EUPATI: European Patients’ Academy on Therapeutic Innovation

http://www.patientsacademy.eu – info@patientsacademy.eu

Walter Atzori,
Senior Programme Officer European Patients’ Forum

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:

- Genome sequencing
- Translational research
- Personalised and stratified medicine
  - Small trial populations
  - Biomarkers, companion diagnostics
- Adaptive design in clinical trials
- New techniques for benefit/risk elicitation
- Need for post-marketing data
- Adaptive pathways
- HTA early dialogues, QoL, endpoints, comparators

Window of opportunity

- Trial design
- Relationship between researchers, regulators, industry, patients

BUT long term pressure on health budgets – here to stay
Patients as partners of research: More needs to be done!

"Rare cancers will never be a priority unless the patients make it one. Patients themselves must therefore play a larger role in driving forward the search for therapies. They are able to see connections that have eluded scientists."
Unmet need of patient and public on information on medicines R&D

- Patients...
  - seek up-to-date, credible, understandable information about innovation in treatments
  - are largely unaware about clinical trials, translational research, personalised medicine, pharmaco-economics, their key role there
Unmet need of patient and public on information on medicines R&D

- Patient advocates...
  - like to advise on protocol design, informed consent, ethical review, marketing authorisation, value assessment, health policy
  - lack the education and training required to participate as a partner in medicines R&D
Patients' organisations key role in building a new environment for the development of new medicines

- Patient’s organisations have unique insights in „real life“ and „real needs“ of patients:
  - Gap analysis in research priorities
  - Clinical trial design
  - Quality of Life measurements
  - Determining the real value of new therapies

- **Training required** to get expertise required to contribute to medicines research & development (R&D) projects

Source: PatientPartner FP7 Project (2010)
Patients have a key role in all aspects of health-related research.

If patients are to be involved in REC on a broad level, we need more patients who understand how trials work.

- 9,400 EU applications for clinical studies/year
- 5,000 clinical studies initiated in EU/year
  - 25% multinational
    = ~1250 studies/year
  - 4.5 Member States on average per multinational study
    - Single opinion per country assumed
  - For 1250 multinational studies, more than 5,000 ethics panels with 35,000 panelists needed

Having a patient (advocate) in every Research Ethics Committee...

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<th>Country</th>
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<th>Number of ethics committees (including local ethics committees)</th>
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Patients have a key role in all aspects of health-related research

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

Research Ethics Committees

HTA agencies & committees

Competent authorities

Policy makers/Research Policy

Clinical Research
Overview of Decision Points and Development Steps in Medicines R&D

3 - 6 years:
- Strategic Framework
  - Start Lead Identification
  - Start Lead Optimisation
  - Start Non-Clinical Development
  - Start Phase I 1st in Human
  - Confirmation of Proof of Concept (POC)
  - 8,000 Candidates
  - 250 Candidates
  - 5 Medicines

6 - 7 years:
- Start Phase II a POC Study
- Start Phase II b
- Start Phase III
- MAA Submission
- MA Granted
- 1 Medicine
- 1,000 → 5,000
- 100 - 500
- 20 - 100
- Trial Participants

2 - 5 years:
- MAA Submission
- MA Granted
- Launch
- Variation Change
- Termination of Market Supply
- Regulatory Review
  - HTA Approval
  - Reimbursement Negotiation 28 Members States
  - New therapies don’t reach patients until this point

Research & Discovery ➔ Non-clinical Development ➔ Clinical Development Phase I, II & III ➔ Post-approval Life-cycle management & Pharmacovigilance

Patient Involvement ➔ Decision Point
Patients want a seat at the table. Currently, there are many empty seats.

This is why we have established the European Patients‘ Academy (EUPATI).
European Patients’ Academy: Paradigm shift in empowering patients on medicines R&D

- Launched in early 2012, runs for 5 years, 30 consortium members,
  Funded by IMI JU to:

  - develop and disseminate objective, credible, correct and up-to-date public knowledge about medicines R&D
  - build competencies & expert capacity among patients & public
  - facilitate patient involvement in R&D to collaborate in academic research, industry research, authorities and ethics committees
Strong consortium & strong governance

- Coordinated by patients (EPF)
- Leading pan-EU patient umbrella groups involved in all key activities
- Strong impetus from key academic partners and research organisations
- Industry expertise in medicines R&D
- Advisory bodies & codes committed to ensure independence and good governance
  - Key experts in bioethics, genetics, HTA, economics, evidence based medicine, patient advocacy provide feedback and expertise
Areas covered by the European Patients’ Academy

We do not educate about disease-specific issues or therapies, but about the process of medicines development in general. Indication-specific information or specific medicine interventions are beyond the scope of European Patients’ Academy and are the remit of health professionals as well as patient organisations.

1. Discovery of Medicines & Planning of Medicines Development
2. Non-Clinical Testing and Pharmaceutical Development
3. Exploratory and Confirmatory Clinical Development
4. Clinical Trials
5. Regulatory Affairs, Medicinal product Safety, Pharmacovigilance and Pharmaco-epidemiology
6. Health Technology Assessment and the economics: how the value of a new therapy is determined
To bring this to life, EUPATI develops education targeted at different levels:

- **EUPATI Patient Experts Training Course** -- for expert patients. Supports 100 patient advocates.
- **EUPATI Educational Toolbox** -- for patient advocates. Supports 12,000 patient advocates.
- **EUPATI Internet Library** -- for the health-interested public. Supports 100,000 individuals.

EUPATI offers educational resources in multiple languages:

- English
- French
- German
- Spanish
- Polish
- Italian
- Russian

Welcome to the EUPATI Expert Patients Course

Module 1: Discovery of Medicines and Planning of Medicines Development
Module 2: Non-Clinical Testing and Pharmaceutical Development
Module 3: Exploratory and Confirmatory Clinical Development
Module 4: Clinical Trials
Module 5: Regulatory Affairs, Medicinal Product Safety, Pharmacovigilance
Module 6: HTA Principles and Practices

CALENDAR

November 2015

UPCOMING EVENTS

Webinar on Social Media
C2 ~ Course Information
EUPATI National Platforms: Partnership on the country level

EUPATI National Platform set to to:

- 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
What’s next?

- Need to continue to train patients at expert level
- Continue to develop educational material and tools for patient advocates (Toolbox) and lay patients (Library) keeping abreast of latest developments on medicines R&D + further languages
- Promote patient engagement at all levels + support patients engaging meaningfully across the board
What’s next?

- Foster attitude change among stakeholders to embrace patient centered innovation by promoting patients' involvement in all aspects of medicines R&D, including ethics committees, regulatory bodies, and HTA.
Thank You

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