Case study 2

BTCure
In search for meaningful involvement of patients in rheumatology research

Maarten de Wit
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Scientific Committee of EULAR

Convenor EULAR PARE Network of Patient Research Partners

Executive Committee of OMERACT

Patient Advisory Board BTcure
Content

- Introducing EULAR
- Patient perspective & involvement in BTCure 2011 - 2015
- Recommendations for future involvement of Patients in PPP consortia
European League Against Rheumatism

Founded in 1947

Located in Zurich, Switzerland

An umbrella organisation of 45 countries
EULAR represents 120 million people with rheumatic and musculoskeletal diseases (RMD) in Europe.
Structure of EULAR

8 Standing Committees

- Investigative rheumatology Chair
- Education & training Chair
- Epidemiology & health services research Chair
- International clinical research Chair
- Imaging Chair
- Pediatric rheumatology Chair
- PARE Chair
- Health professionals Chair

19 HPR associations
36 PARE organisations
45 scientific societies
General Assembly
EULAR Steering Group
Executive Committee
PARE Vice President
Health Professionals Vice President
Secretariat Zurich

45 scientific societies
36 PARE organisations
19 HPR associations
The EULAR PARE Network of Patient Research Partners

Wide variety of rheumatologic conditions

Be The Cure

eular
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.
Empirical research circle

Identify topics

Set priorities

Develop Research agenda

Research agenda setting

Evaluate

Presentations

Implement results

Review lay summaries

Disseminate results

Analysis & Interpretation

Participate fully

Review research protocol

Research grant assessment

Develop recommendations

Patient advisor

Research design

Patient reviewer

Carry out research

Patient respondent

Fill in questionnaire or Delphi
EULAR PARE network of trained PRPs

- Patient respondent
- Patient advisor
- Patient reviewer
- Patient Research Partner

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
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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
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 money, and their institutions are not expected to do good. It amounts to 118 to 19 one that any pain or suffering caused for the better is compensated for.

Any experimental animal should be treated in accordance with the principles of the 3Rs: Replacement, Reduction, and Refinement. This means that alternative scientific approaches to refined, where possible, or that no pain or suffering caused is compensated for.

“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,” said Prof. Lories for his contribution. PARE looks forward to further collaboration with EULAR colleagues.”

Marios Kouloumas
EULAR Vice-President
representing PARE
Ways to optimize patient involvement (3)

- Meaningful involvement of EULR 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)* 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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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
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