

Case study 2

BTCure

In search for meaningful involvement of patients in rheumatology research

Maarten de Wit



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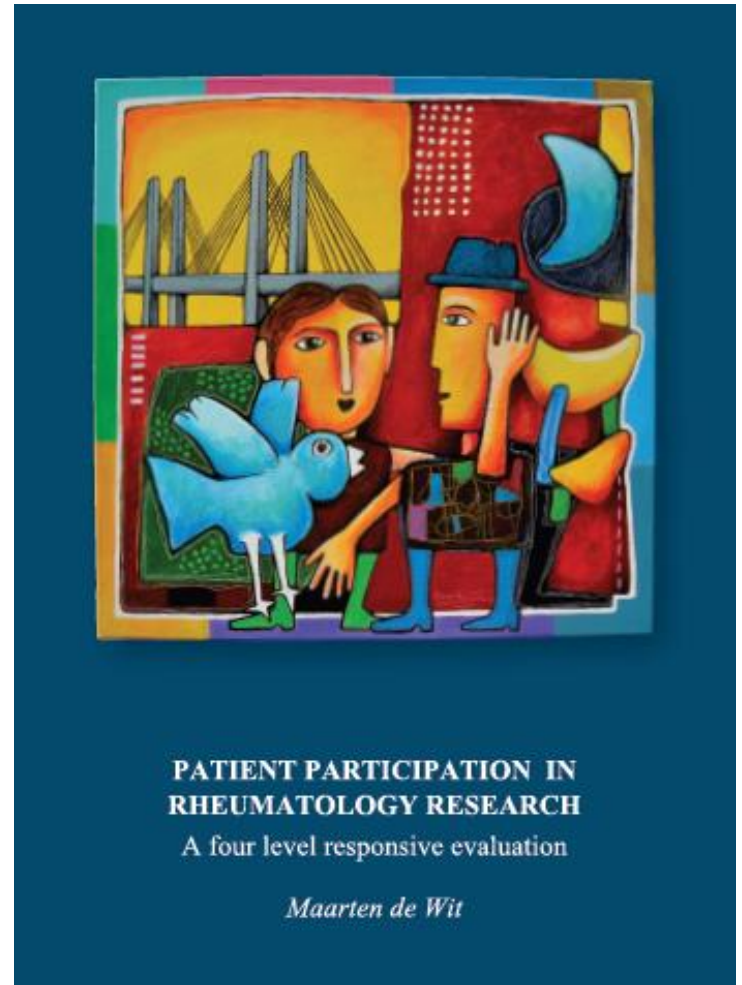
Maarten de Wit

Scientific Committee of
EULAR

Convenor EULAR PARE
Network of Patient
Research Partners

Executive Committee of
OMERACT

Patient Advisory Board
BTcure



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Content

- ❖ Introducing EULAR
- ❖ Patient perspective & involvement in BTCure 2011 - 2015
- ❖ Recommendations for future involvement of Patients in PPP consortia



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An umbrella organisation of 45 countries

📍 European League Against Rheumatism

📍 Founded in 1947

📍 Located in Zurich, Switzerland



Albania



Armenia



Austria



Belarus



Belgium



Bosnia & Herzegovina



Bulgaria



Croatia



Cyprus



Czech Republic



Denmark



Estonia



Finland



France



Georgia



Germany



Greece



Hungary



Iceland



Ireland



Israel



Italy



Latvia



Lebanon



Lithuania



Macedonia FYR



Malta



Moldova



Montenegro



Netherlands



Norway



Poland



Portugal



Romania



Russian Federation



San Marino



Serbia



Slovak Republic



Slovenia



Spain



Sweden



Switzerland



Turkey



Ukraine

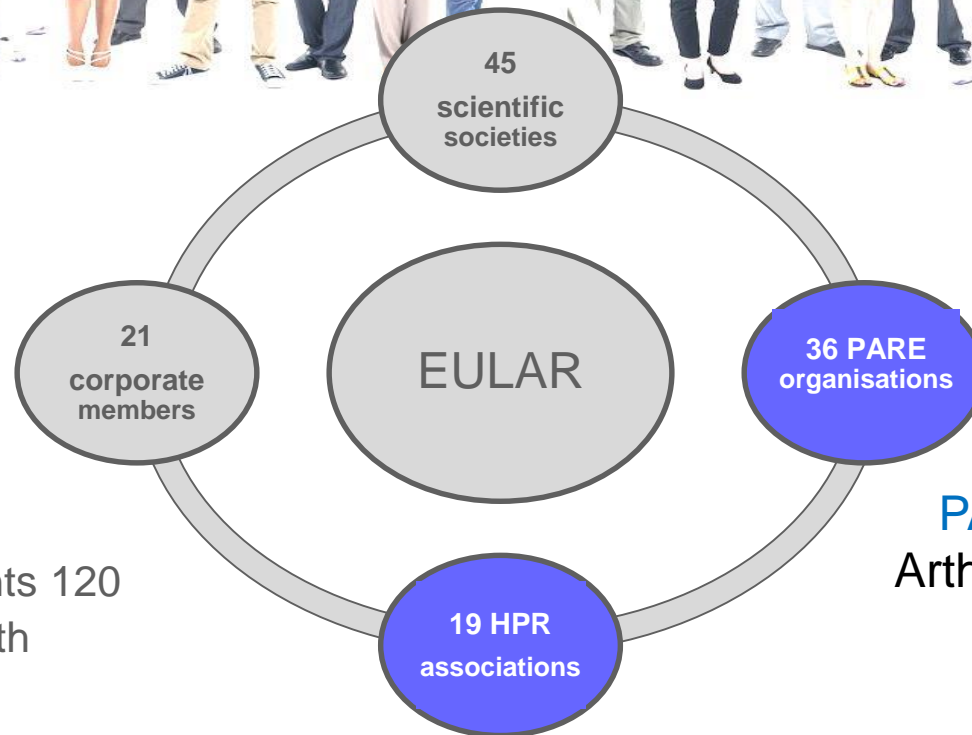


United Kingdom



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EULAR institutional members



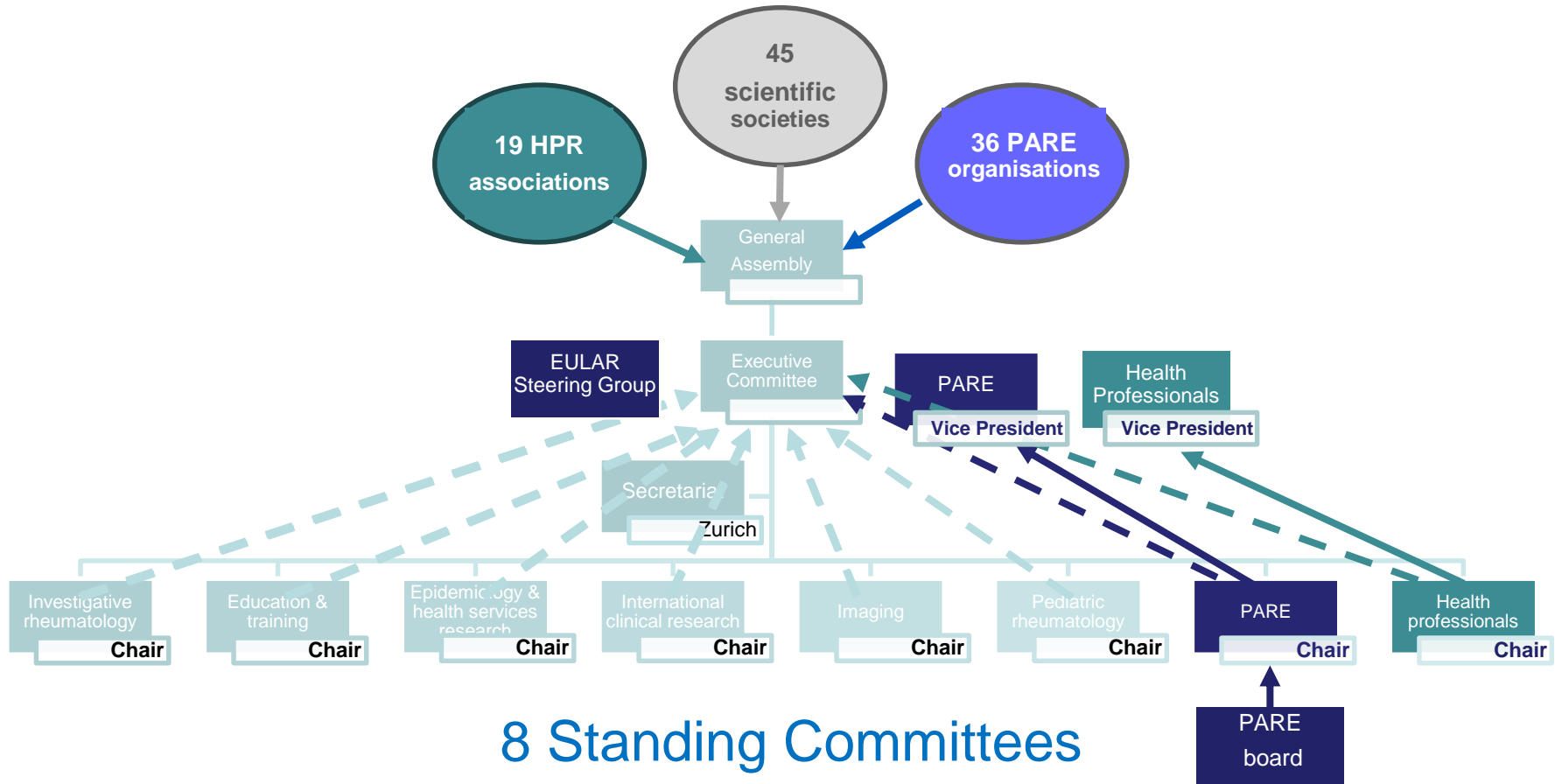
PARE: People with
Arthritis/Rheumatism
in Europe

EULAR represents 120 million people with rheumatic and musculoskeletal diseases (RMD) in Europe.



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Structure of EULAR



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The EULAR PARE Network of Patient Research Partners



Wide variety of
rheumatologic conditions



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ARD

European League Against Rheumatism recommendations for the inclusion of patient representatives in scientific projects

M P T de Wit, S E Berlo, G J Aanerud, et al.

Ann Rheum Dis published online January 20, 2011
doi: 10.1136/ard.2010.135129



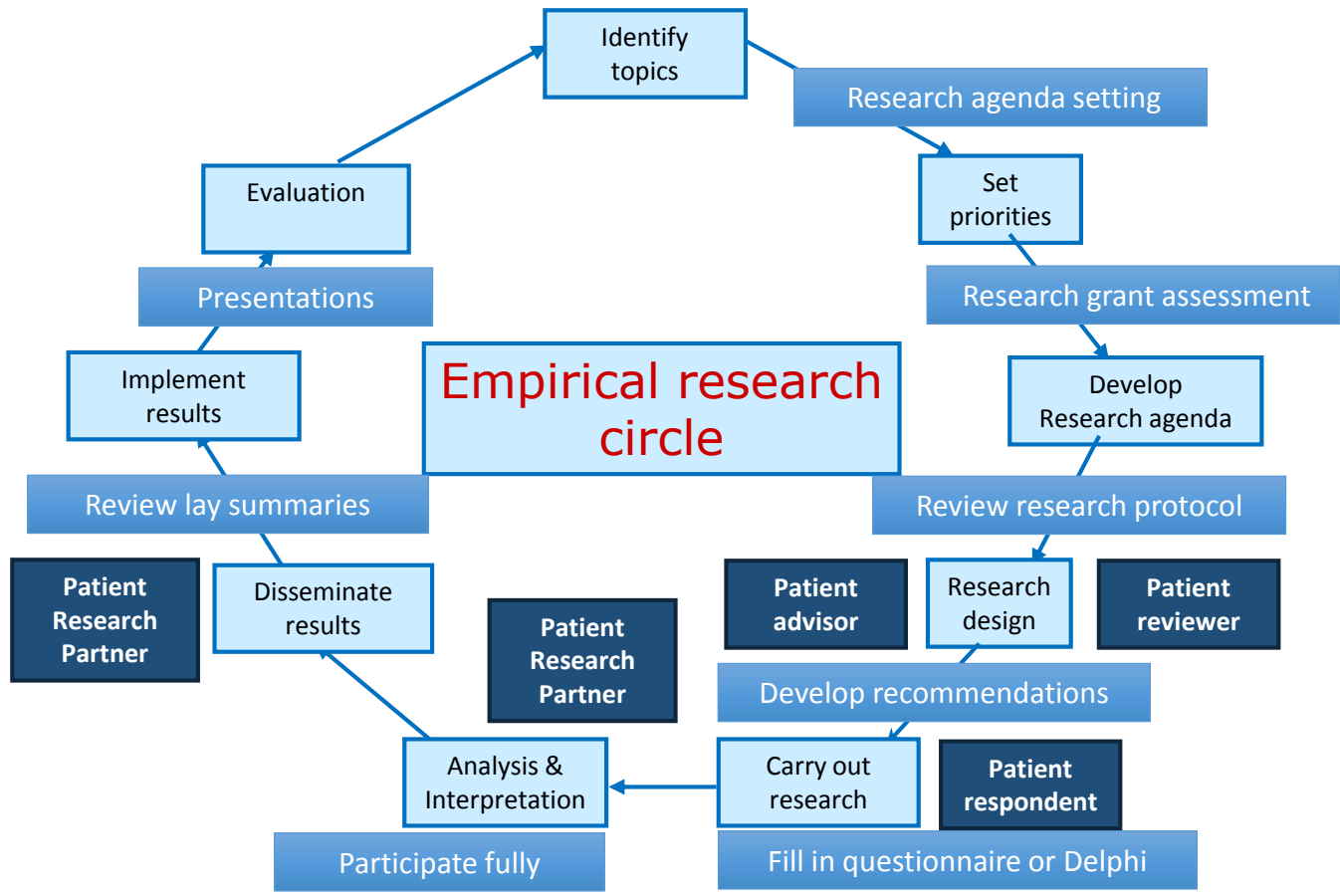
Patient research partners are persons with a relevant disease who operate as active research team members on an equal basis with professional researchers, adding the benefit of their experiential knowledge to any phase of the project.



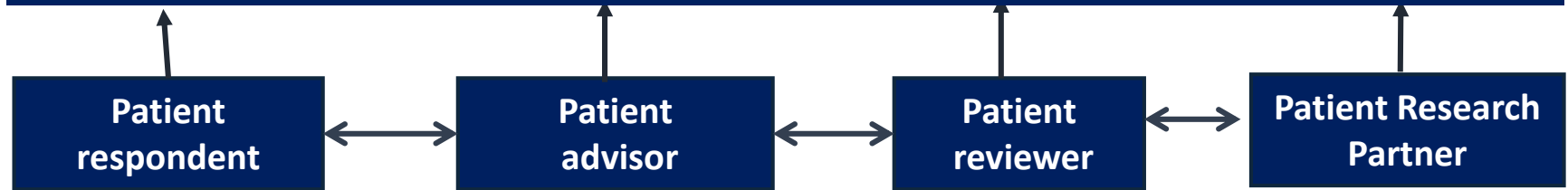
Be
The
Cure
FOR RHEUMATOID ARTHRITIS
FOR RHEUMATOID ARTHRITIS

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EULAR PARE network of trained PRPs



Northern Europe

L. Andersen, Denmark
 R. Hawkins, UK
 A. Higginbottom, UK
 N. Nestor, Ireland
 F. O'Nia, Ireland
 N. Stattin, Sweden
 M. Toft, Denmark
 J. Walker, UK
 K. Lerstrøm, Denmark
 S. Stones, UK
 A. Kent, UK

Central Europe

M. Bakkers, NL
 E. Decantere, Belgium
 K. Eickholt, Germany
 D. Hollander, NL
 G. Severijns, Belgium
 J. Van Rompay, Belgium
 G. Von Krause, France
 J. Welling, NL
 K. Werner, Switzerland
 D. Wiek, Germany
 C. Rusthoven, NL
 F. Klett, Switzerland

Southern Europe

M. Vella, Malta
 C. Carvalho, Portugal
 I. Pitsillidou, Cyprus
 S. Makri, Cyprus
 F. Marchiori, Italy
 E. Mateus, Portugal
 D. Mazzoni, Italy
 D. Papastravrou, Greece

Eastern Europe

P. Bednarova, Slovakia
 M. Godanyiova, Slovakia
 D. Ivanovic, Serbia
 T. Jasinski, Estonia
 C. Zabalan, Romania
 B. Boteva, Bulgaria

EUPATI Training
 participants

Other Research Partner Networks

Belgium, Germany, Netherlands, Norway, Sweden, UK

Content

- ✿ Introducing EULAR
- ✿ **Patient perspective & involvement in BTCure 2011 - 2015**
- ✿ Recommendations for future involvement of Patients in PPP consortia



Patients became gradually involved

- EULAR nor PARE involved in the initial face of developing BTCure study design

Be The Cure' (BTCURE), is an IMI* funded research project which aims to develop new therapies against rheumatoid arthritis. With a total budget of EUR 35 million and 37 partners from all over Europe, it is hoped that by combining academic and industrial resources, basic understanding of disease processes and therapeutic development will be enhanced.

Tasks of Patients in BTCure (2011)

- 👉 Implementing BTCure dissemination strategy
- 👉 Giving input on various questions important for patients: e.g. ethical concerns, informed consent procedures, biobanks.



Patients became gradually involved

➤ Implementation was limited

- 👉 No appropriate selection of patient research partners
 - ❖ WP9 - 3 Patient research partners (PRP) involved in questionnaire on personalised medicine
 - ❖ PRPs did not come to the workshop on informed consent procedures
- 👉 No preparation, support or education of patient research partners
 - ❖ WP5 PRP attended BioBanking Workshop
 - ❖ PRP felt 'lost and worthless'
- 👉 Researchers were of good will, but didn't know when and how to involve patients.

Ways to optimize patient involvement (1)

- Official independent “Patient Advisory Board” for BTCure was founded (2013)
 - 👉 Annual presentation of patient advisors in the BTCure Steering Board meetings
 - ❖ Highlighting the challenges & opportunities for patient involvement
 - ❖ Introducing the EULAR recommendations for the involvement of patients in scientific projects
 - ❖ **Representativeness** of the patient perspective is a responsibility of all members of the consortium
 - ❖ Representativeness of the patient perspective can be obtained using multiple forms of patient participation at different moments and on different levels.

Ways to optimize patient involvement (2)

➤ Meaningful involvement of PRP Network members in BTCure Work Packages

👉 WP5 - Input to BTCure Use of Animal Model report:

- ❖ Letter of Appeal on Animal model work disseminated to PARE organisations and national governments
- ❖ BTCure informed EULAR about EU data regulation initiative → EULAR joined Action for Protecting health and scientific research in the Data Protection Regulation 2012/0011 (COD)

👉 Improved EULAR / BTCure collaboration

- ❖ Closer ties between EULAR Study Group on Animal Models for Rheumatic Diseases – [PARE newsletter Breakthrough article by R Lories for Oct 2015](#)



e - BREAKTHROUGH

News from the Standing Committee of People with Arthritis

Inside

Inside EULAR

The Sep
2015 PA
meeting
Board m

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Planning
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biomedi

World Arthritis Day
2015 in Slovakia

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Animal models in biomedical research

by Rik Lories,* Chair of the EULAR Standing Committee for Investigative Rheumatology

The use of animal models in biomedical research remains a controversial issue. Unfortunately media addressing the general public rarely present a balanced view as spectacular actions of animal rights groups or undercover video footage of certain situations attract more viewers and readers than an academic debate.

This often leaves researchers with a sense of frustration that the debate is not fuelled by arguments but rather by ideology leaving little or no room for balanced discussion. Even worse, in some countries researchers prefer to stay away from the public eye as

illness, and therefore to do good. It is not out with no or rather that any pair compensated for suffering caused

Any experiments in terms of the principles and Refinement scientific practices approaches to re

Arthritis Day action by taking part in our high
www.worldarthritisday.org

“The use of animals in biomedical research is an important topic for patients to understand. It is vital that such information is available in lay language and I am grateful to Prof. Lories for his contribution. PARE looks forward to further collaboration on this topic with EULAR colleagues.”

Marios Kouloumas
EULAR Vice-President
representing PARE



Ways to optimize patient involvement (3)

- Meaningful involvement of EULAR PARE in dissemination of BTCure results
 - 👉 PARE newsletter
 - 👉 PARE educational conference
 - 👉 WP5 – Publishing annual patient activity report targeting all national patient organisations

Disseminating BTCure results: PARE newsletter

(April 2013)



Be The Cure (BTCure)

by Marios Kouloumas, President, Cyprus League Against Rheumatism and Florian Klett, EULAR Project Co-ordinator



Be The Cure (BTCure)* is an IMI funded research project which aims to develop new therapies against rheumatoid arthritis (RA). Marios Kouloumas and Florian Klett were invited to attend BTCure's first Annual Scientific Meeting in Prague in September 2012.

We were honoured to be invited to attend this BTCure meeting as representatives of patient organisations and, in the case of Marios, also as a patient research partner. Participants included principal scientific investigators, key opinion leaders in RA, researchers, industry experts, patient representatives and experts in the field of medical ethics.

It was interesting to see the different stakeholders in this consortium, all specialists in the field, in a very productive and collaborative atmosphere. Expert patients were integrated into the project right from the conceptualization stage. Knowing the challenges faced by patients taking part in scientific initiatives, we were delighted to learn that they and their representatives were being trained to ensure that

their input would be both productive and highly valued.

This public-private partnership consortium has completed its first year and has seen a lot of interaction between the different partners. Major challenges in data collection, sharing and protection, intellectual property rights and standardisation of data across many different stakeholders in Europe are now being tackled. This consolidation phase is common to all complex consortium projects in Europe and vital to the success in developing new methods in researching chronic diseases like RA.

Reports and information will be regularly disseminated over the whole 5-year project duration. We look forward to sharing the eventual outcomes of this important project with you.

For more information please visit <http://btcure.eu>

**BTCure is an IMI JU funded project, contract no 115142-2. The Innovative Medicines Initiative (IMI) is a public-private partnership and Joint Undertaking between the European Union and the pharmaceutical industry association, EFPIA.*



Disseminating BTCure results: PARE conferences (Iceland, Croatia and Ireland)



Improving collaboration and outcomes



“I gave an overview of the PRP involvement and yes, speaking to the assembly and my presence at the whole meeting, I felt that our messages were well received and better integrated at the consortium” (Oct. 2015)

Marios Kouloumas

*EULAR vice-president representing PARE
BTcure Patient Advisory Board*



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- ✿ **Recommendations for future involvement of Patients in PPP consortia**



Suggestions for future involvement of patients

- 👉 Patient organisations should be included in consortium and project development right from the start. PRP networks are an invaluable resource for researchers
- 👉 Develop a governance structure and budget for patient involvement
- 👉 Ensure communication flow, build up trust relationships between patients and their organisations, and foster mutual learning processes – Start small, be sincere and try to do things good
- 👉 Formulate tasks, responsibilities and resources for PRPs to enable meaningful input by patient (organisations)
- 👉 Organize appropriate introductions and training for PRPs
- 👉 **Tokenism** can be avoided if researchers are adequately informed and coached about **the how of participatory research**



Thanks for your listening

martinusdewit@hotmail.com