EUPATI

European Patients‘ Academy
on Therapeutic Innovation

European Patients’ Academy on Therapeutic Innovation

EMA PCWP, 30 Nov 2012

europeanpatients’forum

Jan Geissler
EUPATI Director

Window of opportunity in medicines research and development (R&D)

New opportunities:

- Molecular targets/pathways
- Genome sequencing
- Translational research
- “Personalised” medicine
- Companion diagnostics
- Need for post-marketing data
- HTA, QoL, endpoints, comparators
- Healthcare budgets, drug pricing

Window of opportunity

- new relationship between researchers, regulators, industry, **patients**

Overcoming public scrutiny on research

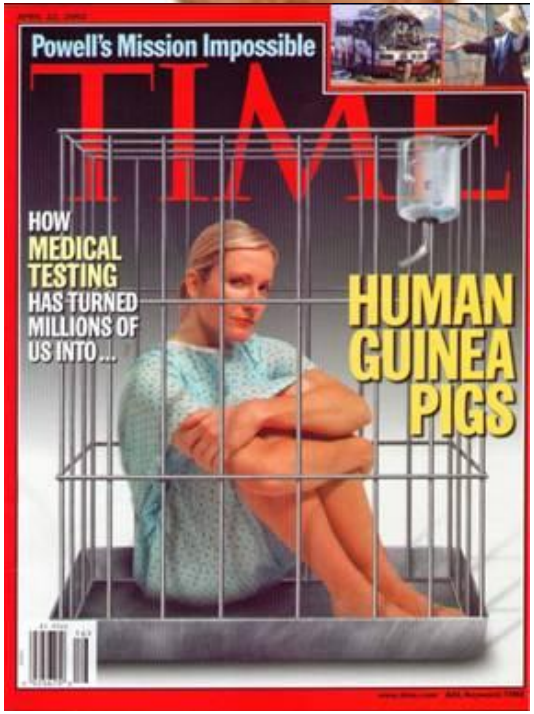
- **Only 6-12% of cancer patients participate in clinical studies**
- **75% of Phase II-IV studies delayed** due to slow patient recruitment
- Bad image one reason for delayed generation of meaningful clinical data

MEDICINE AND THE MEDIA

“We saw human guinea pigs explode”

L Stobbart and colleagues examine newspaper coverage of adverse events in the TGN1412 trial

with death and disfigurement. Science fiction or cinematic imagery is often used to add potency to detailed and gruesome descriptions—although no pictures were printed of the victims’ deformities, references such as “his face now resembled that of the Elephant Man” (*Daily Star*, 16 March) were used with effect.



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.*”

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JOURNAL OF CLINICAL ONCOLOGY

PERSPECTIVES IN ONCOLOGY

To Make Progress in Rare Cancers, Patients Must Lead the Way

Amy Dockser Marcus

Submitted January 9, 2009; accepted February 3, 2009; published online ahead of print at www.jco.org on May 4, 2009.

In January, 2004, I flew to New Orleans, LA, to meet Andy Martin. He took me to the laboratory where he was working. A third-year medical stu-

treat. They recognized that when it came to SNUC, Andy was in many ways the expert on the disease. These physicians learned from the research he did,

Patient advocates' key role in building new environment for R&D

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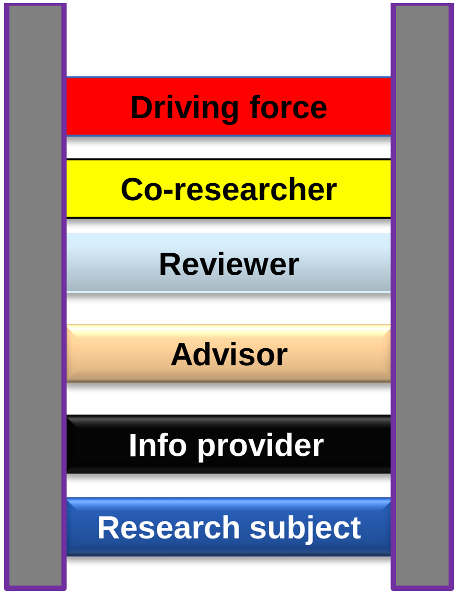
- Patient organisations have unique insights in „real life“ and „real needs“ of patients:
  - Gaps → research priorities
  - Clinical trial design
  - Quality of Life
  - Real-world access to therapies
  - „Value“
  - Patient-centered research policy

Patient Partner



Driving force

Co-researcher

Reviewer

Advisor

Info provider

Research subject

PatientPartner FP7 Project (2010),
www.patientpartner-europe.eu

Unmet need of patient & public, and great willingness to contribute!

- **Patients…**
  - are largely unaware about clinical trials, translational research, personalized medicine, health economics, their role

- **Patient advocates…**
  - **like to advise** on study protocol design, informed consent, ethical review, marketing authorization, value assessment, health policy
  - **some organisations** have contributed for years, but find training new members challenging
  - most **lack the education and training** required to participate as a partner in drug research and development

Educational initiatives to train patients

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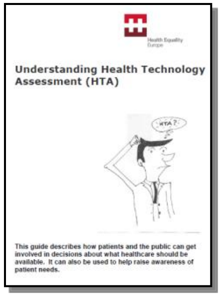
- Great individual initiatives to train patient advocates - by patient organisations, academia, industry, healthcare professionals

DIA Patient Fellowship
Patients' organisations represented
at the 23rd Annual EuroMeeting

EURORDIS
Rare Diseases Europe



Understanding Health Technology Assessment (HTA)

This guide describes how patients and the public can get involved in decisions about what healthcare should be available. It can also be used to help raise awareness of patient needs.

LSE

Skeletal Care Academy

- Complemented by:
The European Patients’ Academy on Therapeutic Innovation

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EUPATI: Training patients as partners in medicines R&D

EUPATI
European Patients' Academy
on Therapeutic Innovation

- Launched Feb 2012, runs for 5 years, 29 consortium members,
- PPP of EU Commission and EFPIA
- will **develop and provide, objective, credible, correct, up-to-date knowledge about medicines R&D**
- will **build competencies & expert capacity** among patients & public
- will **facilitate patient involvement in R&D** to support academia, authorities, industry, ethics committees

Areas covered by EUPATI

1. Medicines development process from research to approval
2. Personalised, predictive medicine
3. Drug safety, risk/benefit assessment of medicines
4. Pharmaco-economics, health economics and health technology assessment
5. Design & objectives of clinical trials (& roles of stakeholders)
6. Patients roles & responsibilities in medicines development

…and *NOT:*
develop indication- or therapy-specific information!

EUPATI Audiences: advocacy leaders and the lay public

EUPATI Certificate Training Programme

100
patient
advocates

EUPATI Educational Toolbox

12.000
patient
advocates

EUPATI Internet Library

100.000
individuals

English
French
German
Spanish
Polish
Italian
Russian

Reflecting European diversity: 7 languages, 12 countries

- **7 most frequently spoken languages:**

  English, French, German, Spanish, Polish, Italian, Russian

- **Serving 12 European countries:**

  UK, Ireland, Malta, France, Luxemburg, the francophone Belgium, Germany, Austria, Switzerland, Spain, Italy and Poland,
  plus Russian-speaking population in CEE

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  - Similarly applied by e.g. WikiPedia, Google, Whitehouse.gov and many others

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Project is led by four key pan-European patient associations

europeanpatients'forum

EGAN
Patients Network for Medical Research and Health

EURORDIS
Rare Diseases Europe

EATG
EUROPEAN AIDS TREATMENT GROUP

- **European Patients Forum**
  - EUPATI Project Coordination
  - >50 umbrella patient organisations. Through 'members of members', potential outreach to 150 million patients
- **European Genetic Alliance Network**
  - Linked with national and regional patient alliances in Germany, Eastern Europe, Italy, Netherlands, United Kingdom and Ireland, Sweden, Spain, Italy, Greece and Balkan countries
- **EURORDIS – Rare Diseases Europe**
  - Representing >500 rare disease organisations in >45 countries
- **European AIDS Treatment Group**
  - More than 100 members in over 30 countries.

Additional partners in other patient organisations and "members of members" via "EUPATI Network"

Multi-stakeholder consortium, transparently governed

- Led by patient organisations
- Strong impetus from academia and NGOs
- Industry expertise in medicines R&D
- **Advisory bodies** help ensuring independence, transparency, good governance
    - EMA, Swissmedic, MHRA, BfArM
    - Key experts in bioethics, genetics, HTA, economics, evidence based med, patient advocacy, e.g. IQWiG, NICE, Cochrane, EUnetHTA
    - Ethics Panel

EUPATI in 2016:
What EUPATI will have achieved

- EUPATI platform fully loaded with training, education, information material in multiple languages
- EUPATI Patient Ambassador, Patient Journalist, Train-the-Trainer Programme in place
- Good practice guideline for patient involvement released
- Annual Conferences and at least 5 Regional Workshops performed. Expert network established.

Get to know us!

europeanpatients'forum

EGAN
Patients Network for Medical Research and Health

EURORDIS
Rare Diseases Europe

EATG
EUROPEAN AIDS TREATMENT GROUP

EF GCP

UNIVERSITY OF COPENHAGEN

EORTC
European Organisation for Research and Treatment of Cancer

IPPOSI
Irish Platform for Patients' Organisations, Science and Industry

DIA
www.diahome.org

nowgen
A Centre for Genetics in Healthcare

HIBERNIA COLLEGE

ISPOR
INTERNATIONAL SOCIETY FOR PHARMACOECONOMICS AND OUTCOMES RESEARCH

BIO PEOPLE

vfa.

AMGEN

AstraZeneca

BAYER

Boehringer Ingelheim

Chiesi

ESTEVE

farmaindustria

genzyme
A SANOFI COMPANY

gsk

janssen
PHARMACEUTICAL COMPANIES of Johnson&Johnson

Lilly

MERCK

NOVARTIS

novo nordisk®

Roche

sanofi

ucb

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