EUPATI
Open Classroom

Flexible and on-demand e-learning platform providing courses in medicines research and development for patients, patient representatives and other stakeholders.

A personalised learning pathway about the end-to-end process of medicines R&D

EUPATI Open Classroom is a new format of the pioneering and well recognised EUPATI Patient Expert Training Programme and now allows learners to take the courses online on-demand at their own pace and preferred order.

Graduates of the programme will be able to act as EUPATI Patient Expert and be involved in medicines research, regulatory deliberations, development of therapeutic innovations and other patient engagement initiatives.

The content of the EUPATI Patient Expert Programme has been developed following the Patient Engagement Roadmap, a process model that provides guidance for patient involvement in the different areas of the medicines R&D process.

EUPATI Open Classroom is:

- **FLEXIBLE:** user-friendly, access from your preferred device
- **PERSONALISED:** follow your own learning plan
- **CONVENIENT:** you decide when to study
- **WORLDWIDE:** participants from anywhere in the world can acquire in-depth knowledge in a selection of topics in medicines R&D or graduate from the programme as EUPATI fellows

Research Priorities → Research Design & Planning → Research Conduct & Operations → Dissemination, Communication, Post Approval

For more information please visit

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EUPATI Open Classroom

EUPATI Learning Catalogue page 1

MODULE	COURSES	LEARNING OUTCOMES
Getting Started	Overview of Medicines Research and Development	• Begin your learning on medicines research and development by taking this overview course.
Introduction to Medicines R&D	Process of Medicines Discovery and Development	• Describe the process of medicine discovery and development and identify the critical factors and decision points • Explain the concepts of efficacy and safety of a medicine • Relate pharmacovigilance to the concept of benefit - risk of medicine • Understand the concepts of life-cycle and intellectual property management of a medicine
	Role of Patients and Patient Organisations in Medicines R&D	• Explain the importance and describe the possible role of patients and/or patient organisations in medicines development.
	Role of Translational Research in Medicines R&D	• Discuss the role of translational research in medicines development. • Discuss the potential application of the concept of personalized/stratified medicine in the medicines development process including the role of biomarkers.
	Concepts of Evidence-Based Medicines and Outcomes Research	• Outline the concepts of evidence-based medicine and outcomes research.
	Predisposing Factors and Underlying Mechanisms of Disease	• Describe predisposing factors and underlying mechanisms of disease.
	Types of Medicines and Their Mode of Action and Use	• Classify types of medicines and their mode of action and use.

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EUPATI Learning Catalogue page 2

MODULE	COURSES	LEARNING OUTCOMES
Non Clinical Development	Requirements for Non-clinical Studies and the Purpose and Relevance of Animal Testing	• Describe the need and requirements for non-clinical studies prior to clinical studies in humans and the purpose and relevance of animal testing.
	Development of Medicines Substance and Final Medicines Product	• Outline the steps in the development of a medicines substance and final medicines product (including chemical and biotechnology-derived products).
	Role of Pharmacogenetics / Pharmacogenomics in the Development of Medicines	• Discuss the techniques that are emerging in specific product development or disease areas. • Understand the role of pharmacogenetics/pharmacogenomics in the development of medicines. • State the ethical challenges.

I enrolled in the EUPATI course because I considered that it was an excellent opportunity to educate myself about medicines research and development so that I would be able to 'sit at the table' and engage with relevant stakeholders in my ultra-rare disease. The EUPATI course provided me with the motivation, knowledge and confidence to establish a charity to support and advocate on behalf of patients. It also provided me with an extensive network of fellow patient advocates who continue to be a source of support, advice and collaboration 7 years later.

Maria Piggin, EUPATI Fellow

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EUPATI Learning Catalogue page 3

MODULE	COURSES	LEARNING OUTCOMES
Clinical Development	Clinical Trials and Trial Management	• Describe basic clinical trial concepts, types and benefits of different clinical trial designs and their practical implications including decisions to alter or end the trial before termination • including the role that patients can play
	Early Clinical Development	• Understand the principles of pharmacology, methods of measuring and; • Describe the types of studies in early clinical development (Phase I and Phase II studies)
	Trial Participants' Rights & Obligations	• Describe trial participants' roles and rights and how they are protected.
	Ethics	• Understand the basic concepts and statistical methods used in clinical research. • Describe the purpose of the statistical analysis plan (SAP).
	Statistics	• Describe types of data and the principles of data collecting and management in clinical trials. • Outline the principles and key elements of overall clinical trial quality management and the stakeholders involved.
	Documentation & Management	• Describe types of data and the principles of data collecting and management in clinical trials. • Outline the principles and key elements of overall clinical trial quality management and the stakeholders involved.
	Interpretation and Dissemination of Results	• Describe the elements of clinical trial results including how to avoid bias, fraud, misconduct and ethics violations during trial and reporting of results. • Describe how to perform critically reading.

EUPATI Learning Catalogue page 4

MODULE	COURSES	LEARNING OUTCOMES
Regulatory Affairs	Introduction to Regulatory Affairs	• Describe the legislative framework for medicines regulation • Understand the current EU regulatory requirements (pre and post-authorisation) for a medicinal product • Describe the various roles patients can play in approval and benefit-risk evaluation pre- and post-approval of medicines
	Epidemiology and Pharmacoepidemiology	• Illustrate the basic concepts of epidemiology • Describe the application of epidemiological research • Explain the concepts of prevalence and incidence in epidemiology
	Pharmacovigilance - Risk management	• Outline the principles of pharmacovigilance • Explain the major steps in pharmacovigilance signal management • Explain the concept and structure of EudraVigilance • Outline the principles of risk management for medicinal products in the European Union (EU) including the risk management plan
	Product information and information to the public	• Describe the components of product information and access to information they contain • Outline the legal mandate and review process of product information • Explain the difference between advertising and promotion of medicines to the general public and healthcare professionals with reference to the legal framework
	Regulatory procedures-Marketing-Authorisations and their lifecycle management	• Understand the basics of regulatory affairs functions in pharmaceutical companies • Understand and explain the principal EU regulatory legal framework and procedures for authorising a medicine • Describe and discuss the regulatory steps in a marketing authorisation application (MAA) for a medicine, including the different types of MAAs and their legal basis

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EUPATI Learning Catalogue page 5

MODULE	COURSES	LEARNING OUTCOMES
Health Technology Assessment	Introduction to Health Technology Assessment (HTA)	• Understand the key definitions and guiding principles of HTA. • Describe the difference between HTA bodies and regulatory authorities. • Understand the role of HTA in health systems
	HTA Bodies and Principles	• Identify principles applicable to structuring and governing HTA organisations • Understand the impact of HTA decisions • Describe the fundamentals of a HTA process • 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. • 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 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 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

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MODULE	COURSES	LEARNING OUTCOMES
Medical Devices	Introduction to Medical Devices and their regulatory framework	• Understand key definitions of Medical Devices and in vitro diagnostics (IVDs) • Understand the key principles for application of the Medical Devices • Acquire knowledge about CE marking and re-certification
	Digital Health Applications Infostructure Infrastructure	• Understand the Medical Devices development and the lifecycle management under the MDR and IVDR • Understand the implementation of the digital health and Artificial Intelligence in Medical Devices • Learn about patient involvement in Medical Devices • Understand the patient involvement roadmap for Medical Devices development
	Digital Health Development Process	• 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
	Legal, Regulatory, and Health Technology Assessment (HTA) Concepts of Digital Health	• Acquire knowledge about the Health Technology Assessment (HTA) principles in Medical Devices and in vitro diagnostics (IVDs) • Acquire knowledge about the EU regulatory framework of HTA and the correlation with Medical Devices • Understand about clinical effectiveness and Evidence generation for HTA • Acquire knowledge about the patient involvement in HTA in the context of Medical Devices

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EUPATI Learning Catalogue page 7

MODULE	COURSES	LEARNING OUTCOMES
Digital Health	Digital Health: Introduction, Classification Impact	• Understand and discuss the major classifications in the field of digital health. • Outline the impact of digital health across the health ecosystem and main stakeholders. • Describe the scope of digital health solutions.
	Digital Health Applications Infostructure Infrastructure	• Explain, with examples, the value of digital health solutions for different patient interactions with the health system. • Recognise the importance of both Infostructure and Infrastructure in digital health solutions. • Understand the development of Infostructure and Infrastructure in digital health solutions.
	Digital Health Development Process	• Summarise the development process of digital health solutions and its different stages. • Understand how stakeholders, across the health ecosystem, offer insights that are vital to the development of digital health solutions.
	Legal, Regulatory, and Health Technology Assessment (HTA) Concepts of Digital Health	• Identify the prerequisites for the European Health Data Space to operate. • Understand basic concepts in information governance, e.g. EU digital health policy, regulatory and compliance, real-world data/evidence (Big data), data protection & data privacy.
	Digital Health Transformation and challenges	• Understand the steps which enable successful digital health transformation and how patients can be involved throughout. • Recognise the conditions that support and nurture digital health transformation. • Understand how digital health transformation, directly and indirectly, impacts patients to foster their empowerment. • Identify the main challenges patients and other stakeholders face enacting digital health transformation.

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HOW DOES EUPATI OPEN CLASSROOM WORK

1. Visit EUPATI Open Classroom website and register
2. Select a Module from the learning catalogue
3. From your Module select a course and click to enrol
4. Access the learning materials
5. Pay the fee to unlock the assessment
6. Pass the assessment and earn a certificate
7. Complete all course assessments within your selected Module and earn a badge – for each Topic fully completed you will earn a new badge!

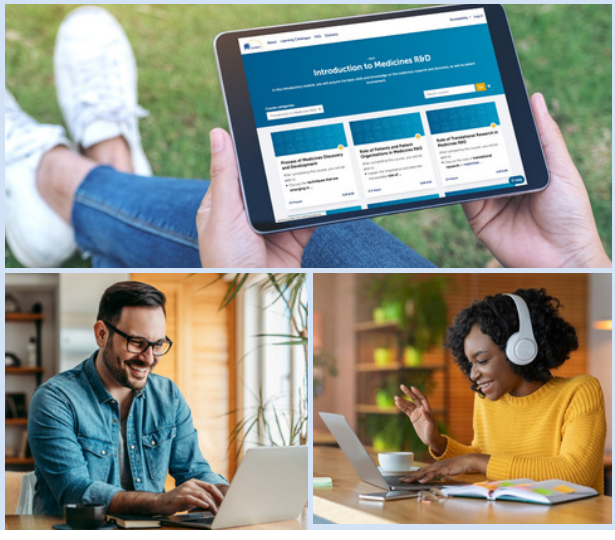
HOW TO BECOME A EUPATI FELLOW

1. Register in the Patient Expert Training Programme. Registrations open every summer.
2. Complete the modules Getting started, Introduction to Medicines R&D, Clinical Development and Non Clinical Development and attend the online event in Spring
3. Complete the Regulatory Affairs and HTA module and attend the in person event in Autumn
4. Graduate and get your EUPATI Patient Expert Training Programme certificate at the end of the fall event

WHAT IS A EUPATI FELLOW?

Graduates of the EUPATI Patient Expert Training Programme are also known as EUPATI Fellows. The title certifies the knowledge gained and will give you the opportunity to be recognised as an expert patient. EUPATI Fellow is a well-known label within the patient engagement landscape. EUPATI fellows are highly sought-after partners by different stakeholders.

Join the EUPATI Alumni of 250+ graduates.



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