



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

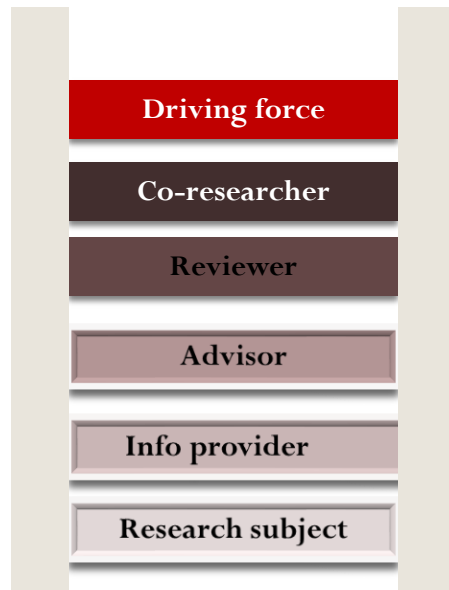
Window of opportunity

- 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)



Source: PatientPartner
FP7 Project (2010)



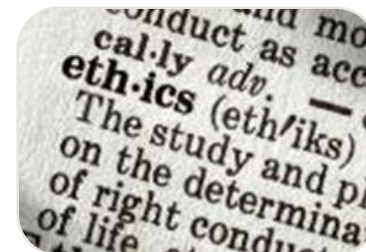
Competent Authorities



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 *stake holders*
- **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

EUPATI trainees graduated from Cohorts 1, 2, 3 –

152



52,776

– European users of most used language



432,089 (613)

– words in the Toolbox
(number of content pieces)



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

European Patients' Academy on Therapeutic Innovation

Challenges in personalised medicine

1. Comparison platforms
2. Challenge
3. Patient experience
4. Ethical issues
5. Regulatory issues

For personalised medicine to make progress, new insights from molecular research and their clinical application as 'precision' interventions must be translated (especially) for use in medicine development and approved therapy.

However, the concept of developing personalised medicines is less simple in the efforts of clinical trials. Even now clinicians should be far enough of the development process. They are engaged in a new era of the society, and the use of this tool will be central to personalised medicine. But not all the medicine is created for patients for the advance of treatment but to be able to use medicine as a tool to help you in your life.

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Articles

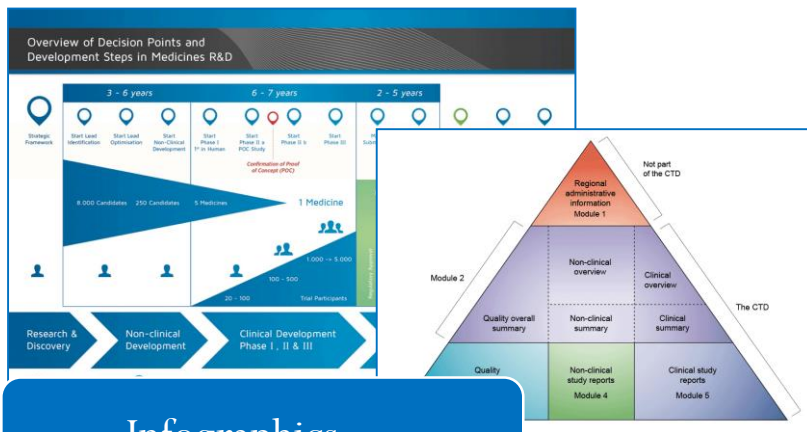


Blinding in clinical trials

Clinical Trial Designs

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PowerPoints



Infographics

Fact Sheet: Marketing and life-cycle

Marketing and post-market surveillance
The marketing process and other health care products, and may provide information on the development of the product.

However, the development of the product should be based on the information provided in the fact sheet.

- in clinical trials
- the product being developed
- in real-life, a lot of other information

Both the clinical trials and the real-life development process are governed by regulations and subject to review in order to ensure the rights, safety and well-being of participants (see Fact Sheet: Informed Consent - Regulatory). As a result, the informed consent discussion, the written consent form, and other written information should include written information according to the Guidelines for Good Clinical Practice.

Life-cycle Management

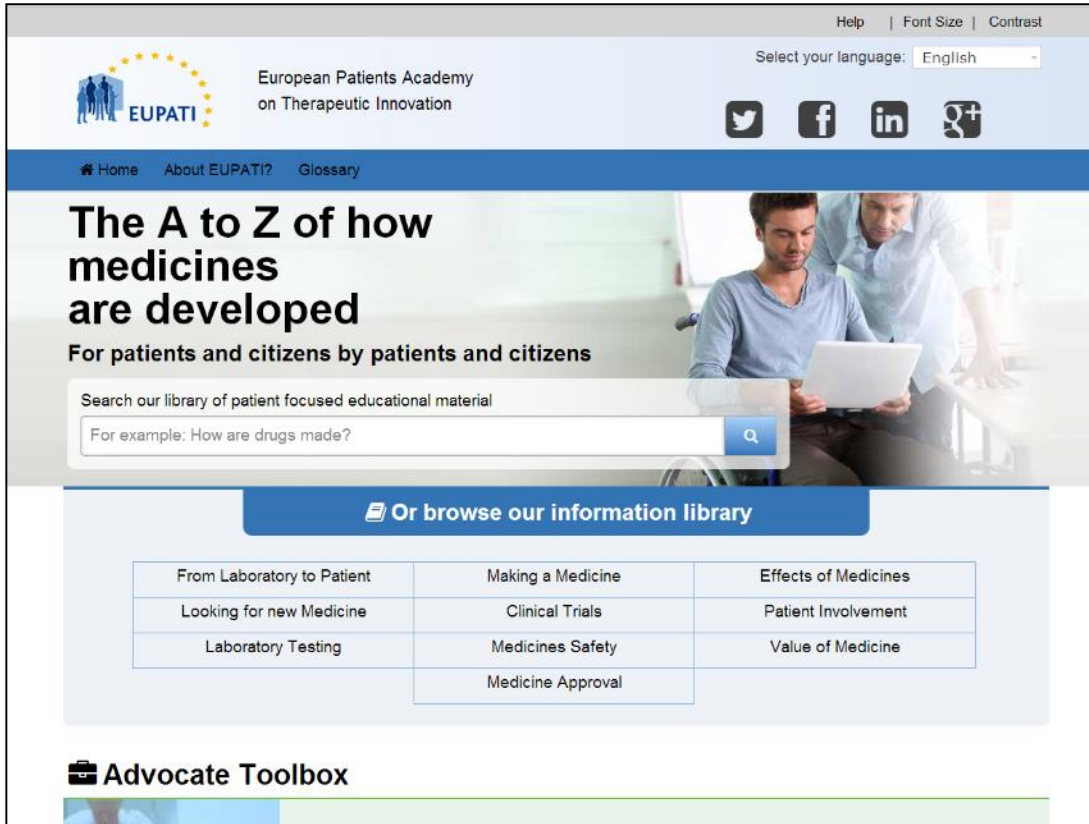
Fact Sheet: Informed Consent

Before a participant can enrol in a clinical trial, they must be screened for eligibility according to the criteria defined in the trial protocol. After screening, eligible participants should have an informed consent discussion with a sponsor representative. During the informed consent discussion, the participant should learn of the purpose and potential benefits and risks of a study before they decide whether or not they wish to participate.

The process of patient recruitment and informed consent is an integral part of the medicine development process, governed by regulations and subject to review in order to ensure the rights, safety and well-being of participants (see Fact Sheet: Informed Consent - Regulatory). As a result, the informed consent discussion, the written consent form, and other written information should include written information according to the Guidelines for Good Clinical Practice.

Fact sheets

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



The screenshot displays the EUPATI website interface. At the top, there is a navigation bar with the EUPATI logo (European Patients Academy on Therapeutic Innovation) and a language selection dropdown set to 'English'. Below the navigation bar, a main banner features the title 'The A to Z of how medicines are developed' and the subtitle 'For patients and citizens by patients and citizens'. A search bar is present with the placeholder text 'Search our library of patient focused educational material' and an example query 'For example: How are drugs made?'. Below the search bar, a blue button reads 'Or browse our information library'. Underneath this button is a grid of nine categories: 'From Laboratory to Patient', 'Making a Medicine', 'Effects of Medicines', 'Looking for new Medicine', 'Clinical Trials', 'Patient Involvement', 'Laboratory Testing', 'Medicines Safety', and 'Value of Medicine'. At the bottom of the page, there is a section titled 'Advocate Toolbox'.

- 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

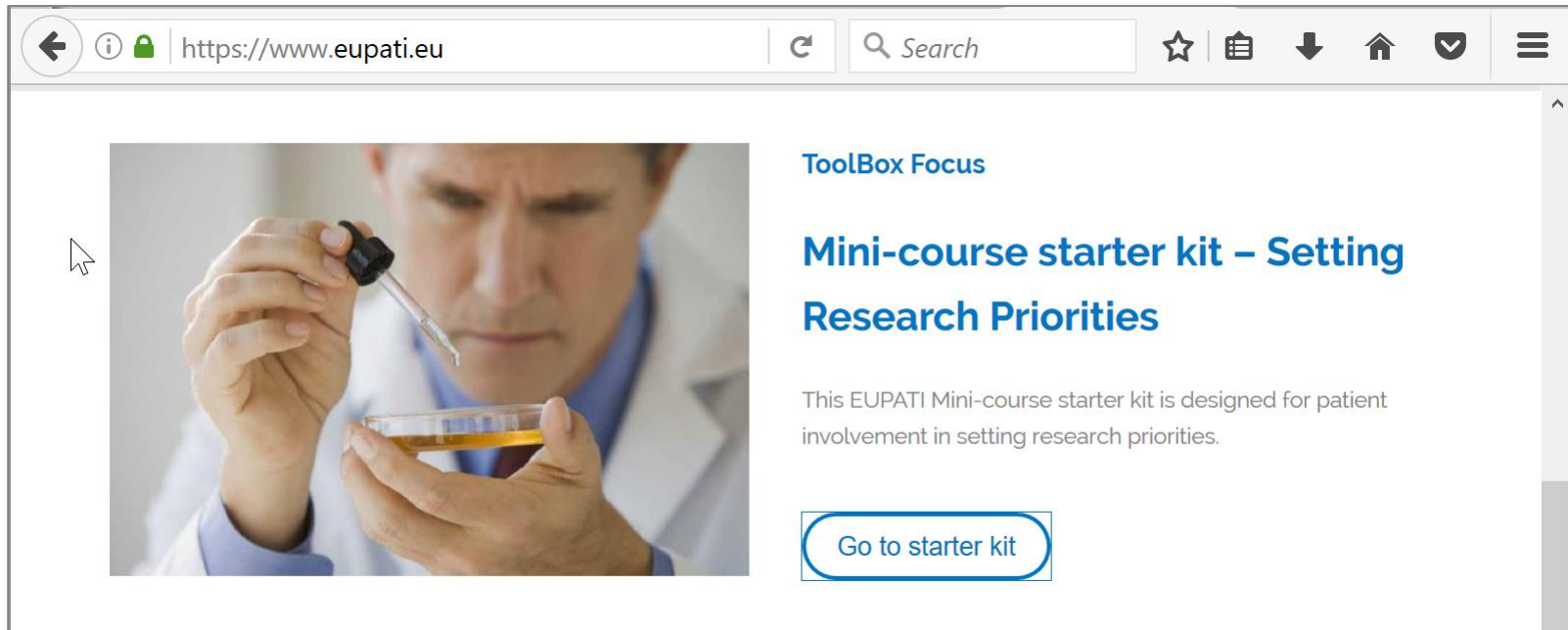
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Patient involvement
forum

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



https://www.eupati.eu

Search

ToolBox Focus

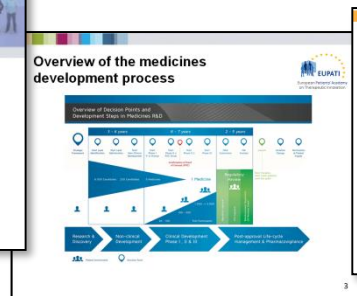
Mini-course starter kit – Setting Research Priorities

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

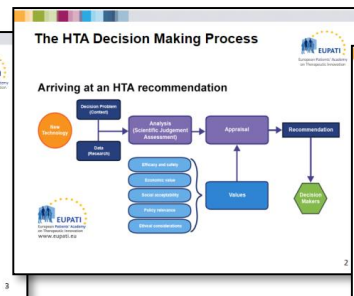
[Go to starter kit](#)



Patient Involvement in the HTA Decision Making Process



Overview of the medicines development process

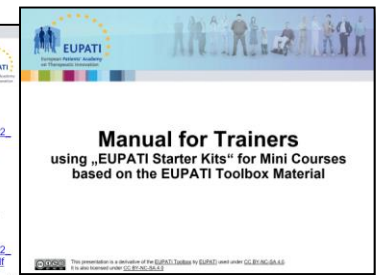


The HTA Decision Making Process



References

- Health Technology Assessment International (2014) 'Values and Quality Standards for Patient Involvement in HTA'. Retrieved 1st March 2016, from http://www.htai.org/fileadmin/HTAI_Files/ISG/PatientInvolvement/v2_files/Info/PCISG-Info-ValuesandStandards-30-Jun14.pdf
- Health Technology Assessment International (2015) 'For Patients and Patient Groups'. Retrieved 1st March 2016, from <http://www.htai.org/interest-groups/patient-and-citizen-involvement/resources-for-patients-and-patient-groups.html>
- Health Technology Assessment International (2014) *Completing a patient group submission template: Guidance for patient organisations*. Retrieved 1st March 2016, from http://www.htai.org/fileadmin/HTAI_Files/ISG/PatientInvolvement/v2_files/Resource/PCISG-Resource-GuidanceandChecklist-Dec14.pdf



Manual for Trainers using „EUPATI Starter Kits“ for Mini Courses based on the EUPATI Toolbox Material



EUPATI IN MALTA

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



<http://www.maltahealthnetwork.org/projects/european-patients-academy-eupati-patient-education/european-patients-academy-eupati-patient-education-toolbox-malti/>



European Patients' Academy (EUPATI) Patient Education Toolbox: Malti

Id-dokumenti hawn taht huma d-dokumenti gwida magħmulin min EUPATI Toolbox Malti.

Fatturi ta' riskju fis-saħħa u fil-mard

Fatturi ta' riskju fis-saħħa u fil-mard-Fact Sheet_II-Progett SCORE

Id-drittijiet tal-partecipanti, responsabilitajiet, organizzazzjonijiet

Informazzjoni fuq prodotti mediċinali

Kif tinkiteb għal studju kliniku

Kif tinkiteb għal studju kliniku-Fact-Sheet-II-Kunsens