



# PATIENT INVOLVEMENT IN CLINICAL RESEARCH

A guide for Sponsors and Investigators



Produced by the PatientPartner project  
funded by the 7th Framework Programme  
of the European Commission

# Table of contents

About this guide .....	1	Ethical Principles of Partnership .....	17
Who wrote this guide? .....	1	Mutual Respect .....	17
What is in the guide? .....	1	Trust .....	17
Patient Organisations .....	3	Integrity and Credibility .....	17
Who they are? .....	3	Reliability .....	18
What they do? .....	3	Accountability .....	18
Benefits of Patient Involvement .....	4	Acknowledgement .....	18
Types of Patient Involvement .....	7	Transparency .....	19
Driving Force .....	7	Sustainability .....	19
Co-researcher .....	9	Other Clinical Research topics for the involvement of Patient	
Reviewer .....	9	Organisations .....	20
Advisor .....	9	Paediatric Research .....	20
Information Provider .....	9	Biobanking and Registries .....	20
Research Subject .....	10	Useful websites/resources .....	21
Stages of Patient Involvement .....	12	Acknowledgements .....	25
Pre-Approval .....	13		
Design .....	13		
Recruitment .....	13		
Dissemination .....	14		
How to facilitate patient involvement .....	15		
Things to consider .....	15		
Who to contact .....	15		
How to disseminate information ..	16		

## About this guide

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This guide was written for Investigators and Sponsors of Research wishing to develop meaningful partnerships with patients and Patient Organisations.

### Who wrote this guide?

This guide was produced by PatientPartner, a three year project funded by the 7th Framework programme of the European Commission (project reference number 201720).

There were four partners working on the PatientPartner project: the European Forum for Good Clinical Practice (EFGCP), the European Genetic Alliances Network (EGAN), Genetic Alliance UK and the Dutch Genetic Alliance (VSOP).

The inventory of the existing views, needs, practices and experiences of patients, forms the basis of the PatientPartner project which aims to identify patient needs for partnership in the clinical trials context.

This inventory consists of literature reviews, interviews with Patient Organisations, opinion leaders and other clinical trial stakeholders as well as a European survey on patient involvement in clinical trials to identify good practices.

PatientPartner also conducted a series of European workshops to promote the dialogue between Patient Organisations, pharmaceutical companies and researchers on patient involvement in the clinical trials' context.

### What is in the guide?

This guide aims to provide sponsors and investigators of clinical research with information and tools necessary for meaningful patient involvement.

By outlining how and what Patient Organisations and patient representatives can contribute to the research process, it is hoped that more partnerships will develop.

This guide also aims to provide sponsors and investigators with recommendations and guidelines on how to make partnerships most effective and ensure all parties are respected and satisfied with the outcomes.

The suggestions that are made have been derived from background reading, surveys, interviews and workshops organised and conducted by PatientPartner.

All of the background information used in this guide can be accessed from the PatientPartner website: [www.patientpartner-europe.eu](http://www.patientpartner-europe.eu).

# Patient Organisations

## Who they are?

All stakeholders involved in Clinical Research will be familiar with the term “Patient” however not all are aware of Patient Organisations, what their function is, how they are set up and what they can contribute to research.

Patient Organisations have been created primarily by patients and their families as a result of a commitment to improve healthcare and social circumstances of those living with medical conditions. They can be of various sizes and operate on a local, national and even international level. They are usually run by a board of volunteers elected by the members or can simply be small informal groups with a less formal structure. Major organisations will have a more sophisticated structure and employ staff led by a director.

## What they do?

Patient Organisations serve a variety of functions. Some are purely set up as a source of support for patients and carers whilst others are actively involved in lobbying for research and promoting awareness for their disease or condition area.

The best way to find out an organisation’s activities is to contact them directly or check their website to see if they have a mission statement (i.e. declaration of their purpose) and code of conduct.

The European Patients’ Forum (EPF) has completed a project called Value + which promoted patients’ involvement in EU supported health related projects. This project which yielded several useful resources such as a handbook and toolkit, also produced a database of Patient Organisations in Europe, listed by country, identifying their condition area and providing contact details. This database along with all the resources can be accessed through their website: [www.eu-patient.eu/Initatives-Policy/Projects/EPF-led-EU-Projects/ValuePlus/Resources/Value-Resources/](http://www.eu-patient.eu/Initatives-Policy/Projects/EPF-led-EU-Projects/ValuePlus/Resources/Value-Resources/).

## Benefits of Patient Involvement

Patients and their representatives are able to offer a unique perspective based on their own or collective *experiential knowledge* (i.e. knowledge acquired through dealing with the effects of their condition on a daily basis). In the pre-approval and design stages of research, the input of patients enables the development of more efficient trials that address issues expressed by those living with the condition. It allows for operational issues to be addressed and ensures that issues which might affect recruitment and compliance are thoroughly considered. Considering these in early stages guarantees saving time and money in the long run. Funders are also very keen on ensuring patient involvement meaning that Patient Organisations can play a key role in enabling research to secure appropriate support and funding.

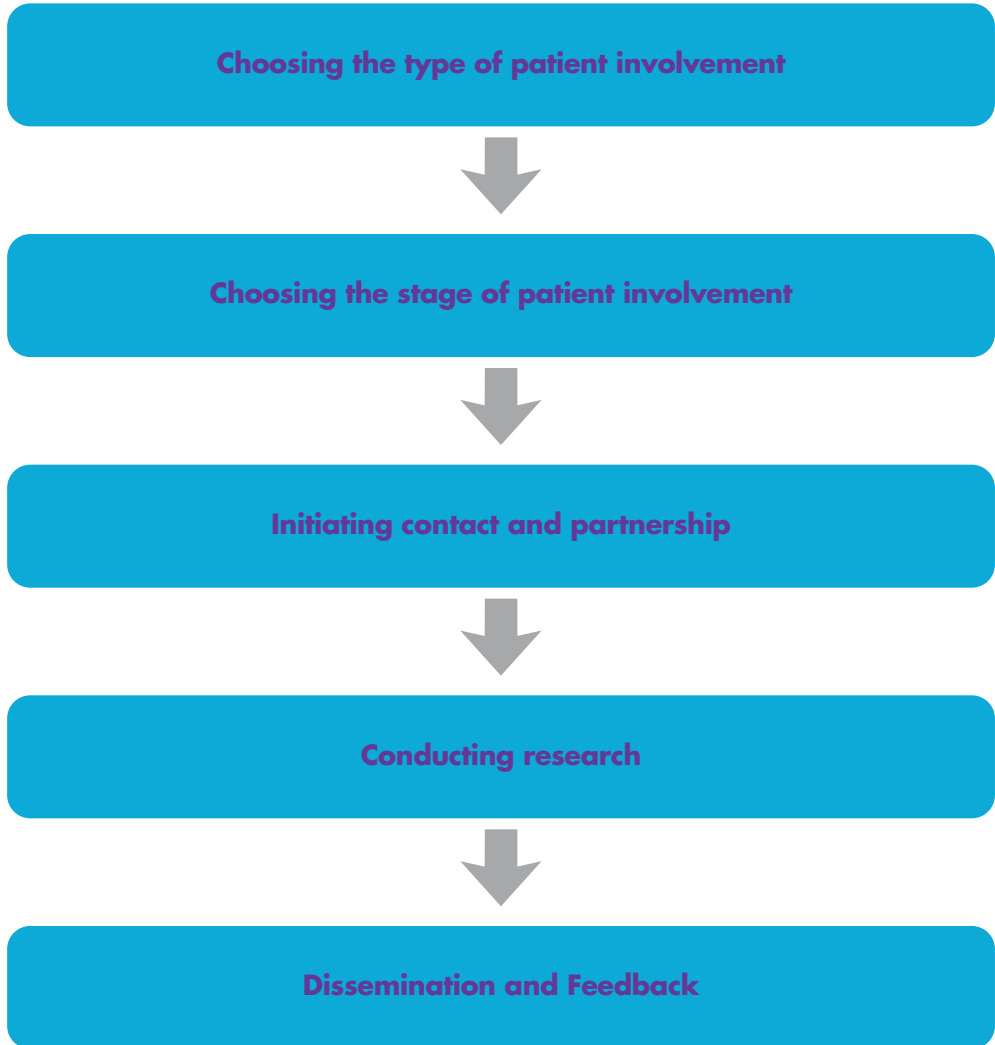
Patients and members of Patient Organisations are often highly motivated to contribute to clinical research. Patient Organisations will usually be able to help with recruitment and dissemination, ensuring that trial results reach a wider audience than just the scientific community.



The AFRT (French association for research on Trisomy 21) is devoted to promoting research in Down's Syndrome (Trisomy 21) and does so by giving grants and fellowships and publishing issues of "Nouvelles du Chromosome 21" (News on Chromosome 21) which provides information on medical, scientific and social events concerning Trisomy 21.

Created in 1990, the AFRT is run solely by parents whose children are affected by Down's Syndrome with only a few of the board members being medical professionals. In the last 12 years, the AFRT have contributed over €370 000 to fund research. Some of their most recent projects include a "*Molecular analysis of cognitive and behavioural deficits in Trisomy 21*" and research into the "*Role of the autonomic nervous system in the onset of fatigue during exercise in young adults with Trisomy 21*".

For 2010-2011, four grants were awarded to Bachelors' and Masters' research projects. A grant was also awarded to fund the realisation of a DVD to accompany research previously supported by the AFRT on speech therapy.



## Types of Patient Involvement

This diagram of patient involvement in clinical trials and research illustrates the different ways in which patients and Patient Organisations can get involved in the clinical trial process and research: As a driving force, a co-researcher, a reviewer, an advisor, an information provider, and as a research subject. Originally the six levels were put on a vertical ladder, but time and research has confirmed that they should not be viewed in a hierarchy but rather horizontally since all roles are of equal importance.



### Driving Force

- (co) Financing a clinical trial
- Raising funds for a particular trial
- Getting a research team together for a clinical trial
- Developing the clinical research protocol
- Lobbying for the development of clinical trials for the condition(s) that you or your organisation represent

Hanna Milczarek from the Dina Radziwillowa Children Heart's Foundation: ([sercedziecka.org.pl](http://sercedziecka.org.pl))

*"The genesis of the co-operation between our Foundation and Prof. Kohl from the University Clinic Giessen-Marburg in Germany was initiated last year, prior to a conference we were organizing in Lodz in Poland. The subject of the conference was the 20th anniversary of the paediatric cardiology and cardiac surgery of the Polish Mother's Hospital Research Institute in Lodz combined with a working session for the parents of the CHD children. I invited Prof. Kohl for a presentation of his unique prenatal surgery methods, especially regarding the hearts of fetuses. Prof. Kohl was so kind to share with me his idea and the very first results of his genuine research regarding the Materno-Fetal Hyperoxygenation Method (MFHO) and I decided to further investigate if we could conduct such a research in Poland according to Prof. Kohl's protocol."*

The project is still in early stages however the foundation is playing an active part in its development as a driving force, establishing strong partnership with academics. They have invited five leading Polish prenatal cardiologists and ultrasound specialists to the project who have committed their participation and assuming the trial will be conducted as planned, are organising a one-day conference on the method and the newest results in Warsaw on the 10th of September 2011. Due to the fact that there are presently no EU funding programs compatible with the trial, the foundation is finalizing the budget of the trial and acquiring financing for it including sponsorship from private companies. The foundation has also taken on the role of facilitating recruitment by informing potential participants and ensuring that pre-selection of eligible patients is done by specialists in health centres. Finally information and results of the trial will be disseminated through the foundations information channels.

## Co-researcher

- Translating research results of the clinical trial into patient friendly information
- (co)Writing a scientific article on the research results of the clinical trial
- Gathering research data
- Gathering information
- Leading a focus group or discussion session for research

## Reviewer

- Review patient information that is to be used in a clinical trial
- Review a scientific paper on a clinical trial
- Review a funding request for a clinical trial
- Review of a clinical trial research protocol

## Advisor

- Giving advice to, or being an advisory member of a clinical research program committee for the development of a clinical trial
- Giving advice to, or being an advisory member of a national or European regulatory authority committee
- Giving advice to, or being an advisory member of an Ethics committee
- Advising on informed consent forms, the procedure for explaining the consent form to patients, or the filling in of the consent form

## Information Provider

- Supplying demographic and/or other characteristic information on the members that are represented by the patient organisation for the use in a clinical trial
- Supplying information to patients on the possibilities of taking part in one of more clinical trial(s)
- Supplying disease specific information for the use in a clinical trial

## Research Subject

- By contributing DNA, cells or other biological material to a biobank or database for the use in a clinical trial
- As a participant in a clinical trial testing the effects of a new treatment or drug

Carol had been wearing dentures since her mid 20's having lost all her teeth during pregnancy. By 2007, her dentist advised her that because of a loss of structure in her mouth, he would be unable to make her new pair of teeth and referred her to her local dental hospital. At her appointment, she was approached and asked if she would be willing to take part in a trial testing new dentures. These new dentures had a higher gum part which made them sit higher up in the mouth and support collapsed gums better. Carol was more than happy to be a research subject and felt enthusiastic about the prospect of a better solution for her condition. Over a period of several weeks, she was asked to wear three different pairs of dentures and complete questionnaires about how comfortable they were. Neither she nor the trial investigator was aware of which of the three dentures was the new type ensuring that the results collected weren't influenced in any way. By the end of the trial, all those that took part were invited back for a meeting in which the results and outcomes of the trial were reported back so that everyone was kept informed. It was at the end of this meeting that Carol was approached and asked to join a clinical trial management team which was reviewing new dental trials. She was asked to review and comment on new research protocols, providing the board with her own specialist knowledge

acquired through years of wearing dentures. Her opinion is greatly valued and she feels included in the process. She has already advised on a trial in which the researchers hadn't considered how long it takes for a person to get used to new dentures and therefore underestimated how long a trial would have to run for in order to get the most accurate results. She also highlighted to the board and those working in research that an issue that needs to be addressed is that of having to remove dentures at night. Carol made a point that for many, having to remove their teeth when going to bed can cause a great deal of embarrassment and insecurity. *"Having had to wear dentures from such a young age, I was very insecure about people noticing my false teeth. If anyone had asked me then whether I was wearing dentures I think I would have died a thousand deaths!"* Carole reminded those involved in research that it is important to consider quality of life when devising new products/treatments.

For more information please see Dr Sue Pavitt's article in the INVOLVE newsletter entitled: *"The impact of PPI on clinical trial design and operations – can we demonstrate value for money?"*.

([www.invo.org.uk/pdfs/Autumn2010d2.pdf](http://www.invo.org.uk/pdfs/Autumn2010d2.pdf))

## Stages of Patient Involvement

There are several stages in which Patient Organisations and patient representatives can be involved. Their input can be vital in ensuring that the research addresses the appropriate issues and may provide suggestions for cost effectiveness.



GlaxoSmithKline

### **GlaxoSmithKline(GSK) and a roundtable of cancer service users**

In July 2010, GlaxoSmithKline facilitated a workshop for 30 cancer service users actively involved in clinical research to brainstorm ways in which to improve the design and recruitment into trials, building a user-led research process in the NHS (the National Health Service in the UK.) This was really successful and everyone who took part was keen to meet again.

Consequently, 10 service users were invited to a roundtable discussion in December 2010 to discuss the role of information and how informed choice for patients about research options could be offered alongside their informed choice about treatment options. A report co-produced by the service users was written and presented to the Under Secretary of State for Health, Earl Howe who invited its authors for a meeting to discuss possible improvements. This successful partnership is a good example of how patients and industry can come together to contribute to policy development and make a difference in how health services are run in their country.

The full report can be accessed on the NCRN (National Cancer Research Network) website ([www.ncrn.org.uk](http://www.ncrn.org.uk)) in the Consumer Liaison Group section, under Patient & Public involvement.

## Pre-Approval

It is useful to have the input of Patient Organisations at the pre-approval stage as they will be able to comment on whether the disease condition they represent would truly benefit from the research going forward. They can comment on the potential size of the recruitment pool and whether there is demand for new/better treatment.

## Design

Patient representatives can comment on operational factors which will help determine whether the timescale is realistic. Carol's case study clearly demonstrates how taking into consideration participant's constraints ensured better recruitment and compliance.

It is also important to consult with patients on any material and information which will be used by them to ensure clarity of language. Participants may be reluctant to take part in a trial if they do not understand the process, how it can benefit them and what their involvement entails.

## Recruitment

Patient Organisations can play a vital role in contacting potential participants. Though they will usually be reluctant to demonstrate endorsement, they will generally be happy to inform all their members of the research. This is particularly important for researchers who wish to get in touch with patients who are not regularly accessing health services. Those that do not need to attend a clinic or hospital on a regular basis are less likely to see information advertising clinical trials taking place.

## Dissemination

Patient Organisations are a great channel for dissemination. They enable researchers and sponsors to publish results to a wider audience than simply the scientific community. What sponsors and investigators must bear in mind though is that Patient Organisations may have certain financial or operational constraints.

# How to facilitate patient involvement

## Things to consider

Before embarking into any type of partnership it is important to consider that partnerships should be founded on certain ethical principles which will ensure due respect to all parties involved. PatientPartner identified eight key principles which are outlined in the following chapter: “Ethical Principles in Partnership”.

It is also important for sponsors and investigators to bear in mind that for patients, research is not part of their job therefore in order for them to be able to participate in trials; the requirements should take into consideration their other obligations.

Lastly, over the course of the workshops and interviews, patients highlighted that there was a lack of follow-up and feedback. It was often the case that once the research had been completed, participants were rarely informed of outcomes or kept apprised of any further developments.

## Who to contact

Patient Organisations are relatively easy to find through a simple search on the internet. Several organisations have already compiled a list of Patient Organisations in Europe and Globally. See the “Useful websites/resources” chapter at the end of the book.

It is important to bear in mind when approaching Patient Organisations that they may not necessarily have any previous experience in partnering with Pharmaceutical companies or Academics however they will usually be happy to take part. Some organisations have specialist contacts who are used to dealing with enquiries from sponsors and investigators however this will not be the case for smaller ones.

## How to disseminate information

When disseminating information regarding research it is important to bear in mind that patients and their families may not have much scientific knowledge therefore clear and simple wording is necessary. Patients and Patient Organisations also have limited resources and this should not prevent them from having access to information therefore it should be freely available and in various formats i.e. online, hard copies.

PatientPartner has also produced a guide aimed at Patient Organisations and patient representatives explaining the clinical trials process and how they can be involved. Therefore it could be worth signposting them to the booklet which can be accessed here: [www.patientpartner-europe.eu](http://www.patientpartner-europe.eu).

# Ethical Principles of Partnership

Through the course of the PatientPartner project, a set of Ethical Principles was devised in order to ensure that the integrity of all parties concerned is upheld. The following eight principles were under consultation at time of printing however they describe the base principles necessary for a successful partnership. The full and final report along with a memorandum of understanding will be accessible on the website:

[www.patientpartner-europe.eu](http://www.patientpartner-europe.eu).

## Mutual Respect

Central to all partnerships between Patient Organisations and other stakeholders in clinical research is that all parties in the partnership act in accordance with the principles of mutual respect. This means that all partners' competence, capabilities, and limitations shall be taken into account and respected. Sponsors and investigators should know, understand and respect the environment and constraints within which patient groups work.

## Trust

Partnership between Patient Organisations, industry, clinicians and all other stakeholders involved must be based on mutual trust. This trust should stem from openness about motives and the confidence that all parties are working towards a common goal, even if the approaches are made from different perspectives.

## Integrity and Credibility

The integrity, credibility and independence of all involved partners, as well as the constraints and obligations under which all stakeholders operate should be respected at all times when negotiating the terms of any partnership.

## Reliability

In order to ensure a fruitful partnership, it is important that terms of agreement are set up at the beginning of the collaboration and that these are adhered to throughout the entire research process. We recommend periodic reviews that will evaluate the progress based on the goals and objectives.

It is also advisable to agree up front how conflicts will be resolved and what are the terms for the readjustment or termination of partnership.

## Accountability

It is preferable to outline in the early stages of the partnership development how each party will be held accountable for its respective input and the outcomes achieved through the collaboration. The ways in which parties will report back to their members, colleagues, partners and general public should be determined at the start.

## Acknowledgement

Agreement as to how each party will be acknowledged for its contribution should be reached before the start of any collaboration. Ownership and intellectual property rights of materials produced in the collaboration should be agreed upon, taking into consideration that Patient Organisations do not necessarily have access to legal advisors and therefore need the terms to be set out in clear and simple language. Endorsement should also be discussed along with the terms of usage of the name, brand and/or logo of all parties including the names of the representatives.

## Transparency

Transparency means ensuring that all parties are clear about each partner's role and responsibility within the partnership. Resources contributed by each party should be used appropriately and any other collaboration that might influence the partnership should be disclosed.

## Sustainability

Collaborations should strive for a sustainable benefit for patients, rather than aiming for short-term goals or competitive advantage. This sustainability can be achieved by ensuring that the demands on administrative efforts from Patient Organisations be minimised so that the limited resources can be utilised in other areas. Results of a trial should also aim to be made public after the conclusion of the collaboration to create value for the whole community rather than just competitive advantage for the partners.

# Other Clinical Research topics for the involvement of Patient Organisations

## Paediatric Research

Paediatric research is a complicated issue on a Europe-wide scale. This is because laws regarding the age of adulthood differ in every European country, impacting the age of legal informed consent.

However, Regulation (EC) 1901/2006 states that all new medicines applying for marketing authorization, which are intended to be used on the paediatric population must provide results from a previously agreed Paediatric Investigation Plan (PIP). The PIP sets out the studies that will be conducted to ensure the product is safe for paediatric use.

The regulation also includes incentives for companies to develop medicines for use in children in order to stimulate paediatric developments.

## Biobanking and Registries

Many patients are unfamiliar with Biobanks and Registries. If you are considering requesting for participants to submit samples to a biobank or registry you may want to provide them with some more information. EGAN has produced useful documents for patients which explain Biobanks and Registries. These can be accessed through EGAN's website:

[www.biomedinvo4all.com](http://www.biomedinvo4all.com).

During the course of the PatientPartner project, it was also mentioned several times that patients feel as though consent for biobanking and registries should be kept separate from consent for clinical trials and this separation should be made clear. Participants should not be discouraged from participating in either of these research activities by being misled into thinking that they are dependent upon each other.

## Useful websites/resources

**AFRT** (French association for research on Trisomy 21) [www.afrt.fr](http://www.afrt.fr)

**BBMRI** (Biobanking and Biomolecular Resources Research Infrastructure) [www.bbmri.eu](http://www.bbmri.eu)

A pan-European and internationally broadly accessible research infrastructure, and network of existing and new biobanks and biomolecular resources.

**Biomedinvo4all** [www.biomedinvo4all.com](http://www.biomedinvo4all.com)

Website created by EGAN to provide information on genetic, biomedical, pharmaceutical and clinical research for the development of therapeutic, preventive and diagnostic tools.

**Clinical Trials.gov** [clinicaltrials.gov](http://clinicaltrials.gov)

A service of the U.S. national Institutes of Health which allows users to search clinical trials taking place in the US and abroad

**ECRIN** (European Clinical Research Infrastructures Network) [www.ecrin.org](http://www.ecrin.org)

The European Clinical Research Infrastructures Network (ECRIN) is a sustainable, not-for-profit infrastructure supporting multinational clinical research projects in Europe.

**EFGCP** (European Forum for Good Clinical Practice) [www.efgcp.be](http://www.efgcp.be)

Is a non-profit organisation established by and for individuals with a professional involvement in the conduct of biomedical research. Its purpose is to promote good clinical practice and encourage the practice of common, high-quality standards in all stages of biomedical research throughout Europe.

**EFPIA** (European Federation of Pharmaceutical companies and Associations)

[www.efpia.org](http://www.efpia.org)

Represents 31 national associations and 40 leading pharmaceutical companies operating in Europe.

**EGAN** (European Genetic Alliances Network) [www.egan.eu](http://www.egan.eu)

Patients Network for Medical Research and Health - is a dynamic collaboration of Patient Organisations that work together because they recognize the value of their involvement in genetics, genomics and medical biotechnology for the prevention and treatment of genetic, multifactorial and congenital disorders.

**EMA** (European Medicines Agency) [www.ema.europa.eu](http://www.ema.europa.eu)

Agency responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union.

**EU Clinical Trials Register** [www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu)

A Public access database which uses information from the EudraCT database to provide information on clinical trials on medicines where the investigator sites are in European Union member states and the European Economic Area.

**EudraCT** [eudract.ema.europa.eu](http://eudract.ema.europa.eu)

**EU Clinical Trials Register** [www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu)

A Public access database which uses information from the EudraCT database to provide information on clinical trials on medicines where the investigator sites are in European Union member states and the European Economic Area.

**Genetic Alliance UK** [www.geneticalliance.org.uk](http://www.geneticalliance.org.uk)

A national charity of Patient Organisations with a membership of over 150 charities supporting all those affected by genetic disorders.

**The International Alliance of Patient Organisations** (IAPO) is a global alliance representing Patient Organisations all over the world across different conditions and has a searchable global directory:

[www.patientsorganizations.org/searchgroup.pl](http://www.patientsorganizations.org/searchgroup.pl).

**INVOLVE** [www.invo.org.uk](http://www.invo.org.uk)

Involve are specialists in public participation; bringing institutions, communities and citizens together to discuss, decide and reshape the things that matter to them. Involve makes a practical difference to democracy by delivering, researching and promoting high quality public participation processes.

**PatientPartner** [www.patientpartner-europe.eu](http://www.patientpartner-europe.eu)

Project set out to promote the role of Patient Organisations in the clinical trials context. See "About this guide" (p.4) for more information

**People in Research** [www.peopleinresearch.org](http://www.peopleinresearch.org)

Website set up by INVOLVE and the National Health Service to advertise opportunities for public involvement in clinical research.

**Orphanet** [www.orpha.net](http://www.orpha.net)

Orphanet is a database of information on rare diseases and orphan drugs for all publics. Its aim is to contribute to the improvement of the diagnosis, care and treatment of patients with rare diseases.

### **Value +**

Project conducted by European Patients' Forum (EPF) in 2008-2010, to promote patients' involvement in EU supported health-related projects. The project produced a Handbook, Toolkit and a set of Policy recommendations. These can be accessed from the EPF website:

[www.eu-patient.eu/Initatives-Policy/Projects/EPF-led-EU-Projects/ValuePlus/](http://www.eu-patient.eu/Initatives-Policy/Projects/EPF-led-EU-Projects/ValuePlus/).

### **VSOP** (Dutch genetic alliance) [www.vsop.nl](http://www.vsop.nl)

Is an umbrella organisation of about 55 national, disease-linked, parent and Patient Organisations whose mission is to optimise the implications of research in the field of genetics, medical biotechnology and life sciences for both patients and the public.

## Acknowledgements

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PatientPartner would like to thank the following for their contributions to this guide:

- Dave Ardron
- Sheila Fisher
- Carol Lee
- Prof. Jacqueline London
- Hanna Milczarek
- Dr Sue Pavitt
- Joanne Rule
- Richard Stephens

We would also like to thank all the members of Patient Organisations, Industry, Academia as well as other stakeholders involved in clinical research who attended the PatientPartner workshops.

Lastly we would like to thank all those that took part in our interviews, surveys and other meetings.

For more information on the PatientPartner project please contact:

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[www.efgcp.be](http://www.efgcp.be)



[www.egan.eu](http://www.egan.eu)



[www.vsop.nl](http://www.vsop.nl)



**Genetic Alliance UK**

Supporting. Campaigning. Uniting.

[www.geneticalliance.org.uk](http://www.geneticalliance.org.uk)

Produced by the PatientPartner project funded by the 7th Framework Programme of the European Commission

