efpia

innovative medicines initiative

The Innovative Medicines Initiative and patients - a partnership

THE INNOVATIVE MEDICINES INITIATIVE'S ULTIMATE GOAL IS TO SPEED UP THE DEVELOPMENT OF SAFER, MORE EFFECTIVE INNOVATIVE MEDICINES, HELPING PATIENTS BENEFIT FROM RESEARCH ADVANCES AS QUICKLY AS POSSIBLE. INPUT FROM PATIENTS AND PATIENT GROUPS IS ESSENTIAL TO MAKING THIS PROCESS SUCCESSFUL. THIS IS WHY WE ACTIVELY ENCOURAGE YOU TO PARTICIPATE IN IMI AT ALL LEVELS, PARTICULARLY AS MEMBERS OF OUR PROJECTS.

WHY SHOULD I GET INVOLVED IN IMI?

IMI projects deliver tools and knowledge that accelerate the process of developing new treatments and reduce delays in patient access. Patients that are involved in IMI have the opportunity to influence and contribute to research that is directly relevant to their own disease areas. To find out more about IMI's philosophy on patient involvement, turn to page 2.

WHAT IS THE BEST WAY TO GET INVOLVED IN IMI?

There are many opportunities to become involved in IMI. It depends of the level of commitment you can give. For example, you can join a project as a full member, placing you on an equal footing to all other partners. Alternatively, you could become a member of an advisory or ethics committee, responsible for bringing the patient perspective to the project. You can find more details on the opportunities to become involved on page 6.

HOW DO I GET STARTED?

Give some thought to what you think you can contribute to a project, and make sure that any potential partners are aware of your interest. Make sure that your network in the patient and academic communities knows that you want to become actively involved. For more advice, go to page 6.

WHEN IS THE BEST TIME TO JOIN A PROJECT?

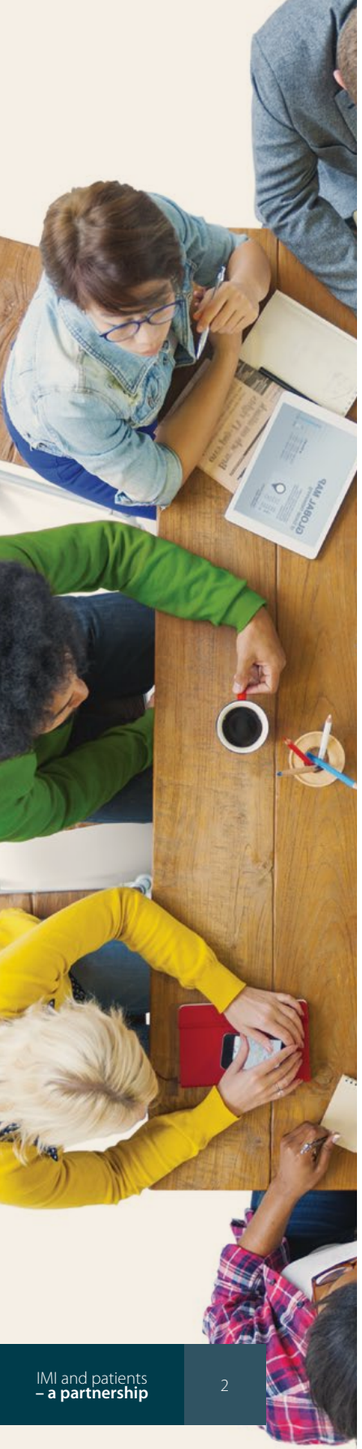
The earlier you can become part of a project the greater the impact your contribution will make. Getting involved at the outset, or even at the scoping stage, is ideal.
You can read more about early involvement by patient groups on page 6.

WHAT IMPACT HAVE PATIENTS MADE ON IMI PROJECTS SO FAR?

Patient organisations are already making valuable contributions in a number of IMI projects. Practical examples include driving recruitment for clinical trials and helping shape the practical aspects of gathering data to make it easier for patients to participate. They are also active in communicating the projects benefits to patients. Turn to page 5.

WHERE CAN I FIND OUT MORE?

If you want further information, or wish to contact us with any questions or queries, you can find all our contact details on page 12.



WHAT IS THE INNOVATIVE MEDICINES INITIATIVE?

Launched in 2008, the Innovative Medicines Initiative (IMI) is the world's largest public-private partnership for health research. It has a budget of over €5 billion for the period 2008 to 2024.

The IMI's mission is to improve health by accelerating the development of new treatments and by reducing the time it takes for these advances to reach the patients that need them. It does this through supporting collaborative research projects and building networks of industrial and academic experts to boost pharmaceutical innovation in Europe. It places an emphasis on those areas with unmet medical or social needs.

WHY ARE PATIENTS IMPORTANT TO IMI?

IMI recognises that patients can make a vital contribution to shaping research, make it more effective and more oriented to patient needs. Therefore, IMI champions a patient-centric approach, encouraging all the projects that it funds to work in partnership with patients wherever possible.

Patients play an essential role when designing and implementing the IMI strategic research agenda, sitting alongside researchers from public and private sectors, including the pharmaceutical industry, biotech companies, academia and regulators. This is why we wish to embed patients and their advocates at all levels; agenda setting for research in medical innovation, project planning, implementation, evaluation processes and content.

For IMI, a patient-centric approach should be the norm for its projects; collaborating with patients as equal partners will be a prerequisite for success.

HOW IS IMI FUNDED?

IMI is funded through a unique collaboration between the European Commission and the European pharmaceutical industry. The EU funds half from its research and innovation programmes, the Seventh Framework Programme (FP7) and Horizon 2020. This funding helps organisations such as patient groups, universities, small/medium-sized companies and medicines regulators to become involved in IMI projects.

EFPIA, the pharmaceutical industry federation, funds the remainder through 'in kind' contributions, i.e. by providing resources such as researchers or facilities. EFPIA companies do not receive any funding from IMI.

IMI is already supporting a large number of projects, some of which have already delivered advances in a range of therapy areas, including neurological conditions, diabetes and infectious diseases. They have also produced progress in medicines safety, drug development, diagnostics and training. There are more projects planned.

You can find further details on current IMI projects on our website: www.imi.europa.eu

PATIENT ORGANISATIONS ARE ALREADY PARTICIPATING IN EVERY STAGE OF DRUG DISCOVERY, ACROSS A WIDE RANGE OF THERAPY AREAS

For more information visit http://www.imi.europa.eu/content/ongoing-projects

Risk – Benefit Appraisal:
PROTECT
International Alliance of Patients' Organizations

Dementia:
EPAD
- Alzheimer Europ

Incorporating Real World data:
GetReal
- International Alliance of Patients' Organizations

Dementia:
PHARMA-COG
- Alzheimer Europe
- Greek Association of Alzheimer's Disease and Related Disorders:

Chronic Obstructive Pulmonary Disease (COPD):
PRO- Active
- Astma Fonds Longstichting
- British Lung Foundation

Neurodegenerative diseases:
AETIONOMY
- Alzheimer Europe

Alzheimer's disease:
EMIF
- Alzheimer Europe

Autism spectrum disorders:
EU-AIMS
- Autism Speaks Inc.

Recognising adverse drug reactions:
WEB-RADR
- European Organisation for Rare Diseases

Asthma:
U-BIOPRED
- European Lung Foundation
- Netherlands Asthma Foundation
- Asthma UK
- European Federation of Allergy and Asthma
- Lega Italiana Anti Fumo

European Patients' Academy on Therapeutic Innovation:
EUPATI
- European Patients Forum
- European Organisation for Rare Diseases
- European AIDS Treatment Group
- Irish Platform for Patients' Organisations, Science and Industry
- European Genetic Alliances Network
- Vereniging Samenwerkende Ouder - en Patiëntenorganisaties
- Genetic Alliance UK

FULL PROJECT PARTNERSHIP EXPERIENCE

THE VIEW FROM SEVERE ASTHMA PROJECT U-BIOPRED, WHERE SEVERAL PATIENT ORGANISATIONS ARE FULL PROJECT PARTNERS

"My input and my voice were being listened to from the outset."
Breda Flood is President of the European Federation of Allergy and Airways Diseases Patients Associations (EFA) and Board Lead for U-BIOPRED as a Dissemination Partner.

After 10 years on the board of Asthma Ireland, I joined the EFA Board in 2009 and was immediately appointed EFA lead in the U-BIOPRED Project as Dissemination Coordinator. At our kick-off meeting, the Project Coordinator, Peter Sterk of the University of Amsterdam, made it clear we would move away from the old model of medical practitioners looking down on non-clinical, patient input. This reassured me that my input and voice were being listened to from the outset.

We demonstrated our value early on. For example, when we found that the Chair of the Patient Input Group wasn't involved in all relevant Work Packages; we helped them gain access to their meetings. In addition, a number of centres had fallen behind in recruitment, risking missing their targets. We developed communication tools to turn around recruitment, and eventually involved more than 1 000 patients. This quickly brought other stakeholders onside.

All future projects should ensure they have patient experts - with particular experience and expertise on how to work with research professionals - as part of the consortium.

"I FIND IT REASSURING THAT IMI IS PRIORITISING THE VALUE OF PATIENT EXPERTISE"

"THE JDRF AND IMI SHARE A SIMILAR APPROACH… PUTTING PATIENTS AT THE CENTRE OF WHAT WE DO."

THE VIEW FROM THE JDRF – ASSOCIATED PARTNERS IN IMI2

"At JDRF, patients' voices serve as a compass. This can also be the case for IMI2."
Dr Dick Insel is the Chief Scientific Officer at the JDRF.

JDRF (formerly the Juvenile Diabetes Research Foundation) is the leading source of funding for research in type 1 diabetes (T1DM). We have committed more than $1.9 billion to T1DM research since 1970, and we currently sponsor scientific research in 17 countries. In 2014, JDRF chose to become an Associated Partner of IMI2.

Our decision to collaborate with IMI was actually very straightforward. When the IMI Joint Undertaking first approached us to become an Associated Partner, we were happy to offer them a warm welcome. It was an easy decision because JDRF and IMI share a similar belief and approach in putting patients at the centre of what we do.

The IMI provided a unique opportunity to demonstrate to industry investors what multi-stakeholder collaboration can achieve. More importantly, it showcased the benefits of involving patients closely. Only T1D patients and their families can tell whether the outputs represent real solutions and genuine innovation. For JDRF, patient input helps to ensure that our research is focused on delivering valuable, life-changing therapies to people living with T1D.

Becoming an Associated Partner also gave us the opportunity to recognise the contributions that patients are making to advance T1D research. We can expand on those valuable contributions by asking patients and their families for their critical opinions where it most matters - on the particularities of clinical trial protocols, on enrolment processes and on the feedback they will receive after the trial is completed, as well as issues of affordability of and access to new therapies. Including patients as true partners from start to finish is crucial to our effort to better treat, prevent and cure T1D.

The desire to include patient input in our work is where the philosophies of JDRF and IMI align, and that is why JDRF was pleased to become an Associated Partner. At JDRF, patients' voices serve as a compass. This can also be the case for IMI2.

PATIENT ADVISORY COMMITTEE MEMBER PERSPECTIVE

"It is not just the professional input that is important in clinical trials. Simple advice from an alternative perspective is often invaluable."
Lina Buzermaniene has been a Patient Representative on the U-BIOPRED Ethics Board since 2009.

"WE NEED TO LEARN TO USE PATIENTS' OPINIONS AND ADVICE FASTER AND BETTER IN THE FUTURE."

My role is to ensure that U-BIOPRED considers the patients' perspective, and check that the projects adhere to the relevant ethical principles. There are 11 members on the Ethics Board, four of whom are patients. The patient members help review the protocols, consent forms and questionnaires, tailoring them to make patient participation as straightforward as possible.

Seeing my contributions make such a clear impact has encouraged me and increased my confidence. We are continuously acquiring new skills. Patients involved in research projects gain insights into how clinical trials work, knowledge they can pass on to other patients. It is a virtuous circle; the more patients know, the greater their contribution.

There is still room to improve. We need to learn from the U-BIOPRED experience, to use patients' opinions and advice faster and better in the future. Training patients in how to communicate their ideas more clearly, to let researchers understand and incorporate their considerations, would be a big step forward. It is not only the professional input that is important in clinical trials; simple advice from an alternative perspective can be equally invaluable. Sometimes, only the patient has the relevant insight, and that is what makes our input so important to these IMI projects.

"IT IS A VIRTUOUS CIRCLE; THE MORE PATIENTS KNOW, THE GREATER THEIR CONTRIBUTION."

HOW CAN YOU BECOME A PARTNER IN IMI PROJECTS?

THE MOST COMMON WAY FOR PATIENTS TO BECOME INVOLVED IN IMI IS AS A **FULL PROJECT PARTNER** OR AS A **MEMBER OF A PROJECT ADVISORY BOARD**.

Full project partner: This recognises the expertise you bring to the project and places you on an equal footing to other partners. Your contribution will include:

- Helping define the outcomes that will genuinely benefit patients
- Determining the appropriate benefit-risk balance in new treatments
- Providing input into the best ways to involve patients in project governance.

Patient organisations are eligible to receive funding from IMI if they meet the conditions set out in IMI's rules.

Advisory board member: You are responsible for bringing the patient perspective to the project. This could be as:

- A member of the project's ethics board
- A member of the project's advisory board
- A body dedicated to gathering patient input.

Advisory board members do not receive funding directly from IMI. However, the project may cover their costs.

HOW DO I **GET STARTED**?

There are a number of things that you can do to become an active partner in an IMI project. The first thing is to let people know about your desire to become involved – make sure you advertise your interest to potential partners.

Activate your network: Word of mouth is a highly effective way to communicate your interest. Tell your academic and patient advocacy contacts that you want to become a project partner, learn from their experiences. In addition to providing all potential applicants with information on the Call topics and procedures, IMI webinars and info days also provide excellent networking opportunities.

Use online tools: Try out the online partner search tools and IMI social media, including a dedicated LinkedIn group.

Start early: IMI does not fund individual organisations; to be eligible, you must be part of a successful consortium of applicants. IMI publishes draft information on forthcoming Call topics several weeks before the launch of a Call for proposals. As soon as you hear about a topic that interests you, begin your networking and study the available information to see where you can contribute to a consortium.

WHAT DOES IMI **EXPECT** FROM FULL PROJECT PARTNERS?

Becoming a partner in an IMI project requires a commitment on the part of your group. Make sure you have the time to fulfil your obligations before committing to a project. Reach out to other groups already involved in projects to gain insights into what will be expected of you.

As a full project partner, you will also have contractual obligations, both to your fellow partners and to the IMI. The relevant rules and regulations are always published with each Call for proposals.

HOW CAN PATIENT PARTNERS **ASSIST** IN PROJECT IMPLEMENTATION?

Governance roles: As a full project partner, your patient group should have a Governance role. Ideally, you should be represented on the Steering Group. This makes sure that the project always considers the patient perspective when making major decisions.

Improving project performance: Should you become a project partner, you will help optimise the project performance. You can assist in defining the project scope, making data collection more patient-friendly, assisting in recruiting participants for studies and in communicating the project results to a wider audience.

CONTRIBUTE TO IMI AS AN IMI ASSOCIATED PARTNER

Patient organisations with their own research funding programmes can become Associated Partners of IMI. Associated Partners are typically involved in the development of new call topics from the outset. This means they can influence the scope of projects.

As is the case with EFPIA partners in IMI projects, Associated Partners do not receive any funding from IMI, but contribute to the projects, mainly through in-kind contributions (such as their experts' time, access to resources / equipment). IMI will match any resources they invest in a project, making an effective way of leveraging precious assets.

Find out more at:
www.imi.europa.eu/content/patients

GETTING INVOLVED

PATIENT INSIGHTS IMPROVE RESEARCH AND ADD HUGELY TO ITS VALUE.

Maria Navarro brings a unique perspective on patient involvement for IMI. Not only is she a member of the IMI Scientific Committee, she is also an active patient advocate with the Spanish Patients' Forum.

"Patient insights and experiences can shape the development of new therapies to ensure they have the greatest impact and an enduring legacy."

As a Member of the IMI Scientific Committee, it is part of my role is to ensure that our projects consider the patient's perspective. Patient-centricity is a core principle for IMI, because we know that patient insights improve research and add hugely to its value. Their practical and personal perspective should be helping to shape R&D. This is why IMI places such an emphasis on genuine patient involvement.

BETTER INSIGHT, BETTER RESEARCH

By focusing on mainly technical perspectives such as lead times and safety and efficacy, researchers and scientists are often detached from the practical application of their work. They lack insight into what are the genuine pressing needs and what could make a real difference. Patients bring this missing dimension to research with real-life, personal experience of their conditions. They know how benefit - risk really looks from their perspective and what will make a genuine impact on quality of life. **By providing scientists with a window into these real, day-to-day needs, research becomes much more patient-oriented, shaping the development of new therapies to deliver maximum impact and an enduring legacy**. I have no doubt that patient involvement in research and development is unquestionably improving medical innovation.

THEIR INSIGHTS AND EXPERIENCES CAN SHAPE NEW THERAPIES TO DELIVER THE MAXIMUM IMPACT AND AN ENDURING LEGACY.

BETTER PATIENTS

At the Spanish Patients' Forum, I also see wider benefits from patient involvement in research. Just as researchers learn from patients, so patients with a better understanding of the potential and the limitations of R&D can make more valuable contributions to the process, leading to better treatments and improved outcomes. This creates better patients and helps cascade knowledge and empower individuals. By sharing their knowledge and insight with other patients, they spread the benefits more widely.

This creates a virtuous circle; researchers understand the pressing needs of patients more fully, while patients see the potential bottlenecks and where they can help. The higher the numbers of patients able to contribute, the greater the impact. This way, innovation becomes more accurately aligned to patient needs.

PATIENTS SHAPING RESEARCH

We can already see patient input is beginning to shape research priorities. Researchers now view patient input in a completely different light to how they did only a few years ago. Where they once only sought validation from patients, they now look for orientation. It tells you just how far this influence has come.

This is the reason why we need this patient perspective, and at IMI, we will do what we can to assist you. If you do become an active partner in an IMI project, you will find it a highly rewarding experience and it will help those who need it most.

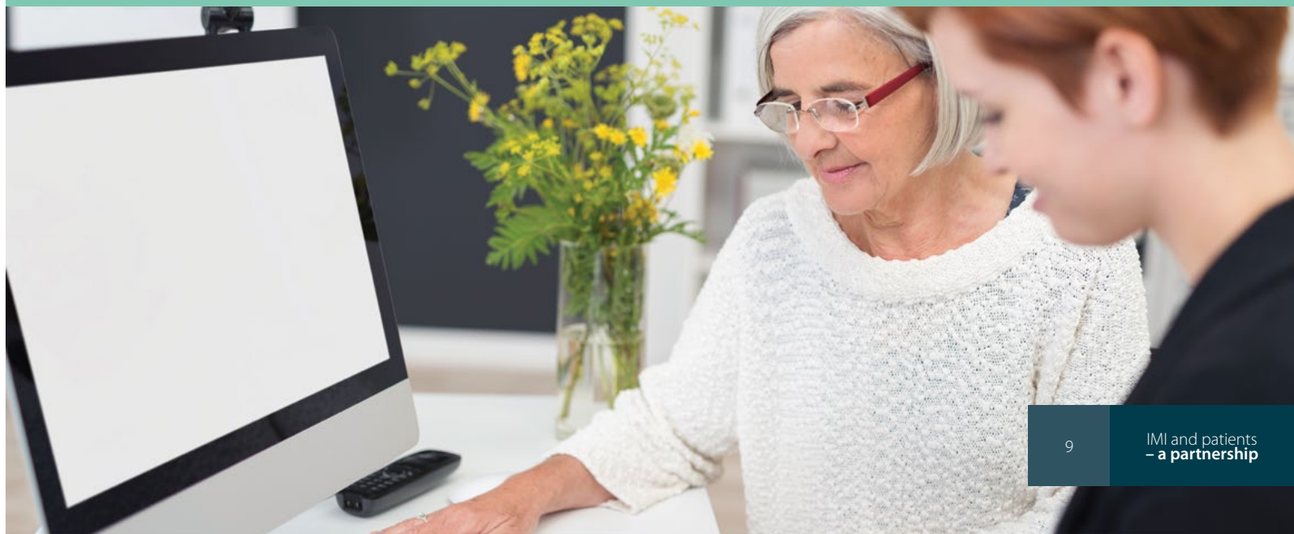
CASE STUDY - EUROPEAN PATIENTS ACADEMY ON THERAPEUTIC INNOVATION

"We're equipping patients to bring insights to the research process to help it better meet their needs."
Jan Geissler is Director at EUPATI - The European Patients' Academy on Therapeutic Innovation.

EUPATI was set up to help patients engage in the drug development process and help orient research towards real world needs. This is not simply about how individuals respond to new treatments, but also about wider issues, such as access to treatment and quality of life. The challenge has been the lack of patients with sufficient knowledge to engage effectively with researchers. EUPATI is creating expert patients who can engage effectively along the entire R&D chain - industry, researchers, ethics committees and regulators – bringing insights from the patient perspective.

The emergence of the first graduates of the 'EUPATI Academy' in 2015 represents an important milestone for EUPATI. Not only do the graduates add to the numbers of expert patients, they are trainers themselves. This will help cascade their expertise within their own patient communities. In addition, national institutions and authorities are using EUPATI as a blueprint for their own training programmes, so patient involvement will increasingly become the norm.

EUPATI is funded by the IMI public-private partnership and is the first IMI project led by a patient organisation, and is going from strength to strength. We now have an independent Project Advisory Board, Regulatory Advisory Panel and Ethics Panel to ensure our objectivity, transparency and independence. From our formation five years ago, we have launched EUPATI National Platforms in the UK, Ireland, Spain, Switzerland and Luxemburg, and by the end of the project, we will have established national EUPATI partnerships in 12 countries. The support of IMI was instrumental in EUPATI's success. They provided critical mass for placing patients at the centre of medicines research and development.



INDUSTRY EXPERIENCE

THE VIEW FROM EFPIA

"Involving patients can actually help to accelerate the drug development process."
Matthias Gottwald is Head of R&D Policy and Networking at Bayer HealthCare and Chair of the EFPIA liaison group. He is also a member of the EUPATI Executive Committee.

I have been involved with IMI since its creation in 2008. I have a particular interest in EUPATI, where I am a member of the Executive Committee. Historically, one of the barriers to patient involvement in research has been the perception that they lacked an in-depth understanding of the detail of medicine development. By teaching patients how to be experts in communicating with researchers, EUPATI is addressing this bottleneck.

From Bayer's perspective, we increasingly recognise how involving patients can actually help to accelerate the drug development process at all stages. We routinely conduct patient validation of clinical trial designs, and ensure that they meet the real-world needs and expectations. This input can be immensely valuable, shortening recruitment and reducing any delays in bringing products to patients.

Inevitably, improved patient advocacy is beginning to shape research priorities; their impact in areas such as rare diseases and HIV are signposts to the future. Although it may take a little longer for this influence to be felt in major indications, a pipeline of 100 EUPATI-trained experts will accelerate this process.

> WE INCREASINGLY RECOGNISE HOW INVOLVING PATIENTS CAN ACTUALLY HELP TO ACCELERATE THE DRUG DEVELOPMENT PROCESS.

ACADEMIA EXPERIENCE

"Ultimately, patients provided highly specific, relevant input on the impact of elements of trial design on patients and helped drive recruitment where it was flagging."
Peter Sterk is Professor of Medicine at the University of Amsterdam and is Project Coordinator for U-BIOPRED, an IMI-supported project to accelerate development of treatments for severe asthma.

I saw from the outset that patient involvement would be pivotal to the success of the U-BIOPRED project. My work in the Netherlands had taught me – often the hard way - that patient insights must be properly used and valued.

In U-BIOPRED, initially we encountered some of the issues and attitudes that we had seen in the past from professionals towards patient involvement. They were not fully comfortable collaborating with patients, and initially sought to limit their involvement to specific work packages - in dissemination and ethics – rather involve them in all elements of the project.

These constraints were initially a barrier to gaining the maximum value from patient insights. Once these barriers were overcome – and the patients themselves played a major role in bringing them down– it quickly became clear the benefits they would bring. Ultimately, they provided highly specific, highly relevant input on crucial elements of trial design that could otherwise have made participation a challenge for patients. They also drove recruitment where it was flagging to keep numbers on target.

The IMI emphasis on patient partnerships is something we should applaud and embrace. If patient involvement at partner level becomes a prerequisite, then that is a good thing; indeed, it should be the model for future research. The era where researchers determine and scope their own projects in isolation, pursuing their own areas of interest, is now in the past. Only by having patients on board will we ensure that we address genuine unmet needs. Equally importantly, their insights will speed the translation of research into real life benefits.

> ONLY BY HAVING PATIENTS ON BOARD WILL ENSURE WE ADDRESS GENUINE UNMET NEEDS.

> THE IMI EMPHASIS ON PATIENT PARTNERSHIPS IS SOMETHING WE SHOULD APPLAUD AND EMBRACE. THIS SHOULD PROVIDE THE FUTURE MODEL FOR RESEARCH.

PATIENT ADVOCATE EXPERIENCE

THE VIEW FROM BT CURE

RESEARCHERS AS WELL AS PATIENTS OFTEN LACK THE EXPERTISE TO MAXIMISE THE PATIENTS' CONTRIBUTION.

"The greatest challenge is encouraging researchers to embrace working with patients"
Maarten de Wit is the EULAR convenor of the network of patient research partners

I have been active for around 15 years in patient organisations at local, national and international levels. For me, the greatest challenge has been to encourage researchers to embrace working with patients. EULAR offered useful guidance in how to make that a reality and how to and demonstrate its value. In EULAR, patients are equal partners, fully integrated in all projects and working with researchers on agreed common priorities. Leadership has been the key; presidents who value patient involvement and professionals who want to learn to collaborate with patients.

EULAR gave us a model to champion at BT Cure. However, despite the openness of the BT Cure leadership to new approaches, transposition of the model was not so easy. Many IMI projects encompass basic research, and both researchers and patients often lack the expertise to get the most from patients' contribution at this stage in the process.

We have already had some successes at BT Cure. The steering group invited us to join their meetings, and we formed a small patient advisory board. They can consult the board over patient relevant issues such as consent procedures or international lobbying for better research legislation on national and European level. Ideally, we would like to make patients as part of the steering group. That way, the advisory board can become a patient panel with a more robust remit, as a sparring partner and sounding board for the steering group.

The IMI projects to increase the numbers of patient experts will be a welcome additional resource.

THE VIEW FROM ALZHEIMER EUROPE

"Working with IMI directly involves Alzheimer Europe in the latest dementia research."
Jean Georges is the Executive Director of Alzheimer Europe.

Alzheimer Europe (AE) is an active partner in all current IMI projects dealing with dementia. We undertake a large amount of dissemination activities, using our unique network of communication channels to reach diverse audiences. As well as talking to people with dementia and their carers, we also enjoy excellent relations with Members of the European Parliament, decision makers in the European Commission and through our member associations, national policymakers.

Working with IMI projects brings AE members a number of benefits. It directly involves us in the latest dementia research, increasing our scientific knowledge and extending our network with researchers and academics. We can pass on these benefits to people with dementia, their families and carers. They tend to be very knowledgeable about their condition and motivated to stay abreast of the latest research.

IMI's patient-centric approach deepens collaboration between scientists and researchers and those who stand to benefit. People with dementia have been at the forefront of this trend. IMI lets AE involve people with dementia in advisory roles within projects. This participation is vitally important; people with dementia are increasingly eager to be part of every decision that concerns their welfare and care.

IMI'S PATIENT-CENTRIC APPROACH DEEPENS COLLABORATION BETWEEN SCIENTISTS AND RESEARCHERS AND THOSE WHO STAND TO BENEFIT.

WANT TO KNOW MORE?

KEEP UP-TO-DATE ON IMI CALLS FOR PROPOSAL

VISIT OUR WEBSITE
www.imi.europa.eu

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CONTACT US
infodesk@imi.europa.eu

efpia

innovative medicines initiative