PATIENT INVOLVEMENT IN CLINICAL RESEARCH

Eibhlín Mulroe, MBA
CEO, IPPOSI
Our Mission
We expedite development of and patient access to innovative therapies through a unique partnership of Patient Groups, Industry and Science

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

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
Leadership

SCIENCE

PATIENT EXPERTS

INDUSTRY

OTHER STAKEHOLDERS

Consensus
Inform
Non-Lobbying
REPORT INTO THE GENERAL PUBLIC’S ATTITUDES TOWARDS CLINICAL RESEARCH

Prepared for IPPOSI
by
Drury Research
November 2009
Agree v Disagree with Attitudinal Statements  RANKING 1 - 5

I think carrying out clinical research in Ireland with the aim of developing new ways to treat many diseases is a good idea
- Strongly agree: 60
- Agree: 17
- Neither/nor: 14
- Disagree: 3
- Disagree strongly: 5
- DK: 2

I would be willing to donate blood to be used for clinical research
- Strongly agree: 56
- Agree: 14
- Neither/nor: 11
- Disagree: 4
- Disagree strongly: 14
- DK: 1

I would be willing to supply personal medical information for medical research if it is done in a confidential manner
- Strongly agree: 50
- Agree: 15
- Neither/nor: 16
- Disagree: 5
- Disagree strongly: 14

I would only participate in clinical trials if I was very sick
- Strongly agree: 26
- Agree: 12
- Neither/nor: 20
- Disagree: 12
- Disagree strongly: 29

(Base: n=1000, All adults)
Conclusion

Public Information Campaign to address the following:

- Limited understanding of how one can participate in clinical research (ie donating blood/tissue, medical information)
- Ethical concerns
- Unnecessary Risk
Expanding our clinical trials information campaign

**NCRC**
Developing written content based on EGAN & Patient Partner’s material and NCRC knowledge

**IPPOSI**
Providing editorial assistance from a regulatory perspective and are developing a communications campaign

The project will produce age appropriate Information for children and parents who have been asked to participate in a clinical trial.
- IPPOSI yearly training
- November 2015 (tbc)
- Need more?
IPPOSI members tell us...

IPPOSI and Clinical Research

- Clinical Research Subgroup of IPPOSI Board
- Multi-stakeholder involvement
- A call to action in 2016
- Patient Organisations and Clinical Researchers invited to be involved
- Limited resources need to work together and not reinvent wheel!
So what is EUPATI and why are IPPOSI involved?

The role of the networking of Patient Associations within the EU projects
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
- Healthcare budgets

Window of opportunity

- trial design
- relationship between researchers, regulators, industry, patients
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)
Why do we need EUPATI?

In 2013, EUPATI set out to measure:
- Knowledge and awareness of medicines R&D
- Interest in learning more in medicines R&D
- Preferences for information formats and providers

7000 people were surveyed across 6 European countries [Spain, France, UK, Germany, Poland and Italy]
### EUPATI RESEARCH into public views of medicines R&D across Europe identified:

- **Low knowledge of R&D**
- **Poor participation in research**
- **Support for more information from patient organisations, academia and medical professionals**

### PUBLIC VIEWS ON MEDICINES DEVELOPMENT

Exploring attitudes, beliefs, knowledge and interest ACROSS EUROPE.

In 2013, we asked 7,000 adults aged 18 years and over in select European countries about their attitudes towards, beliefs about and interest in learning more about the medicines development process as part of the groundwork for EUPATI.

### RESEARCH PARTICIPATION

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>8%</td>
<td>8%</td>
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</tbody>
</table>

### CURRENT KNOWLEDGE

#### HIGHEST

1. Medicines safety **25%**
2. Drug discovery **22%**
3. Clinical trials **22%**

#### LOWEST

1. Patients’ roles and medicines regulation **18%**
2. Medicines R & D **16%**
3. Pharmacoeconomics **15%**

### INTERESTED IN LEARNING MORE

1. Medicines safety **50%**
2. Personalised medicine **47%**
3. Predictive medicine **47%**

### LESS INTERESTED IN LEARNING MORE

1. Pharmacoeconomics **33%**
2. Medicines regulation **36%**
3. Clinical trials and patients’ roles **39%**

### INFORMATION SOURCES

#### TOP THREE

- **59%**
- **59%**
- **52%**

#### BOTTOM THREE

- **15%**
- **20%**
- **21%**

### FAVOURED INFORMATION PROVIDERS

- Doctor or other medical practitioner **70%**
- University / academic institution **41%**
- Patients’ organisation **40%**

### LESS FAVOURED

- Family member, friend or colleague **23%**
- Journalist or news organisation **20%**
- Public-private partnership **15%**

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The Noun Project (thenounproject.com). Creative Commons—Attribution (CC BY 3.0).
EUPATI Audiences: advocacy leaders and the public at large

EUPATI Certificate Training Programme
- Academic Modular Certificate Programme
- Patient Ambassadors & Patient Journalists raising awareness
- Patient Trainers for patient communities & networks

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

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 patient advocates
12,000 patient advocates
100,000 individuals
Content development timelines

**Phase 1:**
October 2014

EUPATI Certificate Training Programme
- e-learning [150+hours]
- classroom style face to face teaching
- Two 4-day sessions Barcelona: April & Sept 2015

**Phase 2:**
October 2015

EUPATI Educational Toolbox
- repository: video, webcast, pdf, presentation, ebook, print ready material (booklets, pamphlets), audio

**Available:**
2015

EUPATI Internet Library
- WebPages
- Streamed media illustrations

**Available:**
2016
Welcome to the EUPATI moodle site

<table>
<thead>
<tr>
<th>Course Overview</th>
<th>Discovery of Medicines and Planning of Medicines Development</th>
<th>Non-Clinical Testing and Pharmaceutical Development</th>
<th>Exploratory and Confirmatory Clinical Development</th>
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</thead>
<tbody>
<tr>
<td>Face-to-Face Information</td>
<td>Clinical Trials</td>
<td>Regulatory Affairs, Medicinal Product Safety, Pharmacovigilance</td>
<td>HTA Principles and Practice</td>
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</tbody>
</table>

First course: started Oct 2014
Second course: starting Sept 2015
Glossary
Multilingual encyclopedia
Multimedia
Read or save content offline
Multilingual downloads and toolbox resources
Responsive library content for mobile devices

Coming soon: 2016
Areas covered by the Patients’ Academy

1. Medicines development process from research to approval

2. Personalized and predictive medicine

3. Drug safety and risk/benefit assessment of medicines

4. Pharmaco-economics, health economics and health technology assessment

5. Design and objectives of clinical trials (& roles of stakeholders)

6. Patients roles & responsibilities in medicines development

...and NOT: develop indication- or therapy-specific information!
EUPATI at the National Level – 12 countries

EUPATI NATIONAL LIAISON TEAMS are temporary task forces of three members: 1) patients 2) academia 3) industry

Teams establish EUPATI NATIONAL PLATFORMS

- ensure EUPATI understands and responds to the educational needs at a national level
- disseminate EUPATI educational and training material to increase the number of patient advocates
- raise general public interest and media interest in EUPATI
- support national initiatives to encourage greater patient involvement in medicines research and development
# EUPATI NLTs and ENPs

<table>
<thead>
<tr>
<th>Country</th>
<th>Status</th>
<th>Major meetings</th>
<th>Country</th>
<th>Status</th>
<th>Major meetings</th>
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<td>Germany</td>
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<td>17 July 2013</td>
<td>Spain</td>
<td>🔴</td>
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<td>Ireland</td>
<td>🔴</td>
<td>30 April 2014 16 Sept 2014</td>
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<td>🔴</td>
<td>19 Feb 2013</td>
<td>Italy</td>
<td>🔴</td>
<td>19 Feb 2013 14 Oct 2014 10 April 2015</td>
</tr>
</tbody>
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*Red: no NLT available*

*Yellow: NLT established, 1st meetings took place, 1st work in common has started*

*Green: NLT well advanced in preparing the establishment of the ENP*
EUPATI Network

** Access to EUPATI Network area

** Copies of EUPATI Newsletters

** Invites to EUPATI Network webinars

** Invites to EUPATI Workshops

Register to join the EUPATI Network at www.patientsacademy.eu
EUPATI LinkedIn Group

EUPATI Facebook Posts

EUPATI Twitter Tweets
Get to know us!

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.

www.patientsacademy.eu
1128 Network members
1200 Newsletter subscribers
1227 Twitter followers @eupatients / #EUPATI
680 Facebook friends
404 LinkedIn members
On our doorstep!

EUPATI 2015 Workshop
Registration opens next week!
Dublin Castle, April 22-23rd
IPPOSI BOARD and Minister 2015

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