

Module Overview

Swiss Institute for Translational Medicine (sitem-insel); University of Bern

The **sitem-center (Swiss Institute for Translational Medicine)** at the **University of Bern** offers a range of accredited, hands-on modules designed for advanced professionals. These modules cover **translational medicine, biomedical entrepreneurship, regulatory affairs, quality management, and artificial intelligence in digital medicine**. If you are interested in a specific module, please contact the directorate via email: school.sitem@unibe.ch

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Part 1: Modules on Translational Medicine and Biomedical Entrepreneurship

For module registration or questions regarding accreditation to your study plan, please contact: school.sitem@unibe.ch

Module TM1: Research and Development

ECTS-Points	4 ECTS-Points (incl. Self-study and performance review)	Scope	100 - 120 working hours (incl. appr. 16 - 20 in person hours)
Performance review	Quizzes and/or exercises and/or team-works and written or oral final exam	Attendance requirement	80 %
Description and contents	The development of biomedical products spans medical devices (MD), in-vitro diagnostics (IVD), and drugs, and increasingly includes software solutions that support diagnosis, monitoring, or treatment in healthcare. The first phase in the commercialization of a biomedical product involves the discovery and identification of products that merit testing in clinical trials. The performance of a biomedical product in the preclinical testing phase has to be sufficiently robust so that clinical trials can be considered and are likely to be granted by an ethical commission and the office of regulatory affairs. The R&D process plays a pivotal role in advancing these solutions by translating insights and potential into new products or services for future users (patients, clinicians, companies or governments).		
Learning objectives	<p>Upon completion of this module, participants should be able to:</p> <p>Medical Device (MD):</p> <ol style="list-style-type: none"> 1. Demonstrate knowledge of medical device (MD) design and validation by identifying key steps in the development process, including verification and validation requirements. 2. Apply principles of prototyping to differentiate between prototypes and final products while understanding material selection criteria. 3. Evaluate designs using criteria-based assessment to ensure functionality, compliance, and risk management considerations. 4. Integrate risk management concepts into MD development by recognizing potential hazards and implementing mitigation strategies. <p>Drugs:</p> <ol style="list-style-type: none"> 1. Demonstrate knowledge of drug discovery and development by outlining key steps, including question-based approaches, hit identification, lead optimization, and proof-of-principle studies. 2. Apply principles of pharmacokinetics, pharmacodynamics, and toxicology to evaluate drug candidates, assess ADME (Absorption, Distribution, Metabolism, and Excretion) studies, and interpret pharmacometric strategies in preclinical testing. 3. Critically assess preclinical data by understanding experimental requirements, interpreting study outcomes, and applying risk assessment strategies in drug development. 4. Integrate preclinical research methods to ensure effective drug testing, including evaluating lead compounds, optimizing pharmacological properties, and considering regulatory requirements. 		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	<ul style="list-style-type: none"> · Basic knowledge of biomedical sciences – Understanding fundamental concepts in biology, chemistry, and pharmacology is essential to grasp translational medicine principles. · Familiarity with research methodologies – Prior exposure to experimental design, pre-clinical testing, and data interpretation will aid in comprehending the R&D process in biomedical product development. · Introduction to regulatory and ethical frameworks – A foundational understanding of clinical trials, ethical considerations, and regulatory approval processes ensures readiness for discussing commercialization aspects. 		

Language	English
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and Extragenomic Medicine

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Module TM2: Intellectual Property

ECTS-Points	3 ECTS-Points (incl. Self-study and performance review)	Scope	75 - 90 working hours (incl. appr. 12 - 15 in person hours)
Performance review	Quizzes and/or exercises and/or team-works and written or oral final exam	Attendance requirement	80 %
Description and contents	Intellectual property rights given to investigators are essential for the successful commercialization of biomedical products. Module 3 covers the different types of intellectual property and specific legal aspects for biomedical products.		
Learning objectives	<p>Upon completion of this module, participants should be able to:</p> <ol style="list-style-type: none"> 1. Demonstrate an understanding of intellectual property rights and their economic significance by identifying different types of protection, their scope, and their role in innovation and commercialization. 2. Apply knowledge of patent law and intellectual property frameworks to assess eligibility, protection terms, and exclusions specific to biomedical and technological innovations. 3. Evaluate intellectual property strategies by comparing patenting alternatives, understanding legal requirements, and analyzing the importance of IP in product development and market positioning. 4. Interpret patent documents and application procedures by distinguishing key sections, recognizing jurisdictional differences (e.g., US-specific regulations), and assessing their impact on securing intellectual property rights. 		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	<ul style="list-style-type: none"> · Basic understanding of biomedical product development – Familiarity with the commercialization process, including research and regulatory pathways, helps contextualize intellectual property considerations. · Introduction to legal and regulatory frameworks – Awareness of patent law, licensing agreements, and regulatory protections ensures participants can engage with intellectual property concepts effectively. · Fundamental knowledge of business and innovation strategies – Understanding how intellectual property supports commercialization, competition, and market strategy is essential for applying legal protections in a biomedical context. 		
Language	English		

Prior knowledge required	<p>MD/IVD:</p> <ul style="list-style-type: none"> · Fundamental understanding of biomedical product development – Familiarity with the translational pathway, including key stages in drug and medical device development, helps contextualize regulatory processes. · Basic knowledge of European regulatory frameworks – Awareness of European Union (EU) and Swiss regulatory landscapes, including the roles of regulatory authorities, is essential for understanding compliance requirements. · Introduction to quality management and risk assessment – Prior exposure to Good Manufacturing Practice (GMP), risk management principles, and regulatory documentation supports learning about product approval and post-market obligations. <p>Drugs:</p> <ul style="list-style-type: none"> · Basic understanding of pharmaceutical sciences – Familiarity with drug development, including preclinical and clinical phases, ensures a foundational grasp of regulatory considerations. · Knowledge of European regulatory frameworks – Awareness of EU legislation, regulatory authorities, and approval pathways is essential for understanding drug compliance and market access. · Introduction to risk management and pharmacovigilance – Prior exposure to Good Manufacturing Practice (GMP), drug safety monitoring, and post-market requirements supports learning about regulatory oversight.
Language	English

Module TM3: Clinical Trial Design and Performance

ECTS-Points	6 ECTS-Points (incl. Self-study and performance review)	Scope	150 - 180 working hours (incl. appr. 24 - 30 in person hours)
Performance review	Quizzes and/or exercises and/or team-works and written or oral final exam	Attendance requirement	80 %
Description and contents	Clinical trials are designed to test how new medical approaches work in humans and how efficient, safe and economic they are. The prerequisites for such studies, the understanding of the pathophysiology of the underlying diseases, the definition of quantifiable end-points by clinicians as well as data management and statistics are discussed. Module 5 contains the review of R&D results, pharmacometrics, study design, trial conduct and ethical, regulatory and financial aspects of clinical trials.		
Learning objectives	Upon completion of this module, participants should be able to: 1. Critically evaluate and contribute to clinical trial development by applying practical knowledge of study design, stakeholder roles, and regulatory requirements. 2. Assess and implement clinical trial protocols by ensuring adherence to ethical standards, recruitment strategies, protocol compliance, and participant safety. 3. Analyze and interpret clinical study data by critically appraising trial publications, applying evidence-based practices, and addressing challenges in data quality management. 4. Demonstrate proficiency in Good Clinical Practice (GCP) by successfully completing Basic and Advanced training recognized by swissethics and integrating GCP principles into trial management.		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	<ul style="list-style-type: none"> · Basic understanding of pathophysiology and disease mechanisms – Familiarity with how diseases progress and impact the body is essential for defining clinical endpoints and assessing therapeutic interventions. · Fundamental knowledge of research methodology and statistical analysis – Prior exposure to study design, data management, and pharmacometric principles ensures a strong foundation for evaluating trial outcomes. · Awareness of ethical, regulatory, and financial considerations in clinical trials – Understanding ethical requirements, regulatory approvals, and cost-management strategies helps participants navigate the complexities of trial execution. 		
Language	English		

Module BE: Biomedical Entrepreneurship

ECTS-Points	13 ECTS-Points (incl. Self-study and performance review)	Scope	325 – 390 working hours (incl. appr. 52 – 65 in person hours)
Performance review	Quizzes and/or exercises and/or team-works and written or oral final exam	Attendance requirement	80 %
Description and contents	Biomedical entrepreneurship involves creating, developing, and managing a new business or venture to bring innovative healthcare products or services to the market. It includes combining scientific knowledge with business strategies and skills throughout the development and commercialization of a new biomedical. Module 6 covers key aspects of entrepreneurship, including creativity and innovation, business strategy, product management, negotiation, and leading entrepreneurial teams. Participants learn to master business plans, navigate critical success factors for their entrepreneurial endeavor, and gain a basic understanding of financial principles, venture creation, and the healthcare system. Individual coaching sessions support the development of their specific innovation projects.		
Learning objectives	<p>Upon completion of this module, participants should be able to:</p> <ol style="list-style-type: none"> 1. Demonstrate an understanding of economic and entrepreneurial principles by analyzing key factors influencing the development and commercialization of therapeutic products. 2. Apply entrepreneurial thinking to science-based innovation by integrating business strategies, market analysis, and commercialization pathways. 3. Evaluate stakeholder dynamics and project management strategies by identifying key industry players, business management concepts, and approaches relevant to life sciences. 4. Develop and assess business models for therapeutic products by translating ideas into structured plans, evaluating market potential, and understanding foundational aspects of enterprise creation and growth. 		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	<ul style="list-style-type: none"> · Basic understanding of biomedical sciences and product development – Familiarity with the translational process, including research, regulatory considerations, and early-stage development, helps contextualize commercialization strategies. · Fundamental knowledge of business administration and financial principles – Awareness of economic concepts, venture creation, and funding models supports strategic decision-making for biomedical innovation. · Introduction to health care systems and market dynamics – Understanding the key stakeholders, regulatory influences, and reimbursement structures ensures effective navigation of the biomedical industry. 		
Language	English		

Part 2: Modules on Regulatory Affairs and Quality Management

For module registration or questions regarding accreditation to your study plan, please contact:
school.sitem@unibe.ch

Catalogue of modules (descriptions)

Module RA1: Introduction to Regulatory Affairs with focus MD/IVD

ECTS-points	4 ECTS-points (incl. self-study and performance review)	Scope	100-120 working hours (incl. appr. 16-20 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	Attendance requirement	80 %
Description and contents	<p>Navigating the healthcare sector requires compliance with stringent regulations, underscoring the importance of a thorough understanding of regulatory affairs for medical devices.</p> <p>RA Module 1 introduces the regulatory landscape and provides an overview of European legislation. It covers the history, structure, interpretation, and application of the regulation and provides a comprehensive study of product qualification and classification.</p>		
Learning objectives	<p>The participant:</p> <ul style="list-style-type: none"> • gains a basic understanding of regulatory concepts and CE-marking processes, • understands the structure of the EU Regulations on medical devices (Reg. 2017/745, MDR) and on in-vitro diagnostic devices (Reg. 2017/746, IVDR), as well as the role of harmonized standards, common specifications, and guidelines, • understands the specifics of device qualification and is enabled to perform comprehensive qualification assessments, • is familiar with the principles of MD/IVD classification and able to apply them, • is able to evaluate and select appropriate conformity assessment routes based on specific device classification and characteristics, • understands the role and responsibilities of various regulatory stakeholders, including notified bodies and economic operators. 		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A.		
Prior knowledge required	No prior knowledge required.		
Language	English		

Module RA2: Pre-Submission Regulatory Affairs with focus MD/IVD

ECTS-points	6 ECTS-points (incl. self-study and performance review)	Scope	150-180 working hours (incl. appr. 24-30 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	Attendance requirement	80 %
Description and contents	RA Module 2 delves into the regulation of all life cycle phases from research and development to submission of a medical device with a focus on the European market. The module aims to provide participants with the skills and knowledge to identify and apply quality, safety, and effectiveness requirements of a medical device and to provide them with comprehensive knowledge on documentation requirements.		
Learning objectives	<p>The participant:</p> <ul style="list-style-type: none"> • is able to identify the applicability of individual General Safety and Performance Requirements (GSPR) for a given type of device, and to determine the type of evidence of conformity required to fulfil such GSPRs, • demonstrates proficiency in the structure and contents of technical documentations required under the EU MDR and IVDR, • can identify and apply European regulatory requirements for specific types of devices, including Companion Diagnostic IVDs, Custom-made devices (CMD), and products without medical device purpose covered by MDR Annex XVI. 		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A.		
Prior knowledge required	This module builds up on knowledge taught in module "Introduction to Regulatory Affairs".		
Language	English		

Module RA3: Post-Submission Regulatory Affairs with focus MD/IVD

ECTS-points	5 ECTS-points (incl. self-study and performance review)	Scope	125-150 working hours (incl. appr. 20-25 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	Attendance requirement	80 %

Description and contents	Following on from the module on pre-submission regulatory affairs, RA Module 3 deals with the stages of the lifecycle of a medical device from submission to discontinuation. It provides participants with the regulatory skills necessary to introduce a medical device to the European market and to effectively monitor and manage its performance. The module also addresses the regulatory considerations and processes involved in implementing post-market changes to therapeutic products.
Learning objectives	The participant: <ul style="list-style-type: none"> • is able to identify and apply MDR and IVDR requirements and best practices associated with product labeling, • understands the requirements and challenges of managing Unique Device Identification (UDI) requirements, • acquires the skills to successfully navigate the EUDAMED (European Database on Medical Devices) registration process, • understands the principles and practices of post-market surveillance (PMS) and vigilance under the MDR and IVDR, • is enabled to develop strategies for managing post-market changes while ensuring compliance and product safety.
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A
Prior knowledge required	This module builds up on knowledge taught in modules "Introduction to Regulatory Affairs" and "Pre-Submission Regulatory Affairs".
Language	English

Module QM1: Introduction to Quality Management with focus MD/IVD

ECTS-points	5 ECTS-points (incl. self-study and performance review)	Scope	125-150 working hours (incl. appr. 24-30 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	Attendance requirement	80 %
Description and contents	QM Module 1 provides fundamental knowledge of systematic quality management processes and practices to ensure that a medical device meets the level of excellence required by customers and regulatory agencies throughout its entire life cycle. Participants will gain comprehensive insight into quality assurance principles and procedures applied through all life cycle phases of a medical device in accordance with ISO9001 and industry specific standards.		
Learning objectives	The participant: <ul style="list-style-type: none"> • gains a general understanding of quality management and its distinction from product compliance, • understand the principles and best practices in medical device industry for quality management systems and to be able to build up a QM-documentation, • develops proficiency in assessing, optimizing, and ensuring the quality of the entire value chain on the production side, including suppliers and manufacturing processes (auditing), • is able to articulate and apply key concepts in quality management, including process management and continuous product safety (ISO 13485), • demonstrates in-depth understanding of the ISO13485, MDSAP and FDA standards, • acquires the knowledge and skills to identify and manage defects within a quality management framework and product quality and systematically apply Corrective and Preventive Actions (CAPA). 		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	Basic understanding of process management in regulated industry or one/two years of working experience in MD/IVD field.		
Language	English		

Module QM2: Design Control with focus MD/IVD: from input to validation

ECTS-points	5 ECTS-points (incl. self-study and performance review)	Scope	125-150 working hours (incl. appr. 24-30 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	Attendance requirement	80 %
Description and contents	QM Module 2 focusses on the legal and normative frameworks that ensure that medical devices meet the necessary quality, safety and efficacy standards through all phases from design to manufacturing. Participants are introduced to the critical processes that ensure that medical devices are designed, developed, and validated in a systematic and controlled manner. The module also introduces relevant principles facilitating a structured and effective approach to implementing changes in the development and manufacturing processes.		
Learning objectives	<p>The participant:</p> <ul style="list-style-type: none"> • understands the applicable requirements for an effective design process, • knows the relevant phases of design control and the respective requirements that apply, • is able to set out a plan for design and development activities and to identify the requirements the product must meet, • acquires the skills and knowledge to define, reflect and verify the output of a design process, • becomes familiar with specific approaches and analytical methods for design verification and validation, • understands the relevant principles of Change Management to implement changes in the design and manufacturing of a medical device, • is enabled to ensure a smooth transition of the design output to manufacturing (design transfer). 		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	This module builds up on knowledge taught in module "Introduction to Quality Management".		
Languag	English		

Module QM3: Risk Management and Usability Engineering

ECTS-points	5 ECTS-points (incl. self-study and performance review)	Scope	125-130 working hours (incl. appr. 24-30 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	Attendance requirement	80 %
Description and contents	QM Module 3 provides participants with an understanding of the purpose, methodology and regulation of risk identification, assessment and mitigation in the context of the development of medical devices. It includes a comprehensive study of relevant risk management principles, various risk analysis methods and usability regulation.		
Learning objectives	<p>The participant:</p> <ul style="list-style-type: none"> • understands the principles of usability engineering, • knows the fundamental principles and practices of risk management, • explores and applies risk-based approaches, • conducts a comprehensive study of risk analysis methodologies applicable to various domains, including product, process, and organizational aspects, • understands how to integrate risk considerations into decision-making processes, • is familiar with different risk management techniques and able to perform Failure Mode and Effects Analysis (FMEA) and Risk-Benefit-Analysis. 		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	This module builds up on knowledge taught in module "Introduction to Quality Management".		
Language	English		

Module ARA1: ATMP Regulatory Affairs

ECTS-points	3 ECTS-points (incl. self-study and performance review)	Scope	75-90 working hours (incl. appr. 12-15 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	Attendance requirement	80 %
Description and contents	This module gives an overview of different ATMP modalities and their regulatory aspects with respect to clinical trials and market authorization. It provides a basic introduction to ATMP related technologies as well as scientific and clinical aspects. This module is offered in collaboration with Swissmedic and knowledge is provided by experts specialized in inspection, quality, pre-clinical, clinical and post-marketing.		
Learning objectives	<p>The participant:</p> <ul style="list-style-type: none"> • understands the basic science behind most common ATMP-related modalities such as cell therapies and gene therapies and tissue engineering products, • is able to position the legislation and the regulatory processes of ATMP within the medicinal drug products regulation, • can navigate in the classification of ATMP and distinguish those products from other medicinal drug products, • is able to better appreciate the expectations of regulatory authorities for ATMP from first-in-human clinical trials to marketing authorizations, • foresees regulatory solutions for future regulatory ATMP application based on real-world examples, • is enabled to anticipate the new product developments in the field of ATMP such as CRISPR-Cas technologies. 		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	Comprehensive knowledge of Swiss and EU regulatory affairs required and basic knowledge of important terminology related to cell & gene therapy products.		
Language	English		

Module ARA2: Combination Products

ECTS-points	3 ECTS-points (incl. self-study and performance review)	Scope	75-90 working hours (incl. appr. 12-15 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	Attendance requirement	80 %
Description and contents	Combination products include a combination of a medical device, and a drug (and/or biologic – only US). This module aims to provide participants with knowledge of the regulatory requirements for each component of a combination product including their similarities and differences. It will additionally provide participants with an understanding of combination product market launch considerations.		
Learning objectives	<p>The participant:</p> <ul style="list-style-type: none"> • understands the definitions in the EU and the US and familiarizes with the regulatory frameworks, • understands regulatory requirements for each component of a combination product including their similarities and differences, • understands use cases of combination products (e.g. diagnostic or therapeutic), • understands the types and use cases of Combination Products, • understands important standards and guidelines, • knows how to categorize and distinguish different medical device software (e.g. standalone, embedded, accessory, etc.) familiar with new regulatory developments (e.g., AI Act EU), • sensitized to moral and ethical issues (algorithm bias, representative data, hallucination, etc.), • knows how to apply transition timelines in EU, • knows how to structure technical documentation (eCTD vs. MDR Annex II, STED, ToC, etc.). 		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	Comprehensive knowledge of Swiss and EU regulatory affairs required.		
Language	English		

Module ARA3: FDA & Foreign Regulatory Affairs with focus MD/IVD

ECTS-points	4 ECTS-points (incl. self-study and performance review)	Scope	100-120 working hours (incl. appr. 16-20 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	Attendance requirement	80 %
Description and contents	In this module participants will learn to navigate through foreign regulatory frameworks. The module provides an overview of the global regulatory landscape and current developments, including practical applications and best practices. The module in particular covers an introduction to the US FDA regulatory infrastructure and framework, with a focus on the expectations in pre-market submissions, including the different types of medical device submission pathways.		
Learning objectives	<p>The participant:</p> <ul style="list-style-type: none"> • acquires a high-level understanding of the global regulatory landscape including harmonization efforts, • is able to evaluate foreign legislation and regulations to ensure compliance with regulatory requirements and understands the roles of the various regulatory agencies and the regulatory framework in selected countries, • develops a fundamental understanding of how to navigate through and apply the US FDA regulations governing medical devices, • understands the different submission document types for US market access and can submit an application compliant to US FDA device regulations, • is able to draft a pre-submission packet and prepare for a pre-submission meeting, • understands the interdependency of regulatory and business considerations. 		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	Comprehensive knowledge of Swiss and EU regulatory affairs required.		
Language	English		

Module ARA4: Medical Device Clinical Evaluation

ECTS-points	4 ECTS-points (incl. self-study and performance review)	Scope	100-120 working hours (incl. appr. 24-30 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	Attendance requirement	80 %
Description and contents	This module focuses on the clinical evaluation process and how such process is interrelated with other processes from the early design and development to post market phases to efficiently define the intended use and related clinical performance claims, establish the benefit risk profile of medical devices, and continuously monitor these aspects for optimal patient safety.		
Learning objectives	<p>The participant:</p> <ul style="list-style-type: none"> • understands the integrated process of clinical evaluation with other processes of the device lifecycle to optimize device design and related claims, • is enabled to position the device in the clinical context of the disease and evaluate regulatory requirements, • knows how to translate safety and clinical performance claims and associated clinical benefits into objectives within the clinical evaluation process, • is able to determine what clinical data are necessary based on the benefit risk profile of the medical device, • can understand the full clinical evaluation/investigation processes and ensure outputs are effectively incorporated in the overall risk management and other processes. 		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	A background in natural science, engineering or medicine, or, relevant fundamental scientific-medical knowledge required.		
Language	English		

Module ARA5: AI & Digital Health Technologies

ECTS-points	4 ECTS-points (incl. self-study and performance review)	Scope	100-120 working hours (incl. appr. 16-20 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	Attendance requirement	80 %
Description and contents	<p>This module provides you with specialized knowledge regarding the regulation of medical device software in Europe and the USA. Since it is difficult to regulate a technical domain one has scant knowledge of, the module will introduce the foundations of modern software engineering with a special focus on which aspects to watch for to ensure smooth approval of even the most complex software-based medical devices.</p> <p>The module offers an overview of the regulatory framework for medical device software, the software development lifecycle, and software quality management. You will also gain understanding in specialised regulations regarding the safety and cybersecurity of devices based on artificial intelligence.</p>		
Learning objectives	<p>The participant:</p> <ul style="list-style-type: none"> • learn about digitalisation/digital transformation, cybersecurity, security by design approach, modern software engineering methods, European and US regulatory frameworks, and artificial intelligence, • become familiar with digitalisation/digital transformation and its impact on the medical device industry, • become familiar with areas of application, opportunities, and risks of medical device software and digital health in general, • understand cybersecurity concepts (difference between connected and unconnected devices), including key cryptographic processes and techniques and their application areas, • understand the unique nature of cybersecurity risk and its assessment and mitigation, • understand modern approaches to software development and their application to ensure the cybersecurity of connected medical devices, • understand general trends, qualifications, and classification of medical device software, • understand the regulatory requirements in terms of cybersecurity and data protection (quality management system, risk management, software life cycle (e.g. IEC 62304), GDPR (privacy by design and default), FDA Cyber Security in Medical Devices Guideline, and data storage and management, etc. • understand the role of the legislator and the public authorities (Swissmedic, BACS, FOPH, FDPIC, notified bodies) within data protection and cybersecurity, but also the role of care providers (hospitals, etc.) • familiarize with basic terms, fundamental approaches and applications in the fields of Artificial Intelligence and Machine Learning in life sciences (e.g. prediction, classification, time series analysis, natural language processing, generative algorithms, robotics), • develop a comprehensive understanding of the business expert's role and the conditions relevant for success in Machine Learning/AI projects. 		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	Comprehensive knowledge of Swiss and EU regulatory affairs required.		
Language	English		

Part 3: Modules on AI in Digital Medicine Program

For module registration or questions regarding accreditation to your study plan, please contact:

school.sitem@unibe.ch

Module AI.1: AI Fundamentals

ECTS-points	2 ECTS-points (incl. self-study and performance review)	Scope	50-60 working hours (incl. appr. 8-16 in person hours)
Performance review	Quizzes and/or exercises and/or teamwork and written or oral final exam	Attendance requirement	80 %
Description and contents	One of the main objectives of the Certificate of Advanced Studies of Artificial Intelligence in Medical Imaging is to equip medical professionals with the necessary knowledge and skills to translate medical problems to data science problems and hence to actively engage in the environment of digital healthcare. Moreover, the participants know the fundamental concepts of AI and can thus judge the feasibility and adequacy of proposed AI solutions. Module 1 therefore aims at providing the participants with the necessary knowledge and skills for problem translation and feasibility assessment for AI-driven projects in medical imaging.		
General learning objectives	<ul style="list-style-type: none"> Identify and differentiate core learning paradigms in AI Explain the role of optimization in model training Apply appropriate evaluation metrics to assess model performance. Demonstrate conceptual understanding of important AI approaches. 		
Specific learning objectives	<ul style="list-style-type: none"> Differentiate the terms AI, Machine Learning and Deep Learning. Understand the basic terminology of inductive learning problems. Being able to correctly identify learning problems in medical imaging & medicine in general. Know the two main strategies for defining data representations (feature engineering/representation learning) and be able to apply them to concrete problems in medical imaging. Explain how binary classification with logistic regression/perception works. Understand gradient-based optimization for learning an AI model. Explain under- and overfitting and how to prevent it. Know how to appropriately evaluate an AI model. Understand the main principles of a deep feedforward network. 		
Didactic methods	The didactic methods may include: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A.		
Prior knowledge required	No prior knowledge required beyond the understanding of medical data analysis gained from a university medical education		
Language	English		

Module AI.2: Developing and validating AI

ECTS-points	3 ECTS-points (incl. self-study and performance review)	Scope	75-90 working hours (incl. appr. 16-24 in person hours)
Performance review	Quizzes and/or exercises and/or teamwork and written or oral final exam	Attendance requirement	80 %
Description and contents	A fundamental goal of the Certificate of Advanced Studies of AI in Medical Imaging is to provide hands-on experience with machine-learning as applied to medical images. This module considers the practical aspects of developing a machine-learning solution to a medical imaging problem, at every stage of the prototyping life cycle: problem definition, data acquisition, data labelling, training a model, and validation. These aspects of Medical Imaging AI are illustrated via the study of research papers, publicly available datasets, and interactive notebooks. The focus lies on the application of proven state-of-the-art methods. The techniques learned in this module form a basis for the successful execution of the capstone project.		
General learning objectives	<ul style="list-style-type: none"> • Translate clinical questions into machine learning tasks (Classification, Segmentation or Detection). • Navigate the complexities of building medical image datasets • Select a state-of-the-art AI model and have hands-on experience training such a model. • Evaluate medical AI systems using domain-relevant metrics 		
Specific learning objectives	<ul style="list-style-type: none"> • Understand which medical imaging problems map onto which machine-learning problems (classification, regression, clustering, detection). • Understand by example how large a dataset needs to be to avoid overfitting. • Understand the importance of data and label quality, and their impact on learning. • Knowledge of current state-of-the-art models for a variety of problem domains. • Understand the tradeoff of model complexity and required training data size. • Understand how pre-trained/foundation models can accelerate learning and reduce required dataset size. • Understand the difference between loss functions, performance metrics, and real-world evaluation. • Understand how to make changes to an existing modelling pipeline to improve performance. 		
Didactic methods	The didactic methods may include: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A.		
Prior knowledge required	Knowledge acquired during Module 1 of the CAS AIMI is a prerequisite.		
Language	English		

Module AI.3: AI Applications in Clinical Settings

ECTS-points	3 ECTS-points (incl. self-study and performance review)	Scope	75-90 working hours (incl. appr. 16-24 in person hours)
Performance review	Quizzes and/or exercises and/or teamwork and written or oral final exam	Attendance requirement	80 %
Description and contents	The landscape of available AI applications, and the tools used to build them, is rapidly expanding. In order to be effective at guiding the development, deployment and evaluation of AI applications in medicine, participants must be able to combine knowledge of existing applications and their technical underpinning with an understanding of their limitations and risks. They need to be informed about coming technologies and how to access these information.		
General learning objectives	<ul style="list-style-type: none"> • Understand the general principles of AI implementation in a clinical environment. • Critically assess limitations of current AI methodologies introduced in Module 2. • Navigate uncertainty, explainability, and interpretability in medical AI • Recognize potential and risks of emerging AI technologies (e.g. Generative AI, Foundation models). 		
Specific learning objectives	<ul style="list-style-type: none"> • Learn the principles behind saliency maps (e.g. GRAD-CAM, SHAP/LIME, uncertainty, CAV). • Understand failure modes, domain shifts and concept drifts of AI models. • Understand practical barriers to translating practical research into commercial AI applications. • Understand limitations of AI in data situations beyond training conditions. • Review current literature on the application of large language models (e.g. Chat GPT) and multimodal generative models. 		
Didactic methods	The didactic methods may include: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A.		
Prior knowledge required	Knowledge acquired during Modules 1 & 2 of the CAS AIMI is a prerequisite.		
Language	English		

Module AI.4: Approaching AI

ECTS-points	2 ECTS-points (incl. self-study and performance review)	Scope	50-60 working hours (incl. appr. 8-16 in person hours)
Performance review	Quizzes and/or exercises and/or teamwork and written or oral final exam	Attendance requirement	80 %
Description and contents	The clinically oriented module introduces practical applications of AI-assisted image interpretation technologies in general in general, via the specific example of radiology. Participants learn how to select appropriate hardware and software on national and international markets, perform benchmarking comparing CE marking with freely available techniques and use it for clinical applications and research. Participants learn how to implement clinical workflows in conjunction with legal services, hospital informatics and imaging departments. The module will introduce the concepts of evidence generation in AI and its different levels, as well as the recent proofs of evidence in clinical domains. The participants learn about AI developments in the context of medical images in the broader clinical environment. They will learn how to establish network collaborations with industry and clinical partners in the implementation process.		
General learning objectives	<ul style="list-style-type: none"> • Evaluate and select appropriate AI systems and platforms for clinical use • Understand the basic principles of reimbursement strategies in an international context. • Assess efficacy metrics for AI in healthcare settings • Apply good clinical and scientific practices in AI deployment • Understand market strategies for multi-AI platform implementation 		
Specific learning objectives	<ul style="list-style-type: none"> • Familiarize with real world applications and case studies via hands-on training. • Interact with representatives from AI vendors and startup communities. • Understand the modes of applications as triage, decision support, metrics. • Communicate results to end-users and integrate new findings into clinical pathways. 		
Didactic methods	The didactic methods may include: face-to-face teaching, clinical visits, online lectures, self-study materials, group works, online activities, discussions, and Q&A.		
Prior knowledge required	Knowledge acquired during Modules 1 - 3 of the CAS AIMI is a prerequisite.		
Language	English		

Module AI.5: Legal and Ethical Challenges

ECTS-points	2 ECTS-points (incl. self-study and performance review)	Scope	50-60 working hours (incl. appr. 8-16 in person hours)
Performance review	Quizzes and/or exercises and/or teamwork and written or oral final exam	Attendance requirement	80 %
Description and contents	<p>AI technologies for clinical decision support usually cannot explain in medical terms why or how they reach the conclusion they do which represents an inherent opacity for medical professionals using AI and for authorities.</p> <p>New and emerging medical technologies and devices are typically regulated for safety and efficacy by competent authorities. Depending on the intended use of AI software, the classification as «medical devices» leaves significant space for interpretation and legal consequences as well as ethical & legal accountability and responsibilities for developers, medical professionals as end users and the public.</p> <p>Participants will learn how to identify and resolve legal and ethical issues, ensure AI algorithm safety and efficacy, and efficiently develop and deploy AI software in medical imaging. The module also emphasizes protecting patients and their privacy throughout the AI software lifecycle.</p>		
General learning objectives	<ul style="list-style-type: none"> • Become aware of the implications of legal and ethical frameworks in the clinical environment. • Apply ethical and fairness principles in the development and deployment of medical AI. • Navigate privacy, data protection, and anonymization in AI systems. • Understand regulatory pathways and validation standards for AI in healthcare. • Evaluate legal frameworks for intellectual property and post-market surveillance. 		
Specific learning objectives	<ul style="list-style-type: none"> • Understand Swiss, EU and US data protection laws and regulations and their implication for the use of AI in medical imaging (e.g. the EU General Data Protection Regulation GDPR, Cybersecurity Directive, Medical Device Regulation MDR, IVDR, FDA Code Federal Regulation CFR, EU AI act). • Know the requirements of transparency, accountability, responsibility and putting the data subject in control for data protection in AI for medical imaging. • Can describe Regulatory standards and guidance documents for the decision if AI software needs to be approved as medical device. • Know the consecutive implications of the classification/ not classification of AI software on the responsibility for medical professionals in diagnosis and therapy. • Know measures to ensure Safety and Efficacy and Risk Management standards. • Know the design development rules for verification and validation of AI software, • Know technologies for AI Software development lifecycle management. • Can describe requirements in documentation to demonstrate that the algorithms are fair, neutral, without human bias and therefore not discriminatory. 		
Didactic methods	The didactic methods may include: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A.		
Prior knowledge required	Knowledge acquired during Modules 1 - 4 of the CAS AIMI is a prerequisite.		
Language	English		