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Digital Medical Devices Path

Certified Innovation Path - Curriculum

Digital Medical Devices for Health Transformation

Curriculum

Mandatory Modules	Organisations	Credits
Leadership, Entrepreneurship, and Innovation in Healthcare Environments	Introduction course	5 ECTS
Introduction to Digital Medical Devices	All	6 ECTS
Digital Medical Devices in Health Transformation	Karolinska University (KI)	4 ECTS

Specialization Modules *(Selection of 4 courses)*	Organisations	Credits
Regulatory Science	Technische Universität Dresden (TUD)	3 ECTS
Standards Applicable to Digital Medical Devices	Swedish Institute for Standards (SIS)	3 ECTS
Digital Medical Devices for Personalized Health	Universitat Politècnica de València (UPV)	3 ECTS
Cybersecurity for Digital Medical Devices	Universidad Politécnica de Madrid (UPM)	3 ECTS
Artificial Intelligence in Digital Medical Devices	Karolinska University (KI)	3 ECTS
Digital Medical Devices Innovation & Adoption	Agencia de Qualitat i Avaluació Sanitàries de Catalunya (AQuAS)	3 ECTS
Digital Medical Devices Real-world Cases	All	3 ECTS

Leadership, Entrepreneurship, and Innovation in Healthcare Environments

5 ECTS

This course is designed to equip students with the essential skills and knowledge required to lead, innovate, and drive entrepreneurship in the complex and everevolving healthcare industry, which operates within the context of Volatility, Uncertainty, Complexity, and Ambiguity (VUCA). The course is divided into three distinct sections: Leadership, Entrepreneurship, and Innovation, with a focus on understanding and addressing the unique challenges and opportunities in healthcare organisations.

Module 1: Leadership (1 ECTS)

In this module students will learn about what is required to lead effectively in healthcare environments, how leadership styles and strategies should be adapted to face the challenges imposed by VUCA. Ultimately the students will learn about the leadership competence that are required for fostering positive organisational change and innovation.

Module 2: Entrepreneurship (2 ECTS)

In this module students will learn the common requirements to develop an entrepreneurial mindset and skills necessary to identify and pursue both entrepreneurial and intrapreneurial opportunities in the healthcare sector, including effectively planning and launch of healthcare ventures.

Module 3: Innovation (2 ECTS)

In this module students will learn what are the key building capacities required to drive innovation in healthcare, including the different methodologies applicable to new product development in healthcare.

Karolinska Institutet

Trinity College Dublin
The University of Dublin

KTH VETENSKAP OCH KONST

AIDFM
Associação para Investigação e Desenvolvimento da Faculdade de Medicina

Introduction to Digital Medical Devices

6 ECTS

Module Description

This module introduces the fundamentals of Digital Medical Devices aiming to the essential knowledge on the different pillars of DMD, preparing learners for the following modules.

Learning Outcomes

By the end of this course, learners will be able to understand the fundamental concepts and principles of DMD in the framework of Digital Health Transformation.

Module Outline

Unit 1. Foundations of DMD
Unit 2. Introducing Regulatory Aspects of DMD
Unit 3. Foundations of P-Health
Unit 4. Role of Standards
Unit 5. Introduction to Innovation and Adoption of DMD
Unit 6. Foundations of Privacy and Cybersecurity

Digital Medical Devices in Health Transformation Credits

4 ECTS

Module Description

This module introduces the field of digital health transformation and its impact on healthcare delivery. It explores the role of medical technologies in driving innovation and improving patient outcomes. Learners will gain a comprehensive understanding of the key concepts, tools, and strategies employed in the digital health landscape.

Learning Outcomes

- Understand the fundamental concepts and principles of digital health transformation.
- Analyse the impact of digital medical technologies on healthcare systems and patient care.
- Evaluate the challenges and opportunities associated with implementing DMD-driven health solutions.
- Explore the ethical, legal, and societal considerations in digital health.
- Critically assess the future trends and advancements in the field of digital health therapeutics and diagnostics.

Module Outline

Unit 1. Introduction to Digital Health Transformation
Unit 2. Foundations of DMD
Unit 3. Applications of DMD
Unit 4. Barriers, Challenges and enabling factors in DMD
Unit 5. ELSA considerations in Digital Health
Unit 6. Future Trends and Advancements in Digital Health Transformation

Regulatory Science in Digital Medical Devices

3 ECTS

TECHNISCHE UNIVERSITÄT DRESDEN

Module Description

This module provides in-depth education and training in medical device regulatory science concepts relevant to the medical devices sector - an acknowledged gap in reports of EU training courses. This provides the foundations and principles of regulatory science and regulatory practice and quality management (QM) needed for entrepreneur medical affairs clinicians, and future regulators. This is a foundation critical for the application of the MDR and IVDR regulations. Learners will develop a comprehensive understanding of high-level regulatory and quality principles, and how this feeds through to QM-system design and product strategy and the discovery of the detailed requirements for products. This module will introduce how high-level regulatory principles interact with specific regulatory requirements, guidelines, and standards for domains (e.g., Cybersecurity), which will be described in detail in other modules.

Learning Outcomes

- Understand the history, development, and possible future directions of medical device regulation in the context of data-driven digital health.
- Understand and know the key structure and content of MDR and IVDR.
- Understand the specific requirements of MDR and IVDR for data-driven digital health including gaps in the regulations and areas of uncertainty.
- Understand the interaction between these regulations and other current and in-progress EU regulations including the AI Act, the EHDS proposal, and the Digital Markets Act
- Understand the hierarchy and relationship between EU regulations, national laws, guidelines harmonized standards, other standards, and the state of the art in regulatory practice.
- Develop an awareness of the ethical and legal considerations associated with cybersecurity in the context of digital health.

Module Outline

Unit 1. Introduction to Medical Device and In Vitro Diagnostic Device Regulation
Unit 2. The challenge of adaption of traditional regulation to Digital Health Systems
Unit 3. The company regulatory approach and quality management in the digital health company
Unit 4. User-centered design, design thinking, and how this is central in medical device regulation
Unit 5. Regulation as code – a needed concept and a challenge
Unit 6. Challenges in Digital Health regulation and new concepts including on-market adaptation

Standards Applicable to Digital Medical Devices

3 ECTS

Module Description

Understanding the standardization process and which standards are relevant to digital medical devices is crucial knowledge for developing new products. Standards consists of international agreements of best practice and are often considered a precondition for successful innovation. In addition, knowledge of how standards relate to regulations would assist both developers and customers in more efficient use of resources, since standards could be a supporting tool to follow laws and directives. This course aims to elaborate on how and who develops standards, standards applicable to medical devices, and standards concerning regulatory framework e.g., EU Medical Device Regulation.

Learning Outcomes

- Understand the standardization process, how standards are developed, and how to contribute.
- Know the importance of using standards when handling, developing, and buying etc medical devices
- Have a brief knowledge of which standards, including its contents, that are applicable to medical devices
- Understand how international and European standards relate to European regulatory framework for Medical Devices, harmonized standards, etc.

Module Outline

Unit 1. The international standardization system, standard development process
Unit 2. Examples of standards applicable to medical devices
Unit 3. Standards relation to European regulatory framework
Unit 4. Implementation and application of standards
Unit 5. Standards as base for innovation, how to contribute to standard development

Digital Medical Devices for Personalized Health

3 ECTS

Module Description

This module provides an in-depth understanding of how digital medical devices as the major data source can be used for the provision of personalised health.

Learning Outcomes

- Comprehend the principles of personalized health and its significance in healthcare.
- Map the relationships between DMD, signals, standards, and chronic disease management population to provide personalized health.
- Infere and specify patient profiles, especially to the chronic disease population in order to introduce sustainable personalised health.
- Analyze real-world case studies and identify personalized health solutions using DMDs.
- Propose innovative solutions to improve patient care and healthcare outcomes from a personalized perspective.
- Cultivate a mindset of continuous learning and adaptability in the rapidly evolving field of digital health, having criteria to move forward in the design of new personalized health solutions.

Module Outline

Unit 1. Personalised Health. What does it mean? Personalised health vs standard health
Unit 2. User profiling and behaviour change concepts and tools for personalized health
Unit 3. Interoperability and data standards for integration of heterogenous data sources for personalised health. DMD and platform requirements for sustainable and scalable personalised health
Unit 4. Use cases and lessons learnt about DMD and personalised health
Unit 5. Emerging technologies and challenges around DMD and personal health

Cybersecurity for Digital Medical Devices

3 ECTS

Module Description

This module provides an in-depth exploration of cybersecurity in the ecosystem of connected digital medical devices. Learners will develop a comprehensive understanding of the challenges and risks associated with securing the communications network used by the DMD and the strategies and best practices for protecting sensitive information within digital health ecosystems. The course will cover various aspects of cybersecurity, including data privacy, threat analysis, risk management, secure system design, and compliance with regulatory frameworks.

Learning Outcomes

- Understand cybersecurity's fundamental concepts and principles in the context of digital medical devices and digital health ecosystems.
- Analyse and evaluate the security and privacy risks of connecting medical devices with IT systems through communication networks.
- Apply scientific and engineering methods to define and solve security and privacy problems by protecting information generated and communicated by DMD.
- Design secure digital health ecosystems that adhere to relevant privacy and security regulations and good practices.
- Assess and manage cybersecurity risks within the ecosystem of DMD.
- Develop an awareness of cybersecurity's ethical and legal considerations in the context of DMD and digital health ecosystems.

Module Outline

Unit 1. Introduction to Cybersecurity in Digital Medical Devices and Digital Health Ecosystems
Unit 2. Threat Analysis and Risk Assessment in Digital Medical Devices and Communications Networks
Unit 3. Data Privacy and Confidentiality in the context of DMD
Unit 4. Security and Privacy Mechanisms for Protecting DMD data and networks
Unit 5. Secure System Design in Digital Health
Unit 6. Compliance and Regulatory Frameworks in DMD development and use

Artificial Intelligence in Digital Medical Devices

3 ECTS

Module Description

This module is designed to provide a comprehensive understanding of how artificial intelligence (AI) can be integrated into digital medical devices to improve healthcare delivery, patient outcomes, and overall healthcare experiences. The course will cover the foundational concepts of AI, its applications in digital medical devices, and the ethical and regulatory considerations involved.

Learning Outcomes

- Understand the fundamental principles of artificial intelligence and how they apply to the healthcare sector.
- Analyse and evaluate the potential benefits and challenges of using AI in digital medical devices.
- Navigate the ethical and regulatory landscape of AI in healthcare, ensuring compliance and best practices in their professional roles.
- Able to assess the contribution to artificial intelligence algorithms for enabling digital medical devices.

Module Outline

Unit 1. Introduction to Artificial Intelligence in Healthcare
Unit 2. AI in Digital Medical Devices
Unit 3. Ethics and Regulations in AI Healthcare

Digital Medical Devices Innovation & Adoption

3 ECTS

Agència de Qualitat i Avaluació Sanitàries de Catalunya

Module Description

In the module Digital Medical Devices Innovation & Adoption learners will get competencies to (1) involve all the affected stakeholders in the value creation and needs identification process, (2) analyse the impact of the eventual adoption into the organization taking into account the different affected stakeholder perspectives (patients, professionals, organization, health system and social economic), (3) evaluate the adoptability of digital innovations (4) understand the different vehicles available to adopt Digital Medical Devices in the healthcare system and when they apply.

Learning Outcomes

- To identify and engage key stakeholders in the process.
- To benchmark with the state of the art in terms of the value expected to be delivered to the different key stakeholders.
- To evaluate the adoptability of digital innovations by identifying the viable vehicles to be used for successful innovation adoption depending on the maturity of the technology and the level of preparedness of the buyers.

Module Outline

Unit 1. Introduction to Digital Medical Devices innovation and adoption
Unit 2. Need desirability assessment
Unit 3. Readiness and feasibility assessment
Unit 4. Feasibility and viability assessment
Unit 5. Reimbursement Approaches and Evaluation

DMD: Real-world Cases

3 ECTS

Module Description

In this module, the learners will have access to cases where real and market-ready Digital Medical Devices are presented. The introduction to each DMD will include a description of the potential application in need, the benefits, the barriers, and the challenges faced by the provider of the solution, service, or technology. The module material will be produced in collaboration with the actual vendors.

Learning Outcomes

- Incorporate the vendor perspective in the development and commercialization of Digital Medical Devices.

Module Outline:

Unit 1. Each real-world case will be presented in a separate unit. The initial target is 4-6 cases.

Contact us for further inquiries

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