

EUPATI: Collaboration between patients, academia and industry to champion the informed patient in the research and development of medicines

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Abstract: The value of collaborations and partnerships between different stakeholders to achieve optimum outcomes in the medicines research and development process is being recognised. Historically, there has been a lack of collaboration with patients and many research consortiums consisting mainly of academia and/or industry partners. Although patient experts are able to bring valuable first-hand experience and insights, they might not possess detailed knowledge about medicines research and development to actively participate in the collaboration process. The European Patients' Academy on Therapeutic Innovation (EUPATI) was established to deliver training to patient experts, and education resources to patient advocates and members of the health-interested public across Europe. EUPATI was launched in February 2012 and is a patient-led Innovative Medicines Initiative (IMI) project, with a multi-stakeholder consortium of patient advocates, academia, industry and not-for-profit organisations. Training and educational materials will be used for capacity building among patients, for educating patient advocates and for informing the health-interested public. The successful uptake of EUPATI's materials will hopefully translate into a new paradigm of increased patient involvement across the entire medicines research and development process, bringing mutual benefits, including better medicines, to all stakeholders.

Keywords: EUPATI, medicines research and development, IMI, patients involved, multi-stakeholder collaborations, informed patient, patients engaged

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1. Introduction: The Era of Partnerships

Traditionally, research in medicines development has been conducted internally within companies intending to develop new medicines. Due to concerns such as intellectual property and data protection, partnerships were often lacking. However,

in current times of rising costs and scarce resources, the value of collaborations and partnerships between different stakeholders to achieve an optimum outcome is becoming more apparent. There have been several cases of industry–academia collaborations. Some challenges in these collaborations include an alignment of priorities between universities and businesses,

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but overcoming such challenges is possible and can lead to accelerated results. For example, Pfizer and University of California, San Diego, have combined teams of university and industry scientists with drug development expertise^[1]. Similarly, the University of Cambridge has placed academic scientists into the laboratories on GSK research campus in the UK^[2].

However, in the field of medicines research and development (R&D), collaborations between patients and other stakeholders have been neither usual nor frequent. This is probably due to the fact that historically there has been public distrust and a lack of knowledge about research in the health-interested public. For example, fewer than 10% of patients with cancer participate in clinical trials and 75% of Phase II–IV studies are delayed due to slow patient recruitment^[3]. Previous health-related scandals and the subsequent bad image of the pharmaceutical industry could be some reasons for a lack of collaboration between patients and the industry. Another reason could be that patient knowledge about clinical trials and the medicines R&D process is low, and thus patients lack the confidence to get involved.

Research shows that patients who take part in making decisions about their healthcare are more likely to have better outcomes^[4]. Put simply, it seems that the more information patients have about healthcare, the better they can make decisions about what is best for them. Nonetheless, patients can be largely unaware about the process of medicines R&D, even as they seek up-to-date, credible, and understandable information about innovation in treatments. In a similar manner, patient representatives have an increasingly complex task of advising on a number of items such as protocol design, informed consent, marketing authorization and health policies, even though they may have gaps in the education and the training required to participate as an equal partner in medicines R&D.

2. Patient Involvement in Medicines Research and Development

Patient involvement in all aspects of medicines R&D makes sense, and it can be across all stages of the research cycle in medicines and research—right from early research, clinical trials, health technology assessments (HTA) and regulatory processes through to the dissemination of information to clinicians, patients and patient organisations^[5]. Patients can bring invaluable first-hand knowledge of their disease states and treatments and contribute to achieve meaningful solu-

tions and benefits.

Thus, it can be argued that patient involvement is essential as it allows patients' perspectives to be considered when generating new medicines of value. Patient involvement will ensure that research topics identified are the relevant ones to both the patient population and the researchers. Moreover, involved patients can contribute to shaping outcomes that are significant to them. Working in partnership with patients may also mean access to a group of patients, which might otherwise have been beyond reach (for example, a rare disease patient group). Trust and openness within the partnership can create value and result in a network, allowing access to vital insights and information for the research community.

Previous successful examples of patient-guided research exist, and well-established patient organisations, such as those from the HIV/AIDS, oncology and Parkinson's communities, have demonstrated the value of patient involvement in medicines R&D. The coming together of the wider community and patient networks were made possible by having informed patients as partners. A concrete example is the European Community Advisory Board (ECAB), a working group of European AIDS Treatment Group (EATG), which was established to facilitate interaction between the community of people living with HIV and AIDS and the pharmaceutical industry^[6]. In another case, the Dutch Cancer Society has a patient advisory committee, which is involved in the review of clinical trials. The participation of this group has confirmed that patients' perspective is very valuable in improving the design of clinical research^[7].

As patient involvement increases and academic and industry collaborators seek to engage more patients, there will be a greater need for patient advocates and experts who can contribute to medicines R&D, clinical research and regulatory processes. However, a lack of such trained advocates has been previously highlighted. For example, the PatientPartner project identified a shortage of training opportunities for developing patient experts^[8].

3. What is EUPATI?

The European Patients' Academy on Therapeutic Innovation (EUPATI) was established to bridge this gap, and deliver the education and training needed for increasing patient involvement across Europe. EUPATI is a public–private partnership receiving support from the Innovative Medicines Initiative (IMI) Joint Under-

taking, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and European Federation of Pharmaceutical Industries and Associations (EFPIA) companies^[9]. EUPATI is a five-year project, launched in February 2012^[10].

Importantly, it is a patient-led partnership, coordinated by the European Patients' Forum (EPF), with the EGAN, the European Organisation for Rare Diseases (EURORDIS) and EATG in key roles. It comprises of a multi-stakeholder consortium of patient advocates, academia, industry, and not-for-profit organisations. Thirty organisations pledged support at the outset, and this number has risen as country-specific EUPATI networks are being established across the twelve European partner countries—Austria, Belgium, France, Germany, Ireland, Italy, Luxembourg, Malta, Poland, Spain, Switzerland and the UK.

EUPATI aims to increase the number of well-informed and trained patients to be effective advocates in medicines R&D. Educational material will be provided in seven European languages, targeting the previously mentioned twelve European countries. These materials will be used for capacity building among patients as well as to inform the health-interested public.

The topics that EUPATI will cover are: (i) Discovery of Medicines and Planning of Medicines Development, (ii) Non-Clinical Testing and Pharmaceutical Development, (iii) Exploratory and Confirmatory Clinical Development, (iv) Clinical Trials, (v) Regulatory Affairs, Medicinal Product Safety, Pharmacovigilance and Pharmacoepidemiology, and (vi) HTA principles and practices. The EUPATI project will also provide indirect benefits to other stakeholders, such as national agencies and regulators who are able to have a wider pool of patients for interaction purposes (e.g. to represent patient views on review boards)^[11]. Consequently, informed patients are able to engage confidently with decision makers at the European and national levels.

4. EUPATI's Governance and Goals

In order to achieve EUPATI's goals, there is a strict governance structure in place. Additionally, transparency and independence are upheld rigorously at EUPATI. The robust governance structure includes key umbrella patient organisations (such as EPF, EATG and EURORDIS), a multidisciplinary project advisory board, a regulatory advisory panel and an ethics panel, comprising of experts in ethics, law, drug develop-

ment, regulatory affairs, evidence-based medicine and patient advocacy. This sets a thorough framework, which guides the rules for confidentiality, data privacy, declaration of interest, social research, ethical review and publications. EUPATI focuses on general aspects of the R&D processes to develop new medicines (Figure 1), and it has seven working groups with specific tasks and responsibilities (Figure 2).

It takes on average twelve years and costs up to \$2.6 billion^[12] to carry out necessary R&D processes before a new medicine is available for patients. Approximately only one in ten of all development compounds entering phase I clinical trials will make it through the whole development process and reach the market^[13]. The success rates may vary within indications, with the highest for infectious disease products (17%) and the lowest for oncology products (7%). The main reason for discontinuation of development compounds is lack of efficacy or safety, although feasibility of commercial potential can also be a cause^[13].

EUPATI's educational material covers neither disease-specific nor product-specific topics, but general themes related to processes, complexities and challenges in the development of medicines. Hence, the educational material reflects a broader spectrum of topics related to medicines research (such as diagnostics and biomarkers), clinical development (such as phases of clinical trials) and market authorization and HTA. EUPATI aims to reach three types of audiences, namely expert patients, advocacy leaders and the health-interested lay public in twelve European countries (Figure 3).

By January 2017, EUPATI will reach out to three different audiences: the first level training for one hundred patient experts through e-learning and face-to-face classroom style teaching. This course, offered in English, will cover general themes related to the medicines R&D process. The second level is an educational toolbox, targeting 12,000 patient advocates. It will be possible to download different types of learning materials in seven European languages. The third level aims to reach 100,000 members of the health-interested public, who will have access to an internet library of resources on medicines R&D. The first audience of approximately one hundred patient experts will complete an intense on-line course, with additional face-to-face meetings, with each course lasting for a total of fourteen months. Three hundred highly qualified applications were received for the initial course and fifty students representing twenty-one countries started in October 2014. The second

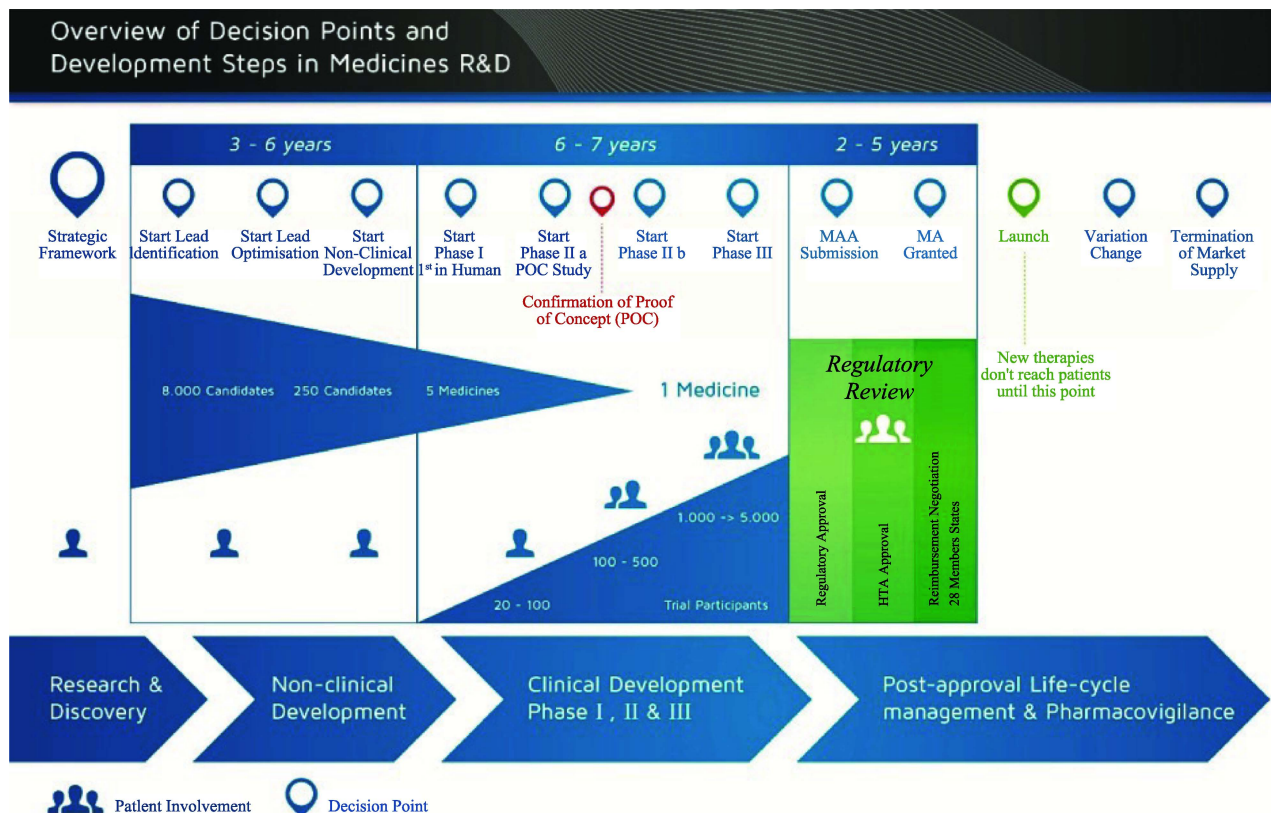


Figure 1. The steps of medicines discovery and development.

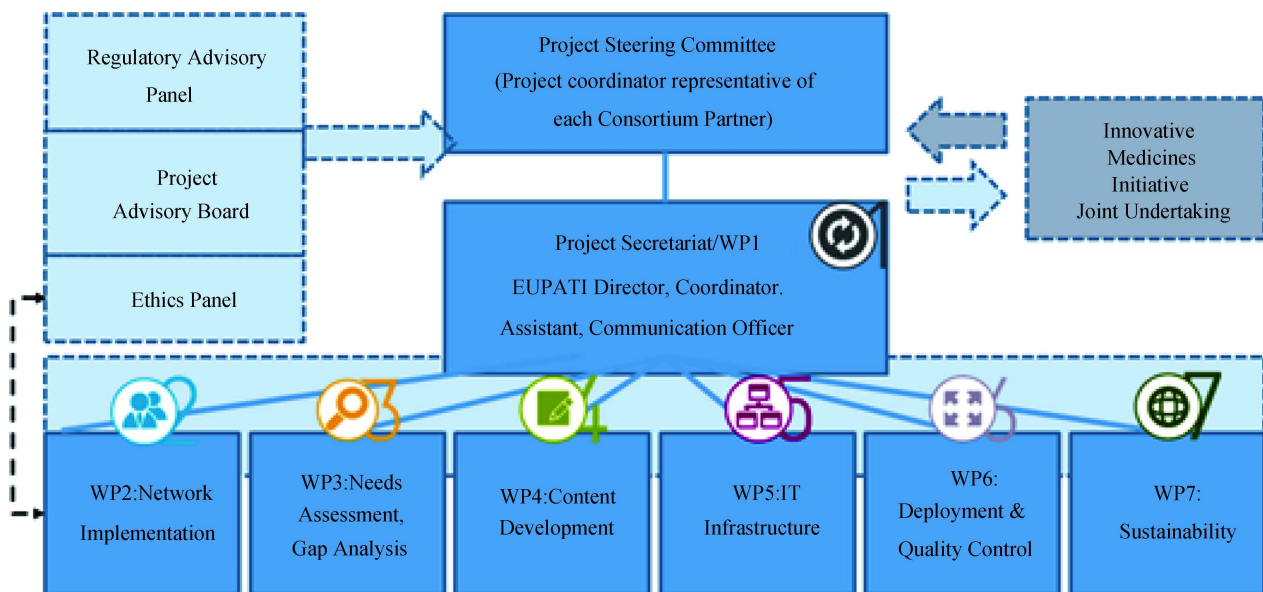


Figure 2. EUPATI's governance structure.

course is due to start in September 2015 and more than two hundred intended applications were received for the second student cohort.

All resources of the EUPATI Toolbox and internet

library will be available for re-use under the 'creative commons licence' agreement and will be available in seven languages: English, French, German, Italian, Polish, Russian and Spanish by 2016.

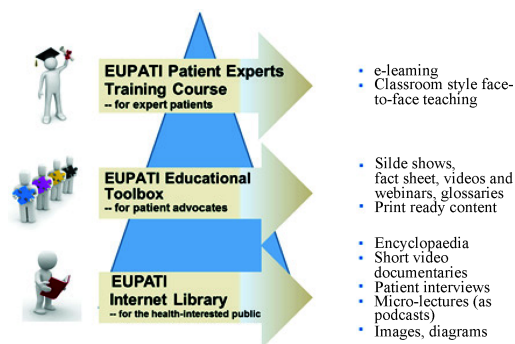


Figure 3. EUPATI target audiences and resources.

5. EUPATI's Survey on Current European Public Knowledge about Medicines R&D

EUPATI carried out a survey of 6,931 members of the public across Europe, to explore public knowledge of and interest in learning more about medicines R&D in six European countries^[14]. Over 75% of respondents reported having no or less than good knowledge of medicines R&D and any knowledge present appeared to decrease with age. Those who were currently or had previously been involved in medical research were almost four times more likely to report good knowledge of medicines R&D overall (43% vs. 13%). Participants were most interested in learning more about medicine safety and personalised and predictive medicine and least interested in pharmacoeconomics.

Older people, women and those with medical research experience were most interested in learning more about medicines R&D. The survey concluded that some groups may need to be specifically targeted to increase their awareness of medicines R&D. For example, women expressed great interest in learning more but reported less knowledge than men and it may be useful to explore further the views of those who are currently disinterested in further learning. Based on these findings, the authors concluded that without increasing patient and public knowledge and awareness of their roles in the medicines R&D process, it would be challenging to facilitate more active engagement in the actual process. The findings of this survey lend support to EUPATI's aim of developing and disseminating objective, credible and up-to-date knowledge about medicines R&D and be a catalyst for broader patient involvement. The differences observed in the data between individual countries also lend support to the fact that materials from EUPATI will be adapted linguistically, as well as recognizing varying levels of interest in different topics by country.

6. Current Milestones from EUPATI and Next Steps

Several activities have already been initiated in order for EUPATI to fulfil its goal, with these activities raising awareness of EUPATI's objectives. EUPATI has successfully conducted four annual workshops dealing with a broad spectrum of themes such as relevant examples of patient involvement in medicines R&D, best practices on patient engagement in medicines R&D and communication tools to reach a public audience on medicines R&D^[15].

The latest workshop took place in April 2015, titled '*EUPATI taking off in your country: An interactive workshop on implementing EUPATI in your country*', where more than one hundred people, representing twenty-six countries were in attendance. Of the total audience, 56% were either patient advocates or from patient organisations, representing the strong role they play within the EUPATI project. The challenges of moving toward a more systematic approach to include patient involvement in R&D were discussed in detail in the plenary session. Three students attending the current EUPATI expert course also gave their views in an open dialogue with the audience on their perspective on the course and how they might influence their communities based on what they are learning and experiencing. In addition, a representative from EURORDIS talked about communication by using social media and gave some successful examples on the use of social media to create public awareness in health campaigns. A novel approach was the virtual snapshots video where nineteen invited participants used the opportunity to share their views on why patient involvement in medicines R&D is important and what is happening in their community^[16].

As a public-private partnership, EUPATI is well placed to further the dialogue around the strategy for increasing patient involvement in R&D. Leveraging this, EUPATI hosted a workshop with fifty-six representatives from patient organisations and industry. The meeting focused on recognising concrete actions, which will enable patient involvement in R&D in a systematic and meaningful way^[17]. Twenty-two case studies were shared by patient organisations and industry representatives in the areas of HIV, neurological diseases, oncology, paediatrics and rare diseases. These formed the basis of the discussions, allowing participants to explore lessons from real-life examples and identify approaches that contributed to successful

outcomes. The sessions also explored the benefits of patient and advocate involvement, current barriers and relevant compliance codes and frameworks that are desirable for smooth and transparent partnerships with patients and advocates during the R&D process.

EUPATI is also involved in organising webinars on topics of relevance to its network members and the wider research community. The first webinar titled '*Improving involvement of patients in clinical research activities*' consisted of panelists from a patient organisation, a university and the pharmaceutical industry, each giving their perspectives on how best to include patients in clinical research. Challenges were discussed and solutions were proposed on how to overcome barriers. The second webinar, titled '*How to enable meaningful patient contribution to ethical review?*' discussed patient involvement in ethics committees, with presentations illustrating the different situations in five European countries. Further webinars are planned on topics such as HTA and patient learning.

Another important activity within the EUPATI community has been to establish EUPATI National Platform (ENP) networks in the twelve countries participating in EUPATI. The overall aim of such platforms is to facilitate local communication, dissemination, and awareness of patient involvement in medicines R&D. As such, the ENP networks seek to attract widespread support from local partners including patient organisations, academia and industry, as well as government officials, regulatory bodies, healthcare professionals, social care workers and medical journalists.

ENPs have been launched in six European countries (France, Ireland, Italy, Luxembourg, Spain and UK), with teams soon to launch in Austria, Malta, Poland and Switzerland. The ENPs grow from three national representatives, one each from a patient organization, academia and industry, with the patient organization representative playing a leading role into a broad platform, or network, of national partners interested in patient involvement. Lastly, an upcoming activity is the development of the EUPATI Ambassador program. This program aspires to create key communicators between EUPATI and the wider public, especially with patient and healthcare communities, in sharing the mission and vision of EUPATI.

7. Conclusion

Medicines research and development is starting to

revolve around the patient and patient involvement in related activities is becoming a reality. It follows that access to informed patients who can confidently participate in multi-stakeholder collaborations is necessary. While established patient organisations can provide the needed education and trainings, EUPATI, as an alternative resource is well on its way to offer credible resources. The first cohort of students are now more than half way through the initial EUPATI training course and the selection process for the second cohort is complete to start the course in September 2015. The next milestone in the EUPATI project is the launch of the EUPATI Toolbox in January 2016. This will enable EUPATI to make educational and training materials available for a target audience of 12,000 patient advocates in seven languages serving the twelve European countries. The third goal is an ambitious one: To increase awareness of medicines research and development in 100,000 members of the health-interested public across Europe. However, positive feedback from the annual workshops, launch of ENPs, webinars and the many enthusiastic stakeholders who are supportive of the EUPATI project, gives the EUPATI consortium confidence in achieving this goal.

Ultimately, the availability of education and training materials will permit capacity building of patients and their representatives to make a positive contribution to the medicines R&D process, in collaboration with industry and academia. The successful uptake of EUPATI's materials will hopefully translate into a new paradigm of increased patient involvement across the entire medicines research and development process, bringing mutual benefit, including better medicines, to all stakeholders.

Conflict of Interest and Funding

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