



EUPATI Patient Expert Training Programme Guidelines 2023 - 2024

What is the EUPATI Patient Expert Training Programme?

The EUPATI (European Patients' Academy on Therapeutic Innovation) Patient Expert Training Programme is a training programme about the medicines' development process. It covers the entire lifecycle of medicines research and development (R&D) (see roadmap [here](#)), from design and execution of research projects and clinical trials to regulatory processes and Health Technology Assessment (HTA). In addition to detailed information on each step of the process, the training also describes how patients can be involved at each stage.

The overall objective of the programme is to obtain a thorough understanding of the medicines R&D process, the patients' role within and build capacity among the patient community to take on an active role in collaboration with the other involved stakeholders.

Graduates of the EUPATI Patient Expert Programme (EUPATI Fellow Programme) are also known as EUPATI Fellows or Alumni. The EUPATI Fellow title certifies the knowledge gained and gives graduates the opportunity to be recognised as expert patients.

You can find more information about this programme on [Open Classroom](#), EUPATI online learning platform.

EUPATI has established 24 [National Platforms](#) (ENP's) across Europe and worldwide. Trainees are encouraged to contact their National Platform.

Who can participate?

While the programme is mainly addressed to patients and patient representatives (e.g., carers and persons working for patient organisations), it is open to all individuals interested in medicines R&D and patient engagement.

The programme does not focus on any specific disease area, examples and case studies are provided from a variety of different disease areas.

The only requirement for enrolment is a good proficiency of English, as the training is provided in English.

Programme Timeline





Registration Process

Please read these Programme Guidelines in full. To register, fill in the registration form. We will ask you to fill in some details and confirm that you wish to participate in EUPATI Patient Expert Training Programme. By clicking on 'submit' you will consent to Programme Guidelines as outlined in this document.

There is a limited number of participants who can enrol for the Programme.

The registration deadline for the 2023-24 Programme is 1 November or when the maximum of registrations has been reached.

How is the EUPATI Patient Expert Training Programme structured?

The programme is a blended training in which participants take 6 online modules (containing 27 courses in total) and attend 2 face-to-face events (1 virtual and 1 in-person). Completing the full programme usually takes 12-14 months.

While the courses and modules can be taken in any order, learners need to have completed the modules Getting Started, Introduction to Medicines R&D, Non-Clinical Development, Clinical Development before the 1st training event and Regulatory Affairs and Health Technology Assessment (HTA) before the 2nd event.

- Getting Started (1 course, free of cost)
- Introduction to Medicines R&D (6 courses)
- Non-Clinical Development (3 courses)
- Clinical Development (7 courses)
 - 1st training event (4 days, online)
- Regulatory Affairs (5 courses)
- Health Technology Assessment (HTA) (5 courses)
 - 2nd training event and graduation (4 days, in-person)

For more information on the individual courses included in each of the learning modules, please consult Patient Expert Training Programme online course catalogue.









- **Completing an online course** means passing the assessment for each of the individual courses with 70% or higher of correct answers.
- **Completing an online module** means all courses within a module have been completed with a successful assessment.
- **Completing the training events** means reading the training material (sent 1 month in advance of the training date) and attending fully both 4-day programmes as well as active participation in breakout sessions.

Absences in training events are tolerated up to 4 hours over the 4-day programme. Longer absences and absences for medical reasons need be communicated in a timely manner to EUPATI and justified.

The table below provides further details on the structure and content of the events.

PATIENT EXPERT TRAINING PROGRAMME EVENTS

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FOR INQUIRIES, EMAIL US AT INFO@EUPATI.EU

	<p>SPRING MEETING Online event</p> 	<p>AUTUMN MEETING In person event</p> 
	<p>The event includes lectures, breakout sessions, open debates and discussions focused on Non-clinical and Clinical Development</p>	<p>The event includes lectures, breakout sessions, open debates and discussions focused on Regulatory affairs & Health Technology Assessment (HTA)</p>
	<p>During the sessions the following topics are covered:</p> <ul style="list-style-type: none"> • Critical reading of scientific publications • Statistics • Review of clinical trials (setup, objective, planning, protocols) • Regulatory environment for clinical trials • Patient involvement in ethics committees • Patient involvement with regulatory bodies • Patient role providing scientific advice • Good Lay Summary Practice <p>The agenda is subject to modifications due to new regulations and developments</p>	<p>During the sessions the following topics are covered:</p> <ul style="list-style-type: none"> • Ethical Principles in Clinical Care • Pharmacovigilance & self-reporting • Benefit-risk in the medicine's life cycle • Communication of safety issues • Package leaflet information • Clinical trial protocol for marketing authorisation • Practical application of HTA • Systematic community-led data collection <p>The agenda is subject to modifications due to new regulations and developments</p>
	<p>Informal networking sessions will be organized at the end of each day to get to know each other better</p>	<p>This is the time for networking and meeting your peers, the faculty and team in person</p> <p>Graduation will take place on the last day</p>  

ATTENDANCE TO BOTH EVENTS IS REQUIRED TO COMPLETE THE PATIENT EXPERT TRAINING PROGRAMME

IMPORTANT Registered participants are required to complete the first part of the programme before attending the first face-to-face event and to complete the second part of the programme before attending the second face-to-face event and graduation. Not completing the required online learning modules before the training events will result in removing the participant from the ongoing cohort. In such cases, placement on the list for the following cohort can be requested by the participant. Such requests will be reviewed and approved on case-by-case basis.

How much does Patient Expert Training Programme cost?

The costs of the programme are divided in 2 parts:

1. Online learning courses: invoice

Upfront payment of EUR 208 (incl. VAT): corresponding to an 8 EUR fee for each of the 26 courses (1 online course is free of charge). **Invoicing:** EUPATI will issue an invoice for each participant registered for the Patient Expert Training programme. Completing the payment will ensure participant's placement in the programme. In case of participants having completed some parts of the online modules already, invoices for the remaining fees will be issued.

2. Face-to-face events: personal expense

First training event: there are no costs for participants for the first virtual face-to-face event.



Second training event: **participants must cover their transportation, accommodation and meals**

Financial Support

Participants are encouraged to contact their patient organizations or their EUPATI national platforms for information about possible avenues for financial support.

Financial support by EUPATI will be made available to cover the costs of travel and accommodation for the in-person training event to a limited number of participants who can prove an economic need or are not able to receive financial support from other sources.

Detailed Timeline for Patient Expert Training Programme 2023-2024

JUNE 2023	JULY	AUGUST	SEPTEMBER	OCT	NOVEMBER 2023	DECEMBER 2023	JAN	FEBRUARY 2024	MARCH	APRIL 2024	MAY 2024	JUNE	JULY	AUGUST	SEPTEMBER	OCTOBER 2024
As of June 2023: rolling assignment to programme. Payment via flat fee.																
					Registration closes. Official launch of the 2023-2024 programme											
						Introductory webinar										
								Kick-off webinar								
Online Modules 1 - 4																
										Event 1: Online. Deadline for completing Online modules 1 – 4.						
												Meet the ENPs webinar				
											Online Modules 5 and 6					
																Event 2: in-person. Deadline for Online Modules 5 and 6. Graduation.

Cancellation/Change Policy

Programme costs are non-refundable. However, participant can request to be placed on the next year’s cohort. Such requests to withdraw from current programme cohort and be placed on the next year’s programme will be reviewed and approved on case-by-case basis. **Trainees can request to be placed in the next cohort only once.**

Useful links

- [Open Classroom](#), EUPATI online learning platform. [Patient Expert Training Programme information page](#) and [FAQ](#) on Open Classroom.
- [Toolbox](#), EUPATI information library about medicines research and development
- [Patient Engagement Roadmap](#), a practical roadmap about patient involvement in medicines R&D



- [EUPATI Website](#), everything about EUPATI, its activities and [National Platforms](#).

Other policies

1. Security policy:

Safety and security are our primary concern for our participants attending face-to-face events. We recommend following travel advice of participants' respective countries and respect health and safety measures in the destination country. EUPATI does cover basic insurance for participants during the in-person events.

2. Audio-visual Recording policy

Audio and video recording from EUPATI will happen only with consent of event attendees and with rights to switch off camera in virtual events and express wish not to be captured on audio/video in face-to-face event. Unconsented video/audio recording done by participants is prohibited. GDPR (General Data Protection Regulation) rules and [EUPATI Code of Conduct and Ethical Framework](#) are in effect and we trust that participants do not use any personal details or content acquired through the programme for commercial purposes or other unauthorized purposes.

3. Governing Law

These guidelines are governed by and construed in accordance with Dutch law. EUPATI and the participant will do their utmost to achieve an amicable settlement or arbitration of any dispute arising between them in the performance of the present guidelines.