools are being explored to reduce regulatory documentation burden, to better understand regulatory requirements and to keep up to date with regulatory system change, to assist post-market surveillance and vigilance monitoring, to assist in the development of regulatory strategy. support faster, more transparent, and more consistent decision-making. Core themes are how AI can assist in preparing regulatory submissions, strengthen risk-assessment activities, and enhance post-market surveillance and even carry out aspects of conformity assessment.</p> <p>Students will study the current and emerging digital quality-management systems, regulatory information-management platforms and the impact and likely evolution of regulatory ontologies, particularly related to studies, traceability, vigilance and documentation. A focus will be on how AI, and particularly large language models, can support regulatory intelligence, automate aspects of requirement analysis, , and assist in computer-system validation processes. Real-world examples illustrate where these technologies are being piloted or adopted within manufacturers' QMS environments, highlighting both their value and the limitations that currently restrict their use. A further focus of the module is the evolving role of AI in conformity-assessment workflows. Students examine how simulation, computation, and model-based evidence may contribute to regulatory submissions and how digital QMS infrastructures can interface with assessment bodies. The module discusses current AI approaches in assessment processes as well as forward-looking scenarios of what conformity assessment may look like by 2040 if digital integration continues to advance.</p> <p>The module also addresses the impacts of new technologies for regulation and quality in broader regulatory-framework innovations concepts, including new concepts of assurance case-based risk assessment, regulatory sandboxes, living-lab evaluation environments, and the development of SMART standards to support AI-enabled medical technologies. Students explore how these tools can balance innovation with oversight, and how market-surveillance processes may be strengthened through AI-driven analytics. Through these explorations, the module provides a realistic perspective on the opportunities and constraints shaping the digital transformation of medical-device regulation.</p> <p><u>Learning objectives:</u></p> <p>By the end of the module, students will:</p> <ul style="list-style-type: none"> - have a deep knowledge of all-important technologies that are or have the potential to reshape regulatory processes (for the manufacturer, notified body, competent authority, consultant and hospital/healthcare system);

	<ul style="list-style-type: none"> - be familiar with how these technologies could work alongside development in regulatory frameworks; - be able to anticipate which technologies will have the most impact and the implications of these technologies for development of manufactures' regulatory strategies and operational delivery of regulatory affairs and quality management
Teaching format	The content is taught through synchronous (physically on-site and online in groups) and asynchronous (individual, guided, time- and location-independent knowledge acquisition) study (approximately 25% for asynchronous study and 75% for synchronous study). Synchronous study time takes the form of courses, face-to-face workshops (block seminars), practical exercises/work shadowing, webinars/consultations with a high level of interaction between students and lecturers, discussions, presentations, and teamwork in small groups.
Prerequisites	The general admission requirements set out in the examination regulations must be met. In preparation for face-to-face events, literature recommendations may be provided, the content of which is then assumed to be known in advance or which should be acquired during the module.
Credit points and grades	<p>Students who successfully complete the module will be awarded 5 ECTS points (credit points).</p> <p>The credit points are awarded if the module examination is passed. The module examination (portfolio format) consists of the following:</p> <ul style="list-style-type: none"> - Development Project Documentation: Description of (a) 'traditional' medical device regulatory/quality process for a device under development and (b) a reflective/realistic assessment of how digital & tools can be used to support aspects of this (taking either a broad or narrow aspect of development) (1/3 of the grade). - Academic Research Proposal (2,500-3,000 words): Extension of (i) into a formal research paper, investigating whether and how a narrow aspect of medical device quality regulatory process could be automated through a digital or AI approach development. Include a literature review, methodology, and expected outcomes - following academic standards. Execution and analysis are not required (1/3 of the grade). - Tool Evaluation Series: Self-exploration of low-code/no-code platforms with documented learning curves and consideration of relevance in medical devices quality / regulatory processes. (1/3 of the grade). <p>The grade ratio is 1:3. All parts of the exam must be passed with a grade of at least 4.0.</p>
Usability and frequency	The module is offered as part of the master's program "AI, Regulatory Affairs and Transformation in Medical Technology" and usually takes place once every two years.
Workload	The total effort is 125 working hours for the in-person classes, self-study, feedback rounds, and the completion of the examinations.
Duration of the module	The module has a duration of one semester.

Module name	Technology competencies for leaders in future healthcare
Module number	M8
Module supervisors	Prof. Dr. Stephen Gilbert
Content and learning objectives	<p><u>Content:</u></p> <p>The aim of this module is to provide students with the essential technology competencies required to lead effectively in an increasingly digital healthcare environment. Rather than developing deep technical specialisation, the module focuses on giving future healthcare leaders the foundational understanding needed to make informed strategic decisions about digital tools, data, and AI-enabled systems. Students explore the core technological domains that underpin modern healthcare—from data literacy and cybersecurity to cloud computing, interoperability, and the ethical application of AI in clinical and operational settings.</p> <p>The module introduces fundamental concepts in AI, data protection, and digital security, alongside key elements of cloud and network infrastructure that support health-IT environments. Through these foundations, students build a practical understanding of how digital systems operate, how they interconnect, and how they can be managed safely and efficiently. Case examples illustrate how technology solutions can improve patient care, streamline workflows, and strengthen organisational resilience.</p> <p>A further focus of the module is the landscape of technology-related roles across digital health, medical device development, and health system operations. Students gain insight into the responsibilities of product owners, system architects, DevSecOps specialists, data scientists, clinical AI administrators, and IT security leaders. Understanding these roles helps students recognise how multidisciplinary teams collaborate in digital health innovation and what competencies are required to support them.</p> <p>The module also covers technology aspects of the core components of health-IT systems, including electronic health records, interoperability standards, national telematics infrastructures, and the technical foundations of wearables, apps, and wireless communication. Students examine real-world examples such as the German electronic patient file, OpenEHR models, and FHIR/SMART frameworks to understand how modern systems exchange data and support clinical workflows. Through this integrated perspective, the module equips students with the practical, conceptual, and ethical competencies needed to navigate and support the growing role of technology in healthcare delivery.</p> <p><u>Learning objectives:</u></p> <p>By the end of the module, students will:</p> <ul style="list-style-type: none"> - be highly familiar with all the important/foundational digital technologies and emerging new technologies. - be able to apply technological knowledge to medical device development teams in non-engineering roles – particularly at the technology regulatory affairs/ technology specialist interface. - be highly aware of the effects of technology developments on the types of roles emerging in healthcare technology companies and the nature of the work in these roles
Teaching format	The content is taught through synchronous (physically on-site and online in groups) and asynchronous (individual, guided, time- and location-independent knowledge acquisition) study (approximately 25% for asynchronous study and 75% for synchronous study). Synchronous study time takes the form of courses, face-to-face workshops (block seminars), practical exercises/work shadowing,

	webinars/consultations with a high level of interaction between students and lecturers, discussions, presentations, and teamwork in small groups.
Prerequisites	The general admission requirements set out in the examination regulations must be met. In preparation for face-to-face events, literature recommendations may be provided, the content of which is then assumed to be known in advance, or which should be acquired during the module.
Credit points and grades	<p>Students who successfully complete the module will be awarded 5 ECTS points (credit points). The credit points are awarded if the module examination is passed.</p> <p>The module examination consists of the following portfolio examination:</p> <ul style="list-style-type: none"> - (broad themed) term paper, approx. 15 pages on "The key senior and newly emerging roles in healthcare system digital and AI transformation and identification of challenges in these roles, their interaction and in coordination and delivery in the EU, with an international comparison") - interactive presentation & Q&A (15 min) <p>Both interactive presentation & Q&A assess the deep integrative understanding of themes and depth of personal understanding related to the submitted written work.</p> <p>The portfolio exam grade is composed of 1/2 from the term paper and 1/2 from the interactive presentation (grade ratio 1:1). All parts of the exam must be passed with a grade of at least 4.0.</p>
Usability and frequency	The module is offered as part of the master's program "AI, Regulatory Affairs and Transformation in Medical Technology" and usually takes place once every two years.
Workload	The total effort is 125 working hours for the in-person classes, self-study, feedback rounds, and the completion of the examinations.
Duration of the module	The module has a duration of one semester.

Module name	Practical Semester (Additional module)
Module number	AddM1
Module supervisor	Prof. Dr. Stephen Gilbert
Content and learning objectives	<p><u>Content:</u> Completion of a concrete task within a professional environment. Discussion of strategy development.</p> <p><u>Aims:</u> The students will</p> <ul style="list-style-type: none"> - be sensitized to management potential in the company; - develop management potential within the scope of technical tasks; - design strategies for practicable solutions, including long-term success assurance.
Teaching format	In the practical semester, proof of employment must be provided. The acquisition of skills must be demonstrated in the examination, with the examination requirements being met by instructor consultations. The independent work of the participants is of critical importance here.
Prerequisites	Other than the general admission requirements for the master's degree which are stated within the examination regulations, no special previous knowledge is required.
Usability and frequency	The practical semester aims to use and transfer acquired professional and personal management skills when working on specific company-related tasks. The organization and the selection of the field of professional activity are the responsibility of the student. It should be possible to reflect on the activity through the specialist perspectives on which the course is based. The module is offered as part of the master's program "name" and usually takes place once a year.
Credit points and grades	<p>Students who successfully complete the module will be awarded 30 ECTS points (credit points). The credit points are awarded if the module examination is passed. The module examination consists of the following examinations:</p> <ul style="list-style-type: none"> - Written examination in the form of a seminar paper (40 to 45 pages), and - Presentation (20-30 minutes) <p>with a weighting of 2:1.</p>
Workload	The total effort is 900 working hours. Of this, 600 hours of professional activity are to be documented and 300 hours are planned for the examination.
Duration of the module	The module has a duration of two semesters.

Module name	Module Analysis
Module number	AddM2
Module supervisor	Prof. Dr. Stephen Gilbert
Content and learning objectives	<p>A module analysis for the teaching content within modules M1 to M5 of the study.</p> <p><u>Content:</u> A comprehensive self-study regarding the specific content of a module, their distinctions, and their relation to one another.</p> <p><u>Learning objectives:</u> The students will</p> <ul style="list-style-type: none"> - expand on and interconnect the learning goals of one module; - scientifically deepen their understanding of the teaching content covered in the modules; - get a deeper insight into the respective fields.
Teaching format	The examination requirements are met through instructor consultations. The independent work of the participant is of critical importance here.
Prerequisites	Other than the general admission requirements for the master's degree which are stated within the examination regulations, the successful completion of the courses for which the module analysis is carried out is a prerequisite.
Usability and frequency	The module is offered as part of the master's program "name" and usually takes place once a year.
Credit points and grades	<p>Students who successfully complete the module will be awarded 15 ECTS points (credit points).</p> <p>The credit points are awarded if the module examination is passed. The module examination consists of the following examinations:</p> <ul style="list-style-type: none"> - Written examination in the form of a seminar paper (25 pages), and - Presentation (20-30 minutes) <p>with a weighting of 2:1.</p>
Workload	The total effort is 450 working hours. Of this, 300 hours of professional activity are to be documented and 150 hours are planned for the examination.
Duration of the module	The module has a duration of one semester.

Module name	Master's Thesis with Colloquium
Module number	MT
Module supervisor	Prof. Dr. Stephen Gilbert
Content and learning objectives	<p><u>Content:</u> The course is completed with the preparation of a master's thesis and a subsequent colloquium. With the master's thesis, students should demonstrate their ability to independently work on a topic of their choice within a specified period of time and in compliance with scientific principles, based on the specialist knowledge and methodological skills acquired in the previous modules. In close coordination with the supervisor, the topic is developed by the student in the form of an exposé for registration with the examination board. In the colloquium, the students have to prove that they are able to present a complex topic in a short time and to defend their arguments against criticism.</p> <p><u>Learning objectives:</u> The student will</p> <ul style="list-style-type: none"> - derive conclusive new scientific knowledge from the acquired theoretical-analytical skills. - assess interdisciplinary relationships, design theories, and derive practical solutions; - explain the scientific methods and sources of information used; and - represent, justify, and present their results in a colloquium.
Teaching format	There is no teaching taking place along this module.
Prerequisites	See §11 of the examination regulations for the master's program "Corporate Digital Leadership & Transformation"
Usability and frequency	The module is offered as part of the master's program "Corporate Digital Leadership & Transformation" and usually takes place once a year.
Credit points and grades	<p>Students who successfully complete the module will be awarded 15 ECTS points (credit points). The module examination consists of the following examinations:</p> <ul style="list-style-type: none"> - Written master's thesis (2/3 of the module grade) - Oral examination in the form of a presentation and defense of 60 minutes (1/3 of the module grade) <p>with a weighting of 2:1.</p>
Workload	The total effort is 375 working hours, though this may be reduced based on the prior knowledge of the participants.
Duration of the module	The module extends over a period of 4 months for the written master's thesis. The colloquium usually takes place within four weeks after a return of the assessment of the master's thesis.