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Contents

Table of Figures

Table of Tables

Executive summary

The EBRA patient involvement strategy is fully embedded in and is implemented in EBRA activities by different means. Patient representatives contributed to all EBRA work packages and major tasks.

- The European Brain Council (EBC) third parties and EBC members, the European Federation of Neurological Associations (EFNA) and the Global Alliance of Mental Illness Advocacy Networks-Europe (GAMIAN-Europe) were part of EBRA's general assembly.
- Representatives from patient organisations were involved in the development of the Shared European Brain Research Agenda (SEBRA), several cluster activities, and the awareness events (e.g., Brain Innovation Days, Brain Awareness Week).
- Dedicated patient involvement workshops were held in the context of the Training Initiatives for Neurology Advocates (TINA) organised by EFNA.
- The EBRA project and SEBRA were presented during the general assembly meetings of the patient organisations, EFNA and GAMIAN-Europe.
- Feedback interviews were organised with each of the patient representatives involved during one or more EBRA activities.

1. Background and Purpose

The European Brain Research Area (EBRA) project was created as a catalysing initiative for brain research stakeholders (i.e., patients, researchers, clinicians, governments, funders, and public institutions) to streamline and better co-ordinate brain research across Europe while fostering global initiatives. The Consortium consists of the European Brain Council (EBC) membership, the Network of European funding for Neuroscience research (NEURON), EU Joint Programme – Neurodegenerative Disease Research (JPND) and the Human Brain Project (HBP). EBRA's goals are to:

- Facilitate efficient collaboration, communication, and operational synergies, including transparent procedures and setting up of governance mechanisms.
- Foster alignment and better co-ordination of research strategies across European and global brain initiatives.
- Facilitate the emergence of research projects in specific areas in active clusters, and provide them with support for effective collaboration, including enabling sharing of data and access to research infrastructures.
- Foster patient involvement.
- Increase the visibility of the brain research portfolio as a whole and promote the uptake of EBRA results to key stakeholders.

A crucial stakeholder in this project is the expert by experience[1] and the patient representatives[2]. The EBRA patient involvement strategy is fully embedded in and is implemented in EBRA activities by 4 different means.

- The patient representatives and experts by experience are part of the governance of the EBRA project through the EBC third parties the European Federation of Neurological Associations (EFNA) and Global Alliance of Mental Illness Advocacy Networks-Europe (GAMIAN-Europe).
- Patient representatives and experts by experience are involved at the strategic (in the development of the strategic European Brain Research Agenda) level.
- Patient representatives and experts by experience are involved at the operational level: Attending cluster events as one of the stakeholders.
- Patient representatives and experts by experience are involved in the general communication and dissemination of EBRA results.

Task 5.3 'Foster patient involvement' and the deliverable 5.6 'report on patient involvement best practice' reflect how patient representatives and experts by experience have been involved in the project. In addition, this document serves as a best practices guideline for for similar initiatives and projects.

2. State of the art

Here below, existing patient involvement guidelines and recommendations are described. Those were suggested by GAMIAN-Europe, EFNA and EBC.

2.1. Patient involvement in neuroscience research report

In April 2020, EFNA produced a report 'Patient involvement in neuroscience research' which arose from their Training Initiatives for Neurology Advocates (TINA) workshop. "The Neuroscience Research &

[1] Experts by experience refer to all persons with a brain disorder, mental and neurological alike.
[2] Patient representatives refer to all persons representing a patient organisation (e.g., EFNA, GAMIAN-Europe and/or their member organisations).

Development: *Influencing, Engaging and Optimizing Opportunities for Patient Involvement"* was held in December 2019. The aim of the report is to explain how to optimise patient involvement in neuroscience research. This document captures the insights from an EFNA workshop held in Brussels in December 2019. Attended by over 50 representatives of patient and health professional organisations, carers, research and industry partners, and other experts, the workshop served to inform EFNA's strategic plan for 2020-2025, particularly in its focus area of: Promoting patient empowerment for more meaningful involvement and engagement. Patient involvement is much more than participation in clinical trials. Patient involvement also encompasses governance and research priority setting, the design of clinical trials and selection of endpoints, involving patients and carers as evaluators and reviewers of research proposals, membership of research consortia and participation in basic research initiatives, etc.

2.2. Patient Engagement Quality Guidance

The Patient Focused Medicines Development (PFMD) developed the Patient Engagement Quality Guidance (see Figure 1). The PFMD is a not-for-profit collaborative initiative benefiting patients and health stakeholders by designing a patient-centred healthcare system WITH patients and all stakeholders. The guidance document is a tool that contains seven quality measures to assess projects to involve patients. It can be used to capture the quality of the patient engagement project and the benefit it brings to the stakeholders involved. Although this tool is mainly used in research projects, the criteria are also relevant for other projects, such as the EBRA project which is not a research project but a coordination and support action (CSA).

Figure 1. Patient Engagement Quality Criteria developed by the Patient Focused Medicines Development (PFMD)

2.3. MULTI-ACT project

EBC has been involved in the MULTI-ACT project, which started in May 2018 and ended in May 2021. It has received funding from the European Union's Horizon 2020 Research and Innovation Programme under the Grant Agreement No. 787570. The EU-funded MULTI-ACT project aimed to increase the impact of health research on people with brain diseases. It created and implemented a new model allowing the effective cooperation of all relevant stakeholders. This is applicable in defining the scope of health research as well as new metrics for the evaluation of its results. The MULTI-ACT project worked with patients and patient organizations, academics, private and public stakeholders to develop brand new tools to assess the value of research. In the project, the MULTI-ACT Patient Engagement roadmap (see Figure 2) and guidelines were developed to provide a strategy to empower the stakeholder "patients" to be engaged in research & innovation and to empower all the stakeholders to collaborate

and co-create with the “patients”. A call to action for effective patient engagement was directed towards policy makers and funders.

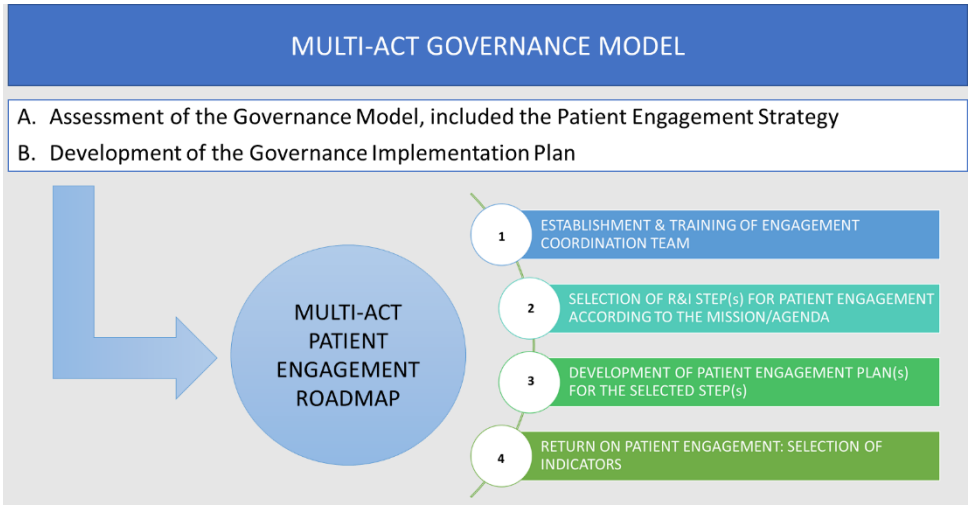

Figure 2. the MULTI-ACT Patient Engagement roadmap

3. The EBRA patient involvement strategy and activities

3.1. The governance level

Patient representatives are part of the General Assembly (GA). In the picture below, you can find the governance structure of the EBRA project.

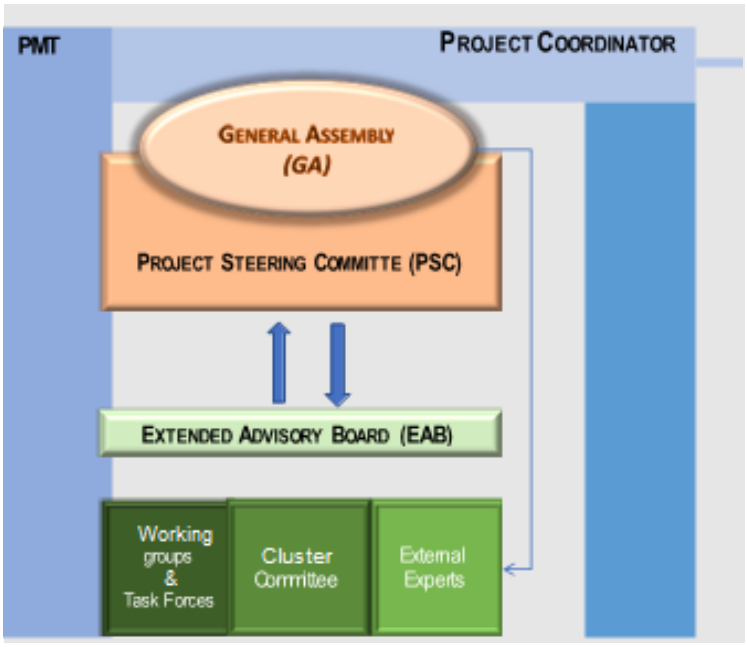

Figure 3. The EBRA governance structure

The GA is the ultimate decision-making body of the project. The EBRA General Assembly is responsible to approve the Project Steering Committee (PSC) proposals and to notify to the consortium. It is composed of the groups list below and Joke Jaarsma, President of EFNA, and Matt Muijen, board member of GAMIAN-Europe, are part of the GA.

Table 1. Composition of EBRA's General Assembly (GA)

EBC board member representatives:	Neuroscience societies: 1 delegate and 1 proxy Clinical societies: 1 delegate and 1 proxy Patient organizations: 1 delegate and 1 proxy
NEURON	1 delegate and 1 proxy
JPND	1 delegate and 1 proxy
HBP	1 delegate and 1 proxy

3.2. The strategic level

The development of the Shared European Brain Research Agenda (SEBRA) was launched in December 2019 and led by EBC. In 2020 and 2021, regular meetings with the EBRA partners the Network of European Funding for Neuroscience Research (ERA-NET NEURON), the EU-Joint Programme for Neurodegenerative Diseases (JPND) and the Human Brain Project (HBP) were organised to define and monitor the development process of SEBRA. This happened in 2 steps. In a first step, existing Strategic Research Agendas were taken into consideration. In the second step, inputs from EBRA experts were collected. To identify future priorities, gaps and enabling actions of brain research in Europe, the existing agendas as well as the overlapping fields have been shared with 90 experts in March 2020. These experts were recommended by the EBRA partners and EBC third parties of which GAMIAN-Europe and EFNA. In 2 surveys (one in March 2020 and another one in July 2020), the experts were asked to share their 5 most important future priorities, gaps and enabling actions, and to rank them in order of priority. In November 2020, those were further dissected with 35 experts during a virtual workshop of which 11% or 4 experts represented patient organisations. This input was shared with the broader brain research community during the SEBRA open consultation. This survey was filled out by 476 players in the brain space of which 10% or 48 persons were experts by experience and/or patient representatives. The input collected during the workshop (i.e., Part I. Coordinating Brain Research in Europe 2021-2027) together with the results of the open consultation (i.e., PART II. Feedback From the Brain Research Community) led to the final SEBRA document.

3.3. The operational level

EBRA supports new and existing transnational research cooperation of European countries, and coordination of research efforts. This effort enables or enhances European and international collaboration and the development of clusters in all areas of brain research. A cluster is understood as a research community that can be directed towards basic research, clinical research and/or methodological approaches under a common topic and disease area within brain research.

In total, EBRA supported 6 clusters:

1. EPICLUSTER: European cluster of epilepsy networks
2. PSMD cluster: Prevention of Severe Mental Disorders
3. TRISOMY21 cluster
4. BRAINFOOD cluster
5. PREMOS cluster: Predictive Model Systems
6. ECIB cluster: European Cluster for Imaging Biomarkers

For each cluster, a programme of activities has been developed aiming at providing the cluster projects with support to:

- Promote external collaborations (T4.2)
- Foster exploitation of results (T4.3)
- Address data sharing issues (T4.4)
- Foster access to research infrastructures (T4.5)

In all those cluster activities, patient representatives and/or experts by experience have been involved and some activities were specifically focused on accelerating patient involvement in research. Here below, we'll give an overview of the role of patients by experience and patient representatives in the clusters and their activities.

3.3.1. EPICLUSTER

The primary objective of EPICLUSTER was to establish a collaborative framework for the coordinated actions of epilepsy research in Europe, based around shared partnerships and research priorities. The Cluster's leadership team is comprised of 10 internationally recognized scientists and clinicians in the field and the leaders of seven EU-projects that came together under EpiXchange as well as leaders from patient and professional organisations. The EPICLUSTER research and funding priorities have been (and will continue to be) informed by involving patients in research questions and study design.

Here below, we'll specify how patients have been involved in the EPICLUSTER activities.

Consensus meeting, June 17th, 2020, online.

The patient organisation, the International Bureau for Epilepsy - IBE joined the first meeting of the EPICLUSTER on June 17th, 2020. The focus of the meeting was to bring together the leaderships, hear from them about their organisations and projects they represent, discuss the originally planned actions and priorities and assign people to responsibilities for delivery. The second part was a multistakeholder meeting in which the EPICLUSTER leadership engaged with external stakeholders and co-created the priorities in the epilepsy field. Patients and carers gave their perspective. The outcome of this meeting was written down in a consensus document. One section of this document reported the patient perspective (see below):

"Patient perspective Persons with epilepsy are major stakeholders and, with patient organisations, have a key role to play in advocacy and awareness around their disease, the process of research selection, drug-discovery, the development of new devices, the assessment of new neurosurgical techniques, and the design of clinical trials. New developments in rare and ultra-rare epilepsies is demonstrating the need for truly collaborative relationship with patients as partners to researchers, clinicians and industry, which is critical for conceiving, developing and establishing transformational treatment options. Experience from rare diseases can serve as a model for the more common epilepsies. Patients perform a vital role at the intersection of medicine and new digital technologies. For example, via education and empowerment to collect and report real-world data through digital diaries and wearable devices, which can drastically change the way we do epilepsy research and care for persons with epilepsy."

Funding, governance and Patient Engagement Workshop, December 1st, 2020, online

The main part of the workshop was on funding for epilepsy. The main target in this regard is Horizon Europe but other opportunities include through partnering with patient representative groups. The second half of the meeting featured presentations from MULTI-ACT on a framework for our Cluster to improve our governance and ensure the inclusion of key stakeholders (e.g., experts by experience). There were 25 attendees at the workshop. This included the complete EPICLUSTER leadership group, several of the affiliated members from other projects and patient representatives, members of EBRA and the invited speakers.

The agenda can be found here below:

14:00 – 14:15	Welcome and introduction (DH)
	Epilepsy Research Funding
14:15 – 14:30	Current (FP7 and H2020) and future (HE-Health Programme) funding landscape for epilepsy in Europe
	Tim Ramaekers, DG Research and Innovation, European Commission
14:30-14:45	NIH/NINDS funding landscape for epilepsy: now and the future
	Vicky Whittemore, Programme Director for Neuroscience (epilepsy), NINDS
14:45-15:30	Promoting and funding patient-focused research: private organisations and philanthropic perspective
	Laura Lubbers, Cure Epilepsy Foundation, USA
	Simona Borroni, President, Gruppo Famiglie Dravet, European Dravet Federation
	Francesca Sofia, Chief Scientific Officer, Italian Epilepsy Foundation
15 :30 – 16 :00	Multistakeholder discussion [ALL]
16:00 – 16:15	Break
	EPICLUSTER's governance and patient engagement strategy
16:15 – 16:25	Introduction to the MULTI-ACT framework [Paola Zaratin]
16:25 – 16:35	EPICLUSTER's baseline analysis + summary of recommendations [Deborah Bertorello +Andrea Gavazzi]
16:35 – 16:55	Multi-stakeholder discussion + actions [ALL]
16:55 - 17:00	Wrap up and next steps [DH]

The outcome of this meeting was written down in a meeting report of which the patient specific parts can be found here below.

Meeting report

Simona Borroni spoke about *Promoting and funding patient-focused research* - President of Gruppo Famiglie Dravet, European Dravet Federation on the challenges and achievements of a smaller, patient-specific charity and how they have raised funding. They typically raise ~€150,000 from donations per year. The contribution of families was strongly emphasised and their expectations for the outcomes and value of research supported by such organisations. In particular, the need for more transparency with project progress and outcomes from scientists. Addressing these gaps is important to achieve impact for patients and ensure support for research continues.

Finally, Francesca Sofia spoke on *Championing the cause of epilepsy through education and engagement of people with epilepsy in research* about the importance of engaging people with epilepsy to ensure sustainable funding and urgency. Also, how patients ("e-patients") are more empowered now in promoting what matters most to patients. There is a sense that other neurological diseases (e.g., Multiple sclerosis) are further ahead than the epilepsy field in incorporating "champions" into research programmes and stigma and lack of public awareness remain major issues in epilepsy. One initiative is the IBE Academy for patients to upskill them to be active and empowered.

The discussion covered the issue of the need to better embed patient values in the design of research.

The second part of the Workshop focused on EPICLUSTER's governance and patient engagement and maximising the impact of research for patients. The first presentation was by Paola Zaratin. The presentation provided an overview of MULTI-ACT and emphasised that multi-stakeholder involvement is key to sustainable healthcare research and alignment of R&I with societal benefits – Responsible Research & Innovation (RRI). This will be a key requirement for the next Horizon Europe programme for success. Andrea Gavazzi then followed with a baseline analysis of EPICLUSTER. Several strengths were identified but also gaps. Deficits in key areas included participatory governance and patient/stakeholder engagement. Recommendations were provided for how to address these deficits. Finally, Deborah Bertorello covered what it means to capture the patient's voice to meet RRI goals. The tools available to EPICLUSTER include a digital toolbox containing patient engagement plans, activities, and measures of success.

The MULTI-ACT presenters were asked about how epilepsy community compares to other major brain diseases in terms of degree to which research is co-designed with stakeholders/patient groups. At least for MS, this is very embedded, with codesign from the beginning and with industry, although acknowledged this is still early. The ideal research "ecosystem" is a challenge for most, however. EPICLUSTER has linked

with patient representatives/experts by experience, but this can be improved. The EpiCare network was mentioned as a great example of an epilepsy network with very active participation of patient experts (15 patient engagement groups). Many of these patients are motivated to be more engaged with research. FS raised the point that the shift toward patient engagement in research brings, however, challenges in that demands from researchers to include patients in projects is outpacing the available experts and the community is too stretched. There is a need to educate more e-patients. This will be time-consuming. MULTI-ACT seeks to mitigate this aspect by making sure patient expertise is used when needed. Another point raised is that EPICLUSTER could bring forward a "white paper" that might delineate the issues around patient and stakeholder involvement in research. Last, the ILAE/IBE have managed to get the WHO to pass a resolution on epilepsy and neurological disorders. This now needs to be translated into action, including the importance of research. This puts responsibility of member states to support research on epilepsy.

Accelerating Patient Involvement in European Epilepsy Research, October 6th, 2021, online.

With the overarching goal of showcasing ways and best practices for bringing people with epilepsy and researchers to work together on common ground, this EPICLUSTER event aimed to unveil the opportunities arising from patient involvement in epilepsy research. The workshop began with an overview of definitions, trends, and key themes around PPI and how they could successfully advance epilepsy research. Hints and case histories lead participants to learn the "why", "how", and "what" of patient involvement in research.

The programme highlights were:

- Understanding the potential of PPI in epilepsy research
- Learning how epilepsy researchers can work with people with epilepsy and their representatives
- Envisioning the way forward: how to incorporate patient involvement into epilepsy research so to fundamentally change the way policymakers, funders, and regulators view epilepsy

This event was designed to encourage researchers to learn about PPI and how to begin to integrate it into their research programs. It was relevant to students, postdocs, and faculty. People with lived experience of Epilepsy interested in getting involved with research teams were also welcomed to attend. In total, 130 participants signed up for the event.

The agenda can be found here below.

9:30 – 9:35	**Welcome and overview of the workshop**
	Prof. David Henshall, EPICLUSTER coordinator
	Dr.. Francesca Sofia, President elect International Bureau for Epilepsy
Session 1	**Patient involvement and health research in Europe**
9:35 - 9:50	**Current best practice on patient involvement**
	Jim Elliott, NHS, Health Research Authority
9:50 - 10:05	**Patient involvement in research: Co-production and why it is essential now.**
	Joke Jaarsma, president, European Federation for Neurological Associations
	Erik Vandereycken, GAMIAN-Europe Project Manager
10:05 - 10:20	**Patient and Public Involvement in EU-funded research: the experience of a scientific project coordinator and reviewer of EU grant proposals.**
	Tsveta Schyns-Liharska, Independent consultant scientific projects
10:20 - 10:35	**Q&A**
Session 2	**Patient involvement: A beginner's guide**
Chair/Moderator:	*Donna Walsh, Executive Director, European Federation for Neurological Associations*
10:35 - 11:15	**Getting patient involvement started – practical advice.**

- Testimonial Basic Scientist

Dr. Heather Mortiboys

- A moderated panel discussion with Patient Engagement through Training (EUPATI) and other patient organisations

Maria Dutarte, Executive Director, European Patients' Academy (EUPATI)

Richard M Ballerand, EUPATI training fellow

Nicholas Brooke, executive director, Patient Focused Medicine Development (PFMD) and founder of The Synergist.

Valentina Strammiello, Head of Programmes, European Patients Forum (EPF)

11:15 - 11:30 **Q&A**

Session 3 **Patient involvement in epilepsy research**

Chair/Moderator: *Francesca Sofia*

11:45 – 11:55 **What are the benefits of patient involvement for people with epilepsy and what are the benefits for researchers?**

Francesca Sofia

11:55 – 12:30 **Patient involvement in epilepsy now – perspective from projects with active patient involvement**

Bojana Mirosavljevic, EUPATI training fellow

Alexandra Moutet, UCB Pharma

Simon R.W. Lees, Patient Advisory Board, RADAR-CNS

Isabella Brambilla, Coordinator EPAG Patient Group ERN EpiCARE

12:30 – 12:45 **Q&A**

12:45 - 13:00 **Closing remarks and wrap-up**

The outcomes of this meeting were written down in a meeting report (see below).

Meeting report

Background and context for event: Over the last decade Patient Involvement has become a central feature of healthcare, with growing evidence of its positive impact on clinical research, and increasing adoption by health authorities, regulators and industry. Patient involvement in basic and preclinical research remains limited, including in the epilepsy field. To unveil these opportunities and to set the stage for multi-stakeholder collaboration, in October 2021, EPICLUSTER organized the first workshop in Europe on patient involvement in epilepsy research. The workshop began with an overview of definitions, principles, and trends in the field. This was followed by a practical session on how to start PI addressed to researchers new to the field. Then, the event went on with a roundtable highlighting opportunities and a number of PPI-enabling initiatives. Finally, the last session presented several case histories to assess the readiness of the epilepsy field with regard to research partnerships between patients and the scientific community.

Patient involvement and health research in Europe

Current best practice on patient involvement

The workshop was opened by **Jim Elliot** (NHS, Health Research Authority) who provided an overview on the definitions and current best practices on patient involvement. To offer some insights into the underlying principles of PPI that might apply to preclinical research, Elliot shared guidelines developed in the United Kingdom to help PPI practices in clinical research. This included involving the right people, to involve enough people, to involve them enough and finally to describe how the involvement has helped the research.

Patient involvement in research: Co-production and why it is essential now.

The second speaker, **Erik Van der Eycken** shared the experience of Global Alliance of Mental Illness Advocacy Networks-Europe (GAMIAN-Europe), an umbrella organization of National Patient Organizations in Mental Health. He focused on the opportunities arising from patient involvement throughout the project and how GAMIAN-Europe has lead a broad range of activities aimed at collecting and integrating the patient perspectives in research. To follow, **Joke Jaarsma, President of the European Federation of Neurological Associations (EFNA),** emphasized the numerous challenges that prevent the realization of meaningful patient engagement, and provided a cross-section of the landscape facing patients with neurological diseases. The session ended with **Tsveta Schyns-Liharska** who shared her journey as a parent and driver of engaged patient communities for a rare genetic disease.

Session 2: Patient involvement: A beginner's guide

Getting patient involvement started – practical advice.

Dr. Heather Mortiboys (Sheffield Institute for Translational Neuroscience) shared practical information and insights into how to implement patient involvement for basic researchers. Working in the field of Parkinson's disease, she explained how she trains early career basic researchers on the value of PPI. This includes how to start, relationship and building the knowledge base and maintaining engagement.

Moderated panel discussion

Experts from various PPI-related organizations and initiatives (Maria Dutarte, Executive Director, European Patients' Academy - EUPATI; Richard M Ballerand, EUPATI training fellow; Nicholas Brooke, executive director, Patient Focused Medicine Development – PFMD - and founder of The Synergist; Valentina Strammiello, Head of Programmes, European Patients Forum - EPF) shared their perspectives in a panel discussion moderated by Donna Walsh, executive director EFNA. This included key learnings on:

1. How patient involvement in research is gaining momentum and is expected to increasingly transform the biomedical research landscape.

2. Lack of readiness and need for researchers' training

3. Treating patients as equal partners and reward their time investment and contribution.

4. How to identify the right people

5. How to incentivize researchers to embrace patient involvement

Session 3: Patient involvement in epilepsy research

The workshop ended with a spotlight on some case histories of patient involvement in epilepsy research. Four testimonies provided practical insights into what people with epilepsy and their organizations can contribute to research, and the reasons why patient involvement can be a game-changer for the epilepsy research. These were by **Isabella Brambilla**, mother of a boy with Dravet syndrome and active epilepsy advocate. She shared her experience of organizing multi-stakeholder meetings, raising funds and supporting research projects, and participating in the creation of a patient registry. EUPATI fellow **Bojana Mirosavljevic,** the founder of a patient organization for families with children affected by rare diseases in Serbia, further emphasized that people with epilepsy and their carers have not only their lived experience with the disease to contribute but are also increasingly equipping themselves with knowledge and skills to better understand and participate in research projects. **Simon R.W. Lees** brought the audience into the realm of digital health technologies and shared his experience as a patient advisor for the RADAR-CNS project (Remote Assessment of Disease And Relapse - Central Nervous System). Finally, the Patient Value Strategy at UCB was presented by **Alexandra Moutet** (Global Head of Patient Engagement at UCB). The initiative's goal is to build a cycle in the R&D process where everything starts from the patients and, ultimately, returns to the patient.

Shaping the future of epilepsy research in Europe, September 29th, 2022, hybrid (Brussels and online)

On September 29th, 2022, the final EPICLUSTER activity took place. This meeting focused on the sustainability and the future of the EPICLUSTER and the European epilepsy researchers. One of the sessions focussed on the patient priorities and patient involvement in epilepsy research. In total, 138 meeting participants signed up to join the meeting. The patient involvement part of the agenda can be found here below.

Session 2	**Patient priorities: Shaping the research agenda**
11:45 – 11:50	Welcome: Why is PPI so important? *Joke Jaarsma, EFNA*
11:50 – 12:20	Shape Network: Building a PPI Community for Research into Epilepsy

	Caoimhe Bennett, Epilepsy Research UK
12:20 – 12:30	Starting PPI in Research: A case study
	Lorna Kerin, RCSI University, IE
12:30 – 13:30	**Lunch**
13:30 – 14:20	Participatory session on planning PPI in your research/work setting
	Caoimhe Bennett, Epilepsy Research UK
	Claire Nolan, International Bureau for Epilepsy
	Lorna Kerin, RCSI University, IE
	Sebastian Winter, International Bureau for Epilepsy
14:20 – 14:30	Future plans of the International Bureau for Epilepsy
	Sebastian Winter, International Bureau for Epilepsy

The meeting outcomes will be published as a meeting report:

Henshall et all. (under preparation): Shaping the future of European epilepsy research: final meeting report from EPICLUSTER.

Abstract Collaboration is essential to the conduct of basic, applied and clinical research and translation into the technologies and treatments urgently needed to improve the lives of people living with brain diseases and the health professionals who care for them. EPICLUSTER was formed in 2019 by the EBRA to support the coordination of epilepsy research in Europe. A key objective was to provide a platform to discuss shared research priorities by bringing together scientists and clinicians with multiple stakeholders including patient organisations and industry and the networks and infrastructures that provide healthcare and support research. Additional objectives were to facilitate access and sharing of data and biosamples, working together to ensure epilepsy is a priority for research funding, and embedding a culture of public and patient involvement (PPI) among epilepsy researchers. In this meeting report, we summarise the shared research priorities discussed by the leadership of EPICLUSTER at the recent final meeting. We also briefly review the discussion on patient and industry priorities, guidance on starting PPI for epilepsy researchers, and the sustainability of funding and infrastructures needed to ensure a comprehensive stakeholder-embedded community for epilepsy research.

Keywords: Research agenda; Brain; Diagnosis; Epilepsy; Horizon Europe; Public Patient Involvement; Stakeholders; Therapeutics

3.3.2. Prevention of Severe Mental Disorders cluster

Ethics of precision and preventive psychiatry workshop, February 23rd and 24th, 2021, online

Precision medicine offers new opportunities to improve mental health but also raises ethical tensions and challenges. The lack of an established ethics framework is one of the core barriers that impede the realization of predictive, preventive, personalized and participatory psychiatry in an ethically acceptable manner that optimizes benefits and minimizes harms. The workshop involved key leaders from different professional backgrounds (day 1) and stakeholders (including patient representatives and caregivers) and gathered consensus on a core blueprint to advance ethics of precision psychiatry. In total, 27 participants joined this workshop.

Representatives from GAMIAN-Europe and EUFAMI contributed on Day 2 during session 2, 3 and 4 (see details below).

14:40-14:45	Session 2: Fighting stigma with precision psychiatry opportunities
14:45-15:05	Q&A Stakeholders discussion *Tineke Mollema* GAMIAN-Europe, *Miia Männikkö* EUFAMI
15:05-15:10	Session 3 A complex lexicon: ethics and communication with patients and caregivers, lay people, and mass media
15:10-15:30	Q&A Stakeholders discussion *Tineke Mollema* GAMIAN-Europe, *Miia Männikkö* EUFAMI
15:30-15:40	Break

15:40-15:45	Session 4 Strengthening the alliance between users, families and mental healthcare services to overcome the ethical challenges of precision psychiatry
15:45-16:05	Q&A Stakeholders discussion *Tineke Mollema* GAMIAN-Europe, *Miia Männikkö* EUFAMI, *Jan Wise* European Psychiatric Association

The output of this workshop consists of a white paper presenting a critical review of the evidence and practical recommendations to manage ethical barriers to precision and preventive psychiatry:

Fusar-Poli P, Manchia M, Koutsouleris N, Leslie D, Woopen C, Calkins ME, Dunn M, Tourneau CL, Mannikko M, Mollema T, Oliver D, Rietschel M, Reininghaus EZ, Squassina A, Valmaggia L, Kessing LV, Vieta E, Correll CU, Arango C, Andreassen OA; PSMD EBRA cluster. Ethical considerations for precision psychiatry: A roadmap for research and clinical practice. Eur Neuropsychopharmacol. 2022 Oct;63:17-34. doi: 10.1016/j.euroneuro.2022.08.001. Epub 2022 Aug 27. PMID: 36041245.

Strategy Planning Meeting with stakeholders, January 28th, 2021, online

To co-create the 3rd meeting of the PSMD cluster together with all important players in the precision psychiatry eco-system, the cluster coordinators organised a Strategy Planning Meeting with stakeholders including patient representatives.

Implementing precision and preventive psychiatry in Europe, September 21st, 2022, hybrid (Brussels and online)

This event was designed to highlight the urgent need to address the lack of parity between mental and physical health in European funding and to aid navigation of barriers to implementation of precision psychiatry. A representative from GAMIAN-Europe joined the panel discussion in session 1 (see session 1 agenda here below).

SESSION 1:	**The importance of precision psychiatry**
	Chair : Ole Andreassen
13:15 - 13:30:	Opportunities for brain research under Horizon Europe
	Tim Raemaekers, European Commission-Directorate General Research and Innovation
13:30 - 13:50:	Industry perspective on precision psychiatry
	Cornelia Dorner-Ciossek, Boehringer- Ingelheim
13:50 - 14:10:	Ethical considerations for precision psychiatry
	Mirko Manchia, Università Degli Studi di Cagliari, PSMD cluster
14:10 - 14: 45:	Panel discussion moderated by *Frédéric Destrebecq, EBC*
	Tineke Mollema, GAMIAN-Europe
	Jan Wise, European Psychiatric Association
	Paolo Fusar-Poli, PSMD cluster
14:45 - 15:00	Questions from the audience

This discussion evolved around how to advance the field while prioritising service user wellbeing and equity of access to mental healthcare, and how funders can best support this effort.

3.3.3. TRISOMY21 cluster

Consensus meeting, November 12th, 2020, online

The patient organization, the European Down Syndrome Association (EDSA) joined the TRISOMY21 consensus meeting. The focus of the meeting was to bring together the leadership of the TRISOMY21-cluster and several relevant stakeholders. They discussed priorities and opportunities for Down syndrome research and consensus was

built on research needs in the short and long term, and on main objectives and priorities for action. 24 participants joined the meeting. The outcome of this meeting was written down in a consensus document of which one part was focused on patient involvement (see here below).

"Patients and Industry Involvement

Down syndrome organisations are major stakeholders that have a key role in advocacy and awareness. The Trisomy 21 Research Society (www.t21rs.org) as already built strong means for engagement and involvement of persons with Down syndrome and their families, but they should be strongly involved in the process of research prioritisation and design.

Down syndrome is a new extremely attractive field for investment by industry and new technology companies. Industry is recognizing the need to focus more on disease-modifying therapies that target specific mechanisms of disease and the underlying pathophysiology, which is very strong in the Down syndrome field already leading to promising therapeutic targets. This should be promoted through dedicated funding programs.

Challenges for the future: *(i) involvement of Down syndrome organisations in research prioritisation through participation in funding decisions; (ii) involvement of persons with Down syndrome and their families as partners to researchers, clinicians and industry; (iii) implementation of adequate tools for co-creation research; (iv) increasing SMEs and biotechnology companies entering the field, allowing truly innovative approaches through specific funding programs (IMI); (v) means to promote access of industry to preclinical trial capabilities and expertise distributed throughout the TRISOMY21 network and to support the participation of industry to translational initiatives; (vi) educate on path to industry (spin-off, start-up); (vii) Involvement of regulatory agencies (EMA)."*

Thematic Workgroup on Down syndrome research priorities: Research infrastructures and biocollections, November 29th, 2021, hybrid (Barcelona and online)

On November 29th, 2021, the TRISOMY21-cluster came together in Barcelona (Spain) with representatives from all stakeholder groups including patient associations (i.e., EDSA).

Science and Society Symposium at T21RS conference 2022: June 11th, 2022, in-person (Long Beach, US)

During the 3rd activity of the TRISOMY21 cluster, a dialog was established between researchers and the families and Down syndrome associations. The agenda can be found here below.

8h30- 8h35- **Introduction**
Anne-Sophie Rebillat and María Carmona-Iragui, *co-chairs S&S Committee T21RS*

8h35- 8h40- **Opening**
Theresa Mabie

8h40- 9h10- **Presentations**

DS and Covid-19, including psychosocial impact
Dr. Sujay Ghosh, *University of Calcutta, India*

Therapeutics: IVIG treatment for regression
Dr. Jonathan Santoro, *Childrens Hospital Los Angeles, USA*

9h10- 10:00- **Panel discussion on research participation: Why families' participation in Down syndrome research is key and how you can get involved**

On the importance of research participation
Hampus Hillerstrom, *President & CEO, LuMind IDSC*

Introduction of the clinical trial networks
Hampus Hillerstrom, *President & CEO, LuMind IDSC*
Dr. Andre Strydom, *King's College, London, UK*
Dr. Michael Rafii, *University Southern California, USA*

Importance of Brain Biobank and how it works
Dr. Lotta Granholm, *University of Colorado, USA*

EBRA T21 cluster (EBRA)
Dr. Mara Dierssen, ***Centre for Genomic Regulation- CRG, Barcelona, Spain***
Dr. Marie-Claude Potier, ***Institut du Cerveau - Paris Brain Institute, France***

Testimonials from research participants in Europe and the USA
Coordinated by Dr. Isabel Barroeta, *Hospital Sant Pau, Barcelona, Spain*

Panel discussion with all the speakers
Moderated by Hampus Hillerstrom and Isabel Barroeta

10h00- 10h30- **Coffee break**

Patient Involvement in European Down Syndrome research, October 10th, 2022, hybrid (Brussels and online)

During the final meeting of the TRISOMY21 cluster, the newest advances in Down syndrome research were discussed as well as the engagement of people with Down syndrome and their families in research. The aim was to share the news on science and to better understand the needs people with Down syndrome that should drive further projects. 30 participants joined the meeting. The agenda can be found here below.

11:30 – 11:35:	Welcome and introduction
	Mara Dierssen, Centre for Genomic Regulation (CRG), Barcelona, Spain
11:35 – 11:45:	Recent Advances in Down Syndrome and European Health Data Space
	Mara Dierssen, Centre for Genomic Regulation (CRG), Barcelona, Spain
11:45 – 11:55:	Data Sharing: The Federated European Genome-Phenome Archive
	Babita Singh, Centre for Genomic Regulation (CRG), Barcelona, Spain
11:55 – 12:10:	Patient Involvement in Brain Research
	Joke Jaarsma, European Federation for Neurological Associations
12:10 – 12:20	A central European Registry for Neurology
	Joke Jaarsma, European Federation for Neurological Associations
Open Discussion:	**What can patients do and how?**
	With patient representatives and TRISOMY21 cluster members
12:20 – 12:25:	Advancing brain health: cognitive activation with non-pharmacological methods
	Jo Lebeer, University of Antwerp, Belgium
12:25 – 12:30:	Registries: what are the problems, and opportunities.
	Andre Strydom, Kings College London, UK
12:30 – 12:35:	Bio samples: opportunities and benefits. Are we yet there?
	Eugenio Barone, Sapienza University of Rome, Italy
12:35 – 12:40:	Patient involvement. Advocacy groups, guidelines
	Pat Clarke, European Down Syndrome Association
12:40 – 13:15:	Roundtable
13:15 – 13:30:	Next steps and actions
	Mara Dierssen, Centre for Genomic Regulation (CRG), Barcelona, Spain
13:30 – 14:30:	**Networking finger lunch**

The outcomes of this meeting will be published in a high-level peer review journal:

Potier et al. (submitted). Improving research for advancing treatments in Down syndrome. Lancet Neurology.

3.3.4. BRAINFOOD cluster

The overarching objective of the BRAINFOOD cluster is ultimately to positively impact on brain health by improving nutrition of European citizens based upon fundamental insights in the bidirectional links between brain health and nutrition.

BRAINFOOD-cluster core group meeting, September 30, 2020, online

The BRAINFOOD-cluster established a core group of external experts that aims to influence the EU agenda to improve brain health via nutrition and better understand the relationship between nutrition and brain health. The patient organisations EFNA and GAMIAN-Europe are part of this core group.

Stakeholder workshop, October 18-19, 2021, hybrid (Brussels and online)

Patient representatives contributed to the stakeholder workshop. The aim of this meeting was to reach consensus on problems and (knowledge) gaps in the field and to hear the different perspectives (i.e., researcher, clinician, patient, industry, health economy, etc). 16 participants joined the meeting. The patient specific agenda can be found here below.

16:00-16:30: **Patient/consumer perspective, prevention and how to communicate about nutrition**

- Patients' considerations on nutrition and mental health: how to influence?

  Erik Van der Eycken, GAMIAN-Europe, a patient-driven pan-European organisation, Brussels, BE

- Responding to consumers demand for evidence-based nutritional science affecting brain health

  Lucie Geurts, International Life Sciences Institute – ILSI, Brussels, BE

16:30-17:00: **Discussion on proving the potential**

Chairs: Suzanne Dickson, UGOT, SE; Suzanne Higgs, University of Birmingham, UK

The discussions and insights gained were written down in publication:

Adan RAH, Cirulli F, Dye L, Higgs S, Aarts K, van der Beek EM, Buitelaar JK, Destrebecq F, De Witte E, Hartmann T, Korosi A, Libuda L, Dickson SL. Towards new nutritional policies for brain health: A research perspective on future actions. Brain Behav Immun. 2022 Jul 20;105:201-203. doi: 10.1016/j.bbi.2022.07.012. Epub ahead of print. PMID: 35868600.

3.3.5. Predictive Model Systems (PREMOS) cluster

The primary objective of the PREDICTIVE MODEL SYSTEMS (PREMOS) cluster is to enhance the alignment of EU disease model development resources and preclinical research expertise with clinical and brain research community needs across academia and industry.

Stakeholder meeting on translational value of animal models, April 1st, 2022, online

During this meeting, the PREMOS cluster liaised with the PERMIT (PERsonalised Medicine Trials) project. First, the results of previous PREMOS cluster working group meetings and the results of the PERMIT (PERsonalised Medicine Trials) project were presented. After, the meeting attendees discussed about the suggestions on how to increase the predictive value of model systems for clinical trials resulting from this previous work of PREMOS and PERMIT. 25 participants attended this meeting.

The meeting outcomes were written down in an executive summary of which the patient relevant conclusions can be found here below.

1. It is important to invite patient organisations into preclinical research discussions because we need their input to make models relevant, as patients and clinicians do not always concur on what is a priority focus.

2. To achieve this, the language must be more accessible and common to non-experts in the field, and relationships with patient organisations must be nurtured.

3. We need to communicate openly and transparency to normalize the role of animal models in scientific research within the public consciousness.

4. Further discussion is needed on the question if primary endpoints for clinical trials should be based on the indicated quantitative biological and translational parameters used for back translation. Changing of primary endpoints would hamper meta-analyses, and there may be primary endpoints that are relevant for patients but not apt to back-translation.

Consensus meeting on translational value of animal models, July 1st, 2022, 10-13 CET, hybrid (Brussels and online)

On July 1st, 2022, the importance of animal research in neuroscience as well as the outcomes from the previous PREMOS cluster meetings was presented to the broader audience. Patient representatives (i.e., executive director EFNA) were included in the programme (see their contribution here below). In total, 18 participants attended the meeting in-person and 67 online.

10:20 – 10:30	Patient perspective
	Dr. Orla Galvin, EFNA Executive Director
11:25 – 11:55	Panel Q&A with the audience
	Moderated by Frédéric Destrebecq, EBC executive director
	Dr. Orla Galvin, EFNA Executive Director
	Dr. Sabine Hölter-Koch, PREMOS Cluster Coordinator
	Prof. Jean-Antoine Girault, FENS president
	Kirk Leech, EARA Executive Director

The outcome of this meeting has been published in the October edition of the Open Access Government journal: *Hölter, S. (2022). European brain research: Addressing translational gaps. Open Access Government.* https://www.openaccessgovernment.org/european-brain-research-addressing-translational-gaps/145399/

3.4. Patient involvement in specific EBRA events

In addition to the GA, the SEBRA working group and the cluster activities which included patient representatives/experts, there were some EBRA events organized with a specific focus on patient involvement.

3.4.1. Patient engagement in EU-funded brain research projects, March 16th, 2020

On March 16th, 2021, on the occasion of Brain Awareness Week 2021, the EBC, in partnership with EFNA and GAMIAN-Europe held an event on Patient Engagement in EU-Funded Brain Research Projects. The event aimed to shed light on the current state of patient engagement in EU-funded brain research projects, exploring how patients have been involved to date, their experiences in this involvement, the challenges continued to be faced, examples of patient-involved projects and initiatives and looking at what can be done to improve engagement. EBC, EFNA and GAMIAN-Europe were pleased to welcome over 100 participants. The event was opened by Prof. Monica Di Luca, Past-President of EBC, who – speaking as a basic scientist – highlighted the fundamental importance of patient involvement in research in order to gain knowledge from the lived experience of patients to boost research findings to work towards understanding and discovering proper treatment and cures for brain disorders. Patient engagement is a central force in many EBC activities, particularly in the EBRA project and in the EBC Policy Roadmap 'Brain Health in Europe: Fostering Innovation, Improving Outcomes' released on the day. The programme featured high-level representatives from patient organisations, policymakers and large-scale project leaders with projects focused or heavily committed to involving patients in all steps of their work. A full event report is available: https://www.braincouncil.eu/event-report-patient-engagement-in-eu-funded-brain-research-projects/

3.4.2. *Training Initiatives for Neurology Advocates [TINA] workshops*

In 2016, EFNA launched its TINA workshops. For many years EFNA has run workshops on Health Technology Assessment and, lately, Pharmaceutical Policy – Pricing, Access and Reimbursement at the London School of Economics. However, feedback from participants indicates that patients now need to be equipped to use the theoretical knowledge gained on these processes, and the wider research and development cycle, in a more practical way. For example, through the development of communication, advocacy and campaigning skills and the generation of patient evidence or patient reported outcomes. EFNA is also eager to ensure that the training activities are targeted to the neurology sector and the specific obstacles faced therein. Working with other stakeholders in the field e.g., neuroscientists, neurologists, industry, regulators and payers is part of our envisaged way forward. Under TINA, EFNA runs workshops annually for neurology patient advocates at both a pan-European and National level.

Neuroscience Research & Development: Influencing, Engaging and Optimizing Opportunities for Patient Involvement, December 3 – 4, 2019, Brussels

EBC and ERA-NET NEURON contributed to the EFNA event 'Neuroscience Research & Development: Influencing, Engaging and Optimizing Opportunities for Patient Involvement' in the session 'Neurology Patient Involvement in the EBRA'. Frédéric Destrebecq (EBC) presented the EBRA project and Hella Lichtenberg presented the recent development in NEURON.

All EBRA partners have contributed to the event to discuss the challenges for patient involvement in brain research. The agenda of the event can be found here below.

DAY 2		
09:00-09:10	Welcome back	Cathalijne van Doorne
09:10-09:35	Patient Involvement in basic research: Experience of a Parkinson's Researcher	Heather Mortiboys, University of Sheffield
09:35-10:00	Introducing the MULTI-ACT project Developing a collective research impact framework – focus on Multiple Sclerosis	Paola Zaratin, Coordinator, MULTI-ACT
10.00-10.25	The importance of patient engagement in EU-funded research	European Commission representative (TBC)
10:25-10:45	Break	
10:45-11:45	Neurology Patient Involvement in the: *European Brain Research Area [EBRA]* With contributions from: ERA-NET Neuron, EU Joint Programme on Neurodegenerative Disease Research (JPND), Human Brain Project (HBP) and European Brain Council (EBC).	Introduced and chaired by: Frederic Destrebecq, EBC – with: - Hella Lichtenberg - Alexandra Alves-Rodrigues - Lars Kluver - Monica di Luca
11:45-12:45	Polling and Panel Discussion – with interactive Q&A	All
12:45-13:15	Table discussions: *Facilitators for neurology patient involvement in European research initiatives*	All
13:15-13:30	Feedback, final comments and questions.	
13:30	Overview of two days and next steps…	Claire Nolan, Donna Walsh and Cathalijne van Doorne
After 13.30	Lunch and Departures	

3.4.3. ERA-Net NEURON workshops

ERA-Net NEURON Patient Training Workshop, April 20th and 21st, 2021 online

On April 20th and 21st, 2021 ERA-Net NEURON, EFNA and TINA organized a virtual lay reviewer/patient workshop with the aim to bring together people affected by neurological conditions, experienced funding panel lay reviewers and secretariat members from ERA-Net NEURON to discuss the role of patients, caregivers and family members in shaping and funding research. The workshop was attended by 22 participants.

ERA-Net NEURON Patient Training Workshop, April 25th and 26th, 2022, online

Due to the great success this workshop was again organized in April 2022 as virtual event with 24 participants.

3.4.4. Brain Innovation Days 2020, 2021 and 2022

EFNA and GAMIAN-Europe representatives attended the Brain Innovation Days 2020, 2021 and 2022 – also with support from a patient bursary to ensure all interested had a chance to take part in the events. During the 3rd digital event of the Brain Innovation Days in April 2021, “Fast-tracking brain innovation in times of COVID-19", people living with neurological and mental health conditions were asked to provide a testimonial on “My COVID-19 Year”, speaking on how the COVID-19 pandemic disrupted and reshaped their lives, treatment and care.

Additionally, patients and patient representatives were heavily involved in the communication and dissemination activities of the Brain Innovation Days, involved in the Brain Talks podcast series with episodes on patient-led policy and advocacy and the impact of COVID-19 on mental health services.

3.4.5. PPI workshop at the annual Dementia Forum X, May 27th, 2021, online

On May 27th, 2021, JPND held a virtual workshop at the annual Dementia Forum where participants gathered ideas and insights from the world's leading researchers, policymakers, and stakeholders in the field of dementia.

1. JPND Workshop on PPI: JPND Patient and Public Involvement (PPI) in Research Workshop | JPND (neurodegenerationresearch.eu)
2. A new PPI tab on the JPND website has been created to increase visibility of PPI: PPI | JPND (neurodegenerationresearch.eu)
3. New PPI videos featuring PPI expert, Professor Mogens Hørder, JPND's management board member and representative of member state Denmark, Mr Chris Roberts and Ms Jayne Goodrick can be viewed here: MH full interview – YouTube, Chris Roberts Jayne Goodrick full interview - YouTube

Here below, background information can be found on PPI in the JPND

In the last 20 years, Patient and Public Involvement (PPI) has become an indispensable component of health and healthcare research. The aim of PPI is to turn the focus of research towards the patient. The JPND developed a PPI strategy in 2015 for the implementation of PPI as part of JPND's annual calls and as a learning process, supported by a PPI expert Professor Mogens Hørder, JPND's management board member and representative of member state Denmark by Alexandra Rodrigues, PPI task leader in JPND.

With PPI, the patient becomes a partner in the planning and conduct of research. The patient has experiential knowledge from living with the disease, which complements the academic knowledge of the researcher. This partnership potentially widens the goal of the research to include the precise needs of patients. The patient may contribute to the various stages of the research project, from its design to its dissemination and finally, the implementation of the project outcomes.

The introduction of PPI in research funded through JPND calls understandably results in a wide variability in researchers' definition and knowledge of PPI, and an even greater variance in their experience of applying PPI to research. When JPND initiated its PPI strategy in 2012, has been seen as a learning process, firstly among the members of the Management Board and subsequently among researchers from the 30 countries. An Action group for PPI was established, leading to recommendations for a strategic approach to PPI. A JPND Advisory Group on PPI gave feedback to the recommendations for the implementation of PPI in JPND research by the Action group.

The implementation of PPI as part of JPND Calls was applied for the first time in the 2015 Call.

PPI is integrated in the Call Process through four steps:

Step one involves the application for funding by the pre-selected consortia. In the full application, researchers must describe how they have planned for PPI in the proposed project, if and how PPI is considered during the development of the idea for research and the conducting of the project.

Step two is a systematic review by a PPI secretariat of how PPI was planned by the consortia. The outcome of the review is a ranking of each application in one of the following three categories: A) satisfactory plan for PPI, B) plan for PPI may be improved, C) unsatisfactory or missing plan for PPI. The outcome of this ranking is considered by the scientific review panel as part of the overall rating of the application.

Step three involves the actual application of PPI by the researchers. Each research consortia with a proposal funded through JPND comprises partners from at least three different countries. The knowledge and experience of PPI differs greatly across the JPND member countries. Collaboration on PPI among the partners of the consortia supports the dissemination of knowledge and learning about PPI.

Step four involves the follow-up by the JPND PPI Secretariat on what took place during step three. This is done after year 1 and year 4 of the research project. From these follow-ups, information about the way PPI has been applied

is identified and can serve as shared information on the progress of PPI application over time. The most relevant part of this information will be available on the JPND website as support for future applicants.

Systematic review of PPI of the proposed projects for funding has shown that between 60 - 80 % of the proposals have a satisfactory plan for PPI. Less than 5% of these proposals have missing or unsatisfactory PPI.

After year one of funding, most projects still adhere to their plans for PPI. With respect to PPI conduct, often, only one representative country instead of every country of the consortium is responsible. As of now, more follow-ups need to be done to accurately assess the impact of PPI on projects (usually over a period of at least 5 years).

Over the next 4 to 5 years, knowledge, and experience from the 2016 to 2020 JPND Calls will be made available on JPND's website, providing a source for shared learning for all researchers taking part in projects funded through JPND.

3.4.6. Your next grant application methodological approach, April 27th – 29th, 2022, Berlin

The ERA-Net NEURON, as partner of EBRA, would like to strengthen the support of researchers in Responsible Research Innovation and Open Science. As fourth event of a series of successful workshops since 2019, the group collaborated again with the Quality, Ethics, Open Science, and Translation Center, QUEST at BIH/Charité to conduct an intense three-day workshop aimed at preparing the clinical and preclinical Principal Investigators (PIs) as well as Early Career Researchers (ECRs) to safely navigate **Public and Patient Involvement (PPI)**, data sharing, data management plans (DMP), ethical self-assessments, justification of animal experimentation, as well as detailed and statistically sound experimental design of projects. The workshop agenda was developed in close cooperation with QUEST, EBRAINS, ELIXIR and the MS Society, UK. The face-to-face event took place in Berlin, Germany on Wednesday April 27th to Friday April 29th, 2022. The participants included 22 PIs and ECRs of EBRA clusters (PSMD, TRISOMY21, and BRAINFOOD) and of ERA-NET NEURON funded projects from nine different countries. The event involved plenary lectures, practical breakout sessions, group discussions, individual consultations, and an eLearning session on DMP generation with the Data Stewardship Wizard. The Patient and Public Involvement (PPI) part across health research was presented by Annessa Amjad (MS Society, UK), PPI expert and trainer, followed by a hands-on case study training on how and when to involve people in research projects. The response to the workshop was overwhelmingly positive, with participants reporting a clear benefit of DMP generation, understanding the data sharing challenges and options in brain research, **and the benefits of Patient and Public Involvement in research**, as well as greatly improved confidence in the conduction of the scientific projects.

3.4.7. EBRA Final conference, October 11th, 2022, Brussels

The EBRA final conference was the opportunity to gather the community to celebrate the achievements of the project and plan for the bright future ahead. It was the occasion to bring the wider brain research community and key players together, to discuss key aims of the project. Together with "Translation from basic to clinical research" and "Digital innovation, technology and data sharing", "Patient involvement' was discussed as one the main priorities in brain research (see agenda of the panel discussion here below).

11:20 – 11:50	**Patient Involvement**
	Moderator: Philippe Amouyel, Chair of the JPND
	Joke Jaarsma, President at EFNA
	Erik Vandereycken, Project Manager at GAMIAN-Europe
	David Henshall, Coordinator of the EPICLUSTER

4. Patient involvement beyond EBRA

4.1. Feedback interviews with patient representatives/experts by experience

At the beginning of 2022, the EBRA team performed semi-structured interviews with patient representatives/experts by experience, involved in one or more EBRA activities to receive feedback on their involvement in the project. According to the Patient Engagement Quality Criteria, questions were developed in a way that each criterion could be analysed. The questions were shared beforehand via mail and discussed during a 30-minute interview that was recorded. These questions can be found in ANNEX I.

8 patient representatives/experts were invited for an interview. In total, 4 interviews (2 patient representatives/2 experts by experience) were performed and analysed, grouping all the comments according to the Patient Engagement Quality criteria.

All the interviewees (n = 4) were at least 2-5 days (n = 2) or more than 5 days (n =2) preparing and/or attending one or more EBRA activities. They were all involved in patient involvement activities on a weekly (n = 2) or monthly basis (n = 2). The feedback from both the patient representatives/experts by experience and other stakeholders involved (e.g., cluster coordinators) was overall positive (see table 2 below). In this table, we have grouped the positive and negative feedback according to the 8 PFMD criteria and added the number of people that mentioned these comments. In general, the feedback shows that it is important to have PPI as a formal part of a project/activity but that it takes time and resources to do it properly.

Table 2. Feedback according to PFMD criteria

	Positive	**Negative**
Shared purpose	It was great that patients were part of the governance of the project (n = 4). As patients know what is important for them, it is valuable to hear their voice talking about the purpose of the project.	The advisory board could have played an even more important formal role so that the pool of experts could have been larger (n = 1).
Respect & accessibility	Online meetings were more accessible for some given there was no need to travel and most of them were used to this (n = 3). Materials were accessible and sent well in advance (n = 3) and the EBRA website contained clear information (n =1). People felt respected and acknowledged (n = 4).	Online meetings were sometimes less accessible as someone mentioned it was harder to interrupt during an online meeting as patients are mostly underrepresented (n = 1). It would also be great to meet the people in person (this will happen during the last cluster meetings after the interviews) (n = 2) .
Responsibility & accountability	3 interviewees mentioned they felt responsible during the SEBRA workshop.	Expectations were not always clear during a cluster event (n = 1). More time was needed to provide input during a cluster meeting (n = 1).
Representativeness of stakeholders	The patient stakeholders were well represented during the SEBRA workshop (n = 2).	We often see the same people (small pool of expert patients) in the cluster events (n = 2). A patient description is needed. For example, do you need a patient expert from a specific disease area or do you need a more general representation. The advisory board could have played a role in defining this (n = 1).

Capacity and capability for engagement	This was well done during the specific PPI EBRA events (see 3.4) (n = 2).	No negative comment here.
Documentation and transparency in communication	2 interviewees mentioned they were thankful for the monthly communication meetings (n = 2). 2 interviewees mentioned they were thankful for the preparation material being sent (n = 2). 2 interviewees mentioned they were thankful for the reports being sent afterwards (n = 2).	Follow-up of deliverables was not always done by the cluster coordinators (n = 1). A follow-up call would have been nice (n = 1). Specific questions that would be asked to the patients before the meeting were missing (n = 2). This would allow them to better prepare and to ask other patients' input if needed (n=2).
Continuitiy and sustainability	For some cluster events the continuity and follow-up were good (n=2T-).	It was not always clear what the real value for the patient is when being involved in the cluster activities and what the continuity/sustainability were (n = 1).

4.2. Recommendations for patient involvement best practice

Based on the feedback interviews, general findings throughout the project and existing resources, recommendations for successful PPI were developed.

Two major general recommendations are:

1. **Patient engagement should not be just an add on to a work package on communication and dissemination:** Within the EBRA project, we showed it can be successfully linked to multiple work packages, so we should also discuss how to embed PPI in various work packages of an EU-funded project in addition to how to do single/specific PPI activities. Here below are some recommendations based on the resources and discussions/reflections we had.
2. **A patient engagement plan to support the operationalization of best practice patient engagement should be developed** containing information about the following topics:

- Governance of the project (e.g., how the patient advisory board or general assembly works)
- How patient engagement is linked to various work packages
- Resources (i.e., time, budget) needed (e.g., time and money needed to prepare everything well and to train stakeholders if needed)
- Clear expectations for all stakeholders involved; see more examples below
- Roles and responsibilities of people involved should be clear (e.g., patient organizations could be asked to support the translation of materials and to spread to their national nodes)
- Methods to ensure patient representativeness e.g., patient advisory board could define a "patient" description for each activity and ensure relevance of people chosen (either as an expert by experience or patient representative)
- Mechanisms to value and acknowledge patient's input; see more examples below

More specific recommendations can be found here below:

1. **Before a PPI activity**

    - Mapping needed from patient representatives/ experts by experience (e.g., is it more relevant to have people with lived experience from a specific disease or a more general patient representative's view)
    - Be prepared and think about what is really expected from the patient representative/expert by experience (e.g., do not send large materials but organize a preparatory call to discuss questions that will be asked during the activity)
    - Time is needed so that patient representatives can check within their community for experts by experience from a specific disease
    - Translation of materials might be desired
    - Don't just ask experts by experience to attend in order to disseminate what you are doing and to check a box

2. **During a PPI activity**

    - Make sure to make it as easy as possible for a patient to interrupt and provide input either during an online or in-person meeting; good moderation is needed
    - Acknowledge patient's input, respect, and make clear why you value their input
    - Go in discussion; don't just listen but ask if the patient's input is not clear

3. **After a PPI activity**

    - Make sure that materials such as reports, notes, deliverables, publications are sent afterwards to all stakeholders involved, including patients
    - Organize a call to follow-up on the activity and to ask for feedback
    - Think about the long-term value for the patient and don't forget to take into account the quality of life of the patient and not just pure research results

ANNEX I. Interview questions

These (or some of these) questions below will be discussed during the interview.

- How much time have you spent on the EBRA project in this context?
    - couple of hours
    - < 1 day
    - between 2-5 days
    - > 5 days
- Have you been involved in other 'patient involvement/engagement' events outside of EBRA? If so, how regularly
    - No
    - Yes
        - on a daily basis
        - on a weekly basis
        - on a monthly basis
        - on a yearly basis
        - less than yearly
- Do you have some feedback (positive and negative aspects) on your involvement/experience within the EBRA project?
- Do you understand the value of patient/patient advocates in the EBRA project?
- Were the EBRA activities accessible for you?
- How was the contact with the other cluster stakeholders? Did you feel heard, did you feel comfortable?
- Was your role in the meeting clear?
- Did you feel your presence added value to the meeting?
- When you received info (mails, supporting documents) from the clusters or EBRA consortium, was it clear?
- Were you given enough time to prepare, was there enough time for specific topics, was there enough time to interact?
- How was the follow-up (e.g., were you involved when a document was published)?
- Do you have any ideas on how to improve in the future?
- Did you benefit from this experience now and how or how will you benefit from these experiences in the longer term?