



Meaningful Patient Involvement in EU-funded Health Research projects

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THE EUROPEAN PATIENTS' FORUM





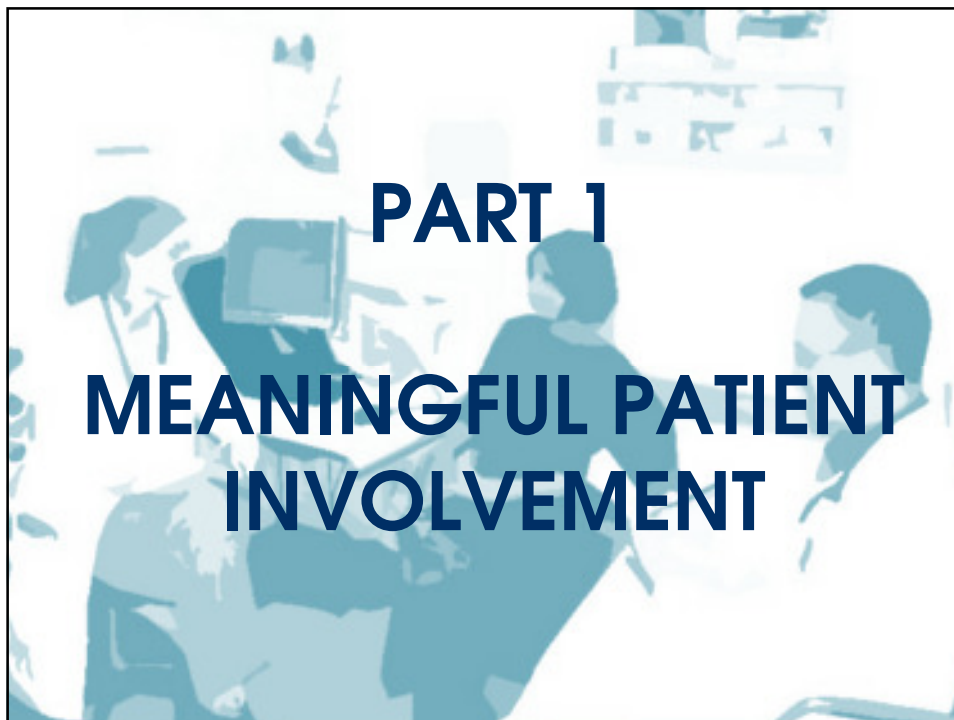
European Patient Forum (EPF)

- Umbrella body of **50** pan-European disease specific patient organisations *and* national coalitions of patient organisations
- **150 million** EU patients with chronic conditions
- **Vision:** high quality, patient-centred equitable healthcare across the EU
- **Areas of work include:**
 - Patient Safety & Quality of Care
 - Information to Patients - Health Literacy (incl. eHealth literacy)
 - Cross-Border Healthcare and Patients' Mobility
 - eHealth
 - Health Research
 - Health Technology Assessment (HTA)
 - Pharmaceutical Package



EPF Role in FP7 Health

- **Cooperation** with **DG RESEARCH** and **National Contact Points** to strengthen patient meaningful involvement – incl. direct involvement in 2010 - 11 EU and National FP7 Health Infodays
- **EU-level workshops** for National Contact Points on involving patients
- **Capacity-building activities** and continuous support for patient organisations
- **Support to project leaders** and **coordinators** in implementing patient involvement straight from the onset
- **Identifying good practice of patient involvement in health research** and share it with stakeholders
- **Monitoring patient involvement** in FP7 Health projects



PART 1

MEANINGFUL PATIENT INVOLVEMENT



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Meaningful Patient Involvement



« Promoting Patients' Involvement in EU supported health-related Projects (2008-2009 EU PHP) »

MPI means that patients take an active role in activities or decisions that will have consequences for the patient community, because of their specific knowledge and relevant experience as patients



- The involvement must be planned, appropriately resourced, carried out, and evaluated, according to the values and purposes of:
 - the participating patients or patient organisations
 - other participating organisations and funding bodies



Why Patient Involvement?

Patients are experts because of their knowledge and relevant experience as patients

Patients are active partners in the research process rather than the subjects of research



MUTUALLY ACCEPTABLE SOLUTIONS TO HEALTH RESEARCH PROBLEMS



Meaningful Patient Involvement in Health Research

Patient meaningful involvement in health research aims to:

- Ensure that the way **research** is designed, undertaken, evaluated and disseminated **reflects the needs and views of the patients**
- **Integrate researchers'** theory expertise with **patients' real-world knowledge** and experiences of the condition
- Ensure that research doesn't just measure outcomes considered important by professionals
- Strengthen **trust and acceptance** of research results
- Promotion of research results by patient organisations because of sense of ownership of the process (**enhanced visibility**)



Produce results that can be used to effectively improve practice in health care for the benefit of the patients

PART 2

UNDERSTANDING THE REALITY OF PATIENT ORGANISATIONS

Characteristics and issues to consider for their meaningful involvement in research



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Patient organisations and patients

Views of a group or individual views?

Understanding the term "representative":

Someone who is chosen to represent other	Someone who is typical of a particular group of people
Puts forward views of a group	Put forwards his/her own experience
Represents a constituency	May not know how other patients are affected
Has behind the structure of a patient organisation	Has no structural support behind
	Personal circumstances

Patient representative & Patient



EMA Definition of Patient Organisation

Patients' organisations are defined as not-for profit organisations which are patient focused, and whereby patients and/or informal carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies

These could be:

- either general umbrella organisations (e.g. representing either European specific disease organisations and/or national umbrella organisations)
- or European disease specific organisations (i.e. representing national organisations or individual patients on acute and/or chronic diseases).



Issues around involvement of patient organisations

- **Representativeness**

- **Mandate** - Mission & Objectives:

It impacts on what the organisation can contribute to

- **Governance:**

It impacts on: Decision-making – Functioning - Representativeness

- **Human Resources** - Staff/volunteers:

It impacts on: Scope and sustainability of contribution of the patient organisation

- **Resources** - Capacity/finances/assets:

It impacts on: Capacity to perform and compliance to projects' eligibility criteria and administrative requirements



PART 3

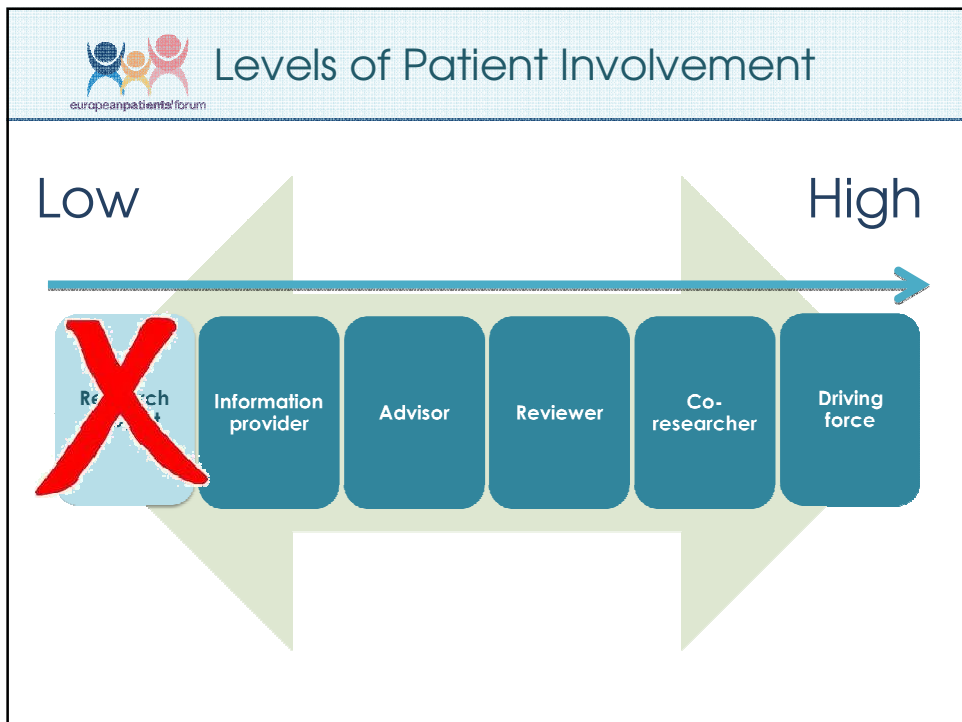
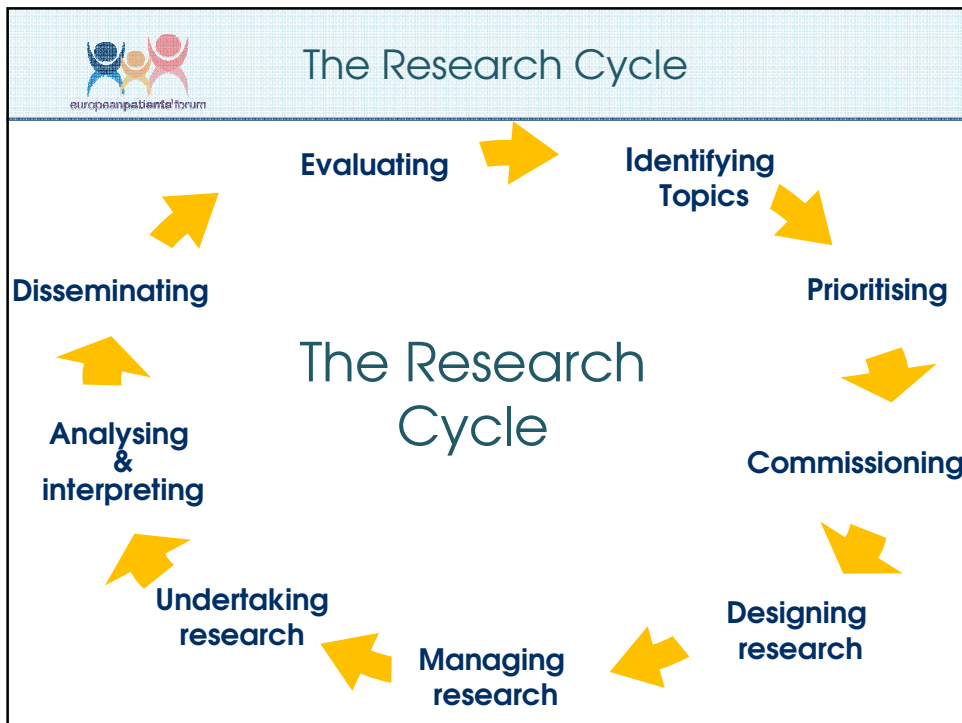
LEVEL AND BENEFIT OF INVOLVING PATIENT ORGANISATIONS IN FP7 HEALTH

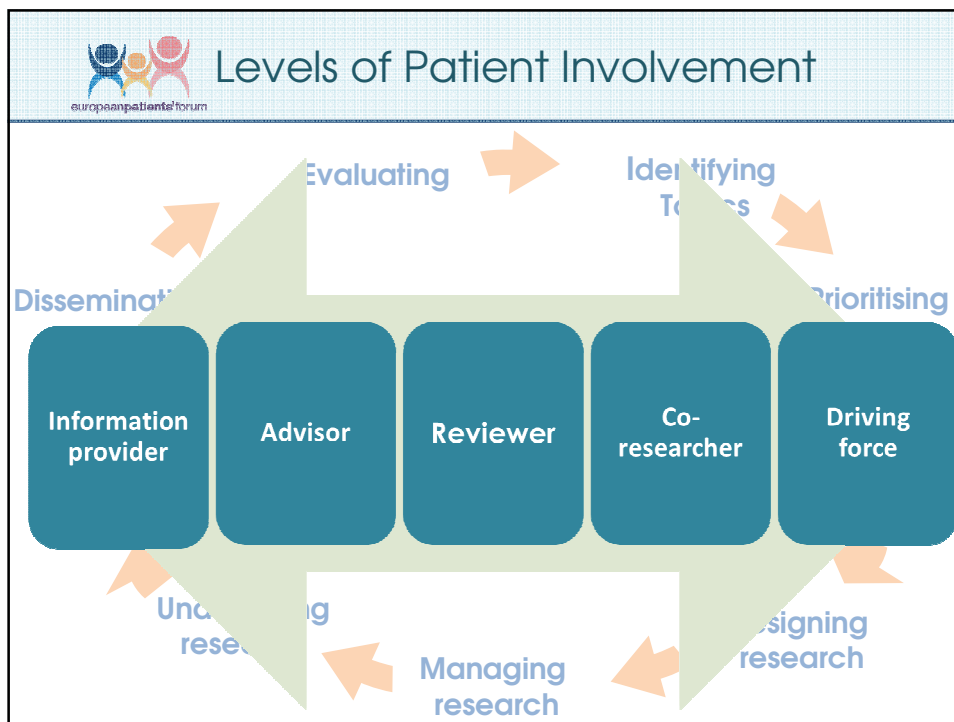


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Research suitable for patient involvement

- Fundamental research
- Qualitative research e.g. quality of life studies
- Clinical research





Levels of Patient Involvement

Which level of involvement is best?

No single answer

Different types of involvement will be appropriate for different research projects depending on:

- the topic of research
- the methodology used
- the patient group concerned
- The skills required
- the requirements of the funding body
- The stage of research (design, implementation, evaluation, etc.)



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Meaningful Patient Involvement

Involvement can occur during any or all of the processes involved in R&D including

- **Planning and designing the research**



Helps you...

- better understand user requirements, needs, expectations and constraints, i.e. eHealth and telehealth
- better understand ethical implications of research
- have a clear understanding of how to manage patient involvement throughout the research projects

.....ultimately

- **enhance your chances to get your research project funded**



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Meaningful Patient Involvement

Involvement can occur during any or all of the processes involved in R&D including

- **Planning and designing the research**
- **Managing the research**



Helps you...

- ensure that user needs, requirements and expectations are effectively integrated throughout the research projects
- ensure that patients have a ownership of the research project
- better manage the involvement of patients in the various project activities



Meaningful Patient Involvement

Involvement can occur during any or all of the processes involved in R&D including

- Planning and designing the research
- Managing the research
- **Undertaking the research**



Helps you...

- Design and fine tune the research instruments (e.g. questionnaires, surveys, various stages of clinical trials)
- Enhance patient participation and motivation
- Benefit from patients' own expertise



Meaningful Patient Involvement

Involvement can occur during any or all of the processes involved in R&D including

- Planning and designing the research
- Managing the research
- Undertaking the research
- **Interpreting results of research**



Helps you...

- Obtain feedback and comments that aid analysis and interpretation
- Understand which areas of the findings are of most interest to them and which they would like to be explored further or featured in the research reports
- Identify options for further actions/research



Meaningful Patient Involvement

Involvement can occur during any or all of the processes involved in R&D including

- Planning and designing the research
- Managing the research
- Undertaking the research
- Interpreting results of research
- **Disseminating research results**



Helps you...

- Effectively reach out to patients through patient-friendly, understandable dissemination tools and language
- Raise the research in different fora outside the researchers community which researchers do not have usually access to
- Give your research project more visibility and enhance its sustainability

PART 4

PATIENT INVOLVEMENT IN FP 7 HEALTH:

STATE OF THE ART and RESOURCES

SEVENTH FRAMEWORK
PROGRAMME



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Assessed patient involvement in EU health projects

Approx. 100 EU-funded health related projects for the period 1998-2008

FP6 and FP7 some key findings:

- **Different understanding of patient involvement**

- **Patient involvement** was generally clearly weaker in research projects than in other projects, especially those focused on **clinical trials, studies or development of technologies and devices**

- Limited patient involvement at the inception and planning stage, and in the governance structures of projects

- **Limited resources** devoted to patient involvement

- Researchers and project coordinators are interested in promoting more effective patient involvement in health research projects but is **difficult to translate this in practice**



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Patient Involvement in WP 2011



SEVENTH FRAMEWORK PROGRAMME

FP7 Health 2011 (last year's Call)



Inclusion of the Meaningful Patient Involvement criterion (in clinical trials)

In the 2011 two-stage call there were (DG RESEARCH data):

- **17 patient organisations** (including 1 coordinating) in 17 rejected proposals while all of those were eligible
- and **27 patient organisations** (incl one coordinating) in 27 successful proposals in the second stage call.



Resources: Value+ Core Publications

Series of Tools:

- to enable patients to become more involved in EU funded projects including research projects (**Value+ Toolkit**) also in German: <http://www.eu-patient.eu/Documents/Projects/Valueplus/German%20Version%20of%20the%20Value+%20Toolkit.pdf>
- for **project promoters** and **coordinator** to acquire more skills to enable them to facilitate in practice (**Value+ Handbook**)
- a series of **Policy Recommendations** looking at linking research project outcomes with patient – centred policy development
- a **database of patient organisations** in all EU Member States: <http://www.eu-patient.org/pos/login.php>



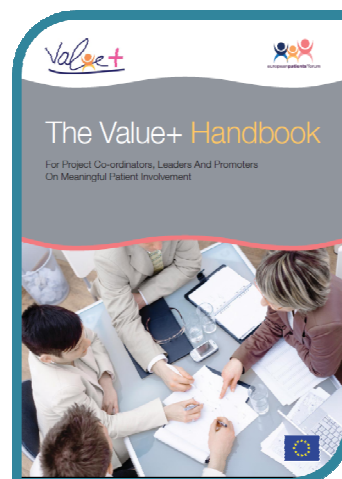
Resources: Value+ Handbook

Purpose

- Two-fold purpose: raising awareness and providing and disseminating know-how

Content

- Value+ Model of Meaningful Patient Involvement
- Involvement at each project stage
- Knowing patients and patient organisations for working with them



Get yourself a copy at:

<http://www.eu-patient.eu/Documents/Projects/Value+%20Handbook.pdf>



Good Practice example

Dutch Asthma Foundation

- Funding body and patient organisation in 1
- Involved lay patients with asthma through asthma patient organisation in agenda setting for the research agenda of the asthma foundation
- Facilitates patient involvement in research with training etc for patients who take part as advisors etc in research
- Involving patients perspectives in agenda setting appeared to be of added value in identifying and exemplifying specific details in research areas in chronic lung diseases, that were previously not the research focus in the Netherlands.



Other Resources

- www.invo.org.uk (Involve)
- www.peopleinresearch.org
- www.patientpartner-europe.eu



Take-Home Message

Paradigm shift

RESEARCH **WITH** THE PATIENT

Patients as equal partners in research



Increase your chances of having your project financed

Thank You



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Annual General
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