BRAIN
MIND
PAIN

Member of the
European Parliament
INTEREST GROUP ON
BRAIN, MIND AND PAIN

The Book of Evidence

2019–2024 mandate

STAKEHOLDER ENDORSEMENTS

COORDINATING PARTIES:

European Federation of Neurological Associations

Pain Alliance Europe

BRAIN, MIND AND PAIN SUPPORTERS:

European Alliance for Patient Access

European Academy of Neurology

European Brain Council

European Pain Federation

European Patients' Forum

BRAIN, MIND AND PAIN ENDORSERS:

ADHD
ADHD Europe

Ataxia
Euro-ataxia

Brain Tumour
International Brain Tumour Alliance

Dystonia
Dystonia Europe

Epilepsy
International Bureau for Epilepsy

Headache Disorders
European Migraine and Headache Alliance

Huntington's Disease
European Huntington Association

Multiple Sclerosis
European Multiple Sclerosis Platform

Myalgic Encephalomyelitis
European ME Alliance

Myasthenia Gravis
European Myasthenia Gravis Association

Neuromuscular Disorders
European Alliance of Neuromuscular Disorders Associations

Parkinson's Disease
European Parkinson's Disease Association

Post-Polio Syndrome
European Polio Union

Restless Legs Syndrome
European Alliance for Restless Legs Syndrome

Retinal Diseases
Retinal International

Stroke
Stroke Alliance for Europe

FOREWORD
EUROPEAN COMMISSION, DG SANTE
MARCH 2019

Non-communicable diseases, including mental health, neurological diseases and the often-associated chronic pain, constitute a major public health challenge. Thousands of lives are unnecessarily lost due to the impact of diseases that are largely preventable. Chronic non-communicable diseases are also the biggest threat to the sustainability of our health systems.

The Commission recently introduced a new approach to non-communicable diseases by joining forces with the EU Member States to identify together innovative solutions to tackle and prevent these diseases. Our new "best practices portal" invites stakeholders to submit best practices for evaluation. The selected ones are then made available to national authorities and the broader public. This new approach is part of a larger strategy to help improve the overall health of the population, reduce inequalities between Member States and regions, as well as to improve the sustainability of the health systems. These shared, collective efforts put the EU and its Member States in a better position to reach the nine voluntary targets of the World Health Organisation by 2025, and the United Nations Sustainable Development Goal 3.

I encourage NGOs to contribute to improving health in the EU through the Commission's Health policy platform, for example by increasing awareness of issues, by sharing information at their disposal and by jointly developing proposals for action.

The Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases is also an important vehicle to help countries reach the health-related SDGs. The Steering Group provides advice and expertise to the Commission on developing and implementing activities in the field of health promotion, disease prevention and the management of non-communicable diseases. It also fosters exchanges of relevant experience, policies and practices between the Member States. Mental health is the focus area for exchange of best practices in 2019.

I congratulate the European Federation of Neurological Associations and its partners – the Pain Alliance Europe and the European Parliament Interest Group on Brain, Mind and Pain – on this timely, informative and comprehensive book. When all actors concerned with non-communicable diseases join forces, we can make a tangible difference in the lives of patients across Europe.

Anne Bucher
Director-General
European Commission's Directorate General of Health and Food Safety

European Commission

I congratulate the European Federation of Neurological Associations and its partners on this timely, informative and comprehensive book

FOREWORD
EUROPEAN FEDERATION OF NEUROLOGICAL ASSOCIATIONS
MARCH 2019

Worldwide, many people suffer from Brain Mind and Pain (BMP) disorders. In Europe, this is definitely the case: hundreds of millions of people of all ages across Europe struggle with BMP disorders in their everyday lives. And while these conditions cause enormous suffering and disability, and the personal impact of BMP disorders cannot be overstated, this is often not fully, or at all, recognised.

The second edition of this Book of Evidence (BoE), a key policy document focusing on BMP disorders and an initiative of EFNA – the European Federation of Neurological Associations – and PAE – Pain Alliance Europe – is a highly valuable and important document, which points to the urgent need for more focus on the many issues surrounding BMP disorders. The BoE provides a clear insight into the urgency of the challenges facing people with BMP disorders, their carers and families. Concentrating on three key challenges that stand in the way of addressing the burden of BMP disorders and tackling each of these in a systematic way followed by clear policy recommendations, the BoE is a must read for policy makers, patient groups, and the broader stakeholder community alike.

It needs to be stressed that the recommendations in this BoE are of the utmost importance. Ensuring that the BMP initiative is capable of impacting policy discussions throughout the 2019-2024 mandate will be key in making progress in the areas identified. And progress is contingent on coordinated and national policy advocacy at an EU and global level.

While today, within the broader picture of value-based healthcare, it is becoming more and more clear that the socio-economic burden of BMP disorders is enormous and still growing, and the treatment gap for many BMP disorders remains high and needs to be addressed, the publication of this BoE could not have been more timely.

EFNA
EUROPEAN FEDERATION OF NEUROLOGICAL ASSOCIATIONS

Joke Jaarsma
President
European Federation of Neurological Associations

We are not working only for the patients of today but also patients of tomorrow

FOREWORD
PAIN ALLIANCE EUROPE
MARCH 2019

According the *Breivik report** one out of five persons above the age of 18 has chronic pain. Various surveys conducted by PAE and by peer organisations show that pain is much more than just a health condition. It is one of the most wide-spread reasons for which patients visit their GP. Chronic pain is, as a disease in its own right, a co-morbidity in a great variety of disease areas, many of them related to neurological conditions. The timeliness of a cooperation between EFNA and PAE to bring these domains to public attention is therefore obvious and commonsensical.

The Book of Evidence constitutes the cornerstone of all the activities of the Interest Group and of everyone who has an interest in changing policies for issues related to Brain, Mind and Pain disorders. The recommendations herein relate to existing policies and are the basis of actions intended to create new policies or amend existing ones in the interest of the patients affected by these conditions.

We are grateful for all the support received within the group and also from peers, politicians, decision-makers and patients themselves. We hope this support will continue and increase in order to create, in harmony, a single voice to speak up and initiate actions aiming to diminish the impact of pain on society and influence the way health and social care resources are spent.

Pain Alliance Europe encourages the community thus generated – of carers, sympathizers, co-workers, employers, healthcare professionals, industry – to stick together no matter what the reason that brought them to this cause.

We need to keep in mind that we are not working only for the patients of today but even more for tomorrow's patients. Considering the current situation, where life expectancy is increasing, as we go into old age most of us could become a Brain, Mind and Pain patient in the future. So your work today will support you tomorrow. Join us!

Joop van Griensven
President
Pain Alliance Europe

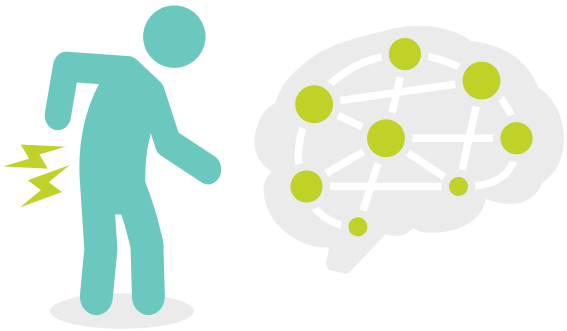
* Breivik,H, Eisenberg, E and O'Brien, T, The individual and societal burden of chronic pain in Europe: the case for strategic prioritisation and acting to improve knowledge and availability of appropriate care BMPC Public Health, 2013

CONTENTS

2 An introduction to brain, mind, and pain disorders
3 Executive summary
4 What is the Brain, Mind and Pain initiative?
4 Key focus areas for change in the 2019-2024 mandate
5 Policy context
6 Focus area 1: Eradicate stigma, isolation, and discrimination
11 Focus area 2: Ensure equitable access to treatment, services, and support
16 Focus area 3: Promote patient empowerment for increased involvement and engagement
22 Advocacy map for 2019-2024 mandate
23 Conclusion
23 Acknowledgements
24 References

AN INTRODUCTION TO BRAIN, MIND AND PAIN DISORDERS

Throughout this Book of Evidence, the term Brain, Mind and Pain (denoted throughout as 'BMP') disorders is a term understood to encompass both neurological and chronic pain disorders.



WHAT ARE NEUROLOGICAL DISORDERS?

In this BoE, neurological disorders are understood as non-communicable and often chronic conditions of the central and peripheral nervous systems.[1]

Some neurological disorders, such as cerebral palsy, are present from birth, while others such as Alzheimer's Disease are more prevalent in older people. Examples of other common neurological disorders include epilepsy, multiple sclerosis (MS), and stroke. Some disorders, like migraine and brain tumours, typically give intermittent pain and also other symptoms, while others such as Parkinson's Disease (PD) involve a progressive neurodegeneration and loss of independence. These disorders affect individuals throughout their life-course, whether survival is long or short, meaning that the quality of care they receive at different stages can significantly impact their quality of life.

WHAT ARE CHRONIC PAIN DISORDERS?

Chronic pain disorders are conditions characterised by long-term pain, defined as 'unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage'.[2] Chronic pain disorders have numerous causes, with disorders such as fibromyalgia caused by nervous system dysfunction and chronic back pain caused by a musculoskeletal injury (involving the bones, muscles, or joints) or by neurological disorders such as MS. Autoimmune disorders, such as rheumatoid arthritis, are further causes of chronic pain.

Furthermore, pain is commonly connected with numerous chronic health conditions, such as cancer. Indeed, chronic pain is one of the most common co-morbidities of long-term illnesses.

THE ECONOMIC IMPACT OF BRAIN, MIND AND PAIN CONDITIONS

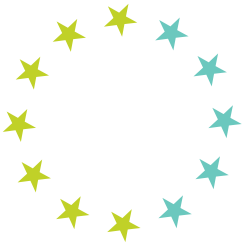
Including direct medical costs, e.g treatments for people with BMP disorders, direct non-medical costs, e.g nursing homes, and indirect costs, e.g lost work productivity, in 2010 the total annual cost of brain disorders in Europe was estimated to be around €800 billion per annum.[3] This is about 6% of GDP, of which 37% is direct healthcare cost, 23% is direct non-medical cost, and 40% is indirect cost.[4] The estimated direct and indirect healthcare costs for chronic pain disorders in the EU varies between 2%-3% of GDP across the EU.[5] In 2016, chronic pain disorders cost an estimated €441 billion.[6]

As life expectancy and medical costs increase across Europe, the prevalence and cost of BMP conditions are likely to grow simultaneously.

EXECUTIVE SUMMARY

Hundreds of millions of people of all ages across Europe struggle with BMP disorders in their everyday lives. According to the European Brain Council (EBC), over 220 million people in the EU suffer from neurological disorders.[7] In 2015, neurological disorders comprised 10.2% of global disability adjusted life years (DALYs), accounting for 16.8% of global deaths.[8] Based on the Thematic Network on the Societal Impact of Pain (SIP) figures over 150 million live with chronic pain.[9] The personal impact of BMP disorders cannot be overstated, with these conditions causing enormous suffering and disability.

Over 220 million people in the EU suffer from neurological disorders



Over 150 million people live with chronic pain

> **"Almost every other European has a neurological disorder ... the burden of neurological disorders in terms of DALYs is higher in Europe, making up 26% of total DALYs, than on a global level where neurological conditions account for 21% of DALYs".**
>
> Prof. Günther Deuschl, Past-President of the European Academy of Neurology (EAN), speaking at the EFNA and EAN policy roundtable on Lifting the Burden of Neurological Diseases in Europe, held in the European Parliament, 23 January 2019

This BoE focuses on the three key challenges which stand in the way of addressing the burden of BMP disorders in Europe, notably:

Stigma, isolation, and discrimination

Stigma, isolation, and discrimination: a lack of public awareness of BMP disorders feeds their stigma and the associated isolation and discrimination which affects the daily lives of BMP patients, carers and their families. This worsens the burden of BMP disorders by preventing people from seeking medical support and treatment for their condition. Employment, for example, is considered as fundamental to well-being and inclusion, however discrimination, exclusion and a lack of adequate support in accessing, retaining and returning to employment is very often a challenge experienced by those affected by BMP disorders. Therefore, tackling stigma and the associated isolation and discrimination through campaigns and, where possible, policy action are key concerns of the BMP initiative.

Access to treatment, services, and support

Large health inequalities persist in the EU and many patients do not receive timely diagnosis and access to effective treatment. Recent data such as the 2018 PAE survey on chronic pain, reflects the impact of suboptimal access to treatment on patient lives and their ability to work in particular.[10] Ensuring equitable access to treatment, services, and support is thus a key area of advocacy for the BMP initiative.

Patient empowerment, involvement, and engagement

Despite patient-centred clinical research and care models having demonstrated better quality of care as well as potential long-term cost-effectiveness, treatments for patients with BMP disorders have been referred to as 'the most under-used resource in the health system'.[11] To make real progress, empowerment through knowledge and training is vital so that patients can be involved in policy decisions and engaged in key processes which affect them such as research, clinical trial design, health technology assessment (HTA), and the delivery of care.

With a view to overcoming these challenges, the BMP programme presents the BoE for the 2019-2024 mandate. The purpose of the BoE is to identify the key challenges facing people with BMP conditions, based on evidence from the BMP initiative and its partners, highlighting how policy makers, patient groups, and the broader stakeholder community can address these challenges through policy-focused advocacy at an EU and global level.

The BoE is a living document which will be periodically updated to reflect major updates in order to ensure its continued relevance throughout the 2019-2024 mandate.

WHAT IS THE BRAIN, MIND AND PAIN INITIATIVE?

The aims of the BMP initiative are to raise political awareness of the impact of neurological and chronic pain disorders in Europe and encourage patient centric policy solutions aiming to prioritise these disorders, decrease stigma, increase access to treatment, encourage research, promote patient empowerment, and improve quality of life overall.

As an initiative led by two patient organisations, the programme aims to ensure that its policy solutions are in line with patients' preferences and that their meaningful involvement is enshrined, and supported, in all arising policy actions.

These coordinating patient organisations are the European Federation of Neurological Associations (EFNA) and Pain Alliance Europe (PAE), both umbrella organisations representing national and European patient advocacy groups in neurology and chronic pain, respectively. The programme has established a cross-party, cross-national MEP Interest Group on Brain, Mind & Pain.

The BoE is commissioned by EFNA and PAE in order to inform and support the activities of the MEP Interest Group as well as other stakeholders associated with the initiative.

For further information:

Website: **www.brainmindpain.eu**
Email: **info@braindmindpain.eu**

KEY FOCUS AREAS FOR CHANGE IN THE 2019-2024 MANDATE

In the 2019-2024 mandate, the BMP initiative has collectively agreed to focus on the following thematic areas:

- **Eradicate stigma, isolation and discrimination**
- **Ensure equitable access to treatment, services, and support**
- **Promote patient empowerment for increased involvement and engagement**

These areas have been chosen to support the MEP Interest Group in leveraging current policy opportunities on the agenda whilst ensuring continuity with the Group's past activity and successes.

KEY SUCCESSES OF THE 2014-2019 MANDATE

During the 2019-2024 mandate, it will be critical to build on the numerous successes of the BMP initiative in the past mandate. The key achievements of the BMP initiative during the past mandate include:

- **13 meetings in the European Parliament with an average attendance of 50+ participants from a multi-stakeholder background at each event – including active participation of MEP representatives from the EU Commission and many patient groups**
- **Over 50 MEP supporters for the Interest Group – as well as Commissioner Andriukaitis, who met the group and issued a statement of support**
- **A Written Declaration on access to employment supported by almost 180 MEPs**
- **Submissions to consultations on *The European Social Pillar*, EU Cooperation on HTA, Pathways for *Reintegration of Workers Following Injury or Illness*, Societal Impact of Pain Thematic Network, etc**
- **Accepted amendments to the EU Strategic Framework on Health and Safety at Work and the Joint Statement on Employment for People with Chronic Diseases**
- **Collaboration with multiple stakeholders with expertise in the BMP sector such as the European Brain Council (EBC), the European Academy of Neurology (EAN), European Pain Federation and others**
- **Invited to participate in Chrodis+ work package 8 (employment and chronic diseases) and Dying to Work campaign**

POLICY CONTEXT

EU policy context

The 2019-2024 mandate brings with it an active policy environment at EU level, with numerous opportunities for advocacy on behalf of people with BMP disorders.

For instance, policy activities which include health under a broader focus, and which primarily rely on implementation by EU member states, such as the EU Social Pillar and the European Semester, are clear opportunities to promote equal access to employment and the positive socio-economic impact of investing in treatment for BMP disorders.

There are a number of more specific hooks which hold great potential for improving the quality of life for patients with BMP disorders. In the digital health space, a number of policy actions are emerging from the European Commission's digital health communication, impacting issues from electronic health records to real world evidence. In the area of HTA, the legislative proposal on EU cooperation on HTA is an opportunity to impact access to treatment policy at EU level.

In terms of research policy, discussions are ongoing regarding *Horizon Europe* and the budget of roughly €7.7 billion is proposed to fund the *Health* cluster that is part of the pillar *Global Challenges and Industrial Competitiveness*. Equally important are the structure of the budget and the following procedures for processing and granting successful research funding requests.

Finally, the BMP group must build upon its collaborative approach to engaging with stakeholders in the neurology and chronic pain space. With organisations such as the EBC taking forward the *Value of Treatment for Brain Disorders* study and EAN developing the *Neuro-Care* project, collaboration will enable the BMP group to inform its activity with the latest evidence as well as contribute to the efforts of other stakeholders such as the European Pain Federation and the Societal Impact of Pain Platform.[12]

Ensuring that the BMP initiative is capable of impacting policy discussions throughout the 2019-2024 mandate will be key in making progress against the three key thematic areas identified. To this end, each chapter of the BoE contains a section on the policy opportunities and subsequent actions that can be leveraged to further progress under each thematic area.

Global policy context

In addition to activity at EU level, it is also important for the activity of the BMP initiative to be placed within the wider context of healthcare priorities at the global level. Historically, neurological disorders and chronic pain conditions have struggled to be included in initiatives on non-communicable diseases (NCDs). However, with the global priority turning more and more towards NCDs, we need to ensure that neurology is part of this conversation – looking beyond EU institutions and to the World Health Organization (WHO) and the Organisation for Economic Cooperation and Development (OECD), for example. To support this, the activity of the BMP group should align with work on the WHO's Sustainable Development Goals (SDG), especially SDG3.4 that aims to reduce premature mortality linked to NCDs by 1/3 by 2030 through better prevention and treatment as well as promoting mental health and wellbeing.[13]

The BMP initiative should also align with other relevant WHO initiatives, such as the Mental Health Gap Action Programme (mhGAP) which aims to scale up access to treatment and services for neurological disorders such as epilepsy.[14]

SUSTAINABLE DEVELOPMENT GOALS

SDG 3
Ensure healthy lives and promote wellbeing for all at all ages

SDG TARGET 3.4
By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being

SDG TARGET 3.8
Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all

FOCUS AREA 1: ERADICATE STIGMA, ISOLATION, AND DISCRIMINATION

What is 'stigma'?

The word 'stigma' is linked to a mark of disgrace associated with a particular circumstance, quality or person. As a consequence, the individual is often isolated, discriminated against, and their social identity deeply affected.[15]

Discrimination occurs when one person is treated less favourably than another is, has been, or would be treated in a comparable situation, based on a particular characteristic they hold or when an apparently neutral provision, criterion, or practice would put one person at a particular disadvantage compared with other persons.

Most people living with BMP conditions experience some level of stigma, but more awareness is needed about the impact that this has on their quality of life. Poor treatment outcomes and adherence are documented among individuals with stigmatised BMP disorders, resulting in a broad recognition of stigma as a legitimate barrier interfering with health and the delivery of care.

The challenge of stigma, isolation, and discrimination

The under-estimation of BMP disorder prevalence

The fact that BMP conditions are hidden behind a curtain of stigma means that their scale is likely to be, with the true prevalence and economic impact of BMP conditions not fully known by governments and healthcare systems. In turn, member states are unlikely to allocate BMP conditions sufficient national budgets and to develop policies and initiatives to aid the management of these conditions.

Lack of awareness of BMP disorders

Patients affected by well-known, but still widely misunderstood BMP disorders such as MS, PD, and epilepsy, often experience stigma due to the motor and non-motor symptoms, such as involuntary muscle spasms, tremors, and sleep problems, which are clinical manifestations of these conditions. However, this is even more of an issue in the case of rare conditions such as Guillain-Barré syndrome, ataxia-telangiectasia, and myasthenia gravis, which are unfamiliar to most healthcare professionals.

Lack of awareness and the associated stigma may cause some patients to conceal their disorder, leading to less social awareness and a lack of understanding in society as a whole. This lack of awareness may also delay a person in seeking medical help, meaning that patients are unable to receive treatment and support in a timely manner. Thereby, a lack of awareness on BMP disorders delays diagnosis and enhances the chances for a misdiagnosis. For instance, 21% of women with MS were misdiagnosed before the disease was detected.[16]

Equally, we must not overlook the impact that a lack of awareness of BMP disorders can have on the carer community. For instance, a recent poll of carers for people with MS has shown that 50% of carers felt that people around them do not truly understand what it means to care for someone with MS, something which potentially compounds their isolation.[17] Additionally, over 54% of carers said that at the time of diagnosis, when they began their caring role, the healthcare professional (HCP) did not explain the disease, its progression, and potential care needs very well, meaning many carers felt unsupported and ill-prepared from the outset.[18]

Stigma and poverty

People with chronic conditions excluded from the workforce are at greater risk of poverty which, in and of itself, is a sustained deprivation of resources, choices,[19] security and life choices. On average, the incomes of people with disabilities are 12% lower than the rest of the population. In some countries, the incomes can be as much as 30% less.[20] Employment can minimise the negative financial impact of chronic illness and can also minimise the risk of social exclusion and poverty.

PATIENT TESTIMONIAL

Anneke Broere-Vonk, 40 year-old
Dutch woman suffering from fibromyalgia

"The doctor says it is as promised: there is nothing wrong with your head. It will be the same as with your other muscles and tendons, you have to learn to live with it.

That's it, you may go now. But how should I go on? It stays in your head. Though you look good and no one sees your pain and enormous grief. I would like to live for a couple of hours without pain, just to feel how it is to be a normal person again."

The 'invisible' nature of BMP conditions

Some BMP disorders are referred to as *'invisible disabilities'*, meaning that the symptoms of a particular condition are not visible or, at least, difficult for the untrained eye to detect. As a consequence, such conditions are generally misunderstood and not properly recognised by the general population.

Where symptoms are invisible, as is the case for many chronic pain disorders such as fibromyalgia, patients can be made to feel that the condition is not genuine and disabling, adding to the stigma. In PD, non-motor symptoms that are not immediately visible, such as mood disorders and hallucinations, can be easily misinterpreted and lead to discrimination against affected individuals.

PATIENT TESTIMONIAL

24 year-old living with myalgic encephalomyelitis (ME), chronic pain, and restless leg syndrome

"I hate asking for help, but I rely on the help I get to get by. I can't stand the stigma, no matter how hard I try to explain, it seems that they don't understand any better because I 'look' healthy. I feel like it's hard getting the help I need."

Access to employment

The stigma attached to BMP disorders in working age citizens can seriously impact their employment opportunities. Patients with neurological and chronic pain conditions can find it difficult to find and/or maintain employment not only because of the physical, cognitive, or behavioural problems linked to their disorder, but also due to stigma, isolation, and discrimination in professional settings. With MS, for example, 80% of those affected stop working within 15 years of diagnosis.[21] Equally, many people who have suffered a stroke are made to feel as though they must leave work during the most productive period of their lives – a major loss for the individual but also for companies and economies across Europe.

Fortunately, Manuela (see across) was supported to get back into work by her employer. However, 40% of the €800 billion cost of BMP disorders can be attributed to the loss of employment and associated social welfare costs.[22] By keeping people at work longer, we can reduce the economic impact, but also improve the quality of life of those affected.

In addition, those who stay in employment while suffering from BMP disorders often experience a loss of productivity while at work, a phenomenon called "presenteeism". This adds to the societal costs of BMP disorders but is often not considered in national statistics due to the difficulty in measuring its impact.[23]

PATIENT TESTIMONIAL

Manuela Messner Wullen, stroke survivor:

"I could not remember what to do, I was not able to recognise the people speaking to me on the phone; my memory and concentration did not exist, my foreign languages had been completely lost. I was in constant pain and always fatigued. I had no self-confidence, always questioning: where have my skills from before gone? I decided there was no option but to leave the company and so informed my boss. What a horror for my ego! I felt deeply depressed, furious, anxious, ashamed, isolated, and totally useless!"

What a horror for my ego! I felt deeply depressed, furious, anxious, ashamed, isolated, and totally useless!

FACTS AND FIGURES

Musculoskeletal disorders
Over 40 million EU workers have musculoskeletal disorders caused by their work, representing almost 50% of all absences from work of three days or more in the EU and 60 percent of permanent work incapacity.[24] The direct and indirect costs are estimated to be €240 billion a year, up to 2% of GDP across the EU.[25]

Epilepsy
People with epilepsy are more than twice as likely to be unemployed as the general population. However, this varies considerably between countries: in Poland, 49% of people with epilepsy are employed, compared with 77% in Germany.[26]

The psychological impact of stigma

Most people living with BMP disorders experience stigma, but little is known about the psychological impact that this has on them. A study on the association between levels of stigma and depression in people with MS showed that people experiencing greater levels of stigma reported more symptoms of depression and were more likely to be clinically depressed.[27] The study concluded that a better understanding of the ways in which stigma contributes to depression would be helpful in developing strategies to reduce its effect on health.[28]

CASE STUDY

Health Advocacy in a Digital World #BrainLifeGoals

In November 2018, EFNA ran a workshop for young patient advocates aged between 18-35 from across the spectrum of neurological disorders – some patients themselves, others working as advocates. During the event, participants discussed the results of EFNA's survey on young people living with a neurological disorder. The main challenges were shown to be access to treatment, isolation and stigma.[29]

How do we overcome these challenges?

Launching public awareness campaigns

To increase the understanding of BMP conditions among the general public, employers, and healthcare professionals across Europe, further public awareness campaigns at EU and national level are necessary. These campaigns should provide general and disease specific messages, aiming to make people more aware of the symptoms of particular disorders and the benefits of early diagnosis and treatment. Successful public awareness campaigns will help reduce stigma, encourage people to seek help for possible symptoms earlier, receive appropriate treatment and support and improve the quality of life for those affected. For disorders such as stroke, where early treatment is extremely important, increasing public awareness can be life-saving and highly cost-effective.

Adapting environments to accommodate BMP patients

Rather than viewing BMP disorders as simply 'dysfunctions' or 'disorders', people with BMP conditions should be able to find a place in society that values their experiences, out-of-the-box thinking, and memory skills. Rather than changing a person to fit the environment or other people's ideas of the norm, we should focus on adapting work, social, and consumer environments to suit people affected by BMP disorders in order to minimise their challenges and amplify their strengths.

Furthermore, to achieve supportive and inclusive working environments, an appreciation of the intersectionality of chronic conditions, exclusion and poverty and therefore cross-sectoral collaboration is vital to moving this issue to a point where the focus is on an individual's ability, first and foremost.

CASE STUDY

European Brain Employers

European Brain Employers is an international network of experts in the field of employees with AD(H)D, dyslexia, dyscalculia, autism, and giftedness. The objective is to identify ways for employers to enhance the management of these skilful employees.[30] Mainly active in the Netherlands so far, the network provides a model that could be expanded more broadly.

Engaging with the European Commission's employment and social rights legislation

European social legislation such as the *Employment Equality Framework Directive and the European Pillar of Social Rights* require consistent implementation by member states to help people with BMP disorders to stay in education and to drive equitable access to employment and non-discrimination at work. This should also include opportunities in the area of work-life balance, carer's leave, and broadening the discussion to include disability leave as well as sickness leave.

Further 'socialising' the European Semester process could also be effective in upholding the rights of BMP patients and any social and economic policy co-ordination at EU level should urge member states to include healthcare actions with a socio-economic benefit, including for those with BMP disorders, in their national economic and social priorities.

Engaging with the European Commission's renewal and implementation of EU level disease and disability strategies

CHRODIS+, the *European Joint Action on Chronic Disease and Promoting Healthy Ageing* across the Life Cycle, in its new cycle, will focus on the uptake and implementation at national level of the initiatives selected by CHRODIS to reduce the burden of chronic diseases. These include activities in the workplace on chronic disease prevention. Here, there is further opportunity to stress the economic benefit of reducing stigma and providing employment support for people with chronic conditions.

The *European Disability Strategy 2010-2020* will be also revised. Employment will certainly remain a priority area, but more can be done to ensure that the share of persons with disabilities working in the open labour market continues to rise, for example by promoting inclusive education and lifelong learning for pupils and students with disabilities.

The upcoming *European Accessibility Act* will aim to deliver benefits for persons with disabilities by removing barriers within the internal market created by divergent legislation, including barriers to accessing education and the labour market. A key concern is ensuring that discussions are informed by the issues faced by patients with BMP disorders.

Engaging with relevant funding initiatives

The *Youth Employment Initiative (YEI)*, as one of the main EU financial resources to support young people who are not in education, employment or training, should also be leveraged. According to the latest report on its implementation, more efforts are required on the part of member states to support young people with disabilities.

EU member states should also be encouraged to leverage the *European Structural and Investment Funds* to finance initiatives in the area of inclusive employment. According to the latest report on the implementation of the Funds, social inclusion saw a strong acceleration of project selection, reaching EUR 16.5 billion (26%).

Incorporating activity within a global policy context

Eradicating the stigma associated with people with BMP disorders is a means to recall and progress the SDG.4 goal. This goal seeks to reduce the premature mortality linked to NCDs by a third by 2010 through the promotion of mental health.

In addition, as of October 2018, the UN NCD agenda has expanded from 4x4 diseases and risk factors to 5x5, with the addition of mental health and [in some texts] neurological conditions.[31] The adoption of disease - specific resolutions in the neurological field, in epilepsy for instance, is a further important development. By achieving international recognition, this would raise awareness of the issues faced by people with BMP disorders and lessen their stigma.

POLICY RECOMMENDATIONS

To eradicate stigma, isolation, and discrimination, the BMP initiative:

- Calls for public awareness campaigns at EU and national level to ensure that the general public and healthcare professionals are aware of the symptoms of these disorders and the benefits of education, early diagnosis, and treatment for both patient and carers
- Supports EU and national campaigns to work towards adapting social, professional, and consumer environments to help people affected by BMP disorders, minimise their challenges and amplify their strengths
- Calls for the consistent implementation of the *Employment Equality Framework Directive* and the *European Pillar of Social Rights* by member states
- Supports the timely implementation of CHRODIS initiatives at national level by emphasising the economic benefits of reducing stigma and providing employment support for people with chronic conditions
- Calls on EU institutions to deliver a revised *European Disability Strategy* and a *European Accessibility Act* to deliver benefits for persons with disabilities by removing the barriers within the internal market created by divergent legislation, including barriers to accessing education and the labour market
- Calls for the EU and its member states to leverage the Youth Employment Initiative to support and fund education, employment, and training for people with BMP disorders
- Calls for the EU and its member states to leverage the European Structural and Investment Funds to finance initiatives in the area of inclusive employment, including those with disabilities, bringing them closer to the labour market
- Supports progress towards the SDG3.4 aim of reducing premature mortality linked to NCDs by one third by 2030 through promoting mental health and wellbeing

FOCUS AREA 2: ENSURE EQUITABLE ACCESS TO TREATMENT, SERVICES, AND SUPPORT

Access to treatment, services, and support

Access to treatment, services and support are always topics of concern for patients in Europe – particularly those living with BMP conditions – where high failure rates, delays in markett access, relatively expensive treatments and inequality in access are more prevalent.

Specifically, 'access to treatment' is understood in terms of timely and consistent access to the right treatment and medical interventions at the right time; 'access to services' as access to health services such as information portals and detection and diagnosis technology; and 'access to support' as access to care and counselling along the care pathway, including access to an effective and resourceful patient organisation. Limited access to any of these three key components not only causes poorer health outcomes and greater health inequalities but increases long-term costs for health systems.

As chronic pain manifests itself over time, it can get harder to diagnose and treat, requiring more resources and time causing particularly severe health consequences for affected patients. In addition, brain disorders are a root cause of chronic disabling diseases, often requiring treatment and long-term management of co-morbidities and relapse episodes. This underlines the need for a continuity of care approach linking health and social care for people suffering from BMP disorders.[32]

Challenges in access to treatment, services, and support

The reasons for limited access are diverse and include the underfunding of national health systems, HTA and reimbursement processes, clinical research design and health system organisation and ineffective use of existing resources.

Up to eight out of ten people affected by brain disorders remain untreated...

...even though effective treatments exist in many cases

The underfunding of treatment, support, and services

The European Union spends just over three Euros a year per patient on research into brain disorders, while access to treatment in various countries declines.[33] Underfunding massively impacts cost-effective BMP treatments being available for patients. For example, the 'treatment gap' in epilepsy, defined as the proportion of people with epilepsy who require treatment but do not receive it or receive inadequate treatment, varies from 10-20% in developed countries to 75% in low-income countries.[34]

HTA

As of January 2018, there is a legislative proposal on EU-wide co-ordination of HTAs with a focus on joint clinical assessment. This is in addition to Member States' continued investment in the development of HTA and value assessment procedures to make the decisions about access to, and reimbursement of, treatments.

However, there is still considerable variation between disorders and across Member States on the extent to which cost, supply, or other considerations dictate access to both new and established treatments for BMP disorders and their symptoms. These issues have already come to the fore in discussions over EU co-operation in HTA. For some conditions, notably chronic pain, patients in many Member States are unable to access even well-established and cost-effective treatments.

Looking ahead, it is also clear that HTA, as well as ensuring robust pricing and reimbursement systems, must be ready to support the arrival of innovative treatments for BMP disorders, such as Alzheimer's disease.[35]

Clinical research

On the clinical research front, there is greater scope to incorporate patients' views, encourage patient participation in clinical trials and ensure patients can access high quality information before and after clinical trials.

The Innovative Medicines Initiative (IMI) has supported projects such as EUPATI, PARADIGM, and PAINCARE to empower patients by creating channels for increased involvement in clinical research and promote the consideration of patient-reported outcomes. However, in reality, patient involvement and empowerment is negligible, urgently in need of both prioritisation and proper resourcing.

For many disorders, regulators now require evidence of patient engagement and how a treatment is changing patients' lives for the better, in addition to relieving symptoms. In neurological and chronic pain conditions, where external markers of disease progress are often absent, this is a positive step which re-orientates drug development towards the most patient-relevant outcomes. To facilitate this development, initiatives which support the collection of robust and high-quality real-world evidence can help better demonstrate the added value of treatment, furthering access to innovative treatments (see thematic area 3 for more information).

Health service workforce and organisation

The treatment gap – 'the number of people with an illness, disease or disorder who need treatment but who do not get it or receive inadequate treatment' is partly due to organisational issues such as delays in detection and diagnosis, a lack of healthcare professionals and a lack of follow-up care.[36] An estimated 3 to 8 out of 10 people living with a brain disorder are inadequately treated or untreated despite the fact that effective treatments exist.[37]

Access to treatment from the patient perspective

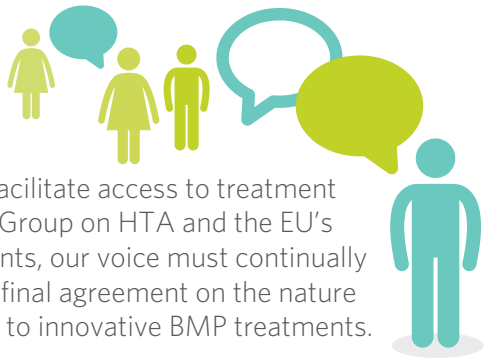
The 2018 EFNA survey of Young Europeans with Neurological Conditions: The survey findings show that a priority issue for young people affected by neurological disorders, including chronic pain is access to treatment. Specifically, many respondents call for quicker access to medication, more effective medication, or medication with fewer side effects underlining the fact that available treatment options are not optimal.

The 2017 survey on chronic pain by PAE: Performed in 17 countries, the findings highlight the treatment gap across Europe while pointing out that expectations of treatment are not met in 78% of cases from the perspective of study participants.

Additionally, lack of multidisciplinary pain education for the health workforce, including doctors, general practitioners, nurses, and physiotherapists, continues to impede improvement in the care of BMP patients. This is underlined by pain management not being a compulsory component of medical education in most European countries, with only 22% of medical schools offering a dedicated pain medicine module.

"Huge health inequalities exist when it comes to accessing the estimated 85,377 trained neurologists in Europe, with an estimated 3394 patients per neurologist in Germany in contrast with an estimated 34,325 patients per neurologist in Ireland".

Prof. Günther Deuschl, Past-President of the European Academy of Neurology (EAN), speaking at the EFNA and EAN policy roundtable on Lifting the burden of neurological diseases in Europe, held in the European Parliament, 23 January 2019



How do we overcome these challenges?

Ensuring a continuous focus on HTA

A continuous focus on HTA is necessary in view of the potential of HTA to facilitate access to treatment for patients with BMP disorders. Given the recent focus of the BMP Interest Group on HTA and the EU's moves towards increasing co-operation in the area of joint clinical assessments, our voice must continually be heard in these discussions. Patient involvement in policy discussions and final agreement on the nature of joint clinical assessments must be guaranteed and facilitate timely access to innovative BMP treatments.

Beyond EU co-operation in this area, the BMP initiative also encourages constructive stakeholder dialogue with national and regional governments on the need for action today to ensure that HTA and pricing and reimbursement systems are prepared for the arrival of innovative treatments in BMP disorders, such as Alzheimer's disease. It is important that this dialogue starts now to ensure access to new treatments once available.

Supporting patient engagement in clinical research

There is an increasing consensus that patient engagement in clinical research supports better patient outcomes and timely access to treatments. Thus, the BMP initiative supports a more patient-centred approach, involving them in 1) setting priorities, 2) clinical study leadership and design, 3) improved access to clinical trials, 4) preparation and oversight of the information provided to participants, 5) post-study evaluation of the patient experience, and 6) the dissemination and application of results. To achieve this, we must change the principles that underpin performing research for patients, but not with them. The graphic below outlines how this could be accomplished in practice.

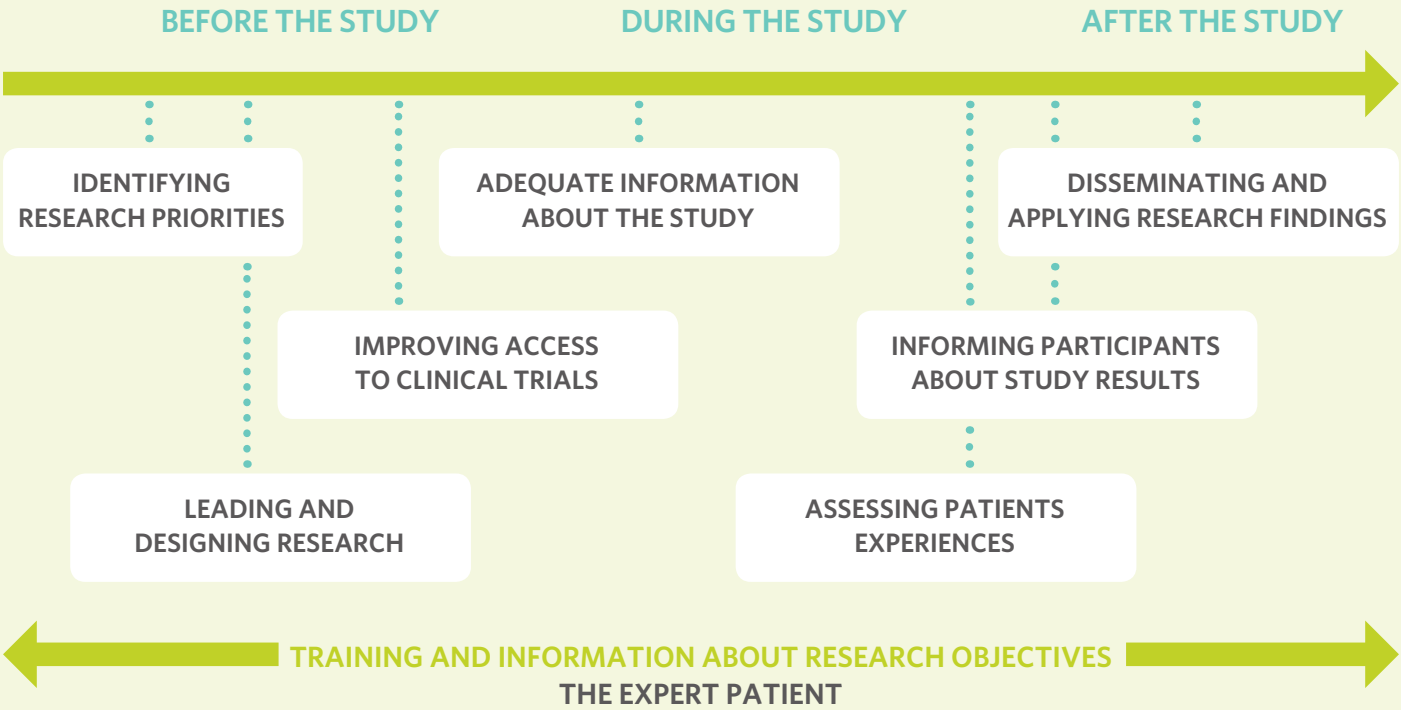


FIGURE 1: A Sacristan, J et al, Patient involvement in clinical research: why, when and how, Patient Preference and Adherence, 2016

Patient organisations should be in a position to provide appropriate, user-friendly information so that patients can fully understand what potential harms and benefits there are of participating, and what the results of trials would mean for them. Simultaneously, medical professionals, research organisations and pharmaceutical companies should be encouraged to promote a patient-centred approach to clinical research.

More broadly, robust strategies at national level and strong EU-wide co-ordination efforts are needed to effectively address the burden of brain disorders. This is why the BMP initiative supports the EBC recommendation for collaboration between national governments, patient representatives, scientific societies, and clinicians to establish National Brain Plans.

Supporting improvements in health service workforce and organisation

To facilitate the detection, diagnosis, and treatment of BMP conditions, better health service organisation is critical. To this end, we must continue working with national stakeholders to improve access to detection, diagnosis, and treatment, and reform care pathways to the benefit of patients. Furthermore, we must reinforce the importance of specialists for BMP disorders through specialised education programmes, within medica schools and postgraduate education programmes. Medical professional associations should be supported in promoting the education on BMP disorders amongst their members and support interdisciplinary medical care for better patient pathways.

The European Pain Federation developed an undergraduate core curriculum entitled: 'The Pain Management Core Curriculum for European Medical Schools' and two core curricula on pain for postgraduate learning: 'The European Pain Federation Curriculum for the European Diploma in Pain Medicine' and the 'The European Pain Federation Pain Curriculum for the European Diploma in Pain Physiotherapy'. Additionally, European Pain Federation is currently developing pain education curricula for nurses and psychologists.

Engaging with leading BMP initiatives on access to treatment, support, and services

To uphold the principle of equitable access across the patient population in Europe, new evidence emerging from leading initiatives in the BMP space should be leveraged to inform adequate policy actions that correspond to actual needs. Recent studies point at the lack of early diagnosis and timely intervention as well as the obstacles faced by patients living with BMP disorders, and the differences in access and care standards across the EU. Among these are the results of:

The EBC Value of Treatment (VOT) project: examining health gains and socio-economic impacts resulting from the best health interventions in comparison with current care standards, while mapping care pathways for different disorders.[39] The VOT projects also consider the importance of adherence to treatment, noting how non-adherence to antiepileptic drugs ranges from 40% to 60% of patients with epilepsy.[40] Mortality rates are more than threefold higher in non-adherent patients compared to adherent individuals with epilepsy.[41] Efforts to empower patients to engage in administering their own care are key in addressing this challenge (see thematic area 3 for more detail).

Forthcoming studies such as *Neuro-Care by EAN* focused on assessing the current situation in terms of the provision of treatment and healthcare services to neurology patients across the EU.

In addition, support for European Reference Networks, the virtual networks connecting healthcare professionals for rare neurological diseases (ERN-RND) and rare neuromuscular diseases (EURO-NMD), is key in facilitating knowledge sharing and good clinical practice about patient diagnosis, treatment, and care co-ordination.[42,43]

The EU and its Member States should continue to play an active role in developing and rolling out policy to support access to treatment, services and support

Incorporating activity within a global policy context

The EU and its Member States should continue to play an active role in developing and rolling out policy to support access to treatment, services, and support. In terms of the global context, action to eradicate stigma at EU level is an opportunity to recall and support progress towards the SDG3.4 aim of reducing premature mortality linked to NCDs by one third by 2030 through promoting access to treatment. There is also a clear opportunity to support the drive towards Universal Health Coverage for all by 2030 aas reflected in SDG Target 3.8 and EPF's UHC roadmap for 2030.[44]

POLICY RECOMMENDATIONS

In order to ensure equitable access to treatment, services, and support, the BMP Interest Group:

- Encourages the EU to coordinate the development of National Brain Plans with the aim of supporting brain research and improving the quality of treatment
- Supports meaningful patient involvement in policy discussions and final agreement on EU co-operation in HTA and joint clinical assessments to ensure that any agreement
  – reflects input from patients with BMP disorders
  – facilitates timely patient access to innovative treatments
- Encourages a patient-centred approach to clinical trials by educating patients and physicians, researchers and the pharmaceutical industry
- Prompts medical associations and national stakeholders to improve access to detection and diagnosis services and optimise care pathways for chronic pain and neurological disorders
- Calls for additional BMP specialists in national health system workforces to facilitate better support for patients
- Supports the implementation of ERN-RND and EURO-NMD as a means of promoting better access to treatment, services, and support
- Promotes digital initiatives focusing on the collection of quality and robust real-world evidence to enable research and actions that reflect real needs of people with BMP disorder
- Commits to the dissemination and operationalisation of the findings of other leading BMP initiatives to achieve high value for all BMP patient populations in terms of treatment, continuous care, and awareness of BMP disorders

FOCUS AREA 3: PROMOTING PATIENT EMPOWERMENT FOR INCREASED INVOLVEMENT AND ENGAGEMENT

Patient empowerment, involvement, and engagement

According to the *EU Joint Action on Patient Safety and Quality of Care (PsSQ)*, patient empowerment is defined as a "multi-dimensional process that helps people gain control over their own lives and increases their capacity to act on issues that they themselves define as important". Empowerment is therefore a means for more effective BMP patient involvement in policy areas which actively affect patients. Here, involvement is understood at two levels:

Individual
'the extent to which patients and their families or caregivers participate in decisions related to their condition and contribute to organisational learning through their specific experience as patients'

Collective
'the extent to which patients, through their representative organisations, contribute to shaping the health care system through involvement in health care policy-making, organisation, design, and delivery'[46]

The challenge of ensuring patient empowerment, involvement, and engagement

Health literacy

Health literacy, defined by the WHO as *"The cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand, and use information in ways which promote and maintain good health",* is a key issue when it comes to enabling patient empowerment.[47]

Patients, particularly those with long-term BMP conditions, many of which are still relatively poorly understood compared to major chronic diseases, need access to clear and reliable information. This will enable them to make sound decisions about their own health, whether to take part in research, and how to inform policy. Patients also need help understanding the potential risks and benefits of starting new treatments in the form of approved medicines or as part of a clinical trial. However, patients often lack awareness regarding the organisations that exist to help them and the information and services that these organisations offer. In many cases, it is easier to access misinformation or incomplete information from the internet.

More empowered patients make informed choices about optimal treatment and care, maintain better relationships with HCPs, and are more likely to adhere to treatment plans. All of these factors reduce healthcare costs in the long run.

Patient involvement in policy

Despite patients' ability to be involved in health policy and research discussions at EU and national levels, the actual outcomes and implementation of legislation often do not reflect this input

In recognition of this, EFNA co-signed a statement launched by EURORDIS calling for European institutions to adopt appropriate measures to fully incorporate meaningful involvement of patients in EU co-operation on HTA.[48] Such calls reflect how, to date, the extent of patient involvement has been inadequate in meeting the quality and legitimacy of recent legislation.

The digital health space is one key area where patient involvement is critical, given the potential of digital solutions to empower patients to take more control over their care and make more informed decisions.

Taking action to defend the principle of *"nothing about us, without us"* will, therefore, be critical in ensuring better patient involvement in the 2019-2024 mandate and beyond.

...the potential of digital solutions to empower patients to take more control over their care...

Patient engagement in the future of healthcare

Patients continue to be left out and under-consulted in clinical research. For key stakeholders, such as governments, researchers, pharmaceutical companies, regulatory authorities, HTA authorities and payers, key questions remain about who should be involved, in addition to how and when.

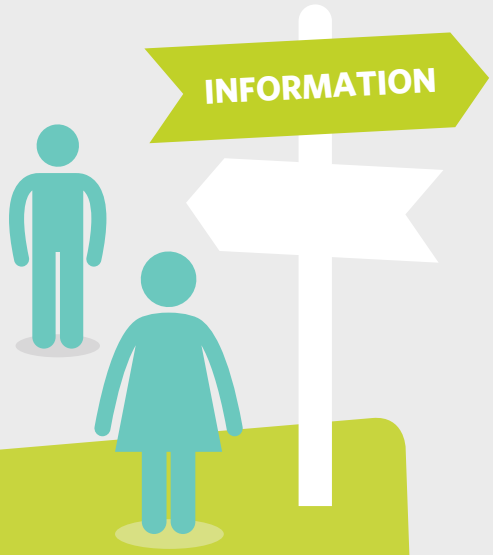
Although initiatives such as IMI-PARADIGM and PREFER show that there is increasing consensus among stakeholders that patient engagement at different points of the clinical research process is critical to fostering patient access and delivering better health outcomes, engagement is still inconsistent.[49]

Once again, in key horizontal areas such as digital health, the engagement of patients is unclear and inconsistent, something which may jeopardise successful digitalisation of healthcare for people with BMP conditions.

How do we overcome these challenges?

Increasing health literacy among BMP patients

Patients can only make informed decisions about their health if they are able to access all the relevant information in an easily understandable format. The two examples below reflect the importance of knowledge and awareness platforms in the empowerment of patients.



The European Patients' Academy (EUPATI) is a pan-European project implemented as a public-private partnership by a collaborative multi-stakeholder consortium from the pharmaceutical industry, academia, not-for-profit, and patient organisations.[50] EUPATI focuses on education and training to increase the capacity and capability of patients to understand and contribute to medicines research and development and also improve the availability of objective, reliable, patient-friendly information for the public.

In 2016, EFNA launched its **Training Initiatives for Neurology Advocates (TINA)**.[51] For many years EFNA has run workshops on HTA and, lately, pharmaceutical policy – pricing, access and reimbursement and patient advocacy in the digital world. Participants are trained to use theoretical knowledge for practical purposes; for example, through the development of communication, advocacy and campaigning skills and the generation of patient evidence or patient reported outcomes.

Engaging and involving patients in research policy

Meaningful patient involvement in research is particularly important in BMP disorders where:

- The most impactful symptoms and disease progression cannot be directly measured and must be assessed using questionnaires or interviews with patients
- Clinical scales against which outcomes can be measured are limited in trials and real-life practice
- Measured outcomes are often different between clinical trials and real-life practice which can lead to a disconnect in evidence
- External markers of disease progress are often absent
- Secondary symptoms are often more burdensome than primary ones (multi-morbidity)

PATIENT TESTIMONIAL

Cathalijne van Doorne on the importance of patient-preferred outcomes

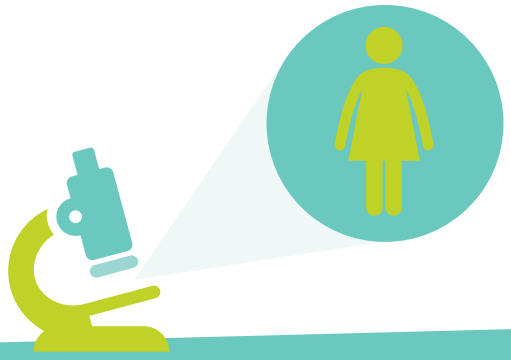
Cathalijne, a person affected by ataxia, gives an example of how what matters most to patients is not always the same as what matters most to researchers. Speaking to the BMP interest group on how the distance walked was used as an outcome measure when testing the effectiveness of an ataxia treatment, Cathalijne said:

"I did a survey on the most burdensome symptoms. Not being able to speak clearly is the most burdensome symptom. Not being able to communicate with your family and friends"

EBC, with support from EFNA, calls on the European Commission, the European Parliament and the Council to increase the budget of the *Horizon Europe* programme to at least €120 billion. Once Horizon Europe is finalised, active patient engagement in the distribution of research funding proposals should be a key principle and pre-requisite for successful funding policies.

Supporting patient focused research projects

As we move into the 2019 – 2024 mandate and work towards greater empowerment, we must continue to support research programmes which are grounded in patient engagement. Opportunities to do this include the European Brain Research Area (EBRA) project, created as a catalysing platform for brain research stakeholders to streamline and better co-ordinate brain research across Europe and the MULTI-ACT project which aims to increase the impact of health research on people with brain disorders by developing a new model of stakeholder cooperation.

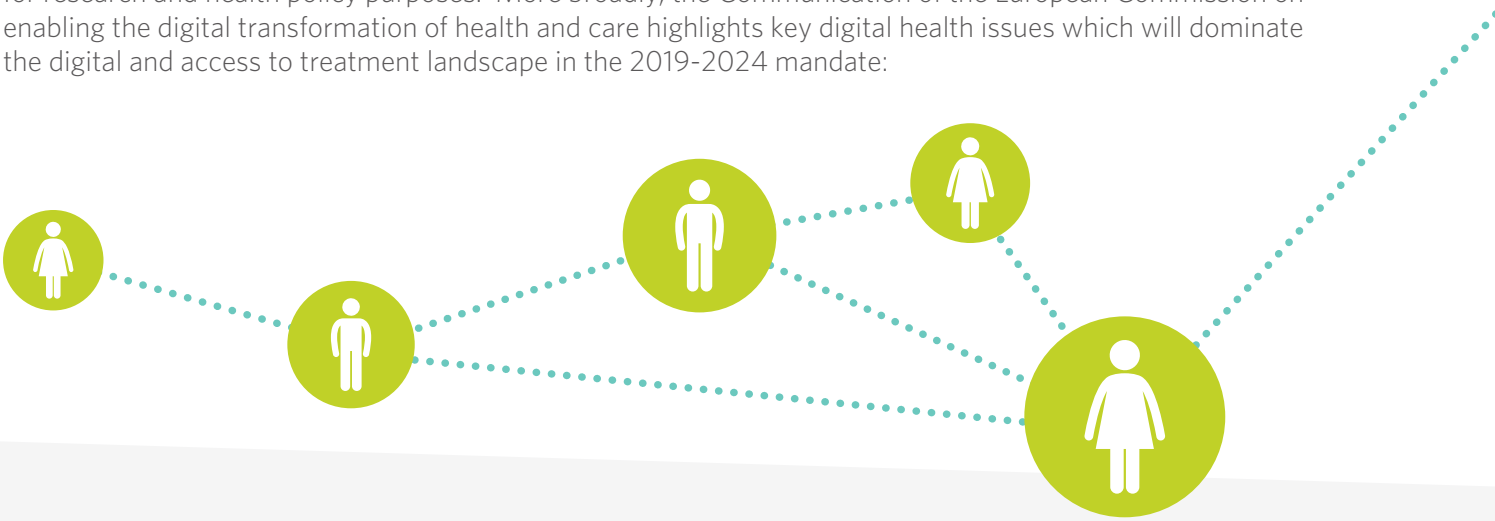


We must continue to support research programmes which are grounded in patient engagement

Engaging and involving patients in the digital health space

Digital solutions are key in empowering patients with BMP conditions to take control of their healthcare data, access safe and reliable online information, manage and personalise their care as well as interact with other people with the same or similar conditions. However, a recent public polling report on digital health in Europe by Incisive Health shows that barriers need to be overcome to turn this potential into reality. Notably, more than half of those polled cited data reliability and protection concerns and a lack of health system endorsement as barriers to their use of digital health technology. Patient engagement in the research, development and approval of digital health technology is at the core of addressing these issues in an effective way.

BMP disorders have been identified as a key challenge facing the EU and as an area where "digital tools for citizen empowerment and person-centred care" are necessary, such as cross-border health data exchange for research and health policy purposes. More broadly, the Communication of the European Commission on enabling the digital transformation of health and care highlights key digital health issues which will dominate the digital and access to treatment landscape in the 2019-2024 mandate:



POLICY FOCUS
REAL WORLD EVIDENCE

Policy action PILOT ACTION TO SUPPORT USE OF RWE AND UNITE DISPARATE INITIATIVES

Outcomes
- Support increased use of RWE to complement clinical trial data
- Fill gap between clinical knowledge and practice
- Better outcomes for patients

POLICY FOCUS
ELECTRONIC HEALTH RECORDS (EHRs)

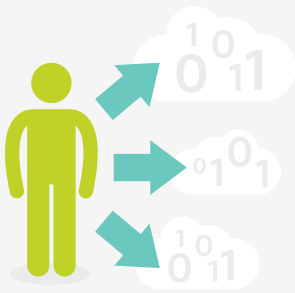
Policy action RECOMMENDATION FOR EHR FORMATS BY EARLY 2019

Outcomes
- EU-wide standardisation of EHR format
- Increase use of standardised EHRs
- Enhance citizen access to EHRs

POLICY FOCUS
BIG DATA

Policy action MECHANISM FOR VOLUNTARY COORDINATION IN DATA SHARING

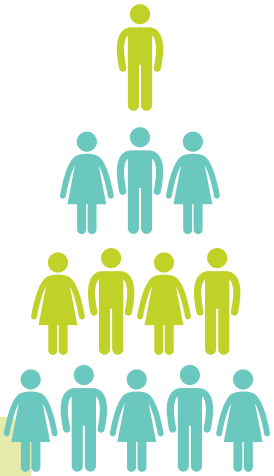
Outcomes
- Improve interoperability of health data and infrastructure
- Technical specification for secure access and data sharing
- Pilot actions on data pooling



It is key that patients, patient groups and policymakers are involved in the development and implementation of these actions by the Commission as well as national discussions on how to best incorporate them into national policy frameworks. This will facilitate a better digital health infrastructure, leading to improved research to underpin digital health initiatives and bolster the impact of existing initiatives. Of course, patient empowerment in digital health is a prerequisite for meaningful involvement and engagement in the above. This is why the BMP initiative is committed to working closely with its partners in the digital health space such as the European Patients' Forum which is coordinating a digital health working group focused on enabling patient centred digital health policy through concrete actions to support patient empowerment.[54]

Ensuring patient engagement in clinical research

The BMP initiative supports effective, meaningful, ethical, innovative, and sustainable patient engagement in areas such as research priority setting and clinical trials and the development of guidelines for industry, regulatory authorities and HTA bodies on how and when to include patient perspectives on benefits and risks of medicinal products (see focus area 2 for more information). Initiatives in this space must demonstrate the 'return on the engagement' for patients as well as other stakeholders involved both before and after clinical research.



MultipleMS is an IMI initiative, the purpose of which to is to develop, validate and use methods for patient stratification in multiple sclerosis.

To do this, the initiative:

- **Translates big data and basic research into evidence-based personalised clinical applications**
- **Combines multiple data types from several large clinical cohorts with publicly available multi-omics maps to identify biomarkers in a real-world setting**
- **Gains in-depth knowledge of distinct pathogenic pathways to allow identification of targets for novel treatments**

In terms of outcomes, MultipleMS aims to:

- **Unlock the potential of personalised medicine**
- **Utilise informed clinical decision support systems**
- **Provide biomarker-guided delivery of efficient therapies in stratified patient populations**

Incorporating activity within a global policy context

Progress towards greater patient empowerment at EU level is complementary to the achievement of SDGs, especially in view of the link between better patient empowerment, involvement and engagement and the prevention of and access to treatment for NCDs as targeted by the SDG3.4. In addition, the EU can look to the FDA's new guidelines on patient engagement as a starting point for EU action in this area.[55]

Progress towards greater patient empowerment at EU level is complementary to the achievement of the SDGs

POLICY RECOMMENDATIONS

To promote patient empowerment for increased involvement and engagement, the BMP Interest Group:

- Supports the development and dissemination of resources that allow patients to benefit from access to all the relevant information about BMP disorders in an easily understandable format
- Commits to continued support for initiatives and programmes which raise awareness and provide knowledge that empower patients to involve themselves and engage with decision makers.
- Supports the involvement of patients, patient groups and BMP policymakers in the development and implementation of the European Commission's digital health actions as well as national discussions on how to best incorporate them into national policy
- Supports active patient engagement in research as a key principle and pre-requisite for successful funding policies under Horizon Europe
- Calls for guidelines for industry, regulatory authorities and HTA bodies on how and when to include patient perspectives in clinical research
- Recalls the importance of achieving the SDG3.4 in view of the link between better patient empowerment, involvement and engagement and the prevention of NCDs/access to treatment for NCDs

ADVOCACY MAP

Please see below an advocacy map graphic based on the key live policy opportunities, associated policy actions and other BMP initiatives identified in the BoE. The purpose of the graphic is to consolidate the opportunities and actions to be pursued across the three thematic areas and provide an indicative timeline for this advocacy activity from 2019-2021. Given that the BoE is a living document, the map will be continually updated to reflect key policy landmarks and intelligence gathered by the BMP initiative.

POLICY OPPORTUNITIES

RESEARCH

HORIZON EUROPE 2021 – 2027

Ensure sufficient investment in BMP disorders

Advocate for a **'Brain Mission'** to overcome the challenges facing people with BMP disorders

Liaise with the European Commission concerning the **budget attributions for BMP** research funding as well as the **structure of the budget and funding flows**

Advocate for meaningful **patient engagement** to be a prerequisite of successful research funding proposals

EMPLOYMENT AND SOCIETY

EUROPEAN PILLAR OF SOCIAL RIGHTS

Advocate for consistent implementation on national level

Support people with BMP disorders to stay in education / work, advocating for **better work-life balance, carer's leave and disability leave**

EUROPEAN DISABILITY STRATEGY AND EUROPEAN ACCESSIBILITY ACT

Ensure a continued focus on the integration of people with BMP disorders in the labour market

Promote **inclusive education and lifelong learning** for pupils and students with disabilities and remove barriers created by divergent legislation

DIGITAL

EUROPEAN COMMISSION DIGITAL HEALTH COMMUNICATION

Support the involvement of patients, patient groups, scientific associations and policymakers to implement the following

Advocate for a **standardised format for EHRs** to be implemented on the national level

Support the national adoption of mechanisms for data sharing under the **big data policy focus**

Raise awareness on the need to **complement clinical trial data with robust RWE** to reflect the real needs of people with BMP disorders

BMP INITIATIVES

EVIDENCE FROM BMP INITIATIVES

Disseminate and operationalise the findings of leading BMP initiatives

Support the recommendations of **EBC's Value of Treatment (VOT)** programme to inform debate on the socio-economic value of treatments for BMP disorders

Support the **EPF Digital Health Working Group** in its efforts to **empower patients** across disease areas

Promote and leverage the findings of **EAN's** forthcoming **Neuro-Care study on access to treatment and services**

2019 **2020** **2021**

CONCLUSIONS

This BoE highlights the key challenges facing people with BMP disorders today, with a focus on three key areas for action:

- **Eradicate stigma, isolation and discrimination**
- **Ensure equitable access to treatment, services, and support**
- **Promote patient empowerment for increased involvement and engagement**

The content of the BoE reflects the scale of these issues and the impact that they have on people with BMP disorders, their families and carers on a daily basis.

It is now the responsibility of the BMP initiative to leverage the policy opportunities and pursue the policy actions identified in this text throughout the 2019-2024 mandate. Progress is contingent on coordinated policy advocacy at an EU and global level, taken forward by BMP initiative as a whole and its partners.

Using the BoE as a springboard for action, let's drive policy change and make a real difference to the daily lives of people living with BMP disorders across Europe!

ACKNOWLEDGEMENTS

EFNA and PAE would like to thank the following organisations for their valued contributions to the report: European Academy of Neurology, European Alliance for Patient Access, European Brain Council, European Pain Federation, European Patients' Forum.

The MEP Interest Group on Brain, Mind and Pain would like to thank the following sponsors for their support: Grünenthal, Merck-Serono, Novartis, Pfizer, Sanofi, TEVA, UCB. All sponsors were invited to contribute to the content of the BoE.

The BoE was developed by Incisive Health and informed by a number of resources including the original BoE developed by Dr Jenny Barnett of Punch Consulting.

INCISIVE HEALTH

REFERENCES

1 Communicable neurological disorders which mostly affect young people from 0-5 years age group such as meningitis, encephalitis, and tetanus are not within the scope of this document

2 International Association for the study of pain (IASP), IASP terminology, **https://www.iasp-pain.org/Education/Content.aspx?ItemNumber=1698**

3 Olesen, J et al., The economic cost of brain disorders in Europe. European journal of neurology: the official journal of the European Federation of Neurological Societies, 2010, **https://www.ncbi.nlm.nih.gov/pubmed/22175760**

4 Ibid.

5 Breivik, H, Eisenberg, E and O'Brien, T. The individual and societal burden of chronic pain in Europe: the case for strategic prioritisation and action to improve knowledge and availability of appropriate care. BMC Public Health, 2013, **https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-13-1229**

6 EuroStat, Eurostat News release, 2017, **http://ec.europa.eu/eurostat/documents/2995521/7962764/1-30032017-AP-EN.pdf/. 52/2017**

7 European Brain Council, Value of Treatment for Brain Disorders, 2017, **https://www.braincouncil.eu/wp-content/uploads/2017/06/EBC_white_policy_paper_DEF26072017_Low.pdf**

8 The Lancet Neurology, Global, regional, and national burden of neurological disorders during 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015, 2017, **https://www.thelancet.com/journals/laneur/article/PIIS1474-4422(17)30299-5/fulltext#seccestitle80**

9 Societal Impact of Pain, Thematic Network on the Societal Impact of Pain Framing Paper, 2018, **https://www.sipplatform.eu/files/editor/media/EU%20Initiatives/SIP%20Thematic%20Network/DRAFT%20Framing%20paper%20SIPv2%20-%2003072018.pdf**

10 Pain Alliance Europe, Survey on chronic pain, 2018, **https://www.pae-eu.eu/wp-content/uploads/2018/07/PAE-Survey-2018-Pain-And-Your-Work-Life.pdf**

11 European Patients' European, Patient Empowerment Campaign, 2015, **http://www.eu-patient.eu/campaign/PatientsprescribE/**

12 The scientific framework of the "Societal Impact of Pain" (SIP) platform is under the responsibility of the European Pain Federation, Cooperation partners are Pain Alliance Europe (PAE) and Active Citizenship Network (ACN). The pharmaceutical company Grünenthal GmbH is responsible for funding and non-financial support (e.g. logistical support)

13 World Health Organization, SDG 3: Ensure healthy lives and promote wellbeing for all at all ages, WHO, 2019, **https://www.who.int/sdg/targets/en/**

14 WHO, WHO Mental Health Gap Action Programme (mhGAP), WHO, 2019, **https://www.who.int/mental_health/mhgap/en/**

15 E. Goffman, Stigma: Notes on the Management of Spoiled Identity, Prentice-Hall, New York, NY, USA, 1963, **https://www.freelists.org/archives/sig-dsu/11-2012/pdfKhTzvDli8n.pdf**

16 Merck, The socioeconomic impact of MS on women in Europe, 2017, **https://www.merckgroup.com/content/dam/web/corporate/non-images/press-releases/2017/oct/en/The-socioeconomic-impact-of-MS-on-women-in-Europe-EN.pdf**

17 Eurocarers, The International Alliance of Caregiving Organisation, Merck, Living with Multiple Sclerosis: The carer's perspective, 2018, **https://www.merckgroup.com/content/dam/web/corporate/non-images/expertise/neurology_immunology/ms-inside-out/Living-with-Multiple-Sclerosis-The-Carers-Perspective-5-10-18.pdf**

18 Ibid.

19 Human rights, Health and Poverty Reduction Strategies: Health and Human Rights Publications Series, Issue No 5, 2008, **https://www.who.int/hdp/publications/human_rights.pdf**

20 Sickness, Disability and Work: Keeping on Track in the Economic Downturn, Background Paper OECD 2009, **https://www.oecd.org/els/emp/42699911.pdf**

21 Brain, Mind & Pain MEP Interest Group, Meeting report: How can the EU #makeworkwork for peoole with brain, mind, and pain conditions?, 2018, **http://www.brainmindpain.eu/how-can-the-eu-makeworkwork-for-young-people-affected-by-brain-mind-and-pain-conditions/**

22 Olesen, J et al, The economic cost of brain disorders in Europe. European journal of neurology: the official journal of the European Federation of Neurological Societies, 2012, **https://www.ncbi.nlm.nih.gov/pubmed/22175760**

23 The Work Foundation. Fit for work? Musculoskeletal Disorders and the Irish Labour Market, 2009, **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3281476/**

24 The Work Foundation, Reducing Temporary Work Absence Through Early Intervention: The Case of MSDs in the EU, Stephen Bevan, **https://www.bl.uk/britishlibrary/~/media/bl/global/business-and-management/pdfs/non-secure/r/e/d/reducing-temporary-work-absence-through-early-intervention-the-case-of-msds-in-the-eu.pdf**

25 Ibid.

26 Ibid.

27 MS research update, Stigma caused by MS contributes to depression, 2018, **https://www.mstrust.org.uk/research/research-updates/180409-stigma-contributes-depression**

28 Ibid.

29 European Huntington Association, 22 March 2018, Survey of Young Europeans with Neurological Conditions, **http://eurohuntington.org/2018/03/22/survey-of-young-europeans-with-neurological-conditions/**

30 European Commission, European Brain Employers, 2016, **https://ec.europa.eu/epale/en/blog/european-brain-employers**

31 United Nations, Political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable diseases, 2018, **http://www.un.org/ga/search/view_doc.asp?symbol=A%2F73%2FL.2&Submit=Search&Lang=E**

32 European Brain Council, Value of Treatment for Brain Disorders, 2017, **https://www.braincouncil.eu/wp-content/uploads/2017/06/EBC_white_policy_paper_DEF26072017_Low.pdf**

33 Ibid.

34 Ibid.

35 MSD, EBC, EFNA, Driving policy to optimise care for people with Alzheimer's Disease in Europe today and tomorrow, 2018, **http://www.brainmindpain.eu/wp-content/uploads/2018/11/Driving-policy-to-optimise-care-WEB.pdf**

36 European Brain Council, Value of Treatment for Brain Disorders, 2017, **https://www.braincouncil.eu/wp-content/uploads/2017/06/EBC_white_policy_paper_DEF26072017_Low.pdf**

37 WHO, Mental Health Gap Action Programme (mhGAP), 2018, **http://www.who.int/mental_health/mhgap/en/**

38 A Sacristan, J et al, Patient involvement in clinical research: why, when, and how, Patient Preference and Adherence, 2016, **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4854260/**

39 European Brain Council, Value of Treatment for Brain Disorders, 2017, **https://www.braincouncil.eu/wp-content/uploads/2017/06/EBC_white_policy_paper_DEF26072017_Low.pdf**

40 Ibid.

41 Ibid.

42 European Reference Network, Welcome to ERN-RND, 2019, **http://www.ern-rnd.eu**

43 European Reference Network, EURO-NMD, 2019, **https://ern-euro-nmd.eu**

44 European Patients' Forum, Taking Action – A Roadmap to Achieving Universal Health Coverage for All by 2030, 2017, **http://www.eu-patient.eu/globalassets/campaign-on-access/taking-action---a-roadmap-to-achieving-universal-health-coverage-for-all-by-2030.pdf**

45 PsSQ, adapted from Luttrell et al., 2009 and the Duque project, 2009, **http://www.duque.eu**

46 Ibid.

47 WHO, Track 2: Health literacy and health behaviour, 2018, **https://www.who.int/healthpromotion/conferences/7gchp/track2/en/**

48 EFNA, Patients call for meaningful involvement in European cooperation on HTA, **https://www.efna.net/patients-call-for-meaningful-involvement-in-european-cooperation-on-lth tech/**

49 Innovative Medicines Initiative, PARADIGM, 2018, **https://imi-paradigm.eu/our-approach/**

50 EUPATI, What is EUPATI, 2018, **https://www.eupati.eu/what-is-eupati/**

51 EFNA, Training Initiative for Neurology Advocates, **https://www.efna.net/training-initiatives-for-neurology-advocates-launch/**

52 Incisive Health, Taking the pulse of eHealth in the EU, 2018, **https://www.incisivehealth.com/wp-content/uploads/2018/08/Report-Taking-the-pulse-of-eHealth-in-the-EU-.pdf**

53 European Commission, Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, 2018, **https://ec.europa.eu/digital-single-market/en/news/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering**

54 European Patients' Forum (EPF), Call for interest to take part in new EPF Working Group on Digital Health, EPF, 2018, **http://www.eu-patient.eu/Members/Weekly-Mailing/call-for-interest-to-take-part-in-new-epf-working-group-on-digital-health/**. Core projects of the working group include a patient survey on EHRs and information resources on digital health

55 Food and Drug Administration, FDA Patient-Focused Drug Development Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making, 2018, **https://www.fda.gov/drugs/developmentapprovalprocess/ucm610279.htm**