# EUPATI TRAINING COURSE

## Patient Experts in Medicines Research & Development

EUPATI
European Patients' Academy on Therapeutic Innovation

**Cohort 4**

**October 2019 – April 2021**

# A Guide for Applicants

# Purpose of this Guide

The European Patients' Academy (EUPATI) was launched in 2012 with the overall objectives of developing reliable information for patients on modern treatment development and educating patient representatives and the public on medicines' research and development.

The EUPATI Patient Expert Training Course has been specifically designed to meet the needs of **patients** and **patient advocates** who have the motivation and skill set to acquire and apply expert-level knowledge across the whole spectrum of the medicines research and development (R&D) process. To our knowledge, such a complete in-depth training for lay people on medicines research and development has never been done before.

This Guide is designed to assist you in preparing your application for this Course. To that end, this Guide compiles much of the essential information you will need to know about this Course. This information includes the profile of participants we are targeting, the application process and form, and the criteria and process we have put in place to ensure we meet the highest standards of integrity and transparency in selecting the participants.

Upon completing this Course, we hope our participants, as patient experts on medicines R&D, will have the knowledge to make a meaningful contribution to the medical community to provide better medicines to patients and to generate a broader dialogue around future patient involvement in the medicines research and development process across Europe.

**We strongly recommend that all applicants read this guide carefully before filling out and submitting the application**.

If you fulfil all the eligibility criteria for this Course and are genuinely committed to becoming a patient expert in the medicines research and development process, we strongly encourage you to submit your application by **28 October 2019, 13:00** (**Central European Time**).

Applications received after that deadline cannot be considered.

Should you have any further questions, please contact us at: applications@patientsacademy.eu.

# Contents

# About the European Patients' Academy on Therapeutic Innovation (EUPATI)

## Objectives of EUPATI

EUPATI has three specific objectives in providing the Patient Expert Training Course:

- **Objective 1**: To improve the availability and dissemination of accessible, well-structured and user-friendly information on new treatment development, clinical trials, the efficacy and safety assessment, personalised medicine, the risks and benefits, their economic implications, along with assessment tools for each area in a format that enables people to access what they need, when they need it.
- **Objective 2**: To improve the capacity of "patient experts" and well-informed patients in patient organisations in order to provide objective, credible, understandable and accurate information to the wider patient community and public.
- **Objective 3**: To facilitate appropriate patient-relevant advice to industry, academia, authorities, and ethics committees by ensuring genuine cross-stakeholder patient partnership in research and development, access, and safety.

More information about EUPATI: http://www.eupati.eu/welcome/

## Who runs EUPATI?

We are a team of various stakeholders, led by the European Patients' Forum (EPF), and including a unique combination of patient organisations (The European Patients' Forum - EPF, the European AIDS Treatment Group - EATG, and Rare Disease Europe - EURORDIS), universities, and not-for-profit organisations expert in public and patient engagement, along with many European and global pharmaceutical companies.

Our common goal is to help you be more educated and involved in your health care.

## Who is our target?

EUPATI targets different audiences:

- **Patient Experts** trained within the EUPATI Patient Expert Training Course. 150+ leading patient advocates (EUPATI Fellows) have already completed the Course since EUPATI launch in 2012. This is the training programme we are presenting in this Guide.
- **Patient Organisations Representatives** interested in advocacy and **the health-interested public at large** are provided with the EUPATI "Toolbox" including cutting edge educational material for patient advocates, including print material, slide shows for face-to-face presentation, internet-based e-Learning Courses, webinars and videos, complemented by face-to-face events.
- The EUPATI website and Toolbox reached 2,250,000 users by September 2019.

With a view of enhancing our efforts to reach out to these audiences, we have helped to establish "EUPATI National Platforms (ENP)" as the main vehicle for implementing our project at a national level.

In particular, the National Platforms support the implementation of our educational programmes for all audiences by facilitating local communication, dissemination and awareness-raising. National Platforms have been implemented in numerous countries: more details can be found on the EUPATI website.

## Why do we need EUPATI?

Due to the complexity of pharmaceutical medicines development, benefits and risks of existing and new treatment alternatives are often difficult to understand even for expert patients. In an era of growing demand and emphasis on both quality and sustainability of healthcare, it is critical to address this major gap in public perception and knowledge. Well-informed patients and carers have a key role to play in the implementation of patient-centred clinical research strategies and approval processes, access to treatments, as well as treatment optimisation approaches.

There is a need for new information resources, designed for a wide spectrum of patients and the public, that explore pharmaceutical research and development. A coordinated approach by all parties involved in this process is therefore needed to develop reliable and up-to-date information for patients.

Patient empowerment is increasingly being recognised across Europe and abroad as an essential element of an effective healthcare system and is advocated as a means to improve patient safety and increase efficiency in developing new therapies.

# The EUPATI Patient Expert Training Course

## Introduction

Our Patient Expert Training Course is an exciting and unique opportunity that offers patients and patient advocates expert-level training in medicines research and development, specifically tailored for them. The Course is designed to improve the understanding of information on medicines Research and Development (R&D) and to stimulate more meaningful involvement of patients in the current discourse of medicine development.

The Course relies on new learning and teaching methodologies which are tailored to patients and patient advocates who have the genuine interest and skill set to acquire and apply expert-level knowledge across the whole spectrum of the medicine research and development process.

Course trainees are expected to dedicate at least **250 hours for the e-learning** part and **8 days (including travel) for two face-to-face training sessions** for the complete training Course throughout 15 months, from October 2020 to April 2021

The Course is divided into 6 Modules covering all aspects of the medicines development process including discovery, development, evaluation, marketing authorisation, and post-marketing evaluation. The Modules are as follows:

**MODULE 1**: Discovery of Medicines and Planning of Medicines Development

**MODULE 2:** Non-Clinical Testing and Pharmaceutical Development

**MODULE 3:** Exploratory and Confirmatory Clinical Development

**MODULE 4:** Clinical Trials

**MODULE 5:** Regulatory Affairs, Medicinal Product Safety, Pharmacovigilance and Pharmacoepidemiology

**MODULE 6:** Health Technology Assessment (HTA) principles and practices

Only those applicants who can commit to **completing all 6 training Modules** – both online learning courses and face-to-face meetings – should apply. The face-to-face meetings will total 8 days, including travel time. No certification will be provided for only partially completing the course.

Each Module is split into several lessons and has specific learning outcomes allocated to it, which indicate what you will learn upon completing the lessons.

The list of learning outcomes is available in Annex 1 at the end of this Guide.

This Course has been designed in such a way as to encourage all our participants to apply knowledge and skills acquired via three main areas:

- **Patient Representation**: EUPATI Patient Experts will be able to actively engage in representing a patient perspective in the medicines development process by interacting

with scientific committees, Health Technology Assessment agencies, industry, regulatory bodies, academia and other relevant stakeholders.

- **Communication**: EUPATI Patient Experts will be able to contribute to raising awareness on patient involvement in medicines research and development amongst lay patients, hard-to-reach patients and the lay public. Some examples of activities include writing articles and press releases, organising press conferences, facilitating cooperation with media, being a spokesperson in TV and radio programmes, and utilising social networks and blogs.
- **Education/Training**: EUPATI Patient Experts will be able to play the role of facilitators/trainers by engaging in activities supporting the dissemination of the education and information programmes for both patient advocates and lay patients and the general public in their countries, through their patient communities and networks. Some examples of activities include: providing training to patient advocates; leading workshops; running information sessions for people interested in participating in clinical trials or wanting to learn more.

## How is the learning organised?

The Course has been designed so that our participants will learn the content primarily online through a dedicated e-learning platform "MOODLE", in the form of text, videos, and audio.

If needed, the participants are welcome to print the materials themselves for offline use. We regret that we are not in position to mail hard copies of the teaching materials directly to any of the participants of the Course.

While the major part of the teaching is delivered via e-learning, Course participants are also required to attend two face-to-face training sessions. Both sessions will take place in Madrid in 2020 and early 2021 and will consist of interactive teaching in order to consolidate learning and to provide opportunities to implement the knowledge gained throughout the e-learning.

The dates of the face-to-face sessions are:

- **First session (focus on pre-authorisation): 5 - 8 October 2020**
- **Second session (focus on post-authorisation), including Graduation: 29 March – 1 April 2021**

In the spirit of the blended approach of this Course, all 6 Modules include an e-learning part as well as face-to-face teaching.

Face-to-face events will focus primarily on clinical development, ethical issues, drug safety, and Health Technology Assessment (HTA). The face-to-face events will also have a strong focus on how patient involvement can be integrated - practically - into medicines research and development all along the process.

Face-to-face events will be delivered by experts in each of the main Modules. They will come from different backgrounds, such as patient organisations, academia, regulatory, HTA, industry, and ethics committees.

It is a requirement of this program to attend both face-to-face meetings in Madrid.

## Module sequence and Course pace

Although the programme allows a flexible learning environment for our trainees to work at their own pace, trainees are strongly encouraged to progress through the programme at a similar pace to their peers by respecting, insofar as possible, the deadlines that have been settled for the completion of each of the e-Learning Modules. By doing so, we will be able to ensure that

opportunities for online discussions and tutoring can be taken advantage of and that when the participants meet together, the time is utilised optimally. To this end, teaching will happen in a linear fashion.

This structured approach is supported by the use of online interaction / question system via an online forum. Dedicated members of the EUPATI team can monitor these discussions and provide tutoring, moderation, and facilitation throughout the Course.

Modules will be open sequentially starting from Module 1 "Discovery of Medicines and Planning of Medicines Development" that will be open on **19 December 2019**, date marking the official kick-off of the Course with a webinar from **5.00 pm until 6.30pm (CET)**.

With the launch of each new Module, all previous Module(s) will remain open, meaning that once released, the materials will be available for download and reference throughout the remaining duration of the Course.

## Assessment

Assessing what trainees have gained in terms of knowledge, understanding, and application is the final part of any learning process. In order to receive a certificate from EUPATI which attests knowledge of the medicines' development process, an assessment is a prerequisite.

The purpose of this training Course is to educate as many patient experts as possible in the process of medicines' research and development. It is in everyone's interest that as many participants as possible successfully complete the EUPATI Course.

To achieve this, assessment on the EUPATI training Course will be carried out via:

- **Unrecorded knowledge checks** at the end of each e-Lesson: Knowledge checks will take the form of 1-2 multiple choice or free-form questions at the end of each e-learning lesson. These assessments may be repeated an unlimited number of times and the result of trainees' attempt will not be recorded. Unrecorded knowledge checks have been set up for the trainees to check for themselves that they have understood the e-Lesson correctly.
- **Recorded multiple choice (MCQ) quizzes** at the end of each Module. MCQ quizzes will consist of 20-40 questions depending on the Module. The fixed pass mark will be 70%. Results will be recorded by the LMS (Learning Management System). In the event that a passed mark is not achieved, participants may retake another version of the test two days after their last attempt.
- **Active participation in the face-to-face events** and in the **patient involvement forum**.

## Advisor

At the beginning of the course, you will be assigned an advisor who will be your first point of contact throughout your studies. They are backed up by a multi-stakeholder team from the EUPATI Consortium who will support you throughout your participation in the EUPATI Expert training course.

## Certification

Upon attaining a pass in each of the six Modules and satisfactory participation in the face-to-face events and the online patient involvement forum, trainees will be issued a "EUPATI Certificate" at the Graduation in the second Face-to-face event confirming their successful completion of the EUPATI Patient Expert Training Course.

## Costs

EUPATI is committed to the provision of free education to the patient community. Participation in this Training Course is free of charge. There is no charge for accessing the e-learning materials, videos, etc.

Participants will need to fund their own travel and accommodation for the compulsory face-to-face trainings in Madrid. In order to minimise costs of the training and participation, EUPATI will negotiate a preferential rate for accommodation at the location of the training, though participants are welcome to make their own arrangements. Lunch will be provided on every training day.

EUPATI will endeavour to help pay for travel costs for those participants who can prove an economic need or are not able to receive financial support from a patient organisation, as financial limitations should not prohibit anyone from applying to or participating in the EUPATI Course.

EUPATI can provide coverage of all travel and accommodation costs for 15 participants on the course. If you need this support to able to participate in the Patient Expert Training Course, please make sure that you complete the relevant section on the application form (Part J of the application form). Please note that if you ask for this assistance and are unsuccessful, your application will not be considered further with your supporting yourself.

## Equal Opportunities and Accessibility

EUPATI is committed to equal opportunities and will endeavour to accommodate the specific needs of applicants with disabilities, medical conditions, and family circumstances that may have an impact on day-to-day activities, to participate in and successfully complete the EUPATI training Course, as far as is reasonably practicable.

To this end, EUPATI will:

- Encourage applications from people with specific needs;
- Judge applicants who disclose specific needs solely based on the selection criteria described in the related section of this Guide;
- Invite applicants with a specific need(s) to contact EUPATI to discuss how their requirements can be accommodated;
- Work towards the earliest possible assessment of needs and offer of reasonable solutions where possible;
- Take steps to encourage participants with progressive conditions, or who develop specific needs during the training Course, to continue their participation;
- Promote an inclusive environment and attitude amongst the wider training Course community.
- Hold the face-to-face sessions in facilities which are accessible and provide adequate numbers of accessible bedrooms.

# Profile of participants and Eligibility Criteria

The EUPATI Patient Expert Training Course has been specifically designed to meet the needs of patients and patient advocates who have the motivation and skill set to acquire and apply expert-level knowledge across the whole spectrum of the medicine research and development process.

Accordingly, applications are open to individuals **who meet all the following requirements**:

1. **Be a Patient Representative committed to applying the knowledge and skills learnt.** Applicants must be one or more of the following:
   - Volunteer or Employee of a patient organisation; or
   - Patient with a chronic and/or lifelong illness/condition who is not affiliated with a patient organisation; or
   - Family member/carer (not affiliated with a patient organisation) of a patient with a chronic and/or lifelong illness/condition.

   We expect applicants to be ready to commit to use the knowledge and skills acquired through this training in their different capacities as patient advocates or patient representatives. When you have completed this Course, we hope you will have the knowledge to make a meaningful contribution to the medicines research and development process to provide better medicines to patients. You are expected to also be able to generate a broader dialogue around future patient involvement in the medicines research and development process across Europe.
2. **Be living in the European Region as defined by the World Health Organisation**. Applications will be accepted from candidates active/living in the European Region according to the WHO definition:

| | | | |
|---|---|---|---|
| Albania | Finland | Lithuania | Serbia |
| Andorra | France | Luxembourg | Slovakia |
| Armenia | Georgia | Malta | Slovenia |
| Austria | Germany | Monaco | Spain |
| Azerbaijan | Greece | Montenegro | Sweden |
| Belarus | Hungary | Netherlands | Switzerland |
| Belgium | Iceland | Norway | Tajikistan |
| Bosnia-Herzegovina | Ireland | Poland | FYR Macedonia |
| Bulgaria | Israel | Portugal | Turkey |
| Croatia | Italy | Republic of Moldova | Turkmenistan |
| Cyprus | Kazakhstan | Romania | Ukraine |
| Czech Republic | Kyrgyzstan | Russian Federation | United Kingdom |
| Denmark | Latvia | San Marino | Uzbekistan |
| Estonia | | | |

3. **Have a keen interest in the medicines research and development process**. Applicants need to demonstrate they have a genuine interest in acquiring expert-level knowledge of medicines' research and development processes.

   Although not a requirement as such, due to the structure and complexity of the Course contents, it is recommended that applicants have at least a basic knowledge and understanding of medicines' research and development processes.

4. **Are ready to commit to:**

   a) **approximately 250 hours** to study the e-learning content;

   b) **actively participate in the online forum discussions** during the entire duration of the Course;

   c) **attend the two face-to-face training sessions**, which will be run over 8 days (twice 4 days) in Madrid, Spain. The dates of the two face-to-face events are **5-8 October 2020** and **29 March – 1 April 2021**.

5. **Possess working knowledge of English**: The Course readings and assessment are available in English only and the two face-to-face sessions will require a high level of interaction and communication in English.

   Accordingly, applicants must have a working knowledge of English **at least B2 Common European Framework of Reference for Languages (CEFR) in reading, listening and speaking** http://www.coe.int/t/dg4/linguistic/cadre1_en.asp .

6. **Have access to high-speed internet connection:** except for the two face-to-face sessions, this Course is designed to be accessed entirely online. Opportunities are provided for online tutoring support and discussions and all lessons include videos and links which would not be accessible without the Internet. Accordingly, it is essential that participants have access to a computer and high-speed Internet connection. No hard copy materials for the online components will be provided to participants. For this course a high-speed internet connection has a speed of 8 mb/s or more.

# Selection Criteria & Selection Process

## Selection Criteria

As mentioned in the previous chapter all applications received by the deadline of Monday **28 October 2019 (13:00 CET)** will first and foremost undergo an "eligibility check" to make sure all eligibility criteria set out above are fulfilled.

Those applications that pass the initial eligibility screening will be evaluated for their content. EUPATI is committed to ensuring that the evaluation process meets the highest standards for transparency, objectivity, and rigorousness.

A number of criteria will be used for selecting the participants to the EUPATI Training Course. These criteria have been endorsed by the General Assembly of the EUPATI Consortium.

The selection criteria are as follows:

1. **Experience related to the 3 EUPATI profiles (PART G of the application form, first three boxes):** Patient Representation, Communication, Providing Education/Training (22.5% of the total score, i.e. 7.5% each).
2. **Experience in interacting with stakeholders (PART G of the application form, fourth box)** (accounting for 10% of the total score)
3. **Please provide up to 2 examples where you have represented your patient community or done advocacy on their behalf directed at other stakeholders. (PART G, fifth box)** (accounting for 10% of the total score)
4. **Quality of the individual motivation for applying.** This will account for 22.5% of the total score which will be assigned to you based on the answers you will provide to the following questions (**PART H of the application form**):
   a) What are your objectives or goals in participating in the EUPATI training Course?
   b) What do you expect to gain from the training?
   c) How will your participation in this Course contribute to and improve medicines research and development in your region or country and/or Europe?
   d) How do you plan to contribute to the EUPATI community once you have graduated?
   e) How does your personal and/or professional experience prepare you for this Course?
5. **Commitment to using and applying knowledge and skills acquired during and after the completion of the Course** (**PART I of the application form**) (35% of the total score). In PART I of the application form, you will need to describe how you intend to apply the knowledge and skills you will acquire during the course putting particular emphasis on the unique contribution you think you can make to the Medicines Research & Development to benefit the patient community.

Current knowledge and experience in medicines' research and development is not used as a selection criterion. The rationale behind that is that with this Course, EUPATI is ultimately aiming to educate patients and patient advocates who have the motivation and skill set to acquire and apply expert-level knowledge across the whole spectrum of the medicine research and development process.

The table below summaries the selection criteria and score percentages which eligible applications will be assessed against:

| Selection criteria | Weight |
|---|---|
| Experience related to the 3 EUPATI profiles | 22.5% |
| Experience in interacting with stakeholders | 10% |
| Two examples where you have represented your patient community or done advocacy on their behalf | 10% |
| Quality of the individual motivation for applying | 22.5% |
| Commitment to using and applying knowledge and skills acquired during and after the completion of the Course | 35% |
| **TOTAL** | **100%** |

## Selection process

The final selection will be made by an **Independent Selection Panel** consisting of four members: 1 representative of patient organisations, 1 representative of a healthcare non-profit organisation, 1 from industry, and one EUPATI Fellow (course graduate). Applications will be assessed using the above criteria according to a transparent scoring system. Each member of the Selection Panel will first perform an independent assessment. All members of the panel will then convene in a meeting to agree on a final assessment and selection.

We aim to have each application assessed individually by at least three randomly assigned members of the selection panel. In assigning applicants to members of the panel, we will make sure that no conflicts of interests arise, e.g. if a member of the panel knows an applicant well.

A specific tool has been designed for the members of the Selection Panel to conduct the assessment. Each member of the Selection Panel shall perform an independent assessment against each of the five selection criteria listed above by means of a 10-point scoring system (1= very poor to 10 = excellent).

To give you a concrete example, if you receive an average score of “7” to the quality of your motivation letter (PART H of the application form), which accounts for 22.55% of the total score, you will get 16.13 points [(7 x 0.225) x 10] in respect of this criterion. If you then receive a score of “7.5” in relation to your commitment to using and applying knowledge and skills, which accounts for 35% of the total score, you will get another 26.25 points [(7.5 x 0.35) x 10], and so on and so forth.

The composition of the selection panel will be made publicly available after the start of the course. This is necessary based on previous experience to ensure they are no solicited by applicants or others on the applicants’ behalf.

The table below provides for an example of how the scoring system works.

| Criterion | Weight | Reviewer 1 | Reviewer 2 | Reviewer 3 | Reviewer 4 | Average Reviewers | Weighted Average |
|---|---|---|---|---|---|---|---|
| **Experience related to EUPATI Profiles (Part G)** (average of a, b, and c) | 22.50% | 6.67 | 7.00 | 8.00 | 7.00 | 7.17 | 16.13 |
| *a) Representation* | 7.50% | 7.00 | 8.00 | 9.00 | 7.00 | 7.75 | 5.81 |
| *b) Communication* | 7.50% | 8.00 | 7.00 | 7.00 | 6.00 | 7.00 | 5.25 |
| *c) Education/Training* | 7.50% | 5.00 | 6.00 | 8.00 | 8.00 | 6.75 | 5.06 |
| **Experience in interacting with stakeholders (Part G)** | 10% | 6.00 | 6.00 | 7.00 | 8.00 | 6.75 | 6.75 |
| **2 examples where you have represented your patient community or done advocacy on their behalf** | 10% | 7 | 8 | 7 | 9 | 7.75 | 7.75 |
| **Quality of the individual motivation for applying (Part H)** | 22.50% | 8.00 | 9.00 | 8.00 | 9.00 | 8.50 | 19.13 |
| **Commitment to using and applying knowledge and skills acquired during and after the completion of the Course (Part I)** | 35% | 8.00 | 8.00 | 7.00 | 7.00 | 7.50 | 26.25 |
| **TOTAL Score** | 100.00% | 74.00 | 78.00 | 74.50 | 77.50 | 76.00 | 76.00 |

The assessment of applicants will be strictly based on merit.

However, it is important that as an applicant you are aware that the EUPATI Consortium is committed to striving toward building knowledge and skills that can be applied in as many European countries as possible.

Similarly, we strive towards having patient advocates representing or working with different common or rare, chronic and/or lifelong, genetic or acquired, mental and physical diseases.

In order to ensure appropriate geographical spread and disease balance among Course participants, the applicants that will be selected may, therefore, not necessarily be the 60 applicants who have received the highest score.

With a view to ensuring full transparency in the selection process the following thresholds will apply:

- **No more than 5 applicants from the same country will be selected** (e.g. if there are 10 applicants from the same country in the top 60, only the five highest-scoring ones will be selected);
- **No more than 5 applicants from the same disease area will be selected** (e.g. if there are 7 applicants from the same disease area in the top 60, only the five highest-scoring ones will be selected);
- **Preference will be given for representation of countries and disease areas not currently represented by EUPATI Alumni**.
- **All applicants selected must score higher than the average of all applications.**

## Application and selection process: key dates

All eligible applicants will receive notification to confirm if they have been successful or not **by 16 December 2019**. We hope you understand that we cannot provide individual feedback to applicants who have not been selected.

All communication in relation to your application will be done by email. **Please ensure that your email address is correct on your application form**.

We kindly ask that candidates refrain from contacting us to inquire about the status of the application.

Should you not hear about the outcome of your application by 17 December 2019, we ask you to send an inquiry to applications@patientsacademy.eu. Successful candidates will receive guidelines for their participation to the programme.

The illustration below fleshes out the key milestones for the selection of the 60 participants of the fourth EUPATI Expert Patient Training Course.

- Launch of the online application: **1 October 2019**
- Application period: **1 October – 28 October 2019 at 13.00 CET**
- Eligibility screening: **28 October – 30 October 2019**
- Independent content-based assessment by Selection Panel: **31 Oct – 6 Dec 2019**
- Final list of 60 selected applicants: **16 December 2019**
- Course starts: **19 December 2019**
- Course ends: **April 2021**

## How to Apply

Applications for the EUPATI Training Course should be submitted online via the following link: https://www.formdesk.com/eupati/EUPATIApplication

Please make sure that you answer each question with as much detail as possible. You may use the Word version of the application (available on the EUPATI website) to prepare your answers in advance.

**We regret that incomplete applications or applications received after the deadline of 28 October 2019 (13:00 CET) cannot be accepted or considered.**

We thank you for your interest in EUPATI Training Course and look forward to receiving your application.

## Application Form

The information below will assist you in filling out the application form.

All personal data collected for the recruitment process will be protected according to the EU General Data Protection Regulation (GDPR) 'on the protection of individuals with regard to the processing of personal data and on the free movement of such data, for more info, click here. Applicants' data will only be used for the purposes of this selection procedure and will in no case be transmitted to any third party outside of the EUPATI Consortium. Any data provided will be treated in the strictest confidence and with high standards of security.

All documents provided to EUPATI during this selection procedure will be kept in EUPATI's files and will not be returned to applicants. Application documents will only be kept for as long as it is mandatory to fulfil the requirements of existing auditing/control procedures applicable to EUPATI.

The application form contains the following sections:

A. **Content of the Course**
B. **Face-to-Face training sessions**
C. **Declaration of Commitment**
D. **Applicant's General Information**
E. **Language**
F. **Experience in medicines research & development**
G. **Experience in the EUPATI Specific Profiles**
H. **Motivation**
I. **Commitment to applying learning acquired**
J. **Specific Requirements**
K. **Data Protection**
L. **Letter of Recommendation**
M. **Certification and Acknowledgements**

You do not have to complete your application in one session – you are able to save your answers and complete your application at a later time. The program will provide you with an access code to retrieve your saved application. Please ensure that all sections are completed

and all questions marked with an asterisk (*) are answered. **You will not be able to submit the application unless all required questions have been answered**.

Upon submitting the completed application form, the system will generate an automatic email message acknowledging the receipt of your application form. If you have not received such an email after submitting your application form within 24 hours, please contact us at applications@patientsacademy.eu well before the deadline. Verification of your email address is the final step of your application process and you will receive a personal message thereafter from the EUPATI team to confirm receipt of your application.

**We advise you not to not wait until the last days to start preparing your application and recommend you make sure you submit your form before the closing day to avoid late submissions**, as they will not be taken into consideration. Support for applications can only be provided during business hours (9.00 to 17.00 CET) from Monday to Friday.

## PART A – Content of the course

Please familiarise yourself with the Course programme, its structure, expectations, and requirements. We have designed this Course to reflect the learning needs and capacities of patients who would like to be more actively engaged in medicines R&D and to represent patients' voice and interest in the current treatment discourse.

## PART B - Face-to-Face training sessions

In addition to extensive online e-learning, two face-to-face training meetings will take place in Madrid, Spain. Successful applicants are expected to attend in full all e-learning modules and the two face-to-face training sessions.

Please confirm that you are available for these days as well as your commitment to cover your expenses or your wish to apply for EUPATI to cover you travel and accommodation. You need to ensure that you have a valid passport/ID card to travel to Spain. Please do not make travel arrangements right away, as the information about this will be communicated to the successful applicants after the launch of the Course.

## PART C - Declaration of Commitment

Only applicants who are fully committed to attend and fully participate in all elements of the EUPATI Expert Training course will be taken into consideration.

## PART D - Applicant's General Information

In this part of the application please ensure that you answer each question, paying particular attention to the accuracy of your email address.

All correspondence regarding your application for the EUPATI Course will be done via email only. If several answers apply to a question, please select all that apply.

## PART E - Language

The Course readings and assessment are available in English only and the two face-to-face sessions will require a high level of interaction and communication in English. Accordingly, applicants must have a working knowledge of English at least at an upper intermediate level or B2 Common European Framework of Reference for Languages (CEFR).

Please refer to the CEFR guidelines for levels of language knowledge: https://europass.cedefop.europa.eu/en/resources/european-language-levels-cefr

## PART F - Experience in medicines research & development

In this section, we would like to understand your experience and knowledge in the medicines research & development process, including your strengths and any areas of knowledge that you would like to develop further. In 400 words or less please describe your involvement with the medicines research and development. If you have not been engaged with R&D, please tell us which skills and knowledge on what topics you would like to gain.

Please note that even though the Course is designed for those who have a keen interest in medicines research and development and would like to further develop and apply the knowledge, due to the length and complexity of the Course contents, we strongly recommend applicants have at least a basic knowledge and understanding of medicines' research and development processes.

## PART G – Experience in the EUPATI specific profiles

The EUPATI Training Course aims at enabling patient advocates to actively participate in medicines research & development processes in different roles. Here we would like to know about your interest, previous experience and skills in different areas where you may apply the knowledge provided by EUPATI after the training Course. For each question please provide a short response of 300 words or less describing your skills and experience in relation to the indicated areas. If you do not have experience in an indicated area, please indicate so in the comment box.

Please note that your answers to these questions (altogether) will represent 42.5% of the total score for your application.

## PART H – Motivation

In addition to submitting the application form, we ask you to answer four questions outlining your motivation, goals, objectives and expectations from attending the EUPATI Training Course. In this part you have an opportunity to demonstrate how your participation in this training can contribute to improving medicines research and development in your country or region and in Europe.

We ask that you limit your response to 150 words per question.

Please note that your answers to these questions (altogether) will represent 22.5% of the total score for your application.

## PART I – Commitment to applying learning acquired

In addition, please mention what will be your unique contribution to the EUPATI training and to your patient community. You may want to highlight how your professional and/or educational experience fit with EUPATI's objectives.

Please note that your answers to these questions (altogether) will represent 35% of the total score for your application.

We ask that you please limit your response to 500 words.

## PART J - Specific Requirements

Please describe any specific requirements you may have in relation to disabilities, medical conditions, and family circumstances that may have an impact on your ability to participate in and successfully complete the EUPATI training Course.

Please indicate if you need support to cover your travel and accommodation for the two Face-to-Face trainings in Madrid.

## PART K - Data Protection

The Applicant expressly agrees to the collection, processing and use of personal data as described below.

Please note that all personal data collected for the recruitment process will be protected according to the EU General Data Protection Regulation (GDPR)on the protection of individuals with regard to the processing of personal data and on the free movement of such data, please click here for more information.

Applicants' data will only be used for the purposes of this procedure and will in no case be transmitted to any third party outside of the EUPATI Consortium. Any data provided will be treated in the strictest confidence and with high standards of security. All documents provided to EUPATI during this recruitment procedure will be kept in EUPATI's files and will not be returned to applicants. Application documents will only be kept for as long as it is mandatory to fulfil the requirements of existing auditing/control procedures applicable to EUPATI

The Applicant is herewith informed by EUPATI in detail on the type, scope, place of and reason for the collection, processing, and use of personal data necessary to process the application. Personal data of the Applicant is used for the following purposes only:

- To ensure accurate communication with the Applicant by e-mail.
- To perform the selection procedure for the training programme.

Moreover,

- EUPATI will not use Applicant's data to send unsolicited materials of any kind;
- EUPATI will not make Applicant's data available to third parties for marketing or promotional purposes;
- The applicant has a right to access and ask to change or delete their personal data, which is kept by EUPATI;
- EUPATI will always answer individual questions concerning the protection of personal data. Please send your questions or comments to applications@patientsacademy.eu.

## PART L – Letter of Recommendation

Applicants may choose to provide letters of recommendations (up to 3), from e.g. a patient organisation, a EUPATI National Platform, someone familiar with the advocacy work of the applicant.

## PART M - Certification and Acknowledgement

Please read this section carefully and indicate your acceptance by inserting your name and the date.

# Frequently Asked Questions

Below we have compiled a list of frequently asked questions. You can always email us if you need further clarifications at applications@patientsacademy.eu.

### Do I need to complete all sections of the application form?

Yes. Incomplete applications will not be considered. If some of the questions do not apply to you, please indicate so by "N/A" in the corresponding answer box. Please note that questions marked with an asterisk (*) are mandatory. The system will not allow you to submit the application form unless all mandatory questions have been answered.

### Do I need to complete my application form in just one session?

No, you are able to save your answers and come back to your application at a later time - the application software will provide you with an access code via email which you can use to return to your saved application.

### What is the deadline for my application form?

Application forms must be submitted by **28 October 2019, 13:00** (Central European Time). We regret that applications received after that deadline will not be considered regardless of the reason for the late submission. We strongly encourage all interested candidates to submit their applications well before the deadline to avoid late submissions due to technical issues.

### I have been on other training courses on medicines R&D, can I still apply?

Yes, you can still apply. The aim of this particular training programme is to equip patient and patient advocates with reliable information on modern research on treatment development topics. Successful applicants are not expected to be experts on medicines R&D at the time of the start of the Course. However, due to the structure and complexity of the Course contents, applicants are expected to have at least a basic knowledge and understanding of medicines research and development processes.

## Selection Process

### How many people will receive a place?

60 people will be granted a place on the 2019-2021 EUPATI Patient Expert Training Course.

### I applied for the EUPATI in the past but was not successful? Can I re-apply?

Yes, you can re-apply. We encourage all previous applicants to try again!

### How are applicants selected?

The selection of the participants is done via a transparent process.

The first step consists of an eligibility check whereby all applications received by the published deadline will be first reviewed for their accuracy, completeness, and eligibility.

In the second step, applications are reviewed by a multi-stakeholder panel* and individually scored by each member before a selection being made as a group decision.

All the results of the selection process are provided to the applicants by the course coordinator.

*For transparency, the composition of the panel will made public after results have been communicated to applicants. The identity of the panellists remains confidential during the application process to ensure no undue influence or solicitation.

### Why are there thresholds for countries and disease areas?

Even though the assessment of applicants will be strictly based on merit, it is important that as an applicant you are aware that the EUPATI consortium is committed to striving toward building knowledge and skills that can be applied in as many European countries as possible.

Similarly, we strive towards having patient advocates representing or working with different common or rare, chronic and/or lifelong, genetic or acquired, mental and physical diseases.

Thresholds have, therefore, been settled in order to ensure appropriate geographical spread and disease balance among Course participants.

### When will I hear if I have a place?

All applicants will receive notification to confirm if they have been successful or not by **16 December 2019.** You will be notified by email so please ensure your email address is correct on your application form. We kindly ask the candidates to refrain from contacting us before 16 December 2019 to inquire about the status of the application. Should you not hear about the outcome of your application by 17 December 2019, we ask you to send an inquiry. The email will come from applications@patientsacademy.eu, please add this email address to your safe list so that the notification email does not end up in your spam folder.

### If my application is successful, what are the next steps?

Attend the kick-off webinar on 19 December 2019 5.00 pm until 6.30pm (CET). Further information on the next steps will be communicated to successful applicants in due course.

### Are there places reserved on the course for EUPATI National Platform?

There are no places on the course 'reserved' for EUPATI National Platform (ENP) members. EUPATI has seen a benefit in countries where trainees (and graduates) collaborate with the ENP in their country (where available) and strongly encourages applicants to establish a relationship before applying to the course, remember and ENP may provide a letter of recommendation for applicants.

### As an active patient advocate at the national level, I'm really interested in EUPATI, but I don't have much time, what should I do?

The course requires at least 250 hours of study and up to eight days to attend the face-to-face events over a 15-month period. This estimate may be much higher for trainees whom English is not their first language. This means that accepting to take part in this course requires trainees to commit a significant amount of time on a weekly basis (approx. 3 hours). Please make sure you have enough time to dedicate to this completing the course starting from December 2019 and throughout the entire duration of the course.

Luckily, the course is just one way people can get involved with EUPATI and it is only one of the educational tools on offer. Anyone is free to study and utilise the EUPATI toolbox for patient advocates. Contacting your EUPATI National Platform and getting involved with their work in your country is probably a good starting point for you!

### Are course participants expected to contribute to the work of EUPATI in their country?

The course seeks to create patient experts who will help drive forward patient involvement in medicines' research and development. EUPATI National Platforms (ENPs) have the task of bringing national patient experts together. As such, in countries where there is an established ENP, it is strongly encouraged that course participants work very closely with their local ENPs, and get directly involved in shaping the local ENPs strategies for the future, along with sharing information with the wider community.

## Participating in the programme

### Do I need to take all six training Modules?

Yes, only those applicants who can commit to taking all six Modules and attending the two face-to-face meetings will be offered a place on the Course. To ensure you are able to make these commitments you might want to consider approaching your employer now to confirm you would be able to take annual leave, in the event that you are successful.

### Do I need to print out the training materials?

The EUPATI Course relies on e-learning which is tailored to patients at large. With the exception of the two face-to-face sessions, this Course is designed to be accessed entirely online. Opportunities are provided for online tutoring support and discussions, and all lessons include videos and links which would not be accessible without the internet. Accordingly, it is essential that participants have access to a computer and high- speed internet connection. Therefore, no hard copy materials for the online components will be provided to participants, although if you wish to download and print them yourself, they are downloadable.

### Will I be able to ask questions, given that this is an online course?

Yes. For each of the Modules we will have a dedicated team of tutors who will be available to provide feedback and assistance to the trainees during the entire Course. Further information will be communicated to the successful applicants.

### Will I need to complete exams at the end?

There is no formal final examination at the end of the Course. However, an assessment quiz will be performed at the end of each Module. This will be either “pass” or “not passed” (70% pass mark): no grades will be given. Trainees’ participation at the Face-to-Face meetings will be assessed by the faculty on a basis of took part/did not take part, all trainees must actively participate in the Face-to-Face to complete the EUPATI Course. There will be no final exam at the end of the Course.

### Will I need to organise and pay for my own travel and expenses to attend the meetings?

EUPATI provides the training for free, including food and beverages throughout the Face-to-Face training days. The training takes place in Madrid, Spain and trainees are responsible for their own travel, accommodation and other expenses. EUPATI will endeavour to help pay for accommodation and travel costs for those participants who can prove an economic need, there are 15 spaces available at this time.

EUPATI estimates the costs of accommodation and travel for each Madrid Face-to-Face meeting at around 600€ based on staying at the event location (approx.115€ per night) and average travel routes of trainees in previous years.

Financial limitations should not prohibit anyone from applying to or participating in the EUPATI Course, we strongly encourage applicants to work with their patient organisations, communities, and the stakeholders they engage with to help fund their participation in this course which will benefit the patient community for years to come.

*For transparency, the first three courses, EUPATI received financial support from the Innovative Medicines Initiative and other grants and was in the position to cover all travel costs for the face-to-face trainings. However, as this is no longer the case, EUPATI is no longer able to cover these costs.*

### Will I need a visa to attend face-to-face training Modules?

Depending on your citizenship and/or country of residence, you may need to obtain a visa. Should you need a visa, we will assist you in obtaining relevant support letters and other documents to receive a visa. More information will be provided to the participants.

## How can I get more information which I cannot find in the guide for applicants?

If you require any further information, please contact the EUPATI Team at applications@patientsacademy.eu.

# Annex: Learning Outcomes

## Module 1: Discovery of Medicines and Planning of Medicines Development

After completing this Module, you will be able to:

- Explain the importance and describe the possible role of lay people/patients/patient organisations in medicines development;
- Describe the process of medicines discovery and development and identify the critical factors and decision points along the way;
- Describe the background to the development of regulation of medicines and the roles of the various stakeholders;
- Discuss the role of biomarkers in medicines development;
- Discuss the potential application of the concept of personalized/stratified medicine in the medicine development process;
- Discuss the role of translational research in medicines development;
- Outline the concepts of evidence-based medicine and outcomes research;
- Describe predisposing factors and underlying mechanisms of disease and the different classes of medicines and their mode of action;
- Describe how can patients, patient representatives, and patient advocates contribute to this process.

## Module 2: Non-Clinical Testing and Pharmaceutical Development

After completing this Module, you will be able to:

- Illustrate the predictive value of non-clinical testing as part of the overall medicine development plan (including scheduling of toxicology tests with respect to clinical trials) for chemical and biological compounds;
- Describe the non-clinical development steps of medicines; explain the milestones a compound needs to reach during non-clinical development in order to progress to the next phase;
- Illustrate non-clinical outcomes that can stop the development of a medicine;
- Discuss the need and requirements for pre-clinical studies prior to human studies, and the purpose of animal testing (including toxicology, pharmacology, non-clinical safety studies);
- Outline the steps in the development of a medical agent and the final medical product (including chemical and biological compounds);
- Based on the understanding of the blinding process, identify ways in which you as a patient advocate can contribute to the choice of blinding mechanisms;
- Outline differences in generic development vs. classical medicines development;
- Describe guidelines for the use of generics;
- Discuss how patients and patient advocates can contribute to this process of non-clinical testing.

## Module 3: Exploratory and Confirmatory Clinical Development

After completing this Module, you will be able to:

- Define intended therapeutic indication, including its limitations and criteria for “go/no-go” development decisions;
- Describe the early clinical development plan and clinical study types (and Phases) and their objectives beginning with “first-in-human”;
- Critically appraise the role of pharmacogenetics / pharmacogenomics in the development of medicines and discuss the ethical challenges;
- Outline the basic principles of pharmacokinetics and their application to dose-finding and all subsequent phases of medicines development;
- Define the Life Cycle Management of a medicine, its purpose and possible approaches via post-marketing trials;
- Evaluate and compare the emerging techniques in specific product development or disease areas;
- Discuss the advantages and challenges of global coordination / harmonisation of clinical trial programmes, before and after marketing authorisation;
- Discuss the different ways in which patients and patient organisations can contribute in clinical development.

## Module 4: Clinical Trials

After completing the Module, you will be able to:

- Outline the key strategic and operational issues in the clinical trial process, including legal, regulatory and practical aspects and the possibilities of collaboration of different stakeholders;
- Appraise the principles and practical relevance of ethics in clinical research and the role patients can play, e.g., in ethics committees;
- Explain and demonstrate the clinical trial approval process, including the required documentation, and the roles of patients/patient reps/patient orgs and provisions for special/vulnerable patient populations;
- Describe the main statistical methods used in clinical research;
- Critically evaluate the concept of benefit-risk, the collection, evaluation and reporting of adverse event data and risk management in clinical trials and the various roles patients/patient reps can play;
- Describe the principles of data management and the associated quality measures and study documentation in clinical trials;
- Appraise the relevant aspects of patient compliance for study medication including its labelling and handling;
- Understand and be able to critically evaluate the content of clinical trial websites and their use in identification of trials in any disease area (including reporting of adverse events);
- Differentiate types of clinical trials and their design, and evaluate their relation to Good Clinical Practice (GCP);
- Discuss all aspects of the interpretation, publication and communication to patients of all clinical trial results;
- Discuss the various roles patients and patient representatives can play in this process.

## Module 5: Regulatory Affairs, Medicinal Product Safety, Pharmacovigilance, and Pharmacoepidemiology

After completing this Module, you will be able to:

- Critically review the current EU regulatory requirements (pre- and post-authorisation) for a medicinal product;
- Critically evaluate the pharmacovigilance of a medicinal product and the role of the various stakeholders, including patients and patient reps;
- Discuss the various aspects of shortages of medicines and the role of the different stakeholders;
- Discuss the role and importance of Regulatory Agencies and all stakeholders in the lifecycle of a medicinal product;
- Describe the provisions of (1) off-label use (2) compassionate use and (3) controlled medicinal products at a national and EU level;
- Outline the European legislative background and review processes for product information;
- Explain the role of different organisations in the development and implementation of regulatory legislation in Europe;
- Critically discuss treatment compliance and comprehension;
- Locate and navigate regulatory agencies' websites and other trusted sources of information on medicinal product interactions;
- Discuss patients' possible roles in this process.

## Module 6: Health Technology Assessment Principles and Practices (HTA) After completing this

Module, you will be able to:

- Understand the meaning of "Health Technology Assessment" (HTA) and "Health Economics" (HE) in relation to medicines development;
- Understand the key principles, elements, methods of HTA and HE;
- Outline the fundamentals of what a good HTA process looks like including clinical benefit assessment, economic evaluation, as well as ethical, legal and social implications;
- Understand the practical steps involved in developing and using HTA reports in different countries and health care systems;
- Understand meta-analyses, systematic reviews, and how this can contribute to HTA reports;
- Understand the concept of value of medicines for the different stakeholders;
- Describe the importance of patient evidence and how it can be used;
- Understand the principles, practical application and importance of patient-reported outcomes in developing evidence;
- Outline the difference between quantitative and qualitative research;
- Describe how patients can become involved in the HTA process.