



# The Value of Patient Involvement in EU Health Related Projects and Policy

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**In order to achieve meaningful patient involvement, it is critical to pursue it on both a European Union and national level.**

**For effective involvement it is crucial to establish partnerships on equal terms between patient organisations, health professionals, carers' association, industry, insurers and health managers and authorities.**



## ACKNOWLEDGEMENTS

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We thank the Swedish Presidency and in particular Minister Göran Hägglund for their support and participation.

We are grateful to Agrenska for providing support to logistics organisation.

# Introductory Remarks

Dear readers,

We are pleased to present to you our report on the Value+ final conference, which took place in Gothenburg, Sweden in December 2009 under the patronage of the Swedish Presidency. The final event of the two-year Value+ project gathered 100 health stakeholders: patient leaders, policy-makers, Member States' and EU institutions' representatives, and health professionals. The conference aimed to enhance political commitment on patient involvement at both policy and project level.

In all areas of healthcare today patient involvement is key to developing sustainable policy that really meets the needs of patients – and therefore putting patients at the heart of EU healthcare policy is essential. Empowerment and involvement of patients and patient organisations at both the European and national level can help build and improve on existing healthcare systems. However, a gap exists between the recognition of the 'expert' patient as an essential constituent to the effectiveness of healthcare policy and health projects to how patients are involved in practice.

Value+ was designed around this idea. When patients and patient organisations are involved in health-related projects in a meaningful way, the results can contribute more effectively to patient-centred, equitable healthcare.

During the conference, we unveiled the outcomes of the project which included three key deliverables to support patient involvement. The Value+ Toolkit will be helpful for patients and patient organisations in becoming involved as equal partners in European projects and political processes. The Toolkit has been translated into Bulgarian, French, German, Lithuanian, and Spanish to ensure that a wide group of European patient organisations will have access to this information. The Value+ Handbook provides specific information to project coordinators, leaders and promoters on how to involve patient organisations and work effectively with them. Finally, the Value+ Policy Recommendations will provide the EU institutions effective strategies on involvement in EU programme and projects.

The overall principles of patient involvement were addressed by speakers representing different perspectives. Projects of excellence identified by Value+ shared their experiences and provided concrete examples of how they successfully integrated patient involvement in their work.

There was a general consensus that in order to achieve meaningful patient involvement, it is crucial to pursue it on both an EU and national level and that information and education are essential to engaging patients. Conference participants shared many ideas and reflections on how to move forward in practical terms on meaningful patient involvement, transforming it from concept to reality.

Although there is still some way to go to achieve meaningful patient involvement in EU health-related projects and policies, it is possible through breaking down existing barriers and continuing to build capacity. We hope that this report will provide you with an overview of the points discussed and that the conclusions will inspire future action.

Yours sincerely,  
Anders Olauson  
EPF President

# Conference Conclusions

- In order to achieve meaningful patient involvement, it is critical to pursue it on both a European Union and national level.
- For effective involvement it is crucial to establish partnerships on equal terms between patient organisations, health professionals, carers' association, industry, insurers and health managers and authorities.
- Information and education are essential for properly engaging patients in health policy debates.
- Healthcare systems need to be built with the involvement of patients, both at national and European level.
- The higher incidence of chronic diseases expected in the years to come needs to be tackled in cooperation with patient organisations.
- There are numerous barriers which make that meaningful involvement of patients in various contexts is still to be achieved.
- It is necessary to find different models of patient involvement and communication.
- Patient involvement in European health projects has proven essential for achieving good results.
- Patients' involvement in research as researchers benefit both the patient and the researchers' communities. It leads to research outcomes that are more relevant to patients' needs and are more reliable.



# Summary of Presentations

## PLENARY SESSIONS: CONFERENCE OPENING AND SETTING THE SCENE

### WELCOME

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By Mr. Anders Olauson, President of the European Patients' Forum (EPF)

- EPF's vision is patient-centred, equitable high quality healthcare for all patients across the European Union (EU). To achieve that vision, Meaningful Patient Involvement in health projects, programmes and policy is absolutely essential.
- The Swedish EU Presidency will be remembered for two important reasons:
  1. Commitment to transparency
  2. Commitment to stakeholder involvement and particularly to patient involvement.
- During recent years the inclusion of the patients' voice and views has become a core requirement in health policy developments. Collaboration between health stakeholders, social and healthcare professionals, insurers and industry confirms this statement.
- However, there is still a gap between the recognition of patients' experience and expertise as crucial to the quality and sustainability of healthcare policy and how that is done in practice in a transparent and democratic way. This knowledge and skills gap is present among three main constituencies: policy makers, health projects' promoters and coordinators and patient organisations themselves. Value+ is about filling this gap and providing the necessary tools to do this effectively.
- Patient organisations in addition to defending patients' rights need to live up to patients' responsibilities as active citizens – to do this effectively they need the tools and support from society.

### 'REFLECTIONS ON PATIENT INVOLVEMENT IN SWEDEN AND UNDER THE SWEDISH EU PRESIDENCY'

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Göran Hägglund, Minister of Health and Social Affairs, Sweden

#### SUMMARY OF PRESENTATION

There are several measures needed to ensure patients are at the centre of healthcare policy-making:

#### **Shortening healthcare queues and waiting times for treatment**

Treatment should be accessible to all citizens. Sweden is proposing legislation to strengthen the position of patients by means of a national healthcare guarantee to reduce waiting times by 60-70%.

#### **Increase in healthcare is to increase healthcare providers**

The New Act on Free Choice System provides a framework for municipalities and county councils to cooperate with private companies and NGOs to compete with public care providers. Patients can choose between public and private providers. Patients' choice will be crucial for healthcare providers; they can decide what good quality is. This will enhance patient involvement in healthcare and social services.

#### **Increase patient safety**

In the near future a proposal will be made to the Swedish Parliament to put in place a complaint system for patients in case of injuries. There is a need to encourage stakeholders in the health sector to present and not hide problems and to learn how to deal with them. This system should empower patients to share their view and will show patients' contribution in improving the healthcare process.

## Summary of Presentations

### eHealth

Sweden has a new Patient Data Act to increase the use of eHealth. eHealth enables patients to access information on their diagnosis and treatment, thus increasing patient involvement. It allows health professionals to exchange information of patient details. Hence, eHealth is an important strategic measure to improve the healthcare system. From the Council conclusions on eHealth and the epSOS project, Sweden and other Member States will move forward with more collaboration at governance level through a Joint Action.

### Importance of Cross-Border Healthcare

eHealth is not only an instrument to improve patients' health; it is also a tool to facilitate crossborder healthcare. Although no agreement was reached during the Swedish presidency, the Directive on Patients' Rights in Cross-Border Healthcare must remain a priority and the Swedish government will continue working towards adopting the directive. Cross border healthcare will act as a catalyst for quality and safety development at national level.

**Information and education are essential for properly engaging patients in health policy debates.**



**Healthcare systems need to be built with the involvement of patients, both at national and European level.**

### 'A VISION FROM POLAND'

**Adam Fronczak, Undersecretary of State,  
Ministry of Health of Poland**

### SUMMARY OF PRESENTATION

#### Patient involvement

Poland realised that a modern healthcare system cannot be built without its patients. A framework needs to be defined to provide collaboration both at the national level in each EU Member States and at the EU level. Patients have expectations and they all want high quality access to healthcare. However, there are economic, organisational and political conditions which lay outside the scope of our influence. Therefore the dialogue with patients and engaging them in the process of defining goals and aspirations in health policy becomes even more important.

#### The importance of information and education

Engaging patients in shaping the health policy of the EU requires the provision of information. In the age of information society, it should be easy to access information. However, due to their disease patients often are not in the position to be proactive in searching for information. Therefore particular efforts should be done for a meaningful involvement.

At the healthcare delivery level, priority should be given to education for healthcare professionals to provide them with the necessary knowledge to interact on equal terms with patients such as providing them with appropriate information. New educational models are being developed around the world to meet the educational needs of health professionals. Developing such a model is not only beneficial to the patient but to the healthcare system as a whole.

#### Patient involvement and disease prevention

Engaging patients in EU health policy means also enabling patient organisations to be involved in prevention healthcare, both primary and secondary. Member States together should consider the implementation of common actions aimed at lowering the incidence rates of chronic diseases.

The participation of patients in this discussion is very much needed and welcomed. The engagement of patients and organisations representing them in the development of processes and structures they use is indispensable in order to make these more effective and patient friendly.

## **‘WHY PATIENT INVOLVEMENT IS CRUCIAL – THE LESSONS AND OUTCOMES OF VALUE+’**

Nicola Bedlington, Director European Patients’ Forum

### **SUMMARY OF PRESENTATION**

#### **Purpose of Value+**

The aim of this project was the collection of information on good practices among stakeholders on meaningful involvement of patients in EU supported health projects. There were four things that the project wanted to accomplish: 1) assess the degree of patient involvement, 2) encourage involvement in ongoing projects, 3) develop tools and 4) reaffirm political commitment to patient involvement. The project started with a literature review looking at over 650 research articles and reports, the second part consisted of a survey addressed to approximately 100 EC co-financed health projects. Furthermore, focus groups and workshops played a big role. Finally, interviews were conducted to determine what the critical success factors in patient involvement were to make sure to include that in the project.

#### **Status of patient involvement**

The project assessed approximately 100 EU funded health projects and received feedback from 30%. The majority of these declared that there was some form of patient involvement but in most there was low involvement in the project development phase and in coordinating bodies and leadership roles. Half of them had specific resources allocated for patient organisations or patients; this was the case mostly when patient organisations were associate project partners. Gender and diversity issues related to patient involvement were not properly addressed.

#### **Benefits of Patient Involvement**

Because patients know their own medical condition and problems they can best provide solutions that can be more effective and lead to better project results and better policy-making decisions. Patient involvement legitimises results and good practices and can make them more widely available. Communication is more patient friendly and accessible.

#### **Barriers**

There is a lack of legislation on patient involvement in contexts that are not clinical or medical and linked to the treatment of individual patients; as much as there is poor political culture and tradition in involving patients’ communities in health policy and decision making. Meaningful patient involvement requires access to resources: financial, human, know-how. Language and communication also constitute important barriers in relation to technical and bureaucratic jargon and to the fact that the working language at EU level is English. Administrative barriers, lack of mechanism for planning, attitudes and perceptions also play a big role.

#### **Factors supporting patient involvement**

A number of elements are recognised to be supporting meaningful patient involvement: working within a context of equal power relationships; specific resources for involvement; evidence-based knowledge and good practices; working in alliance with other patient groups and health stakeholders.

#### **Conclusions**

Although positive work has been going on, patients still struggle in being involved meaningfully in European projects. Patient involvement is not an objective in itself at the moment and it is important that it becomes one and that mechanisms to achieve it are put in place. The tools that Value+ developed can contribute to bridging that gap.

## Summary of Presentations

### PLENARY SESSIONS: DEFINING PATIENT INVOLVEMENT – VOICES FROM EUROPEAN AND NATIONAL PROJECTS

#### THE TREAT NMD PROJECT

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Ms. Pauline McCormack, Research Centre  
Newcastle University

#### SUMMARY OF PRESENTATION

The Treat NMD Project is a framework for collaboration in the field of neuromuscular diseases (NMD). It aims to address the fragmentation currently hindering translational research for cutting edge therapies in rare NMD. The aim is to provide a common roadmap for progression of therapies from laboratory to clinic.

##### **Multilevel involvement**

The network consists of 21 partners, four patient organisations, clinicians, researchers and industry. There are different levels of involvement within the network. The partners of the network receive the funding and report to the EU, lead the network, are on the forefront of the research developments (including the patient organisations) and lead on patient communication. As a result after two years more patient organisations wanted to get involved in the network and most of them are now working as collaborators on specific areas.

##### **Challenges**

The network has an overlap with patient organisations' aims and also needs to balance between the different aims that the patient organisations may have. As it is a network, it is also often not clear who takes the initiative in the process and who actually makes the decisions or has the authority to do so. Finally there is the fact that one patient consortium is responsible for informing other patient organisations. This raises the question as to whether this is the best model of providing communication in relation to the above mentioned problems.

##### **Take home message**

The network has to find different models of involvement and communication for different patient organisations – “From each according to their abilities, to each according to their need”.

#### MULTIPLE SCLEROSIS INFORMATION DIVIDEND PROJECT

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Mr. Sverrir Bergmann, University Reykjavik,  
Iceland

#### SUMMARY OF PRESENTATION

This project, launched in 2006 was initiated by the European Multiple Sclerosis Platform and the EU. Its main aim was to create a standardized European Multiple Sclerosis (MS) register for general and informative purposes across Europe and to activate the national implementation of the European Code of Good Practice in MS. The participants of the projects were from Germany, the UK, Iceland, Poland, Romania, and Spain. The pilot study results will soon be published.

##### **Project components**

One dimension of MS ID was the development of a medical and a socioeconomic register that explores the feasibility of a European level register on MS. In doing so the project tried to decrease the inequalities of treatments across Member States concerning MS. It also provided a basis for cost benefit studies. The medical register was completed by the neurologist after an interview with the patient. The socioeconomic register was filled in by the patients themselves. Having this additional register was very important to identify patients' perspective on aspects like life adjustments, understanding of information received and quality of life.



### **The involvement of the patients**

The interaction between neurologists and patients while working on the registers improved the knowledge of the patients regarding their disease. Vice-versa it provided the neurologists with the patients' view and more reliable information. Moreover and very importantly it gave patients more control on their own situation and improved the patient-doctor relationship.

### **PROJECT 'GOOD PRACTICES FOR COMBATING SOCIAL EXCLUSION OF PEOPLE WITH MENTAL HEALTH PROBLEMS' – INCLUSION OF HARDLY-TO-EMPLOY PEOPLE IN THE LABOUR MARKET**

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Ms. Andreja Štepec, Slovenian Association for Mental Health (ŠENT)

#### **SUMMARY OF PRESENTATION**

The Slovenian project presented was a follow-up of the European project led by Mental Health Europe whose objectives were to collect good practices for combating social exclusion of people with mental health problems, to assess the transferability of these practices and to organise exchange visits between stakeholders, policy-makers and partner organisations. In the context of Slovenia, the project aimed to offer an employment possibility to 10 persons with mental health problems.

#### **Key activities and outcomes**

The main activities implemented were exchange of information between employers and users, consultation for employers, a shared website of employers and unemployed persons with a mental health problem, and a specific work centre at ŠENT. The working centre provided tools to enhance good practice (pilot project) and 10 people were employed within the project phase. The project thus ensured a larger employment percentage, and increased the cooperation between employers, persons with a mental health problem and patient organisations.

The involvement of patients was the central theme of the project; they advised and provided information to employers and patients, coordinated the website, and got employed at the final phase of the project.

#### **Take home message**

A project is successful only when participants from the target group (users) are involved equally in all project activities from the start until the end.

### **FORSKNINGSPARTNER PROJECT**

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Ms. Caroline Akerheim, the Swedish Rheumatism Association

#### **SUMMARY OF PRESENTATION**

The project focuses on patient involvement in research. It is a cooperation between the Swedish Rheumatism Association, the Swedish Heart and Lung Association, the Swedish Asthma and Allergy Association and the Swedish Psoriasis Association. These associations have in common that they all fund research (projects).

#### **Aims and objectives of the project**

The main objectives are: to promote and increase patient involvement in medical research, to train the associations' members to become research partners and to give the board members of the associations increased knowledge of the need for medical research and patient involvement.

The aims are developed to benefit both the organisations and the researchers as patient involvement in research leads to research that is more relevant to people's needs and concerns, more reliable and more used.

## Summary of Presentations

### Involvement of patient research partners

The patient research partners can contribute in clinical research by identifying and suggesting areas for future studies. However they can also provide assistance in the ethical issues (risk/benefit) concerning the design of a study and review study protocols. Furthermore they can provide guidance in recruiting patients and interpreting (unexpected) results. An expected spin-off of this project would be that the patient research partners may become excellent ambassadors and contribute to an increase in money raising for research. Currently 37 patient research partners are involved and 25 of them are working in different research projects. A manual for involving patients within the research projects has been developed.

### Learning points

The project gave new insights into the involvement of patients and patient organisations into research. The main lesson learned is that training is very important in order to create good patient research partners. Furthermore the time between the training and the actual start date of a research project should be very short. Also the research can be slow and take a long time; this could be a strain on the patient research partners. It is therefore important to discuss clearly the terms of the research before starting it.

## PLENARY SESSIONS: INNOVATION IN PATIENT INVOLVEMENT IN EU POLICY-MAKING THE DIALOGUE BETWEEN PATIENTS AND HEALTH STAKEHOLDERS FOR A EUROPE FOR PATIENTS

### EHEALTH

#### INNOVATION IN PATIENT INVOLVEMENT IN EU POLICY-MAKING CONCERNING EHEALTH

Mr. Haris Neofytou, Thalassaemia International Federation

#### SUMMARY OF PRESENTATION

eHealth encapsulates information and communication technologies applications and services for healthcare. As a field it is situated at the crossroads of multitude socio-economic objectives set out by the EU (Lisbon Treaty) and the i2010 Initiative. It is also an important part of the renewed Social Agenda and of the Programme of Community Action in the field of health.

### The eHealth landscape

From a patient perspective there is an access to a vast volume of health information. There is also an increase usage of the Internet and novel technologies to assess health risks, manage a chronic condition and learn more about the symptoms and self-treatment. Furthermore the patient can consult his/her healthcare provider from home and can have the option to receive support or medical assistance while travelling or living abroad.

### Policy developments

eHealth has a clear European dimension that makes the health system more patient-oriented. Nevertheless eHealth benefits are more evident at the level of Member States. Although the aim of the Member States is the same, namely to provide increased quality of care in an efficient way, the national strategies towards eHealth differ significantly between the Member States. The EU has supported various Member States initiatives to coordinate this in a more efficient manner. What is important from a patient perspective is that the need to build confidence and trust in eHealth systems is finally being addressed.

### **Beyond today**

eHealth is increasingly becoming an integral element of national healthcare systems and patients are demanding more efficient systems to manage their health. There is a huge potential in eHealth regarding options to create holistic and personalised healthcare and to create a patient-centred approach to chronic disease management. It also provides possibilities to create a more professional means of communication between healthcare providers and the patient, provide mobility of healthcare and improvement of the quality of care.

### **Effective patient involvement**

Patient organisations, with the help of all stakeholders, need to further empower and activate patients through the promotion of education on eHealth literacy skills. Furthermore they should actively get involved in EU, national and industrial developed projects regarding eHealth. Finally patients' organisations need to build transparent and valuable relations with industry to promote the needs and demands of patients.

### **Take home message**

Patients need to be involved in a formal way in European and national health-related projects and policies.

Mr. Michael Wilks, CPME, e-Health Users Stakeholders Group

## **SUMMARY OF PRESENTATION**

### **Key eHealth policy areas**

The five policy areas regarding eHealth that are the most interesting from a patient perspective are: the electronic record, cross-border healthcare, information to patients, the workforce green paper, and data protection and consent.

### **Electronic health record**

The traditional doctor and patient relationship is still important today, however the relationship is shifting as more healthcare providers (nurses, dentist, pharmacist, physio-therapist, etc) are playing more and more an important part in the healthcare provision.

The focus is thus shifting to maintaining a relationship between a team of healthcare providers and the patient. In coordinating these different healthcare providers the electronic record is a useful instrument.

On **cross-border healthcare** eHealth plays a huge role as the different healthcare providers from different countries need to be able to communicate with each other and also need to develop standard quality of health.

With regards to **information to patients**, eHealth needs to provide a good framework for patients to be able to control the information, and also to select the information that is relevant and reliable for them. The selection and interpretation of the vast amount of information on health is an important aspect that needs to be covered by eHealth.

In **data protection and consent** in eHealth there needs to be a shift in focus. The legal contract of data protection is focused upon the situations after an event took place, in which we can punish the person that breached the contract. This discourages cooperation, therefore the shift should be made towards a more consensual model where the situation precedes the event and is based on trust rather than penalties.

### **eHealth governance**

It is an initiative that encourages constructive cooperation between Member States on eHealth deployment and aims also to improve governance and coordination of ongoing activities. It will address several eHealth aspects including standards, identification, legal and ethical issues, trust and acceptance. This initiative will represent an important platform to enable decision makers to build on results of operational projects. It is vital that user stakeholders, health professionals and patients themselves are involved in any future eHealth governance model.

## Summary of Presentations

### CROSS-BORDER HEALTHCARE

Mr. Anders Olauson, European Patients' Forum

#### SUMMARY OF PRESENTATION

##### **Directive on patients' rights in cross-border healthcare**

EPF has been involved in the process related to the Directive from the beginning, responding to the Commission's Consultation in 2007 and providing the patients' perspective on the debates that followed this consultation. The proposal recognised the new rights for EU citizens and patients to get healthcare abroad, and to be reimbursed by the Member State of affiliation up until the level of costs of the healthcare that the patient would have received at home.

EPF has called for more cooperation between Member States on this Directive, to share information, good practices and research outcomes. Furthermore EPF has urged for upholding quality and safety standards, and for the involvement of patient organisations within the provision of information regarding cross-border healthcare. EPF finally has demanded that no up-front payments by patients should be allowed.

##### **State of the art**

The European Parliament approved a good report in April 2009, during the First Reading in the European Parliament in which many elements of EPF's input were incorporated. Good progress was made during the Czech and Swedish EU Presidencies. However on the 1st of December 2009 the Health Council blocked the Directive as five member states voted against it. EPF will continue to engage with the upcoming Spanish and Belgium EU Presidencies, the new Health Commissioner and the European Parliament on this. The dilemmas that the Member States have regarding the financing of their healthcare systems in relation to the cross-border healthcare directive have to be acknowledged. However, EPF urges Member States to overcome this as it is unacceptable that patients cannot access to important – and sometimes life-saving – medical treatments in other EU countries.

Ms. Liene Sulce, Latvia's Patients' Ombud Office  
Latvia's Patients' Ombud Office

#### SUMMARY OF PRESENTATION

This organisation was founded in 2008, with the support of the Ministry of Health of the Republic of Latvia and the largest hospital in Latvia, the Riga Eastern Hospital. The patient's Ombud office is an independent NGO that acts as a mediator and counsellor in patients' rights and legislation in healthcare systems. It provides an effective complaint handling management to address the problems and concerns of patients and to provide comprehensive feedback to medical staff and management of healthcare organisations. The main goal is to create a high level of quality communication and cooperation between all the actors in the healthcare sector.

##### **Cross-border healthcare**

There is a serious lack of knowledge on cross-border healthcare at the level of the Member State. There is especially confusion about the terms by which a patient can receive healthcare in another country. Many healthcare providers consult the Ombud Office on what they need to specifically observe or manage when dealing with a foreign patient. In response to this situation, the office provides information to patients and healthcare services, organise seminars about the main principles of cross-border healthcare, and provide information to the media about the possibilities represented by the cross-border healthcare directive.

##### **The role of patient organisations**

Patient organisations need to have regular communication with national governments, institutions, and EU institutions to present their input and patients' perspective and experiences. Especially because the patient organisations can provide the real case stories that will indicate which decisions and systems work and which do not. They will therefore provide the most realistic and practical advice.

### Take home message

Health needs to be the base of all other issues both on a national and European level. The differences regarding the quality of healthcare between the Member States must decrease, it is very important that the EU plays a crucial role in this. Finally, patient organisations are not only the best instrument to provide information to policy-makers and stakeholders, but also to inform patients and citizens about opportunities offered by cross-border healthcare.

## RESEARCH

Mr. Stephane Hogan, DG Research, European Commission

### SUMMARY OF PRESENTATION

#### The Framework Programme 7 funded research

The main policy drivers for the collaborative research in the area of health are: improving the health of EU citizens, increasing the competitiveness of health-related industries and businesses, and addressing global health issues. The research actions incorporate different countries through a multinational consortium, including researchers from other countries than the EU member states and different types of organisations – public and private sector, academic sector, industry, patient organisations, etc. Funding can support basic and applied research, including discovery activities, translational research and early clinical trials.

#### Patient involvement in the programmes

Examples of projects that put the patient at the centre are PatientPartner, which focuses on the involvement of patients and patient organisations in clinical trials (<http://patientpartner-europe.eu/>). Another project is RESPECT that is relating expectations and needs around the participation and empowerment of children in clinical trials (<http://www.patient-needs.eu/>). The third project is the CHD Platform project that is an establishment of a European parent and patient-oriented information and communication platform on congenital heart defects.

Two other projects that are important to patients are EPOC and O3K that work on off-patent medicines to the needs of paediatric populations. Since clinical trial research has been set as a priority, future calls for projects will focus specifically on this subject. Patients and patient organisations are very much inclined to participate as DG Research increasingly wants to involve patients in a systematic way into research.

### PARTNERPATIENT PROJECT

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Mr. Cor Oosterwijk

### SUMMARY OF PRESENTATION

#### Patient involvement in clinical trials

Patient observations and demands improve research and the outcomes of the clinical trials. Researchers of clinical trials therefore need to take into account the observations made by patients and listen to their specific needs.

#### The challenges of a clinical trial

Clinical trials face several challenges: the cost and administrative burden in order to start and structure the clinical trials; patients' recruitment especially regarding minority disease populations and children; the risk/benefit assessment still has several unresolved issues; ethical and regulatory issues; and finally the public perception and awareness of clinical trials.

#### The PatientPartner project

This project focuses on the perspective of the patient during the clinical trial and tries to answer two main questions: a) how can patients be better mobilised and empowered in the clinical trial landscape? b) which clinical outcomes really matter to patients and how can these be integrated in the clinical trials process? In relation to these questions, the project identifies the needs and demands of patients, keeps a constant dialogue with other stakeholders and develops strategies and recommendations.



## Summary of Presentations

### Added value of patient involvement in clinical trials

Before the clinical trial starts, the patient can contribute in the identification of indicators, give a patient perspective on ethical and risk/benefit dilemmas, and define patient oriented outcome measures. During the clinical trial, patients can provide a better overview on managing the expectations, improve data quality and participate in creating patients' and public confidence in clinical research. The role of the patients after the clinical trial finishes is important as they provide a better insight to the quality of life aspect, increase compliance and overall benefits cost effectiveness.

### Recommendations

The recommendations provided by the PatientPartner project would be to stimulate and facilitate contacts between clinical research and patient organisations.

Also information and education to patients and citizens is needed in order to avoid inequalities. It is also crucial to improve the involvement of patient representatives at governance level: in the setting of research priorities, protocol development and ethical reviews. And lastly involve media to address the negative current public perceptions.

### Take home message

Patient partnership is not only an issue of emancipation, but is also a medical, scientific, ethical and economic necessity. Start with those areas where all stakeholders are convinced of the added value and explore further possibilities for partnership.

## PLENARY SESSION: VALUE+ DELIVERABLES – HOW THEY CAN BE USED

### INTRODUCTION TO VALUE+ DELIVERABLES

Ms. Liuska Sanna, EPF – Ms. Elizabeth Winder, ENUSP – Ms. Diane Whitehouse, Empirica

### SUMMARY OF PRESENTATION

#### The Value+ Toolkit

The Toolkit was developed to support patient organisations and patients in becoming involved in a meaningful way in EU co-funded health projects. It is meant to spread good practice, explaining why certain issues are important to patient organisations and patients. Furthermore, it provides a definition and a model for meaningful patient involvement.

The toolkit addresses the following areas:

- **Meaningful Patient Involvement:** includes the Value+ research findings on the barriers and challenges to patient involvement and good practice in patient involvement, including the Value+ Model.
- **Your Own Organisation and Meaningful Patient Involvement:** provides basic information which may help patient organisations prepare themselves for taking on an EC-funded project.
- **European Projects:** gives information about the European Commission, and what to consider when putting together a proposal for an EC-funded project.
- **Working in Partnership:** provides guidance on how to find prospective project partners, and how to build working partnerships with them.
- **Resources:** contains tools and examples from Value+ and other sources, examples of good practice, a list of websites, the Value+ Literature Review, a list of patient organisations that operate at European and national level, information on patient rights specific to individual countries, and national contacts for the European Commission.

### The Value+ Handbook

The purpose of the Handbook is to maximize the benefits of involving patients and patient organisation. It targets project coordinators, project leaders and project promoters. The motivation for writing the Handbook came from the Value+ analysis which showed that patients/patient representatives and project coordinators can have very different backgrounds and perspectives. Successful patient involvement in projects require a sound understanding of mutual experiences and motivations and the Handbook is an acknowledgement of the need to bring together potentially divergent expectations from different sets of stakeholders.

In terms of content, the Handbook looks at:

- Why is patient involvement important?
- What is meaningful patient involvement?
- Co-ordinating projects to involve patients meaningfully
- Working with patients and patient organisations
- Resources that include the Value+ Model, examples of good practice, reading materials, and information on patient organisations, diseases and patient rights.

### The Value+ Policy Recommendations

The Recommendations call for action to ensure that meaningful patient involvement is integrated in health policy-making and programmes. They are targeted at the European Commission, European Parliament, Member States and health stakeholders.

They were formulated through findings from the Value+ survey, focus groups and workshops; comments from EPF members and from some health stakeholders.

The Recommendations focus on three main areas:

- **The right to involvement** highlights the need for an EU policy instrument on patient involvement, Guidelines, a Code of good practice, Monitoring & Evaluation systems.
- **Resources** tackle the need to increase access to EU and Member State funding.
- **Capacity building** calls for the setting up of a European Centre of Excellence, Patient Involvement units and capacity building programmes.



**The higher incidence of chronic diseases expected in the years to come needs to be tackled in cooperation with patient organisations.**

**There are numerous barriers which make that meaningful involvement of patients in various contexts is still to be achieved.**

# Summary of Workshop Sessions

## VALUE+ MODEL OF MEANINGFUL PATIENT INVOLVEMENT: HOW TO USE IT AND ADAPT IT FOR DIFFERENT STAKEHOLDERS' PURPOSES

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Moderator: Ms. Elizabeth Winder, ENUSP  
Rapporteur: Mr. Jan Van Emelen, AIM

### PROJECT PLANNING

- Patient organisations should be involved before the project priorities are established and the timing and planning of this intervention is important.
- Understanding the drivers and expectations of each stakeholder in the project is crucial. The project outcomes and goals should be clear to all including the patient organisations.
- It is important that information is available for and on patient organisations for those seeking project partners.

### INFORMATION AND COMMUNICATION

- For meaningful involvement it is very important that key information is translated in languages and/or lay terms so that patient organisations and patients understand fully what they are signing up to.
- Financial support for information and communication is absolutely needed and this should be established at the budget planning phase.

### PROJECT END

- Patients and patient organisation involved on an ad hoc basis and not directly involved in project consortia need to receive feedback on what the project achieved.
- There should be monitoring of patient involvement as it is quite difficult.
- There is a gap between project results and the delivery of these so as to impact the patient community. Although researchers stop at the end of the project, the patient continues to stay a patient.

## GOOD PRACTICES IN PATIENT INVOLVEMENT – HOW TO REPLICATE THEM

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Moderator: Ms. Victoria Thomas, NICE  
Rapporteur: Mr. Rainald Von Gizycki, Retina Europe

- It is important to address issues related to status and hierarchy between the patient and the clinician/ researcher/policy maker. The power balance needs to be redressed to arrive to a true power sharing.
- Capacity building on patient involvement is certainly an issue. This capacity could be built through patient organisations' pooling and sharing resources – it could be the role of the Centre of Excellence on Patient Involvement that EPF recommends establishing.
- The decrease of available clinical workforce is a clear challenge for the healthcare sector. There is a role for patient organisations and patients there to fill the gap in providing information outside clinical consultations. We would therefore move towards a scenario with 'expert patients'.
- Decision-making and patients – often patients are at the table but they are not part of the decision-making or they do not sign up for the decisions made at the end of the day.
- Contribution of patients to evidence – patients' experiential evidence adds to the context of research. Patients can set the research agenda and also contribute to protocols and to informed consent forms and process.
- Are patients really represented properly? There is a tendency to pull the 'usual suspects' without really putting much thought into the matching of the skills of the patient representative with the project or activity that is being pursued. Patient representatives need to be trained to voice the interest of the patient community they represent.

## CHALLENGES IN PATIENT INVOLVEMENT FROM THE PERSPECTIVE OF HEALTH STAKEHOLDERS

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Moderator: Mr. Stanimir Hasurdjiev, Hepasist  
Rapporteur: Erick Savoye, EMHF

### GOVERNMENT, EC, INDUSTRY

- There needs to be trust between these stakeholders and patients. This could be improved by increasing transparency and developing codes of practice.
- Funding remains one of the key challenges. With regard to patient organisations there needs to be a diversity of funding streams.
- There is also a need for addressing perceptions and attitudes towards patients and their role. Still today patients are not viewed as equal partners by other stakeholders.

### PUBLIC HEALTH AUTHORITIES/PUBLIC HEALTH PROFESSIONALS

- Patients are not treated as equals in a dialogue. These stakeholders are sometimes unclear about representativeness of the patient interlocutors because patients come from a wide range of backgrounds such as professionals representing their organisation or individual patients representing themselves.
- The doctor-patient relationship is still unbalanced with a tendency of doctors to talk down to their patients. Training for healthcare professionals on communicating effectively with patients could help redress that imbalance.
- It is a problem for patients who do not belong to a patient organisation to get their voice heard and to receive information.

### PATIENTS AND CITIZENS

- Capacity and time are the main issues for patients who want to be active as patient representatives. Moreover, they need to learn how to translate individual experiences into generic and meaningful patient issues.

- Patients are not a homogeneous group, they need to be recognised as human beings with a wide diversity of backgrounds such as ethnic and socioeconomic differences.
- The European Institutions should adopt a charter of rights on patient involvement – EPF should lobby for this process to take place.

## HOW TO USE VALUE+ POLICY RECOMMENDATIONS IN DIFFERENT CONTEXTS

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Moderator: Mr. Cees Smit, EGAN  
Rapporteur: Ms. Piera Poletti, ESQH

There is broad support to the recommendations by EPF members as well as other stakeholders participating who are keen to discuss them within their constituencies. Possible actions to maximise the potential of the recommendations were suggested:

- Translate the recommendations and other Value+ deliverables into all EU languages
- Ally with various stakeholders to promote the recommendations
- Provide training and capacity building on patient involvement to different stakeholders
- Implement a media campaign – make use of the web and of the EPF's members' networks
- Need to send the recommendations directly to Member State authorities – EPF's members can help with that
- Involve policy makers by using evidence of the impact of patient involvement including benefits related to cost effectiveness
- Centre of Excellence on Patient Involvement – it should be a branch of EPF – Build on already-existing national and regional expertise and examples.

## Summary of Workshop Sessions

### CLOSING SESSION – MAINTAINING THE MOMENTUM AND NEXT STEPS

Mr. Tomasz Szelagowski, Federation of Polish Patients

#### KEY POINTS

The current patient involvement at health policy level is still too low – on one hand patient organisations are not properly acknowledged for their expertise and on the other patient organisations need to strengthen their leadership, management and communication skills to be effective partners.

EPF has carried out a number of activities to draw the political attention on patient involvement – the EPF Manifesto, the project Value+ and work with the membership strive all to making patients' voice heard.



**It is necessary to find different models of patient involvement and communication.**

**Patient involvement in European health projects has proven essential for achieving good results.**

To achieve our goals of meaningful patient involvement, patient empowerment and sustainable patient organisations we need to act both at European and national levels:

- European context: stronger relationship with EU Institutions and better access to EU funds are key facilitators for patient involvement.
- National context: need for more influence of the EU Institutions on member states; the exchange of good practices is essential and joint project with health professionals should be developed.

#### TAKE HOME MESSAGE: BE EMPOWERED TO SET NEW STANDARDS!

EPF President Anders Olauson closed the session with warm thanks to the speakers, moderators, the EPF Secretariat and last but not least to all of the participants. "The patient's view counts but we are not yet there" he said. This conference marks both a starting point and a milestone. There is a need for EPF to develop a strategy with policy-makers and fellow stakeholders to take forward the three core resources from the Value + project and EPF commits to driving this in the coming weeks and months.

EPF will also look into developing a follow-up project to Value+ that builds on its outcomes and addresses some of the key gaps identified during the project.



# About the European Patients' Forum (EPF)

The European Patients' Forum was set up in 2003 to become the collective patients' voice at the European level, manifesting the solidarity, power and unity of the European Union patients' movement. EPF is a not-for-profit, independent organisation and umbrella representative body for patient organisations throughout Europe. We currently represent 44 member organisations that consist of chronic disease specific patient organisations working at the European level and national coalitions of patient organisations. In total, we reflect the voice of an estimated 150 million patients affected by various diseases in the EU.

EPF's vision is to establish patient-centred equitable healthcare through the European Union. Our core values emphasise a patient-centred approach to healthcare, inclusiveness, non-discrimination, patient empowerment, consultation and independency and transparency. We adopt a holistic interpretation of healthcare to include prevention, and the social, economic, environmental, cultural and psychological aspects of health.

EPF acts as a catalyst and consultative partner for positive change in EU healthcare systems and as a "watchdog", closely monitoring EU policy and legislative initiatives. We offer our members EU healthcare intelligence, and baseline patient rights policy responses to enable them to focus on disease specific responses. We support dialogue and negotiation among a broad range of EU level health stakeholders and facilitate the exchange of good practice and challenges of bad practice on patients' rights, equitable access to treatment and care, and health-related quality of life between patient organisations at the European and Member State level.

For more information visit [www.eu-patient.eu](http://www.eu-patient.eu).

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**Patients' involvement in research as researchers benefits both the patient and the researchers' communities. It leads to research outcomes that are more relevant to patients' needs and are more reliable.**

