EUPATI PROJECT: EXECUTIVE SUMMARY

Table of Contents

1 Overall objectives of EUPATI

Involving patients in research can hugely benefit the medicines development process: by bringing in their priorities and perspectives, patients can contribute to developing better treatments for them and others. Greater patient involvement in R&D will boost the efficacy and safety of new treatments and increase public support for medical research.

The European Patients' Academy on Therapeutic Innovation (EUPATI) was funded within call 3 of the Innovative Medicines Initiative in the period February 2012 to January 2017. It aimed to trigger a major rethink in the way patients and the public understand the medicines development process and their own involvement therein. Armed with a deeper understanding, patient experts and advocates will be empowered to work effectively with the relevant authorities, healthcare professionals and industry to influence the medicines development process for the benefit of patients.

The main objectives of the consortium, led by the European Patients' Forum, which includes patients' organisations, academic groups, NGOs and pharmaceutical companies were:

1. to develop and disseminate accessible, well-structured, comprehensive, scientifically reliable and user-friendly educational material for patients on the processes of medicines R&D, especially on end-to-end R&D processes, i.e. non-clinical R&D, clinical trials, personalised medicine, efficacy and safety assessment, risk benefit assessment, health economics, HTA and patient involvement in these processes,
2. to increase the capacity of "patient experts" and well-informed patients in patient organisations to be effective advocates and advisors in medicines research and development,
3. to empower patients to provide appropriate patient-relevant advice and insight to industry, academia, authorities and ethics committees.

2 Results and successes of the EUPATI Project

The EUPATI project has generated educational resources in six key areas, namely

- Discovery of Medicines & Planning of Medicine Development
- Non-Clinical Testing and Pharmaceutical Development
- Exploratory and Confirmatory Clinical Development
- Clinical Trials

- Regulatory Affairs, Medicinal Product Safety, Pharmacovigilance and Pharmacoepidemiology
- HTA principles and practices

To train patients, patient advocates and the lay public about those topics, **educational material** has been developed in 7 languages (English, German, Spanish, Polish, French, Russian and Italian), serving 12 European countries with those native languages (UK, Ireland, Malta, France, Luxemburg, Belgium, Switzerland, Germany, Austria, Spain, Poland and Italy). With Russian, the Patients' Academy reaches a large population within countries in Central and Eastern Europe where a relatively large part of the population speaks or at least understands Russian. Additional languages were in preparation by the end of the IMI project in January 2017.

To ensure quality, factual accuracy, neutrality, accessibility and readability, EUPATI has established a **robust content production, review, and approval process** that involved patient advocates, academics, pharmaceutical industry professionals, regulators, and professionals from independent non-profit organisations, complemented by content reviews by an independent international ethics committee, regulatory advisory board, and project advisory board, as well as an academic institution specialised in the communication of science to the lay public. The expertise and insights from EUPATI consortium members, network members and external advisors was supported by qualitative and quantitative research as well as a systematic literature review conducted by EUPATI prior to content production. (See the detailed content production methodology described at https://www.eupati.eu/reliable-information/).

The EUPATI project addressed **two main audiences**. The 'Expert Level' has delivered two English-language EUPATI Patient Expert Training Courses to patient experts, patient ambassadors and patient journalists. The 'Education Level' material in the EUPATI Toolbox on Medicines R&D addressed patient advocates, patients and the health-interested lay public in seven languages.

Two **EUPATI Patient Expert Training Courses**, each with a duration of over 14 months, were conducted in 2015 and 2016. The syllabus of the EUPATI course comprises of 103 topics in 6 modules and 81 online lessons, 178 optional further readings, 14 videos, 65 unrecorded quizzes and 6 assessments, complemented by the content of 2x4 days of face-to-face training material. In an official ceremony on 13 December 2016, 96 patient experts from 31 different countries in 58 disease areas graduated from the first two EUPATI courses. The names and contact details of all EUPATI Fellows are available on eupati.eu. The graduates have been awarded the title "Fellow of the European Patients' Academy" (in short: "EUPATI Fellow").

The impact of the EUPATI Patient Expert Training Course has been huge, evidenced by the leading roles in the debate on patient involvement in R&D the 96 EUPATI Fellows have taken. A survey of experience and involvement of EUPATI Fellows after graduation, completed in December 2016, explored the longer-term impact of the course, documented the progress and impact of Fellows working as expert patients. It gained insight on the value the course has added to the EUPATI Fellows' work as patient advocates. Amongst other results, the survey, comparing activities before and after the course, revealed that the share of Fellows having a leadership role in patient organisations grew from 62% to 71%, those advising a pharmaceutical company grew from 13% to 44%, a regulatory agency from 21% to 42%, and advising a reimbursement / HTA body from 4% to 8%. For example, EUPATI Fellows engaged in advisory roles, acted as trainers, were involved in health policy advocacy, became speakers at conferences, started community advisory boards, assisted and advised other patient organisations, improved informed consent documents, reviewed trial protocols and contributed to trial designs.

The third Patient Expert Training course (post-IMI project) with 60 trainees is starting in summer 2017. See https://www.eupati.eu/eupati-training-course.

EUPATI's second "core product", the **EUPATI Toolbox on Medicines R&D**, was launched in January 2016 (www.eupati.eu). The EUPATI Toolbox is covering almost all topics of the EUPATI Patient Expert Training course, but is provided in 7 languages after extensive reviews by the editorial board. Across all languages, the EUPATI Toolbox contains 1463 articles, 254 presentations, 97 videos, 5 webinars, 246 images, 160 factsheets, 25 video interviews, 1 documentary, 148 infographics, 4708 glossary items and 2695 acronyms. More than 110.000 individual users have accessed the EUPATI Toolbox by end of January 2017, a 10-fold higher outreach than initially planned. By January 2017, most users of the EUPATI Toolbox came from Europe (more than 76.000), but also from the Americas (18.000+). EUPATI users extend to Asia with almost 10.000 visitors and to Africa with more than 2.700. 70% of EUPATI's visitors were between the ages of 25 and 44. English content was most used (30.600 visitors), followed by Spanish (16.000), Italian (12.500), French (11.000), German (11.000), Russian (8.700) and Polish (7.200). It has become the key knowledge resource and reference for any party interested in learning about medicines R&D. It is a testament to the impact of EUPATI and an indication of the value of the EUPATI Toolbox that additional countries continue to request Toolbox translations.

EUPATI National Platforms have been set up in 18 countries, more than the 12 countries that were originally planned in this project. National Platforms have been established in Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Spain, Switzerland and UK. Additional National Platforms are currently in different stages of creation in Serbia and The Netherlands. The EUPATI National Platforms have organised and are preparing a variety of activities, including webinars, information days, mini trainings, and social media campaigns. Interest in developing platforms has also been received from outside the EU (e.g. Turkey, Brazil) which reflects the global impact of EUPATI.

To increase the interaction with the wider EUPATI Network, EUPATI organized several **EUPATI Webinars** on the topics "Informed Consent for Vulnerable Populations", "Creating Trainings with the EUPATI Toolbox", "Revision of CIOMS Ethical Guidelines for Biomedical Research", and "Early collaboration - a recipe for solutions: drug development and treatment strategies may go hand in hand". Recordings are available online through the eupati.eu website. (See https://www.eupati.eu/category/webinar/)

EUPATI conducted **annual workshops and conferences**. The final EUPATI Conference on 14 December 2016 in Brussels gave the opportunity to provide a final report on progress of the IMI project, but allowed also to collect tangible feedback from all stakeholders about EUPATI's work. 214 participants attended, 120 of them being patient advocates, sharing experiences and developing new thinking about how to spur progress at the national level through EUPATI's National Platforms (see https://www.eupati.eu/category/workshop/).

Following a 6-month public consultation process which gathered and incorporated hundreds of comments, in December 2016, WP7 published four "**Guidance Documents on patient involvement in R&D" covering ethics committees, health technology assessment bodies, regulatory processes and pharmaceutical industry-led medicines R&D.** Each guidance document recommends working methods and processes, and suggests specific activities and areas for patient involvement (http://www.eupati.eu/guidances).

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EUPATI has been a game changer for patient involvement in medicines R&D, and continues to be one of the **key drivers of the public debate on patient involvement in medicines R&D** on a pan-European level in all stakeholder groups including industry, regulators, academic researchers, ethics committees, HTA bodies and evidenced in the media and conference footprints that EUPATI had in 2016. EUPATI has empowered European health-interested citizens and patient advocates to become

main actors in R&D. Academic and industry researchers have intensified discussions and implementation of patient involvement in their research activities (in addition through related activities like Patient-Focused Medicines Development, PFMD), and regulators have started to network on best practice in patient involvement in regulatory processes, following the EUPATI workshop held in Berlin in July 2016. Inter alia, EUPATI has increased the competitiveness of Europe and helped establish Europe as a preferred place for medicines research and development by developing into one of the most patient-centric R&D communities world-wide. With its educational resources on eupati.eu and its highly trained group of EUPATI Fellows, EUPATI has provided the self-growing, key resource for any kind of research that relies on knowledgeable patients, patient organisation representatives, patient advocates and patient experts.

Overall, the IMI project EUPATI has been very successful, has kept well on track and not only has delivered to plan and beyond objectives of an IMI project, but has substantially over-delivered.

3 EUPATI's Future

The "EUPATI Programme", under the auspices of the European Patients Forum, whilst maintaining the spirit of a Public Private Partnership, based on approximately 25% of the annual budget of the IMI EUPATI project, combined with the full course content released under Creative Commons, was chosen in 2016 as the post-IMI sustainability model for 2017 and beyond. The EUPATI Programme can be described as *a "Patient community-driven educational programme to maintain EUPATI throughout 2017-2019, focused on maximum exploitation of the EUPATI Patient Expert Training Course, on conduct of further EUPATI Patient Expert Training Courses, maintenance of the EUPATI Toolbox and the EUPATI brand, the EUPATI National Platforms, the EUPATI Fellow Alumni Network, the IT infrastructure, and on implementing updates of core EUPATI educational material".* This approach ensures the continuity of EUPATI as a programme as well as a trusted brand for patient education in R&D, while facing the realities of a post-EU-funded project period and working towards longer term financial sustainability.

The EUPATI Programme will focus on the EUPATI Patient Expert Training Course and the EUPATI Toolbox on Medicines R&D as the core products of EUPATI in all available languages. Content will be updated to keep pace with external developments as necessary. The programme will further support the development of local trainings and "mini-courses" based on the EUPATI Toolbox by e.g. EUPATI National Platforms and pan-European capacity building programmes. The third EUPATI Patient Expert Training Course kicks off in Summer 2017, addressing the identified need to train more than the present number of patient experts/EUPATI Fellows. In a train-the-trainers programme supported by the preparation of "Toolbox Starter Kits" systematic training opportunities in various formats will be enabled in all EUPATI National Platforms to maximise the exploitation of the EUPATI Toolbox and to grow the knowledge of the health-interested public in the medicines R&D process. Efforts continue under the new Sustainability Programme to explore other means of sustaining EUPATI financially long term, through IMI2 and other pathways, driven by the "EUPATI FUTURES" team.

In terms of the evolution of EUPATI, the EUPATI project identified several areas for the design and development of future topics inside and beyond the EUPATI Programme in more detail. In brief, this includes:

1. **Increase depth and breadth of EUPATI course content in identified topic areas** (e.g. National Competent Authority procedures, medical devices, personal and precision medicine, biosimilars and generics, real-world evidence, big data, registries, data ownership, vaccination, antimicrobial resistance, management of international trials, identification of comparators, primary prevention, etc.)

2. **Patient involvement and engagement in R&D and patient advocacy** (e.g. patient advocacy capacity building for patient engagement in R&D, support patient engagement in R&D – in all stakeholders, support development of specialist knowledge in specific vertical topic areas, development of a professional model of "Patient Advocacy Expert", training on publications / article assessment / scientific publications / science articles in the media, training and support of patient advocates to lead/engage in other IMI2 and H2020 projects, matching advocates, opportunities and projects, etc.)
3. **EUPATI interaction and collaboration with other projects and initiatives** (e.g. partnerships, sharing knowledge and experience, advisory role and consultation on patient and public involvement)
4. **Increase innovation robustness** (e.g. assessment of the impact of innovation and new technologies on health systems, moving to an enabling HTA environment reflecting label changes more rapidly, better integration of technology and social systems innovation)
5. **Future ventures – e.g. in the form of Public--Private Partnerships** (financing models, reinvestment in research)
6. **Widening the EUPATI training audience to patients and carers at large** (addressing citizens, not only patients, addressing patients with low health literacy, addressing younger and older patients and citizens specifically).
7. **Widening the EUPATI training audience to other stakeholders** (e.g. pharmacists, nurses, physicians, psychologists, HCP students, industry staff in medical/ clinical/ legal/ compliance/ patient relations, policy makers, regulators/ assessors, and members of ethics committees)
8. **Geographical expansion** (e.g. USA / FDA sphere or other world regions; ICH, WHO and associated bodies)

4 About this document

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