Why EUPATI?

What is EUPATI?

EUPATI in Malta
Health research & policy is changing at a fast pace

Innovation transforms the lives of patients with serious, lifelong conditions:

- Molecular targets/pathways
- Genome sequencing,
- Translational research
- Personalized medicine
  - Small trial populations
  - Biomarkers, companion diagnostics
- Need for post-marketing data
- Health Technology Assessment, QoL, endpoints, comparators
- BUT long term pressure on health budgets – here to stay

Window of opportunity
- trial design
- relationship between researchers, regulators, industry, patients
Patients as partners: partnership model requires a paradigm shift, and more training for patients and advocates

Patient roles in Medicines R&D (academia + industry)

- Driving force
- Co-researcher
- Reviewer
- Advisor
- Info provider
- Research subject

Source: PatientPartner FP7 Project (2010)

Competent Authorities
Policy Makers/Research Policy
HTA Agencies/Committees
Research Ethics Committees
What is EUPATI?

• A Public Private Partnership within the Innovative Medicines Initiative
• Joint Undertaking*
• A 5-year project, launched in February 2012 but which is now continuing on as an EPF training programme since March 2017
• A patient-led project coordinated by the European Patients’ Forum, with other stakeholders
• A strong multi-stakeholder consortium of patients’ organisations, academia, NGOs and industry – 33 organisations
• The key pan-European initiative to build competencies & expert capacity among patients and the health-interested public

* Resources are composed of financial contribution from the European Union’s Seventh Framework Programme and in-kind and financial contributions from EFPIA companies
The EUPATI objectives are directly contributing to this paradigm shift

Key objectives:

1. Develop and disseminate objective, credible, correct and up-to-date public knowledge about medicines R&D
2. Build competencies & expert capacity among patients & public
3. Facilitate patient involvement in R&D to collaborate in academic research, industry research, authorities and ethics committees

...and NOT: develop indication- or therapy-specific information!
Last 24 months in facts and numbers

- 216 countries use the Toolbox
- 3,307 users on busiest day in April 2018
- 52,776 European users of most used language
- 432,089 (613) words in the Toolbox (number of content pieces)
- 152 EUPATI trainees graduated from Cohorts 1, 2, 3
- 13 6 ENP run webinars
- 7 general webinars
- 8 new sessions developed for Cohort 3 Event 1
- 1,200,000 total users since launch
Engage in
19+ EUPATI National Platforms

EUPATI National Platforms…

• bring all stakeholders together in countries
• address educational needs in R&D
• disseminate EUPATI’s training material to patient organisations

National platforms set up in AT, FR, DE, IE, IT, LU, MT, PL, ES, CH, UK, DK, SK, PT

Additional platform initiatives ongoing in NO, GR, RU, SRB, BE
EUPATI Toolbox on Medicines R&D: >3,500 content items

- Articles
- Infographics
- PowerPoints
- Fact sheets

Blinding in clinical trials

Clinical Trial Designs

Fact Sheet: Informed Consent

Informed consent is a critical step that plays a major role in ensuring the ethical conduct of a clinical trial. It involves the process of providing patients with information about the study in a way that they can understand it. This process must be transparent and proactive, allowing patients to make informed decisions about whether to participate in the study.

Before a participant can consent to a clinical trial, they must be informed about the study in a way that allows them to make an informed decision. This process is called informed consent. It is important that information is provided in a clear and concise manner, using language that is easy to understand. Participants should be given the opportunity to ask questions and discuss any concerns they may have. This process is ongoing and should be conducted throughout the trial.

Informed consent is a legal document that outlines the study's purposes, procedures, risks, and benefits. It also includes the participant's rights to withdraw from the study at any time without affecting their rights or benefits. Participants should be informed that they can withdraw from the study at any time, without any penalty, and that their data will be de-identified before being used for research purposes.

The informed consent process is an important part of ensuring that clinical trials are conducted ethically and in compliance with regulatory requirements. It is a crucial step in protecting the rights of participants and ensuring the integrity of research findings.

Lifecyle management
EUPATI Toolbox on Medicines R&D in 10 languages including Maltese

- Fact sheets, detailed papers, PPTs, videos, illustrations, glossary.

- In Danish, English, French, German, Italian, Maltese, Netherlandish, Polish, Russian & Spanish.
Patient Expert Training Course

Online self-learning + 2 Face-to-face events + Patient involvement forum

150-175 hours of e-learning and 8 days for two Face-to-Face meetings over a period of 14 months
EUPATI Mini-Course Starter Kits to run training days

ToolBox Focus

Mini-course starter kit – Setting Research Priorities

This EUPATI Mini-course starter kit is designed for patient involvement in setting research priorities.

Go to starter kit
EUPATI was launched in Malta in 2014. I became a EUPATI expert after my Graduation, in December 2016. I became part of EUPATI National Platform (ENP). This allowed me to delivered presentations to different Patients Groups, Professionals Organisations, Lectures to University Students to raise awareness about Eupati and that people can access the module for more information.
With the medical professionals, we encouraged them to promote the EUPATI site since it is a reliable and an easy site to follow for information on medicines since people like to surf the internet for medical information.
Positive aspects

- MHN kept project alive in Malta despite of various difficulties
- 2 patient experts trained and 3rd person accepted hopefully to start training later this year as patient expert
- Opened up discussions with Medicines Authority who saw the value of investing in patient training and signed MOU to assist MHN in this.
- Patient representative appointed on the Appeal Board of the Pharmacy regulatory Body and Smoking and Health Advisory Committee.

Difficulties

- We evaluated the possibility of translating the whole site in Maltese Language but due to financial limitations, it did not allow us.
- In Malta there are very limited research and development studies and these are often carried out at University, need to strengthen relationship with University of Malta.
- Due to limited man-power although we would like to carry out training events using the mini-training material, so far opportunities have been very limited.
EUPATI Tool box in Maltese