EUPATI: An initiative to provide expertise in patient advocacy and in medicines development processes

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Abstract

Grassroots movements by patient advocates, calling for greater involvement in decisions about healthcare research, have evolved to the point where publicly funded initiatives are now in place to educate patient groups and patients on the processes by which research is identified, prioritised, designed, conducted and disseminated.

This article describes the work of EUPATI, a patient-led initiative coordinated by the European Patients' Forum. The consortium provides key expertise in patient advocacy and processes for medicines research and development.

Introduction

Patient and public involvement (PPI) representatives have an ever-increasing role in all aspects of medicines research and development (R&D). PPI is now evident across all stages of the research cycle for translational medicine and clinical research (see Figure 1) – from commissioning and funding research, clinical trials, health technology assessment (HTA) and the associated regulatory processes through to the dissemination of information to clinicians, patients and patient organisations. PPI has grown rapidly from a limited consultation activity to active involvement where the importance of embracing patients and the public as equal partners in research design, operations and regulatory oversight is the norm. PPI representatives bring invaluable knowledge of a lived experience of illnesses and treatments, and importantly shape the evaluation process to maximise patient benefits.

PPI is increasingly seen as an important asset that contributes to improving clinical research success, specifically in securing funding and ensuring implementation. In the UK, the National Institute for Health Research (NIHR), with more than £1 billion budget per annum for clinical research, views PPI as a virtually mandatory activity. Other funders (eg, EU Horizons 2020, the Wellcome Trust and the UK's Medical Research Council) view patient involvement and public engagement activities as good practice and their guidelines encourage it as a planned, integral activity. The UK also has a coordinated infrastructure support for PPI, with national initiatives such as INVOLVE (www.invo.org.uk) and the Research Design Service. These initiatives have facilitated advancement of PPI in the UK by enabling access to recommendations of codes of good practice for PPI; some limited financial support to develop PPI forums; coordination of information; knowledge transfer; and training for researchers, patients and the public in building effective research partnerships, with the shared core goal of delivering benefit to patients.

More widely across Europe, PPI is gathering momentum, although many EU countries lack the national coordination seen in the UK, and patient organisations are struggling to provide adequately-trained PPI representatives to meet the current needs of the research community. In particular, the "PatientPartner project" (www.patientpartner-europe.eu/) has identified a lack of coordinated training opportunities for patients and patient organisations to provide the skills required to develop confident PPI representatives who understand sufficient aspects of medicines development, the clinical research cycle and the regulatory processes. The European Patients' Academy on Therapeutic Innovation (EUPATI), a non-profit organisation, was established to bridge this gap and deliver the information, education and training needs for effective PPI across Europe.

EUPATI aims to increase the capacities and capabilities of well-informed patients and patient organisations to be effective advocates and advisors in medicines research. It will provide educational material in seven European languages, targeting 12 European countries (see Box). Initial educational material will become available after the first 18 months of the project.

An ethical framework

Objectivity, transparency and independence are vital prerequisites to ensure EUPATI achieves its goals and is accepted and valued by both the patient community and the wider public. Its commitment to transparency and independence is reflected in all aspects of the project. EUPATI has established a robust governance structure, led by major umbrella patient organisations, as well as a multidisciplinary project advisory board, a regulatory advisory panel and an ethics panel, comprising experts in ethics, law, drug development and patient advocacy. This ethical framework sets the ground rules for anonymity, confidentiality, informed consent, social research, ethical review, professional integrity and publication ethics.

Specific initiatives to enhance PPI

EUPATI's goal is to develop and disseminate objective, credible, user-friendly and up-to-date information and educational resources – through a widely used, sustainable infrastructure – relating to medicines R&D and regulatory requirements for patient advocates, patients and the lay public.

While the project scope focuses on the R&D processes to develop medicines, much of its material will embrace the wider arena of clinical evaluation such as diagnostics and biomarkers that provide patient benefit through improved treatment and healthcare management.

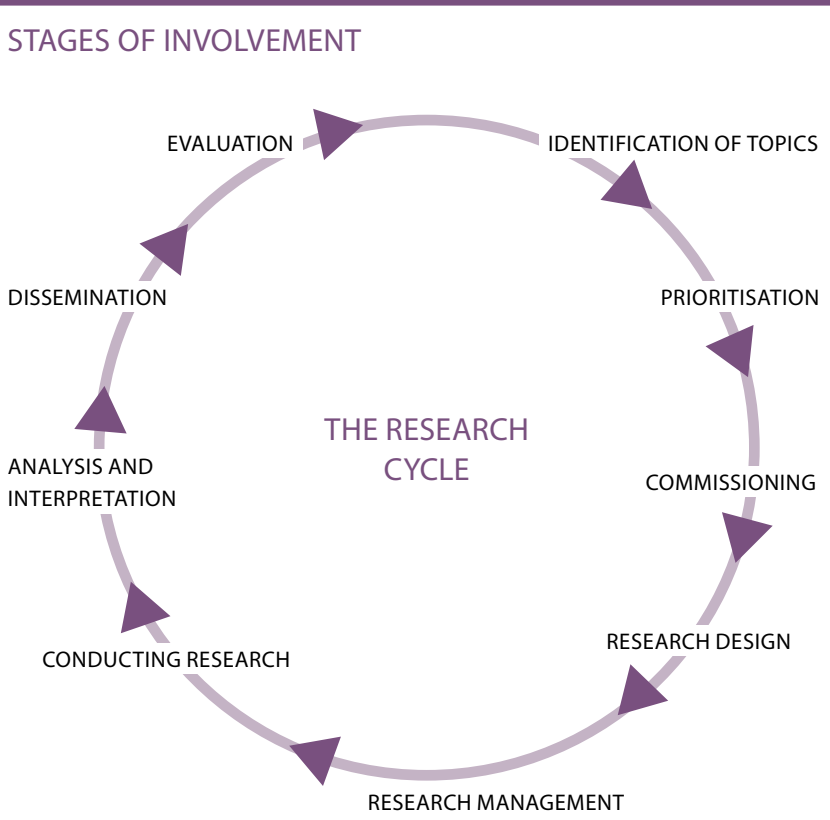
EUPATI will not inform patients and the public about disease-specific issues or therapies – the focus will be on the process, complexity and issues related to new medicines development, as well as access issues in general. Indication-specific information will only be used to illustrate specific issues on medicines development, eg, clinical trial design, informed consent procedures, vulnerable groups, etc.

To develop or enhance the necessary skills for better PPI, EUPATI will provide a range of training and educational offerings and reach out to three audiences (see Figure 2) in the 12 EU partner countries – expert patients, advocacy leaders and the lay public:

What is EUPATI?

The European Patients' Academy on Therapeutic Innovation (EUPATI) is a Public Private Partnership within the Innovative Medicines Initiative (IMI) Joint Undertaking, with resources of approximately €10 million comprising financial contributions from the EU's Seventh Framework Programme and largely "in kind" contributions from members of the European Federation of Pharmaceutical Industries and Associations (EFPIA). EUPATI is a five-year project which was launched in February 2012. Importantly, it is a patient-led initiative, coordinated by the European Patients' Forum, with the European Genetic Alliance Network (EGAN), the European Organisation for Rare Diseases (EURORDIS) and European Aids Treatment Group (EATG) in leadership roles. It comprises a strong multi-stakeholder consortium of patients' advocates, academia, industry and not-for-profit organisations – with 30 organisations pledging support at the outset, it is anticipated this will rapidly expand as country-specific EUPATI platforms are established across 12 EU partner countries – Austria, Belgium, Switzerland, Germany, Spain, France, Ireland, Italy, Luxembourg, Malta, Poland and the UK.

Figure 1: PPI across the research cycle.



Source: Involve, www.invo.org.uk/posttyperesource/where-and-how-to-involve-in-the-research-cycle

1 **Expert level.** This will include patient experts, EUPATI ambassadors, and patient journalists. EUPATI will develop the capacity of these PPI experts through a training and certification programme based on the European Credit Transfer and Accumulation System (ECTS) academic modular structure, to deliver a high level of competency among patient advocates and patients. Around 100 patient experts and advocates across the 12 EUPATI partner countries are expected to complete the courses.
2 **Education level.** This will comprise advocacy leaders from patient organisations, who will be provided with the EUPATI "toolbox", including cutting edge educational material for patient advocates, print material, slide shows for face-to-face presentation, "e-learning" courses, webinars and videos, complemented by face-to-face events. Around 12,000 patient representatives are expected to use the toolbox.
3 **Information level.** This will involve patients and the lay public, who will be served by a comprehensive internet library of resources on medicines R&D. The library will be developed by EUPATI, and have resources covering topics on personalised and predictive medicine, design and conduct of clinical trials, drug safety and benefit–risk assessment and health economics. It will contain information on therapeutic innovation, explaining, for example, specific aspects of the development process of medicines and related products for patients and consumers with low (health) literacy. Resources will be translated into seven European languages: English, German, Spanish, Polish, French, Russian and Italian. The material will be provided under a "creative commons licence" for re-use by the public. It is envisaged this will reach 100,000 individuals.

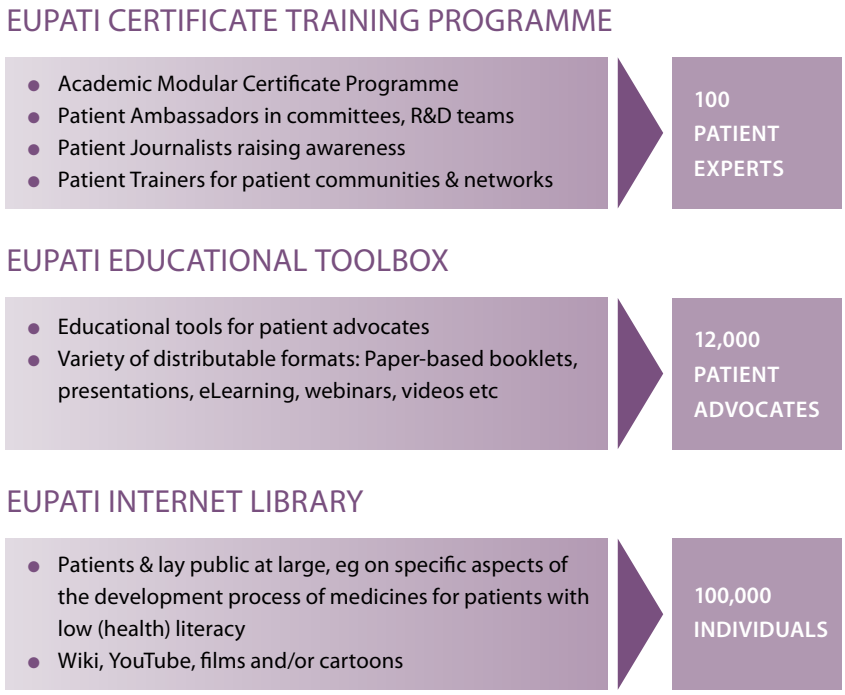
Experiences and next steps

A meeting among EUPATI members was held in Barcelona in March 2013 to assess the best country-specific approach to implement national platforms, to raise pan-European awareness of the programme, to disseminate information in the national media, and to identify future topics of national interest. It concluded that:

- EUPATI will be disseminated in environments with largely negative attitudes towards, and low awareness levels of, medicines R&D
- EUPATI's three-way collaborative work (patient advocate, academia and industry) is largely new to most of the 12 EU partner countries, although such practice has become more common in the last six years in, for example, Ireland
- There are, in comparison to the other European countries, several examples of PPI and Patient Engagement (PE) in the UK.

The EUPATI initiative will not only benefit patients and the public in providing credible information and training, but there will be spin-off benefits for national agencies, ministries and regulators. Training the public and expert patients on the medicines development pathway will further empower the public and patients to engage with decision-makers – not only at a European level but also more tangibly at country level.

Figure 2: EUPATI audiences.



Source: EUPATI – European Patients' Academy

EUPATI's first conference: "EUPATI: a Vision for 2020", was held in Rome in April 2013, just 14 months after the launch of EUPATI. It demonstrated just how far the initiative has developed. More than 180 delegates from 28 countries heard about the plans underway for the three clear areas of training and education (Figure 2). The atmosphere was positive, and for good reason. As several speakers said, there is now a "window of opportunity" for effective patient involvement in medicines R&D. All the stakeholders understand the huge benefits that can flow to them, from early research discussions to better trial designs, more meaningful patient involvement in HTA and regulatory processes, and ultimately a faster stream of properly tested and adapted innovative medicines. The basic structure of the EUPATI project has now been successfully established. Implementation has begun and first ideas and visions are developing into feasible tasks and projects.

Note: We are publishing this article to raise awareness among our readers of the EUPATI network and its initiatives – this is an edited version of information available on the EUPATI website: **www.patientsacademy.eu.**