EUPATI
European Patients‘ Academy
on Therapeutic Innovation

# Patient involvement in medicines R&D: The European Patient Academy on Therapeutic Innovation

**Nicola Bedlington, European Patients‘ Forum**
**Coordinator EUPATI**

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.

# Medical landscape is changing at a rapid 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**

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

# 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 have a key role in building new environment for R&D

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

Training essential to get expertise to contribute to medicines research & development (R&D)

Patient Partner

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

With more than 200 cancers and >4000 rare diseases, we need many qualified patient experts!

# Addressing public scrutiny and distrust of research…

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- **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

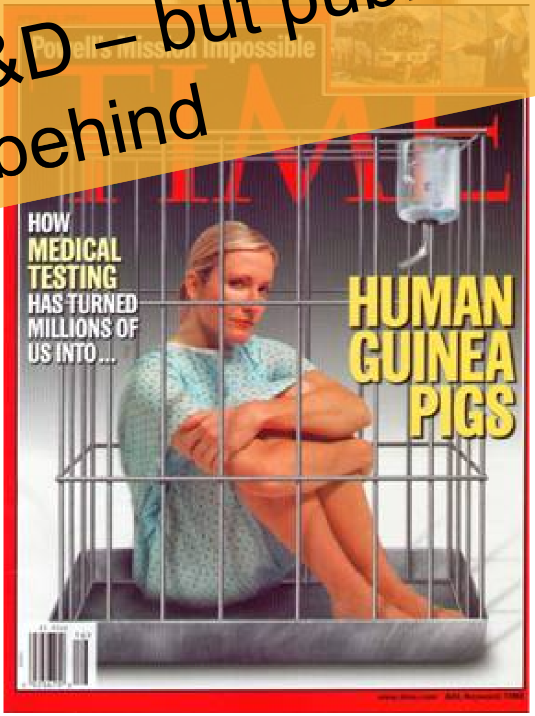
Europe has a lot of safeguards in medicines R&D – but public image lagging behind


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.



# Patient advocates working with regulators…

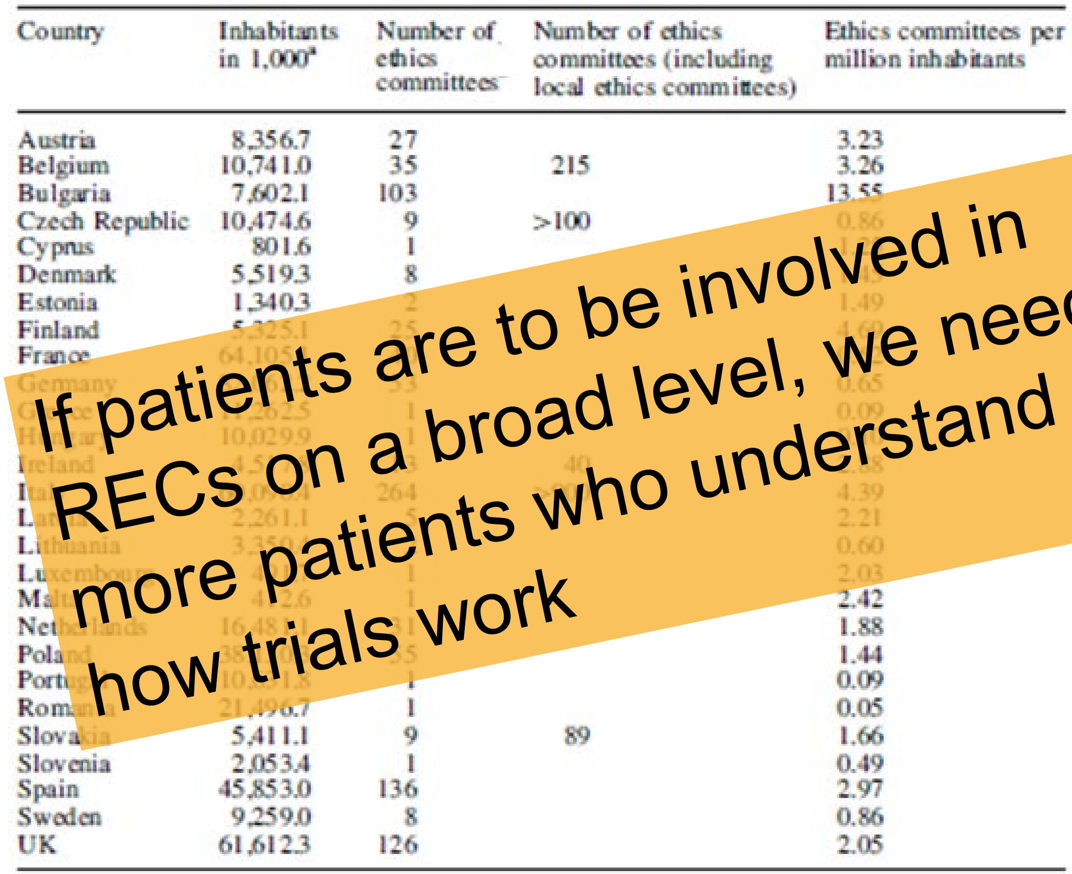
EMA track record since 2005…

- Patients‘ and Consumers‘ Working Party (PCWP, 34 POs)
- Full members of MA Management Board, COMP (rare diseases), PDCO (pediatric), CAT (advanced therapies)
- Assessment of EPARs, Package leaflets, safety information
- Ad-hoc support in CHMP: Product assessment, guidelines, Pharmacovigilance WG, protocol assistance
- Speakers and participants at EMA conferences/workshops .....

- AND AT THE NATIONAL LEVEL
  ... Patient involvement ‚by accident‘

Patient organisations need more qualified advocates to engage with regulators

# Having a patient (advocate) in every Research Ethics Committee…



| Country | Inhabitants in 1,000ᵃ | Number of ethics committees | Number of ethics committees (including local ethics committees) | Ethics committees per million inhabitants |
|---|---|---|---|---|
| Austria | 8,356.7 | 27 | | 3.23 |
| Belgium | 10,741.0 | 35 | 215 | 3.26 |
| Bulgaria | 7,602.1 | 103 | | 13.55 |
| Czech Republic | 10,474.6 | 9 | >100 | 0.86 |
| Cyprus | 801.6 | 1 | | [illegible] |
| Denmark | 5,519.3 | 8 | | [illegible] |
| Estonia | 1,340.3 | 2 | | 1.49 |
| Finland | 5,325.1 | 25 | | 4.69 |
| France | 64,105.[illegible] | [illegible] | | [illegible] |
| Germany | [illegible] | 53 | | 0.65 |
| Greece | 11,262.5 | 1 | | 0.09 |
| Hungary | 10,029.9 | 1 | | [illegible] |
| Ireland | [illegible] | [illegible] | 40 | 2.88 |
| Italy | [illegible] | 264 | [illegible] | 4.39 |
| Latvia | 2,261.1 | 5 | | 2.21 |
| Lithuania | [illegible] | [illegible] | | 0.60 |
| Luxembourg | [illegible] | 1 | | 2.03 |
| Malta | 412.6 | 1 | | 2.42 |
| Netherlands | 16,481.1 | 31 | | 1.88 |
| Poland | [illegible] | 55 | | 1.44 |
| Portugal | [illegible] | 1 | | 0.09 |
| Romania | 21,496.7 | 1 | | 0.05 |
| Slovakia | 5,411.1 | 9 | 89 | 1.66 |
| Slovenia | 2,053.4 | 1 | | 0.49 |
| Spain | 45,853.0 | 136 | | 2.97 |
| Sweden | 9,259.0 | 8 | | 0.86 |
| UK | 61,612.3 | 126 | | 2.05 |

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

Sources: Impact on Clinical Research of European Legislation (ICREL), Final Report, Feb. 2009, and Rokus de Zeeuw 2010

- 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‘s voice in pharmaceutical policy at both European and national level

– needs qualified patients

# EPF survey on HTA agencies, decision makers and patients

- Patient involvement in HTA has the most impact in putting forward patients' needs in terms of QoL and providing a real-life context to the use of health technologies; this is acknowledged by all
- To facilitate patient involvement, HTA agencies and decision-makers provide access to
    - HTA reports/guides/protocols,
    - easy-to-read HTA summaries
    - – but no training support for patients

Patient organisations need more capacity to engage on HTA

**Patients want a seat at the table.
Currently, there are many empty seats.**

**This is why we have
established the
European Patients‘ Academy (EUPATI).**

# PATIENT'S LEADING THE DISCUSSION

Eibhlín Mulroe, MBA
CEO, IPPOSI

# IPPOSI Strategy 2012-2014

**Our Mission**

We expedite development of and patient access to innovative therapies through a unique partnership of Patient Groups, Industry and Science

**To deliver on our Vision**

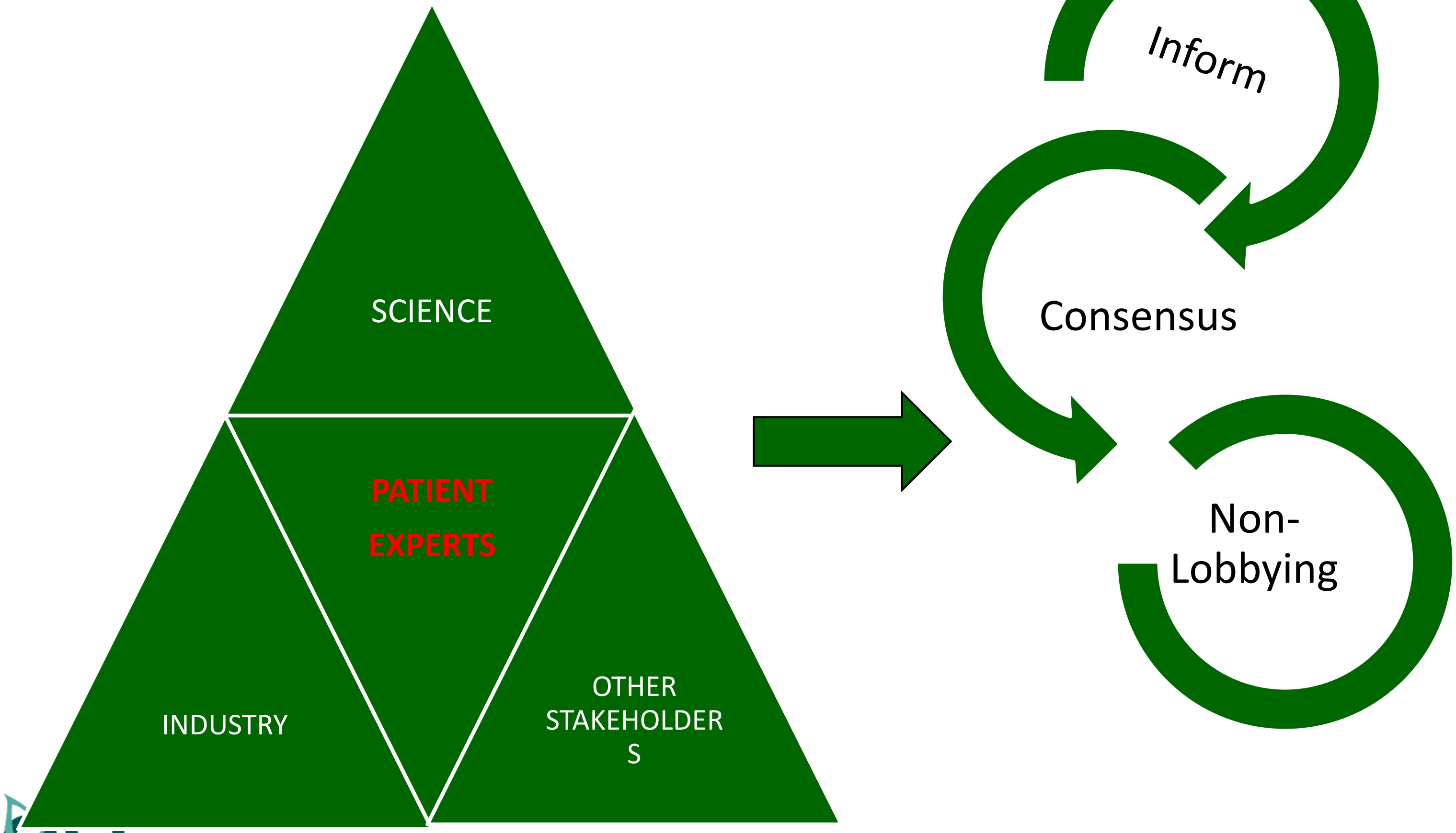
## Our Strategic Priorities

- Bring a patient perspective to clinical research in Ireland
- **Actively influence policy that impacts on research and access to innovative therapies**
- Increase understanding of the work done by IPPOSI
- Source funding to ensure IPPOSI's sustainability

**Vision**

Patients in Ireland have prompt access to new and developing innovative therapies

# Leadership


SCIENCE
PATIENT EXPERTS
INDUSTRY
OTHER STAKEHOLDER S
Inform
Consensus
Non-Lobbying

# IPPOSI Funding

- **Membership subscriptions**
- **The Health Research Board**

HRB
Health Research Board

IPPOSI
patients
science
industry

# REPORT INTO THE GENERAL PUBLIC’S ATTITUDES TOWARDS CLINICAL RESEARCH

Prepared for IPPOSI
by
Drury Research
November 2009

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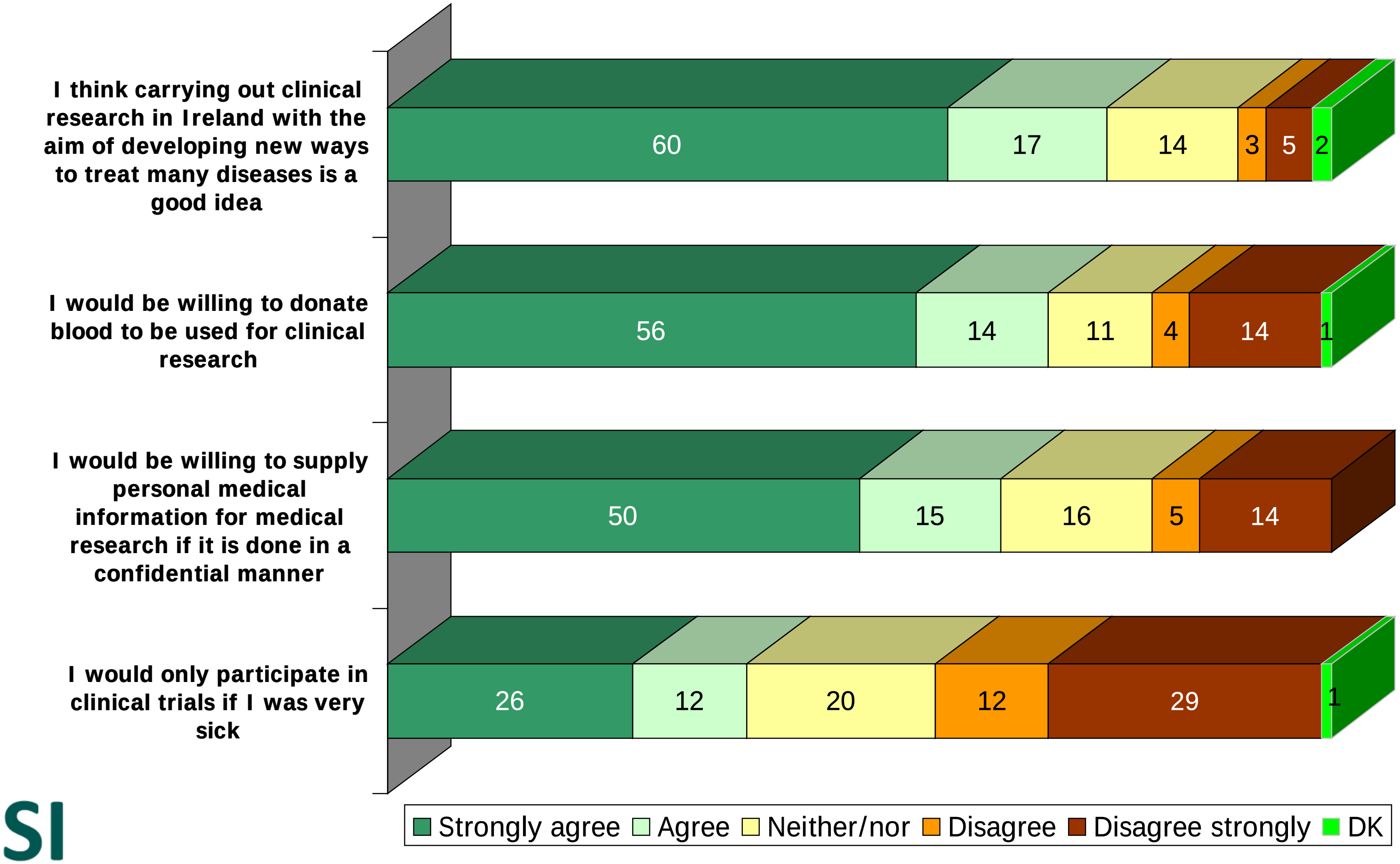
patients
science
industry

# Agree v Disagree with Attitudinal Statements RANKING 1 - 5



***{Base: n=1000, All adults}***

# Public and Patients want information ipposi.ie

Access to Innovation

Round Table

Wednesday 6th June, 2012
at 3pm

Venue:
EU Parliament Office,
Molesworth Street,
Dublin 2

IPPOSI
Irish Platform for Patients' Organisations, Science and Industry

Patients' Organisation
the Code of Marketin
for the Pharmaceutic

An IPPOSI Information Day for Patients' Organisations, Sc

Wednesday 24th October, 2012
at 10am (Registration 9.30am)

Venue:
Boston College,
42 St Stephen's Green,
Dublin 2.

IPPOSI patients science industry

Health Technology As
the Theory and Practi

An IPPOSI Information Day for Patients'
Scientists and Industry members

Thursday 11th October, 2012
at 10am (Registration 9.30am)

Venue:
EU Parliament Office,
Molesworth Street,
Dublin 2.

IPPOSI patients science industry

Clinical Research for
Non-Clinical Researc

An IPPOSI Information Day for Patients' Organisations, S

Tuesday 28th August, 2012
at 10am (Registration 9.30am)

Venue:
EU Parliament Office,
Molesworth Street,
Dublin 2

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IPPOSI
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IPPOSI
Access to Innovation Round Table

Acc
Innov

at the European Parli

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So you've been asked to take part in a clinical trial?

"EPF has been a guiding light to work of IPPOSI in the context of new EU legislation and Initiatives eg Transparency Directive, Clinical Trials Regulation, Patient Involvement in HTA, Patient Compliance and Adherence, the Cross Border Directive etc.. Thank you!" Eibhlin Mulroe, 23rd May 2013

IPPOSI
patients
science
industry

# IPPOSI and the European Patients' Academy on Therapeutic Innovation

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

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.

# Key stakeholders of the Patients' Academy

Academia

Patient Advocacy Orgs (national/ int'l)

Industry & CROs

Ethics Com-mittees

Research networks, & projects

Regulatory authorities

Policy makers (EU & Member States)

Health-related NGOs

Journa-lists (medical, lay press)

# Audiences: advocacy leaders and the public at large

## EUPATI Certificate Training Programme

- Academic Modular Certificate Programme
- Patient Ambassadors in committees, R&D teams, …
- Patient Journalists raising awareness
- Patient Trainers for patient communities & networks

**100 patient advocates**

## EUPATI Educational Toolbox

- Educational tools for patient advocates
- Variety of distributable formats: Paper-based booklets, presentations, eLearning, webinars, videos etc.

**12.000 patient advocates**

## EUPATI Internet Library

- Patients & lay public at large, e.g. on specific aspects of the development process of medicines for patients with low (health) literacy.
- Wiki, YouTube, films and/or cartoons

**100.000 individuals**

# Patients' Academy: up, running and real. Workshop, 5 Sept 2012 and National Liaisons Workshop in March 2013

- ~100 participants from 24 countries
- Majority patient advocates
- 14 countries building national platforms

# EUPATI: A paradigm shift in empowering patients on medicines R&D

- Launched Feb ’12, runs for 5 years,
  30 consortium members,
- **PATIENT LED**
  PPP of EU Commission and EFPIA
- will **develop and disseminate objective, credible, correct knowledge about medicines R&D**
- will **build competencies & expert capacity** among patients & public
- will **facilitate patient involvement in R&D** to support industry, academia, authorities and ethics committees

Nicola Bedlington

# EUPATI by 2017:
# Where we want to be.

- EUPATI platform complete with training courses, education, information material in multiple languages
- Good practice guidelines on patient involvement available and in use
- Public conferences and regional workshops will lead to an extensive expert network established.
- 12 National Platforms established in 12 countries
- Robust strategy on sustainability and political buy-in

# EUPATI can make the difference. creating the tipping point for patient engagement in medicines R&D

# It‘s for all of us to make it happen.

# 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
INFARMA
janssen
Lilly
MERCK

NOVARTIS
novo nordisk®
Roche
sanofi
ucb

Welcome to the European Patients' Academy on Therapeutic Innovation!

First public meeting of EUPATI held during DIA EuroMeeting on 27 March 2012

Veröffentlichungsdatum / Geschrieben von Jan Geissler

EUPATI
European Patients Academy on Therapeutic Innovation

**Web:**
www.patientsacademy.eu

**Twitter:** @eupatients
as well as: