EUPATI Open Classroom

MODULE 3. HEALTH TECHNOLOGY ASSESSMENT (HTA) AND MEDICAL DEVICES

EUPATI

Introduction and summary

The importance of patient involvement in medicines R&D is commonly acknowledged and offers benefits for all involved parties. Patients should have access to knowledge and experiences that enable effective participation. EUPATI training responds to the need for educated patients in the current medicines R&D system and allows patients to develop their capacity to collaborate and engage with other stakeholders as equal partners.

This module is composed of two of the modules available in the EUPATI Open Classroom, the Health Technology Assessment (HTA) module and the Medical Devices module.

The **Health Technology Assessment (HTA)** module introduces what a health technology is, what stands for and why it is becoming increasingly popular in European healthcare systems.

This module introduces the different approaches to HTA and details which approaches might be considered best and how patients can be engaged in HTA within their respective health systems. It also outlines the HTA principle bodies as well as quantitative and qualitative assessment methods. Understanding what health systems need and how HTA is a key mechanism for addressing patient needs should help to promote and make patient engagement in HTA more effective.

The **Medical Devices module** provides an overview of medical devices and their regulatory framework. It also details the history of medical devices, the different classifications, the role of notified bodies and conformity assessment, CE marking and recertification.

The module delves into medical device development and life cycle management under MDR and IVDR and new technologies in the context of medical devices and in vitro diagnostics (IVD). It also elaborates on the general principles of market access and market entry for medical devices and the different aspects of value-based innovation.

The module provides key definitions of Health Technology Assessment (HTA) in medical devices and the principles of HTA in medical devices and in vitro diagnostics (IVDs).

Learning and Assessment

The objective of EUPATI is to provide appropriate academic and rigorous training, yet presented in a way that enables concrete and applicable learning outcomes for the patient community, leading to measurable impact in medicines development.
Each on-demand training unit has a short multiple choice assessment that is available to learners wanting to receive a certificate for the training unit.

Training is delivered through the **EUPATI Open Classroom**, a Moodle workplace learning management system that includes instructional text content, infographics, videos and case studies. The learner has also access to an online **toolbox and glossary.**

The **Toolbox** is an online library on the A-Z of medicines research and development (R&D) and patient involvement. The purpose of the Toolbox is to provide access to well-structured, comprehensive, scientifically reliable, and user-friendly educational materials for patients on a variety of topics in these areas. The information is not medicine- or disease-specific, but is applicable to the majority of diseases and/or medicines.

The **Glossary** is integrated into the content and allows learners to read keyword descriptions as they go through the learning process.

Learning is **modular, flexible and on-demand**, supported by the EUPATI team. The Trainees can access learning materials at their own pace and convenience. Once they finish a course or module, the certificates is generated automatically after successfully completed assessment.

The **assessments** are made for each course and are problem-based multiple-choice questions. Assessments are used to determine the competency of the established learning outcomes for each course in the module.

During the course learners are encouraged to:

- Make connections between what they have learned and their personal and professional situation.
- Think of opportunities to apply the training in their personal and professional life.

Learning and assessment strategies

EUPATI Open Classroom uses the following learning strategies to effectively deliver educational content to trainees in a digital environment:

- **Asynchronous Learning**: Trainees can access learning materials at their own pace and convenience. They can read course materials including lectures and infographics, watch videos, listen to audios and complete assignments without being constrained by a specific schedule.

- **Microlearning**: Breaking down complex content on medicines R&D into small, easily digestible units allows trainees to absorb information more effectively. The content is separated into different pages with short text lessons that are combined with images, infographics, and videos.

- **Gamification**: Open Classroom uses badges after the completion of each module. Learners get rewards for completing their profile or finishing modules which can boost their engagement and progress. They can also share these badges on LinkedIn and get public recognition of their learning.

- **Self-assessment and feedback**: The online modules include self-assessment quizzes at the end of each course. This module includes 6 courses, therefore, to obtain the certificate for this module it is necessary to complete 6 quizzes. Along the lines of microlearning, Open Classroom encourages frequent, small-quantity assessments that help learners calibrate their understanding of the material. Immediate feedback on their performance helps learners identify areas for improvement and reinforces their understanding of the content.

- **Multimedia integration**: The modules offer multimedia elements, such as videos, images, infographics, to enhance the presentation of content and meet different learning styles. User-friendly content is available on different devices such as desktops, tablets and cell phones.

- **Real-world application**: Incorporating real-world examples and case studies as part of the content helps learners understand how the knowledge they acquire can be applied in practical life situations.

- **Accessibility and Inclusion**: The content meets the accessibility features to ensure that learners with disabilities can fully participate in the learning process.

Curriculum

The Module of Health Technology Assessment (HTA) is composed of 5 courses and the module of Medical Devices is composed of 4 courses.

Completion of all 9 courses is mandatory to obtain the module Health Technology Assessment and Medical Devices

Courses	Hours*
Health Technology Assessment (HTA)	
Introduction to Health Technology Assessment (HTA)	4
HTA Bodies and Principles	6
HTA and Evaluation Methods: Quantitative	8
HTA and Evaluation Methods: Qualitative	8
Patient Involvement in HTA	6
Medical Devices	
Introduction to Medical Devices and their regulatory framework	4
Medical Device development, Lifecycle management, New Technologies, Patient involvement	4
Introduction to market access, key elements and patient involvement	2
Introduction to Health Technology Assessment (HTA) of Medical Devices and IVDs	4
Total hours	**46**

*This is an estimate based on the volume of content, although the actual hours required vary on an individual basis.

Learning Outcomes per course

The learning outcomes of the different courses of this module are:

Health Technology Assessment (HTA)	
Courses	**Learning Outcomes**
Introduction to Health Technology Assessment (HTA)	• Understand the key definitions and guiding principles of HTA. • Understand the major use of HTA. • Describe the difference between HTA bodies and regulatory authorities. • Understand the role of HTA in health systems • Describe the principles for decision making • Describe the rights that govern HTA proceedings • Describe the composition of a HTA committee, including patients
HTA Bodies and Principles	• Describe the fundamentals of a HTA process Identify principles applicable to structuring and governing HTA organisations • Understand the impact of HTA decisions • Describe the key principles for the conduct of HTA • Describe the fundamentals of a HTA process • Describe and explain differences in HTA structure and remit • Understand how health care systems influence HTA structure • Understand HTA networks and collaboration
HTA and Evaluation Methods: Quantitative	• Understand the differences between HTA, regulatory and patients' purposes and interests. • Describe which domains should be included in a standard HTA • Understand the use of different outcome measures in HTA • Understand the synthesis of clinical research data • Understand the principles and standard approaches to economic evaluation • Understand which information contributes to cost-effectiviness analyses • Understand how purpose and perspectives impact HTA • Understand the differences between medical outcomes and societal effect and ethical issues in HTA • Understand the legal aspects and implications of HTAs

HTA and Evaluation Methods: Qualitative	• Understand the difference between quantitative and qualitative research • Understand the role each type of research plays in HTA • Understand the principles of Patient Reported Outcomes • Understand the practical application and importance of Patient Reported Outcomes in developing evidence for health technologies • Understand where and how patients can apply these to the HTA process and formulary decision in their country • Understand HRQoL as a sub-set of PRO concepts • Understand the main approaches to measuring HRQoL • Know the main domains and understand the methods of measuring HRQoL • Understand the limitations of current approaches and potential alternatives
Patient Involvement in HTA	• Understand how patients can contribute to HTA • Understand different methods for obtaining evidence for patients' priorities • Understand how to use evidence for patients' priorities in HTA
Medical Devices	
Courses	**Learning Outcomes**
Introduction to Medical Devices and their regulatory framework	• Understand key definitions of Medical Devices and in vitro diagnostics (IVDs) • Acquire knowledge about the regulatory framework of the Medical Devices and in vitro diagnostics (IVDs) • Follow the history of the Medical Devices and the regulatory framework • Understand the key principles for application of the Medical Devices • Describe the classifications of the Medical Devices and in vitro diagnostics (IVDs) • Understand the role of the Notified Body and Conformity assessment • Acquire knowledge about CE marking and re-certification

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Medical Device development, Lifecycle management, New Technologies, Patient involvement	• Understand the Medical Devices development and the lifecycle management under the MDR and IVDR • Acquire knowledge about the new technologies in the context of Medical Devices and in vitro diagnostics (IVDs) • Understand the implementation of the digital health and Artificial Intelligence in Medical Devices • Acquire knowledge about borderline products • Learn about patient involvement in Medical Devices • Understand the patient involvement roadmap for Medical Devices development
Introduction to market access, key elements and patient involvement	• Understand the general principles about market access and market access for Medical Devices • Acquire knowledge about procurement for Medical Devices • Learn about Value-based Healthcare as an approach in Medical Devices • Understand the different aspects of Value-based innovation