EUPATI TRAINING COURSE

Patient Experts in Medicines Research & Development

Third Cycle

September 2017 – December 2018

A Guide for Applicants

Purpose of this Guide

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 **31 March 2017, 23:59** (**Central European Time**).

Applications received after that deadline will not be considered.

Should you have any further questions, please contact us at: eupati@efgcp.eu.

Contents

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

Objectives of EUPATI

EUPATI was launched in 2012 with the overall objectives of developing reliable information for patients on modern medicines development and educating patient representatives and the public on medicines research and development.

EUPATI has three specific objectives:

- **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 is implementing the EUPATI project?

We are a team of various stakeholders, led by the European Patients' Forum (EPF), and made up of 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 pharmaceutical companies.

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

Who is our target?

EUPATI targets three different audiences:

- **Audience 1 - Patient Experts,** trained within the EUPATI Patient Expert Training Course. 100 leading patient advocates are expected to complete the Course by the end of the project. This is the training programme we are presenting in this Guide.
- **Audience 2 - People from Patient Organisations** interested in advocacy 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. Through our Toolbox, which will be available in several European languages, we aim to reach out to 12,000 patient advocates
- **Audience 3 – The health-interested public at large** is served by our Internet Library and news articles, explaining, e.g., specific aspects of the development process of medicines for health-interested patients and citizens, including those with low (health) literacy. Our goal is to reach out to 100,000 people.

With a view of enhancing our effort to reach out to these three audiences, we have helped to establish “EUPATI National Platforms” 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 either exist or are being established in the following countries: Austria, Belgium, France, Germany, Ireland, Italy, Luxembourg, Malta, Poland, Spain, Switzerland, and the United Kingdom.

Why do we need this project?

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 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.

Two cycles of the training Course have been organised as part of the EUPATI project, enabling about 100 participants to be trained on medicines' research and development processes. The first cycle began in October 2014 and went through December 2015. The second cycle ran from **22 September 2015 to end-November 2016**.

Course trainees are expected to dedicate at least 250 **hours for the e-learning** part and **8-10 days (including travel) for two face-to-face training sessions** for the complete training Course.

The Course is divided into six 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 six training Modules** – both online learning courses and face-to-face meetings – should apply. The face-to-face meetings will total 8-10 days, including travel time.

Each Module is split into several topics 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.

The EUPATI Training Course encourages participants to apply the knowledge and skills acquired through the Course in three main areas according to their experience and aspirations.

This Course has been designed in such a way as to encourage all of 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 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 "eBooks", videos, and podcasts.

All materials will be available for download. If needed, the participants are welcome to print the materials. 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 Barcelona in 2018 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: 26 February-2 March 2018**
- **Second session: 17-21 September 2018**

In the spirit of the blended approach of this Course, all six 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 Barcelona.

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 in September 2017, with the exact date marking the official kick-off of the Course to be announced.

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 (100 in the remit of EUPATI) 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). Trainees will be allowed three attempts to attain the pass mark.
- **Active participation in the face-to-face events** and in the **patient involvement forum**.

Tutors

During the entire learning process, highly-qualified content tutors will be available. The tutors represent three main stakeholders that are part of the EUPATI project, namely representatives of patient organisations, academia, and pharmaceutical companies. For each Module, a dedicated team of content tutors will be at your disposal to facilitate and moderate the learning process.

Apart from Module-specific online tutoring, participants of our Course will also benefit from the support of a team of Course Advisers who will accompany them throughout the entire duration of the programme.

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" confirming your successful completion of the EUPATI Patient Expert Training Programme.

This certificate will also include a note about the organisations/institutes/companies which recognise the certificate. In order to make sure this has value, EUPATI has committed to driving efforts to receive buy-in from as many organisations/institutes/companies as possible ahead of the issue of the first certificates (starting with all consortium partners and members of advisory group).

A page on the website will be maintained detailing an expanding list of these stakeholders and also explaining the achievements of the participants.

Costs

Participation in this Training Course is entirely free of charge. There is no charge for accessing the eLearning materials, videos, etc.

For the face-to-face training, EUPATI will cover the costs of accommodation in Barcelona and the cost of breakfast and lunch for each day of the training. Participants are expected to cover their own travel to and from Barcelona, along with the cost of their own evening meals. 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.

*For the first two cycles of the Course, EUPATI was in the position to cover all travel costs for the face-to-face trainings. However, as EUPATI is no longer receiving financial support from the Innovative Medicines Initiative (IMI), we are no longer able to cover these costs. If EUPATI is able to acquire additional project funds throughout the Course, this policy can possibly be revised and full cost coverage for the face-to-face events may become available.

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 on the basis of 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.

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**: applicants must be one or more of the following:
   - Employee or volunteer 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.
2. **Be living in the European Region as defined by the World Health Organisation**. Applications will be accepted from candidates 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) **at least 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 8-10 days in Barcelona, Spain. The dates of the two face-to-face events are **26 February-2 March 2018** and **17-21 September 2018**.

5. **Are willing to commit to applying the knowledge and skills learnt** to increase patient representation, communication, or facilitate knowledge and education in others. We also 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.

6. **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 at an upper-intermediate level or B2 Common European Framework of Reference for Languages (CEFR) http://www.coe.int/t/dg4/linguistic/cadre1_en.asp** . You will find an explanation of the English language levels a bit further down in this Guide.

7. **Have access to high-speed internet connection**: 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. No hard copy materials for the online components will be provided to participants.

Selection Criteria & Selection Process

Selection Criteria

As mentioned in the previous chapter all applications received by the deadline of **31 March 2017 (23:59 CET)** will first and foremost undergo an "eligibility check" to make sure all eligibility criteria set out above are fulfilled.

Applicants who fall short of fulfilling all eligibility criteria will be notified by 21 April 2017 by email. That email will provide an explanation of the reason why your application could not be retained by indicating which eligibility criterion/criteria you have fallen short of. As an applicant you have the right to challenge such decision in case you think a mistake has been made in appraising your application against the eligibility criteria.

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 after consultation with our three independent advisory bodies: the Regulatory Panel, the Project Advisory Board, and the EUPATI Ethics Committee.

The selection criteria are as follows:

1. **Quality of the individual motivation for applying.** This will account for **35% 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 does your personal and/or professional experience prepare you for this Course?
2. **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 patient community.
3. **Experience related to the 3 EUPATI profiles** (**PART G of the application form, first three boxes**): Patient Representation, Communication, Patient Facilitators/Trainers (**22.5% of the total score**, i.e. 7.5% each)
4. **Experience in interacting with stakeholders PART G of the application form, fourth box)** accounting for **7.5% of the total score**.

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
Quality of the individual motivation for applying	35%
Commitment to using and applying knowledge and skills acquired during and after the completion of the Course	35%
Experience related to the 3 EUPATI profiles	22.5%
Experience in interacting with stakeholders	7.5%
TOTAL	**100%**

Selection process

The final selection will be made by an **Independent Selection Panel** consisting of five representatives of patient organisations, academia, and industry. 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 at having 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 four selection criteria listed above by means of a 10-point scoring system (1= very poor to 10 = excellent).

The total score for each participant will be calculated according to the following algorithm:

TOTAL SCORE = [(Motivation x 0.35) + (Experience in interacting with stakeholders x 0.075) + (Experience in patient representation x 0.075) + (Experience in patient communication x 0.075) + (Experience in patient education and training x 0.075) + (Commitment to applying learning x 0.35)] x 10.

The lowest possible total score is 10 (only possible if an applicant receives 1 on all selection criteria) while the maximum is 100 (only possible if an applicant receives 10 on all selection criteria).

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 35% of the total score, you will get 24.5 points [(7 x 0.35) x 10] in respect of this criterion. If you then receive a score of “5”in relation to your commitment to using and applying knowledge and skills, which also accounts for 35% of the total score, you will get another 17.5 points [(5 x 0.35) x 10], and so on and so forth.

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

Criterion	Weight	Reviewer 1	Reviewer 2	Reviewer 3	Average TOTAL x10
Quality of the individual motivation for applying	35%	7	8	6	24.5

Commitment to using and applying knowledge and skills acquired during and after the completion of the Course	35%	9	8	8	29.17
Experience related to EUPATI Profiles (average of a, b, and c)	22.5%	6.67	5.33	4.67	12.50
a) Representation	*7.5%*	*8*	*7*	*6*	*5.25*
b) Communication	*7.5%*	*7*	*6*	*5*	*4.5*
c) Education/Training	*7.5%*	*5*	*4*	*3*	*3*
Experience in interacting with stakeholders	7.5%	6	6	6	4.5
TOTAL Score	**100%**	**75.51**	**72.49**	**64.01**	**70.67**

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)
- **No more than 1 applicant from the same organisation will be selected**.

Application and selection process: key dates

All eligible applicants will receive notification to confirm if they have been successful or not **by 30 June 2017**. We hope you understand that we can't 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 30 June 2017, we ask you to send an inquiry to eupati@efgcp.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 second EUPATI Expert Patient Training Course.

- Launch of the online application: **31 January 2017**
- Application period: **31 January 2017 – 31 March 2017**
- Eligibility screening: **1 April – 21 April 2017**
- Independent content-based assessment by the Selection Panel: **1 April – late May 2017**
- Face-to-face meeting of the Selection Panel: **late May 2017**
- Final list of 60 selected applicants: **30 June 2017**
- Course starts: **September 2017**
- Course ends: **November 2018**

How to Apply

Applications for the EUPATI Training Course should be submitted online via the following link: http://www.formdesk.com/epf/EUPATI3. Please make sure that you answer each question with as much detail as possible. You may use the Word verison 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 31 March 2017 (23:59 CET) will not 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 'Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[1]'.

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 (February 2020).

The application form contains the following sections:

A. **Content of the Course**
B. **Declaration of Commitment**
C. **Face-to-Face training sessions**
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. **Certification and Acknowledgements**
L. **Data Protection**

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 and asking you to verify your email address. If you have not received such an email after submitting your application form within 24 hours, please contact us at email 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.

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML

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.

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 - Declaration of Commitment

Please indicate your commitment to attending the Course as described. Only those applicants who answer "YES" to all questions in Part B will be taken into consideration.

PART C Face-to-Face training sessions

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

Please indicate your availability for these days. 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 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 find below an explanation of the English language levels.

The codes below refer to the CEFR guidelines for levels of language knowledge. Should you wish to know more about the CEFR levels, please click on this link: https://europass.cedefop.europa.eu/en/resources/european-language-levels-cefr

- "**Advanced/C2**" – You have language proficiency equivalent to that of an educated native speaker. You are fluent in all of its features, including breadth of vocabulary and idiom on all levels and as normally pertinent to professional needs.
- "**Good/C1**" – You can speak the language with sufficient structural accuracy and vocabulary to participate effectively in most conversations on practical, social, and professional topics. You rarely have to search for a word and unsubstantial errors virtually never interfere with understanding and rarely disturb the other speaker.

- "**Upper intermediate/B2**" – You can interact with a degree of fluency and spontaneity that makes regular interaction with native speakers quite possible without strain for either party. You can produce clear, detailed text on a wide range of subjects.
- "**Lower intermediate/B1**" – Your language skills satisfy routine social demands and limited work requirements. You can handle with confidence most basic social situations including introductions and casual conversations about current events, work, family, and autobiographical information, but you do not have thorough or confident control of the grammar and/or vocabulary.
- "**Elementary/A2**" – You can communicate in simple and routine tasks requiring a simple and direct exchange of information on familiar and routine matters.
- "**Basic/A1**" – You can understand basic daily questions and speech, but may need slower speech or repetition to aid understanding.
- "**None**" – You do not understand the language at all.

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 500 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 30% 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 300 words per question or a total of 1,200 words for the four questions.

Please note that your answers to these questions (altogether) will represent 35% 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 ensure that your answers to the questions in this part are no longer than 300 words each.

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 1,000 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.

PART K - Certification and Acknowledgements

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

Please note that all personal data collected for the recruitment process will be protected according to 'Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data'[2].

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 (February 2020).

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 eupati@efgcp.eu.

[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML

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

PART L – Data Protection

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

Frequently Asked Questions

Below we have compiled a list of frequently asked questions. You can always email if you need further clarifications.

The EUPATI Expert Training Course

What is the EUPATI Project?

European Patients' Academy on Therapeutic Innovation (EUPATI) is an initiative designed by the leading patient organisations, academic institutions, and pharmaceutical companies to help those interested in being more educated and involved in medicines' research and development processes. EUPATI aims at developing reliable information for patients on modern treatment development and educating patient representatives and the health interested public at large on medicines' research and development.

What is the EUPATI Expert Patient Training Course?

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 medicine 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.

Is the programme only open to people with chronic diseases?

No, our definition of "patient" stretches beyond people with chronic conditions. The Course is open to individuals belonging to one of the following groups:

- Employee or volunteer 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.

In addition, there are several additional criteria (country of residence, language proficiency, etc.) that need to be met by prospective candidates. Please refer to the section "Profile of the Participant" in this Guide.

Applying for this Course

How do I apply?

Please complete the online application form available **here** before the deadline of 31 March 2017.

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.

Do I need additional documents to support my application?

No, all information needs to be provided directly in the application form and no further documents (e.g. reference letters, diplomas, etc.) are required. Please refrain from sending any additional documents by email as those will not be considered further.

What is the deadline for my application form?

Application forms must be submitted by **31 March 2017, 23:59** (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 2017-2018 EUPATI Patient Expert Training Course. For the second cycle (2015-2016), we received more than 300 applications for 55 places available. This is quite indicative of the strong demand and need from the patient community for in-depth training on the medicines research and development process. This also means that the selection process for our Course is very competitive.

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 order to for an application to be further considered ALL seven eligibility criteria listed below shall be fulfilled.

1. **Be a Patient Representative**: applicants must be either:
    - Employee or volunteer 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.

2. **Be living in the European Region** as defined by the World Health Organisation.
3. **Have a keen interest in the medicines research and development process**.
4. **Are ready to commit to a total of at least 250 hours to study the e-learning content, actively participate in the online forum discussions during the entire duration of the Course, and attend the two face-to-face training sessions**, which will be run over 8-10 days in Barcelona, Spain.
5. **Are willing to commit to applying the knowledge and skills learnt** to increase patient representation, communication, or facilitate knowledge and education in others.
6. **Possess working knowledge of English** at least at an upper-intermediate level or B2 Common European Framework of Reference for Languages (CEFR) http://www.coe.int/t/dg4/linguistic/cadre1_en.asp.
7. **Have a computer or a tablet and access to high-speed internet connection**.

Those applications that pass the initial screening will be evaluated for their content.

The selection will be made by the EUPATI Selection Panel against the following selection criteria:

Selection criteria	**Weight**
Quality of the individual motivation for applying	35
Commitment to using and applying knowledge and skills acquired during and after the completion of the Course	35
Experience related to the 3 EUPATI profiles	22.5
Experience in interacting with stakeholders	7.5
TOTAL	**100**

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 55 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)
- **No more than 1 applicant from the same organisation will be selected**.

The applicants that will be selected may, therefore, not necessarily be the 60 who have received the highest score after content assessment.

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 **30 June 2017 at the very latest.** 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 1 July 2017 to inquire about the status of the application. Should you not hear about the outcome of your application by 5 July 2017, we ask you to send an inquiry.

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

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 or EUPATI National Liaison Team members?

There are no places on the course 'reserved' for EUPATI National Platform (ENP) or EUPATI National Liaison Team (NLT) members, but ENP/NLT members are of course welcome to apply. All applications are judged according to a predefined set of criteria by an independent selection panel.

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 ten 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. Please make sure you have enough time to dedicate to this completing the course starting from September 2017 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 toolkit for patient advocates and the online resource library for the health-interested public. 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 ENP, it is hoped that course participants will work very closely with the ENPs, and even get directly involved in helping ENPs strategies for the future and share 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 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 new learning and teaching methodologies which are 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 then 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. 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?

For the face-to-face training, EUPATI will cover the costs of accommodation in Barcelona and the cost of breakfast and lunch for each day of the training. Participants are expected to cover their own travel to and from Barcelona, along with the cost of their own evening meals. EPF 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.

*For the first two cycles of the Course, EUPATI was in the position to cover all travel costs for the face-to-face trainings. However, as EUPATI is no longer receiving financial support from the Innovative Medicines Initiative (IMI), we are no longer able to cover these costs. If EUPATI is able to acquire additional project funds throughout the Course, this policy can possibly be revised and full cost coverage for the face-to-face events may become available.

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 eupati@efgcp.eu.

Can I be overqualified for this course?

This course is open to all eligible applicants regardless of their current level of knowledge and experience of medicines' research and development processes. Experienced individuals who fulfil all eligibility criteria set out for this course are therefore encouraged to apply. It is however important to bear in mind that current level of knowledge/experience of medicines R&D processes will not be used as a selection criterion, meaning that you will not get a higher score if you already are very knowledgeable about the topics taught in this course.

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 (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.