eit Health

Co-funded by the European Union

# Health Data for Innovation Path

Certified Innovation Path - Curriculum

Co-funded by the European Union

# Harnessing Health Data for Innovation

Curriculum

| Specialisation Modules | Organisations | Credits |
|---|---|---|
| Leadership, Entrepreneurship, and Innovation in Healthcare Environments | Introduction course | 5 ECTS |
| Introduction to Digital Health Transformation Driven by Data Technologies Credits | Karolinska University | 4 ECTS |
| Data technologies and Artificial Intelligence in healthcare | Trinity College Dublin | 5 ECTS |
| Cybersecurity of medical data networks | Technical University of Madrid | 4 ECTS |
| Personalised and Precision Medicine | Association for Research and Development of the Faculty of Medicine | 4 ECTS |
| Data management in Clinical Trials | Association for Research and Development of the Faculty of Medicine | 4 ECTS |
| European Health Data Space and other Regulations relevant to health | Trinity College Dublin | 5 ECTS |
| Data-driven optimisation with process mining | Valencia Polytechnic University | 4 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 Health Transformation Driven by Data Technologies Credits

4 ECTS

**Module Description**

This module provides an introduction to the field of digital health transformation and its impact on healthcare delivery. It explores the role of data technologies in driving innovation and improving patient outcomes. Students will gain a comprehensive understanding of the key concepts, tools, and strategies employed in the digital health landscape. The course will introduce several topics such as electronic health records, health data analytics, Fair principles, telemedicine, digital health, and ethical considerations in digital health.

**Learning Outcomes**

- Understand the fundamental concepts and principles of digital health transformation.
- Analyze the impact of data technologies on healthcare systems and patient care.
- Evaluate the challenges and opportunities associated with implementing digital health solutions.
- Apply data analytics techniques to derive insights from health data.
- Explore the ethical, legal, and regulatory considerations in digital health.
- Critically assess the future trends and advancements in the field of digital health.

**Unit 1.**

Introduction to Digital Health Transformation.

**Unit 2.**

Health Data and Information Management.

**Unit 3.**

Health Data Analytics and Insights.

**Unit 4.**

Telemedicine, e-health Health and Wearable Devices.

**Unit 5.**

Ethical Considerations in Digital Health.

**Unit 6.**

Legal and Regulatory Frameworks in Digital Health.

**Unit 7.**

Future Trends and Advancements in Digital Health

# Data Technologies and Artificial Intelligence in Healthcare

5 ECTS

**Module Description**

This module introduces students to advances in information technology that facilitate other technological innovations such as advanced imaging, sensors and omics and enable the creation of data-rich products that can be used in patient care from digital therapeutics to clinical trials. The module will explore the underlying infrastructure applications such as Cloud Computing, Big Data Frameworks and mobile devices. It will describe the functions and sub-functions of Artificial Intelligence and Data Science and how these can be used for health data and health solutions. It will explain information technology developments in robotics and Augmented and virtual reality and their application in health. The important topic of health data sources, types and coding standards such as ICD and SNODMED will be explored.

**Learning Outcomes**

- Describe the major technological developments such as Cloud Computing, Software-as-as-service, mobile, blockchain and Big Data that are driving innovation in health data.
- Explain the foundational data technologies in data warehousing, Big Data and key concepts in data engineering to collect, cleanse and store data for application in advanced analytics.
- Describe and explain the field of Artificial Intelligence and the key modelling and mathematical approaches for machine learning, natural language processing, visual image recognition, audio processing and deep learning.
- Explain concepts of data management including governance, standards and major healthcare data standards and nomenclatures.
- Define the challenges and approaches to complex data engineering for advanced imaging, sensor streaming and omic data.
- Describe other applications used in digital health such as Telemedicine, iPhone Apps and Electronic Patient Record.
- Explain the application of advanced computing and data technologies to create digital health innovations across digital therapeutics, digital diagnostics, patient digital tools, clinical trials and digital endpoints, and AI-embedded smart devices.

# Data Technologies and Artificial Intelligence in Healthcare

5 ECTS

**Unit 1.**

Major advances in foundational computing innovations that have enabled the emergence of disruptive innovations.

**Unit 2.**

Major areas in the fields of Big Data, structured data, data science and artificial intelligence and how they may be applied to healthcare.

**Unit 3.**

Artificial Intelligence and underlying models of Data Science used in the different fields of AI.

**Unit 4.**

Uses of Robotics and AR and VR in healthcare.

**Unit 5.**

Data management approaches and methods of managing key data types within healthcare.

# Cybersecurity of medical data networks

4 ECTS

**Module Description**

This module provides an in-depth exploration of cybersecurity in the ecosystem of data-driven digital health. Students will develop a comprehensive understanding of the challenges and risks associated with securing health data, as well as the strategies and best practices for protecting sensitive information within the context of digital health systems. 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 data-driven digital health.
- Analyze and evaluate the security and privacy risks associated with health data and digital health systems.
- Apply appropriate techniques and strategies to protect health data from unauthorized access, disclosure, and manipulation.
- Design secure digital health systems that adhere to relevant privacy and security regulations.
- Assess and manage cybersecurity risks within the ecosystem of data-driven digital health.
- Develop an awareness of the ethical and legal considerations associated with cybersecurity in the context of digital health.

**Unit 1.**
Introduction to Cybersecurity in Digital Health

**Unit 2.**
Threat Analysis and Risk Assessment in Digital Health Systems

**Unit 3.**
Data Privacy and Confidentiality in Digital Health

**Unit 4.**
Security and privacy mechanisms for Protecting Health Data

**Unit 5.**
Secure System Design in Digital Health

**Unit 6.**
Compliance and Regulatory Frameworks in Digital Health

**Module Description**

This module provides a comprehensive introduction to precision medicine and its impact on healthcare. Precision medicine is a rapidly developing field that aims to tailor medical treatments to individual patients based on genetic, environmental and lifestyle factors. Through a combination of lectures, case studies and interactive discussions, students will explore the principles, technologies and applications of precision medicine, as well as its challenges and ethical considerations. The course covers topics such as genomic medicine, molecular diagnostics, targeted therapies, data analytics and patient engagement. Students will understand how precision medicine is revolutionising healthcare and how it has the potential to improve patient outcomes and healthcare delivery.

**Learning Outcomes**

- Understand the concepts and principles of precision medicine.
- Explore the technologies and tools used in precision medicine, including genomics, proteomics and data analysis.
- Explore the applications of precision medicine in different medical specialities, such as oncology, cardiology and neurology.
- Discuss the challenges and limitations of implementing precision medicine in clinical practice.
- Analyse case studies to understand real-life examples of precision medicine in practice.
- Explore the ethical, legal and social implications of precision medicine.
- Discuss the importance of patient participation and shared decision-making in precision medicine. 8. Develop critical thinking and analytical skills to evaluate and interpret research in precision medicine.

# Personalised and Precision Medicine

4 ECTS

**Unit 1.**

Introduction to precision medicine. Definition and principles of precision medicine. Historical background and milestones . Key components of precision medicine: genomics, biomarkers, data integration .

**Unit 2.**

Technologies and tools in precision medicine. Genomic sequencing and analysis. Molecular diagnostics and biomarker discovery . Big Data analytics and machine learning.

**Unit 3.**

Applications of precision medicine. Oncology: targeted therapies and liquid biopsies. Cardiovascular medicine: pharmacogenomics and risk prediction. Neurology: precision therapies for neurodegenerative diseases. Rare diseases: Diagnostics and therapeutic approaches.

**Unit 4.**

Challenges and limitations of precision medicine. Ethical considerations and privacy concerns. Integration into clinical practise and health systems. Health inequalities and access to precision medicine.

**Unit 5.**

Case studies on precision medicine. Analysis of real-life examples and success stories. Discussion of challenges and lessons learned.

**Unit 6.**

Ethical, legal and social implications of precision medicine. Informed consent and data sharing. Genetic discrimination and data protection issues. Equity and justice in precision medicine.

**Unit 7.**

Patient engagement in precision medicine. Patient empowerment through education and communication. Shared decision-making and patient-centred care. Patient perspectives and experiences.

**Unit 8.**

Evaluation and interpretation of research in precision medicine - Critical appraisal of scientific literature. Evaluation of study design and methodology. Interpretation of research findings and implications.

# Data Management in Clinical Trials

4 ECTS

**Module Description**

This module provides a comprehensive overview of clinical trial data management, its principles and best practises. Data management plays a critical role in ensuring the accuracy, integrity and reliability of clinical trial data. Through a combination of lectures, practical exercises and case studies, students will learn the fundamental principles and best practises of data management in the context of clinical trials. The course covers topics such as data collection, data quality assurance, data cleaning and validation, data privacy and security, and regulatory requirements. Students will also gain hands-on experience with data management tools and software commonly used in clinical research.

**Learning Outcomes**

- Understand the importance of data management in clinical trials and its impact on trial outcomes and patient safety.
- Learn the basic principles and processes of data management throughout the life cycle of a clinical trial.
- Become familiar with regulatory guidelines and standards for data management in clinical research, such as ICH-GCP and CDISC.
- Acquire practical skills in data collection, data entry and database design for clinical trials.
- Explore strategies to ensure data quality, including data cleaning, validation and discrepancy management.
- Understand clinical trial data privacy and security principles and adhere to relevant regulations, such as GDPR and HIPAA.
- Develop skills in using data management software and tools commonly used in clinical research.
- Discuss emerging trends and advances in data management, such as electronic data capture (EDC) systems and risk-based monitoring.

# Data management in Clinical Trials

4 ECTS

**Unit 1.**

Introduction to data management in clinical trials. Role and importance of data management in clinical research. Regulatory guidelines and standards (ICH-GCP, CDISC, etc.). Data management plan and its components.

**Unit 2.**

Data collection and data entry - Design and development of case report forms (CRF) . Electronic data capture (EDC) and paper-based data entry systems - Data entry and quality control procedures.

**Unit 3.**

Database design and data validation - Principles of database design for clinical trials . Data validation and edit check programming. Query management and discrepancy resolution.

**Unit 4.**

Data quality assurance. Strategies for data cleaning and data validation. Data monitoring and source data verification. Risk based monitoring approaches.

**Unit 5.**

Data protection and security in clinical trials . Data protection regulations (GDPR, HIPAA, etc.). Anonymisation and pseudonymisation techniques. Data security measures and secure data transmission.

**Unit 6.**

Regulatory compliance and audits. Regulatory inspections and audits. Good clinical data management practises (GCDMP). Data archiving and retention.

**Unit 7.**

Data management tools and software. Overview of data management systems and tools Electronic data capture (EDC) systems and their functionalities. Data cleansing and validation software

**Unit 8.**

Emerging trends in data management. Risk-based data management and monitoring Integration of electronic health records (EHR). Data management in adaptive trials and real-world evidence.

# European Health Data Space and other Regulations relevant to health

5 ECTS

**Module Description**

This module will introduce learners to the relevant legislation that has been passed and is pending within the European Union in relation to health data. This may include GDPR, EHDS, AI Act and Data Act. Other legislation will be included as the legislative framework evolves. The module will introduce learners to the sources of information about health data legislation requirements and the actors within the regulatory landscape. The needs of patient ethics, local data privacy and other local data governance actors will be explored at a general level. Learners will be taken on the path to incorporate the timelines and governance requirements of health data privacy and the impacts and requirements for projects or pilots that require the use of health data.

**Learning Outcomes**

- General introduction to students to data regulation and the system in Europe and the US.
- External actors in the health data regulatory system in Europe (i.e. notified bodies, National Competent Authorities, European Commission etc.).
- Internal actors such as the role of the Data Privacy Officer and Ethics Committees.
- Interpreting legislation to understand the impact on requirements for data privacy and management.
- Incorporating legislative requirements into project plans for health data-related initiatives.
- Patient ethics and considerate use of sensitive data.
- Working with regulation requirements across geographical boundaries

# Data-driven optimisation with process mining

4 ECTS

**Module Description**

Process mining is a field that combines data mining techniques with process modelling and analysis to gain insights into business processes. In the context of healthcare, process mining can be used to analyse and improve patient care processes, identify bottlenecks, optimise resource allocation, and enhance the overall quality of healthcare delivery. This course aims to provide students with a comprehensive understanding of process mining concepts, techniques, and their application in the healthcare domain.

**Learning Outcomes**

- Understand the fundamental concepts of process mining and its relevance in healthcare.
- Learn various process discovery techniques and apply them to healthcare data.
- Gain knowledge of process conformance-checking methods and their application in healthcare processes.
- Acquire skills to analyse and visualise healthcare processes using process mining tools.
- Explore advanced topics in process mining, such as causal analytics and process enhancement.
- Develop critical thinking and problem-solving abilities by applying process mining techniques to real-world healthcare scenarios.

**Unit 1.**
Introduction to Process Oriented Data Science in Healthcare.

**Unit 2.**
The Interactive Process Mining Methodology for Healthcare.

**Unit 3.**
Data Curation in Process Mining.

**Unit 4.**
Process Discovery and Process Conformance Checking in Healthcare applications.

**Unit 5.**
Process Analysis and Visualization in Healthcare.

**Unit 6.**
Use Cases for Process Mining for Healthcare.

## Contact us for further inquiries

https://eithealth.eu/certified-innovation-path/

https://eithealth.eu/health-data-innovation/

Co-funded by the European Union