European Patients' Academy on Therapeutic Innovation

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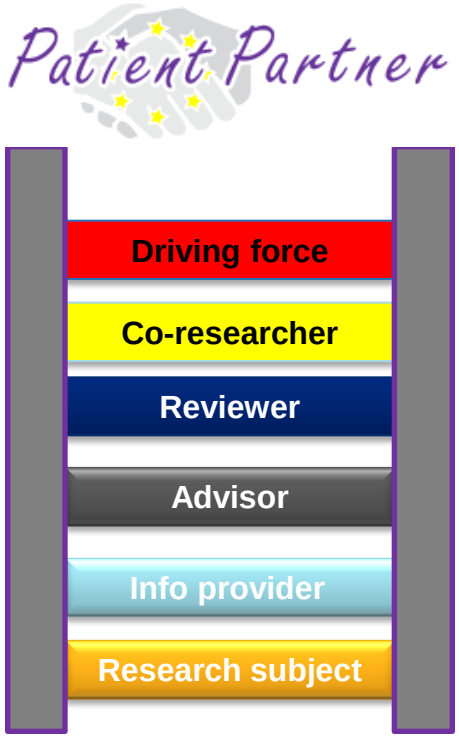
Unmet need of patient and public on information on medicines R&D

- **Patients…**
  - seek up-to-date, credible, understandable information about innovation in treatments
  - are largely unaware about clinical trials, translational research, personalized medicine, pharmaco-economics, their key role
- **Patient advocates…**
  - like to advise on protocol design, informed consent, ethical review, marketing authorization, 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
  - Priority setting
  - Research policy

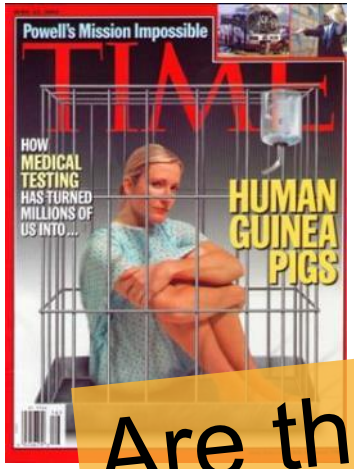
- **Training required** to get expertise required to contribute to medicines research & development (R&D) projects



Source: PatientPartner FP7 Project (2010)

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

EUPATI
European Patients' Academy on Therapeutic Innovation



Public

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
BfArM
MHRA
swissmedic

Competent authorities

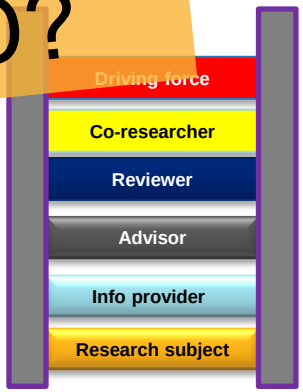
Policy makers /Research Policy

Trial protocol design, information, consent, clinical review, marketing authorization, value assessment, health 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

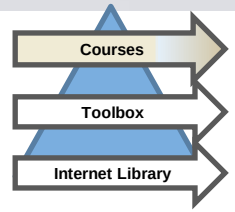
- Launched Feb '12, runs for 5 years,
  30 consortium members,
  Funded by IMI JU

- will **develop and disseminate objective, credible, correct and up-to-date public knowledge about medicines R&D**

- will **build competencies & expert capacity** among patients & public

- will **facilitate patient involvement in R&D** to collaborate in academic research, industry research, authorities and ethics committees

EUPATI Patient Experts Training Course has started on 6 Oct 2014



Outline

- 150+ hours of e-learning and two 4-day sessions
- Two cycles of 50 participants
- Open to patients, carers, patient advocates and volunteers

Selection

- By the application deadline for the first 50 trainees, more than 300 applications were received! Great demand from the patient community!
- Selection was done by selection panel based on solid criteria
- Start of course:
  Oct 2014 (1st 53 trainees),
  Sept 2015 (2nd 50 trainees)

Blended learning

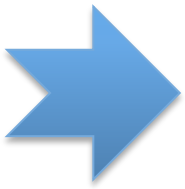
EUPATI provides …

- **online lessons** for one year
- two on-site **face-to-face sessions** with a team of interdisciplinary tutors and trainers
- dedicated course committee
- Moodle-based learning **platform** with content and general tutoring
- continuous integrated **assessment**
- **flexible**, novel methodologies

Conveying scientific knowlegde and advocacy in parallel

- **develop and disseminate** accessible, well-structured and user-friendly information and education on medicines R&D
- **build expert capacity** by training patient advocates, and **competencies** among patients and the public
- convey and collect **best practices** across patient organisations and advocates
- **encourage interaction and cooperation** among trainees and fellows and across disease areas

It is also about power relations

Know what you want  **Know how to achieve it**

Scientific and policy work go hand in hand

The expert patient

- It’s your body, you (should) know best
- Information is key, information is empowerment
- Work along joint interests
- Patient ➔ Expert patient ➔ Conscious consumer ➔ Empowered citizen
- Expert patients are multipliers of
  - knowledge
  - coping strategies
  - empowerment

Achievements/outcomes

- National Platforms
- Speaker Panel
- Standard procedures for interaction
- Empowerment
- Continuous interaction among participants/expert patients
- Theoretical debates about interaction among stakeholders
  - Industry and patients?
  - Academia and patients?
  - Academia and industry?
- Increased awareness of rights and possibilities

To bring this to life, EUPATI develops education targeted at different levels

EUPATI Patient Experts Training Course
-- for expert patients

100 patient advocates

EUPATI Educational Toolbox
-- for patient advocates

12.000 patient advocates

EUPATI Internet Library
-- for the health-interested public

100.000 individuals

English
English
French
German
Spanish
Polish
Italian
Russian

Areas covered by the European Patients' Academy

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
7. Methodologies of advocacy and activism

Mechanisms to ensure independence a credibility of EUPATI

- **Quality control** in task forces and by experts:
  Materials will be reviewed and tested prior to release (multi-stakeholder editorial board, Ethics Panel, external advisers and experts)
- **EUPATI Regulatory Advisory Panel** involving
  5 regulatory bodies EMA, BfArM, Swissmedic, MHRA, AIFA.
  - ensures objectivity, transparency, impartiality and independence of EUPATI's content
  - supervises adherence to the **'Core Quality Principles of information to patients on diseases and treatment options**' (Pharmaceutical Forum)
  - Provides guidance and advice to the project teams
- **EUPATI Project Advisory Board** with leading independent experts from different areas
- **EUPATI Ethics Panel** with genuine ethics expertise,
- **Effective Codes of Practices in place**
  - **EUPATI Code of Practice**
  - **EUPATI Ethical Framework**
  - **EFPIA Code** for industry partners and **'Code of Practice between patient organisations and healthcare industry**' endorsed by patient organisations

Uniqueness of the partnership

- **Unique and unprecedented partnership** between patient organisations, other public partners and pharmaceutical industry based on the philosophy of the IMI
  - **Unique in IMI** that EUPATI is patient- and not industry-led
  - Opportunity to establish an **effective, transparent and credible partnership**
  - **Exceptional learning experience** for industry representatives to work with patient organisations in a constructive and reflective manner, which could serve as a role model in other environments as well
  - **Making best use of industry expertise** in medicines R&D, incl. e.g. the legislative environment and development of ITP as required by law
- **Opportunity to strengthen the voice of the patients** in the search for innovation and new medicines
- **Chance to reduce fear, lack of trust and misconception** among patients regarding the pharmaceutical industry

Key stakeholders of the European Patients' Academy

Get to know us!

EUPATI

European Patients Academy on Therapeutic Innovation

Web:
www.patientsacademy.eu

Twitter: @eupatients
as well as: