



An update on the state of play for EPF members EPF AGM 13 May 2014

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The project is receiving support from the Innovative Medicines Initiative Joint Undertaking under grant agreement n° 115334, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies.

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 are probably here to stay



Patients have a key role in all aspects of health-related research



Competent authorities



Policy makers / Research Policy



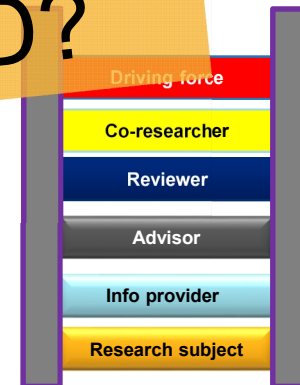
Are there enough patient advocates to engage in R&D?



Research Ethics Committees



HTA agencies & committees



Clinical Research

European Patients' Academy: Paradigm shift in empowering patients on medicines R&D



- ▶ Launched Feb '12, runs for 5 years, 30 consortium members, Funded by Innovative Medicines Initiative
- ▶ **will develop and disseminate objective, trustworthy, public knowledge about medicines R&D**
- ▶ **will generate knowledge and facilitate patient involvement in R&D** to collaborate in academic & industry research, authorities and ethics committees
- ▶ Will address informational needs and help reduce myths and misconceptions.



Project coordinated by EPF, led by 4 key pan-European patient associations, strong consortium



Content production of objective, reviewing material is currently in full swing

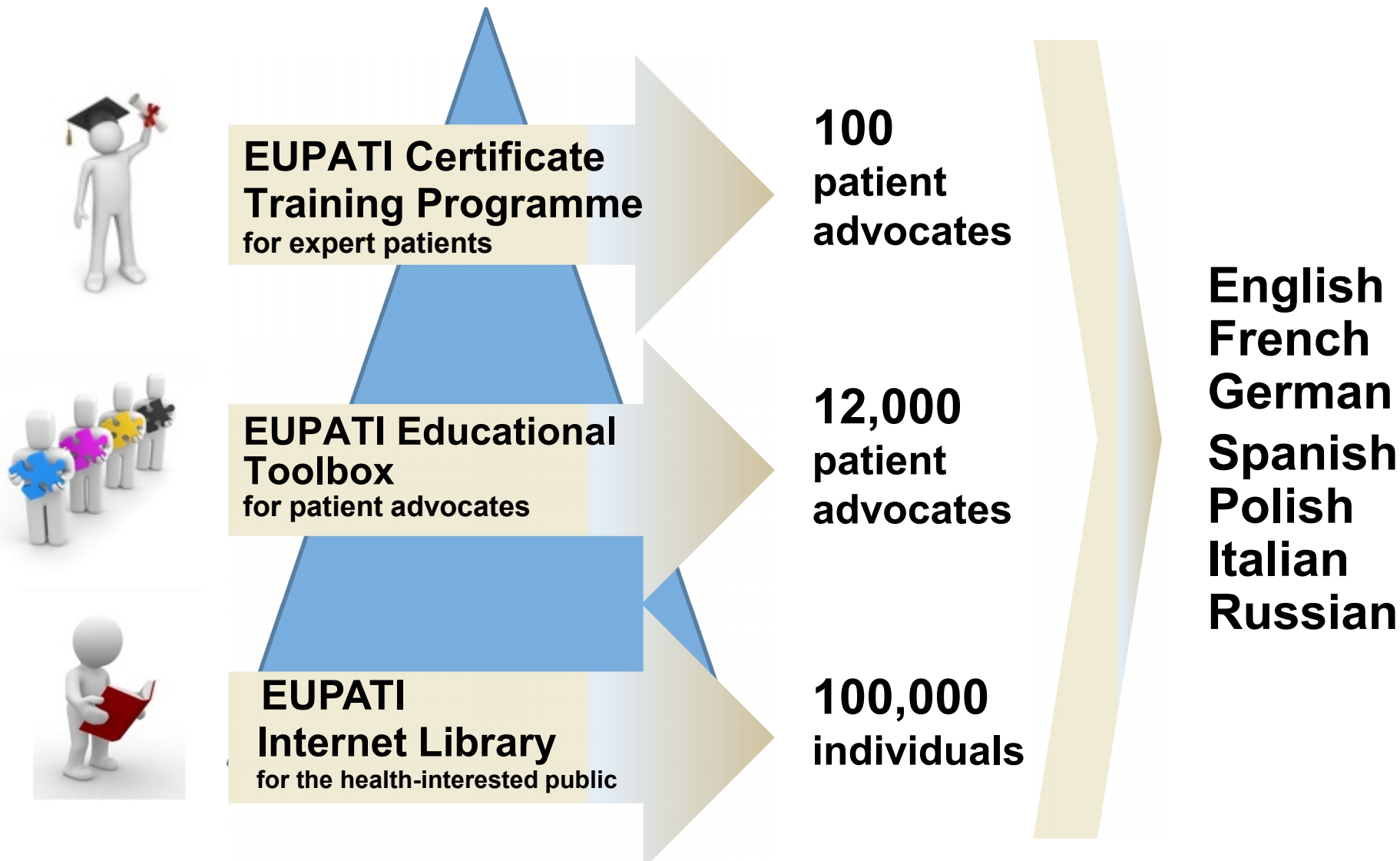


1. Discovery of Medicines & Planning of Medicine Development
2. Pre-Clinical Testing and Pharmaceutical Development
3. Exploratory and Confirmatory Clinical Development
4. Clinical Trials
5. Regulatory Affairs, Medicinal Product Safety, Pharmacovigilance and Pharmacoepidemiology
6. HTA principles and practices

+ Patients' roles and responsibilities

***...but NOT:
indication- or therapy-specific information!***

We develop education material targeted at different levels

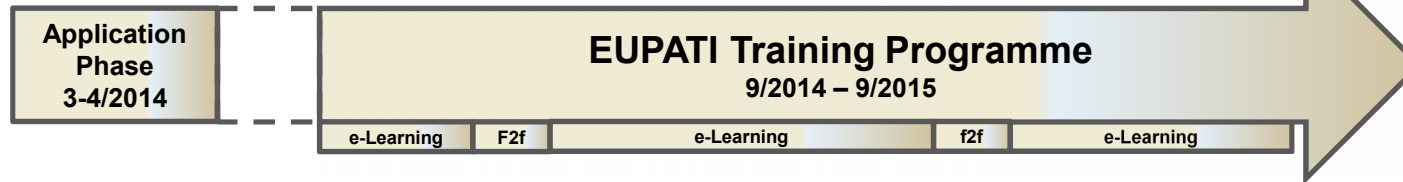
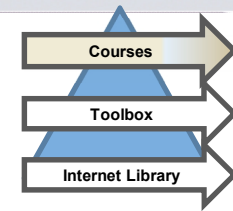


Two years of EUPATI: Much has been done! ...

For example in Frankfurt 2012, Barcelona 2013, Rome 2013, Warsaw 2014...



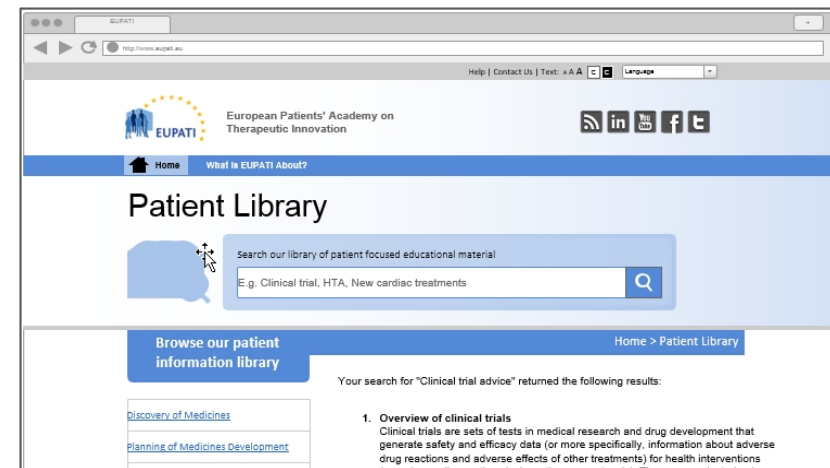
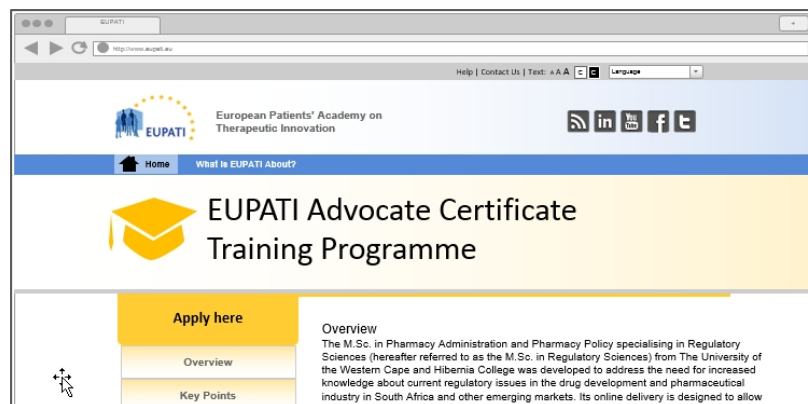
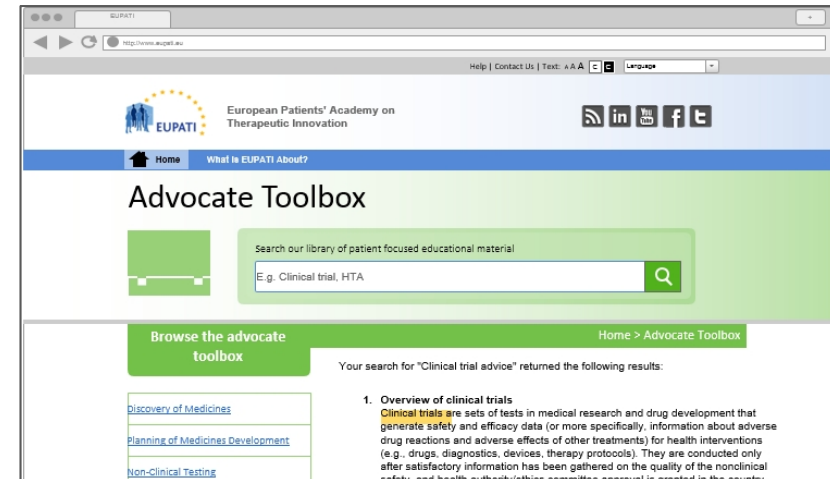
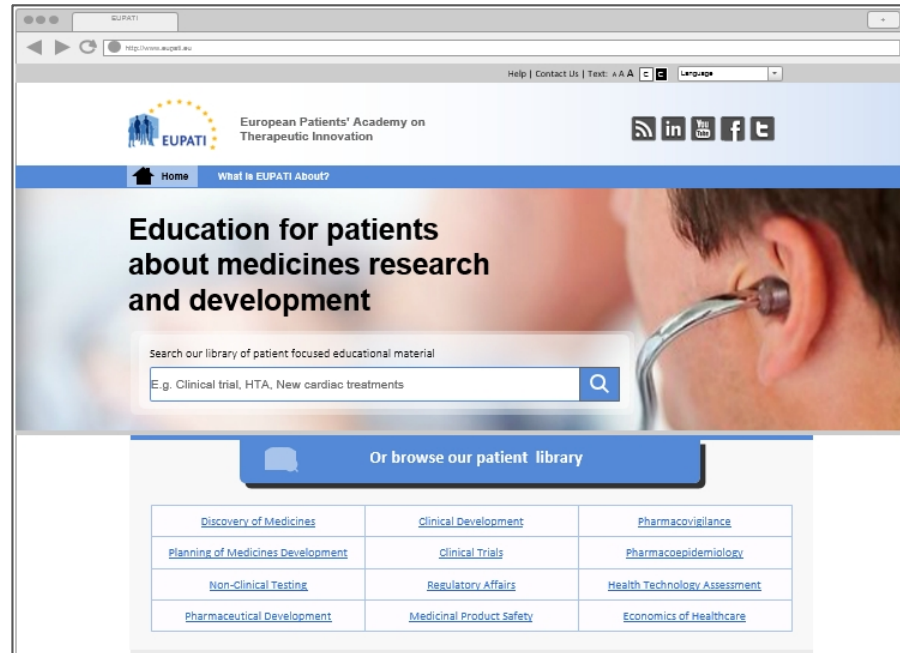
EUPATI Certificate Training Course



- 150+ hours of e-learning and two 4-day sessions
- Two cycles of 50 participants
- Open to patients, carers, patient advocates and volunteers
- **By the application deadline for the first 50 trainees, more than 300 applications were received!** Great demand from the patient community!
- Start of course:
Sept 2014 (1st 50 trainees),
Sept 2015 (2nd 50 trainees)

A screenshot of a web browser displaying the 'Guide for Applicants' page on the EUPATI website. The browser address bar shows 'www.patientsacademy.eu/index.php/en/edu/guide#about-the-training-topics-timing-cost'. The page features the EUPATI logo and the text 'European Patients' Academy on Therapeutic Innovation'. A navigation menu on the left includes 'Home', 'Main Menu', 'About EUPATI', 'EUPATI News', 'EUPATI Training Course', 'Guide for Applicants', 'Questions and Answers', 'Apply here', 'EUPATI Events', 'EUPATI Glossary', 'Subscribe to Newsletter', 'File Download', 'Search this site', and 'Contact us'. The main content area is titled 'Training Course - Guide for Applicants' and includes a PDF download link, a table of contents with links to 'Introduction', 'Who can apply', 'About the Training, Topics, Timing, Cost', and 'Filling out the Application Form', and sections for 'The Programme', 'Patient Representation', 'Communication', 'Education/Training', 'Topics covered in the course', and 'Discovery of Medicines & Planning of Medicines Development'.

The (future) EUPATI web platform and content is taking shape



EUPATI's first R&D Glossary... (Your input is appreciated!)

- EUPATI's first glossary of terms and definitions of medicines R&D.
- ~460 terms drawn from course content
- This is a **first draft**.
→ Feedback form & return address on last page
- A more lay friendly version is being developed for public use, plus an interactive version within online training course.



ANALYSIS OF VARIANCE

analysis of variance
Also known as ANOVA, the Analysis of Variance is a statistical technique for looking at multiple groups and multiple factors, to help define the cause of any variability affecting a set of observations. This technique provides a basis for analysing the effects of various treatments or other parameters (variables) that may have an effect on the patients being investigated (see also Variance).

analysis plan
The strategy for analysis predefined in the statistical section of the protocol and/or protocol amendments. The plan may be elaborated in a separate document (internal to the sponsor) to cover technical details and procedures for implementing the statistical analyses.

animal model
An animal (rat, mouse, monkey, woodchuck, etc) with a disease either the same as or very similar to a disease in humans. Animal models are used to study the development and progression of disease as well as to test new treatments before they are given to humans.

ANM
Agence Nationale de Medicaments et des produits de sante, the French Regulatory (Competent) Authority (see NCA).

approved drugs
Before a drug can be marketed, it must be approved by a regulatory authority who scientifically evaluates it and then continues to supervise or monitor its use once on the market. The approval process involves several steps including preclinical laboratory and animal studies, clinical trials for safety and efficacy, filing of a New Drug Application (USA) or Marketing Approval Application (EU) by the manufacturer of the drug.

area under the curve (AUC)
The area under the curve is the concentration of the amount of a drug in chart form. It is useful in measuring the amount of drug absorbed by the body and so is helpful in calculating the correct dosage; it is often divided by time after drug administration to measure the drug's concentration.

ANM
Agencia Nacionala de Medicamentului i a Dispozitorilor Medicale, the Romanian Regulatory (Competent) Authority (see NCA).

ANCOV
Also known as Analysis of Variance, ANCOV is a statistical technique for looking at multiple groups and multiple factors, to help define the cause of any variability affecting a set of observations. This technique provides a basis for analysing the effects of various treatments or other parameters (variables) that may have an effect on the patients being investigated (see also Variance).

Figure No. 5: BLOOD LEVELS OF A DRUG OVER TIME

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EUPATI National Platforms: Partnership on the country level

EUPATI National Platforms will...

- **make sure EUPATI understands educational needs** in R&D on national level when developing content
- **disseminate EUPATI's existing training material and information** on the national level
- **To raise public interest about EUPATI** in 12 countries
- **To identify training faculty, logistics and financial support** on the national level



EUPATI in 2016: What we will have achieved



- ▶ EUPATI platform fully loaded with training, education, information material in multiple languages
- ▶ 100 patient advocates trained in-depth and received the ‘EUPATI Certificate’
- ▶ 12 EUPATI National Platforms set up (with your help!)
- ▶ Good practice guideline for patient involvement released
- ▶ Annual Conferences and Regional Workshops performed. Expert network established.
- ▶ Sustainability strategy and long-term implementation of an “European Patients’ Academy” beyond 2017 completed



Be in touch!

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