



Appendix 2 – PAE General Assembly 2022

2022 Activity Updates and Activity Plans 2023

Pain Alliance Europe (PAE) will always aim to improve the quality of life of people with chronic pain in Europe and to be "the voice of people with chronic pain". We must keep in mind, however, that all planning for 2023 is subject to obtaining the necessary funding. Adjustments may be made during the year depending on the given situation.

PAE's activities can be divided into 2 areas our Core activities and the 3 Pillars that make up the main body of our work: Societal Impact of Pain, PAE Patient-Centered Innovation Grant (formerly BMP), and research collaborations.

Core Activities

The core activities of Pain Alliance Europe are those activities necessary to keep the Alliance functioning and meeting its legal obligations. These are:

- Organising one General Assembly per year, organising Board meetings, keeping minutes, receiving and sending out mail, and doing all other necessary secretarial work.
- Carrying out all necessary legal obligations that an organisation such as PAE is obliged to do under Belgian law.
- Keeping records of all financial transactions and presenting these records, audited by an accountant, to the General Assembly.
- To maintain and strengthen relationships with PAE's existing sponsors, and also to recruit additional sponsors.
- Organising and maintaining PAE's website, Facebook and Twitter accounts and all other social media areas; keeping member organisations and other organisations informed of our activities through our newsletter.
- Build relationships with our current partners, both health care professionals and patient advocacy groups, and seek to expand them.
- Maintaining relationships in the political arena, such as with MEPs, policymakers at Directorate-General for Health and Food Safety (DG SANTE), DG for Research and Innovation, DG for Employment, Social Affairs and Inclusion (DG EMPL), DG for Economic and Financial Affairs (DG ECFIN), and so on; with the European Commission and the European Council; and supporting members through the semester. Also maintaining and developing relations with European institutions such as the EMA and the OECD.



- Contributing to the public discourse on pain with some reoccurring publications in the Guardian supplement, Health Europa, and several stakeholder newsletters.

Our reputation and standing have gained recognition and respect in Europe. This has ensured that we are more involved in scientific research projects seeking funding under Horizon 2020/Horizon Europe/Innovative Medicines Initiative (IMI). We will not only be involved in scientific projects, but also serve on advisory boards, steering committees, and jury members for other stakeholders in the pain community.

3 Pillars of PAE's Work:

1. Societal Impact of Pain (SIP) Platform

In 2018, EFIC and PAE were invited by the European Commission to organise a Thematic Network on the Commission's Health Policy Platform. The Thematic Network brought together a large number of health stakeholders to work on a Joint Statement on the societal impact of pain. The Joint Statement was the most comprehensive piece of policy advocacy that the partners had committed to paper, and therefore serves as the underlying basis for most of its work going forward.

The Joint Statement covered the following areas:

1. *Pain as an indicator*
2. *Pain education*
3. *Pain in employment*
4. *Pain research*

2021/22 SIP Milestones:

In January 2021 SIP responded to the EU Commission Health Data Space Roadmap. In March 2022 we held a summit on Digital health where we launched the position paper. In August 2022 SIP's letter on the importance of ICD-11 implementation was published in the European Journal of Pain.

SIP has position papers in 4 policy areas: The EU Beating Cancer Plan, 'Healthy Workplaces' Health Data Space Roadmap, and ICD-11.

Social impact of Pain Stakeholders group on the EU Health Policy platform:

PAE, together with EFIC, runs the SIP stakeholder group. The aim of this group is to get as much positive noise about chronic pain as possible to influence policymakers. The SIP Stakeholders' Group will remain active in the coming years.

Upcoming events:

31 October 2022 - the annual stakeholder forum will take place online.

29 November 2022 - a forum on ICD-11, implementation, and results from the Roadmap Survey is free to attend online.

PAE in SIP will continue with its activities into 2023. Learn more here: www.sip-platform.eu.

2. PAE Pain Patient-Centred Innovation Grant: PAE PPCIG

Currently known as Brain, Mind, and Pain Patient-Centred Innovation Grant, we are in discussion of rebranding the grant for the 4th edition, as it is no longer in synergy with the BMP MEP Interest Group.

The European Federation of Neurological Associations (EFNA) had financial responsibility for the BMP MEP Interest group. In line with their strategic goals, they are renaming and reprioritising the MEP interest group to Neurological disorders. As an ENFA member PAE will remain active in keeping pain on the agenda within the interest group.

Pain Alliance Europe retains the BMP Patient Innovation Grant and will rename it according to our strategic priorities i.e. pain, while keeping patients at the centre. This is a great opportunity to expand the scope of the grant to all disease areas that involve pain as a significant symptom, and neglected disease areas such as pain in diabetes and in cancer survivorship. Therefore we will rename the grant to the PAE Pain Patient-Centered Innovation Grant (PPCIG).

The criteria will remain applicable to Brain Mind and Pain conditions and will state that the project must impact patients living with any health condition that involves pain as a symptom. This includes a wider breadth of conditions such as diabetes, long covid, and cancer while keeping at the core pain and neurological conditions.

The third edition was the first on the theme of self-management directly addressing sleep. The fourth edition will be self-management-focused again with a specific theme to be determined in that area, e.g., pacing.

To maintain and grow interest in the grant PAE would like to run workshops for our membership and network on how to apply to the grant and what successful projects look like ahead of the 4th Edition. The feedback we have received is that it is difficult for patient organisations to find academic or technology partners. They are also not familiar with leading a grant application.

Significant development is also necessary for the application and judging processes. The application criteria need to be clarified with weighting allocated to each category. In correspondence, the judging needs more effective scoring that is easily understandable and facilitates transparent and swift feedback to applicants. Outlines for the reporting structure and content for winning applications should be redeveloped so that it is easy to understand the completion requirements and standards.

We would also like to replicate and expand on the previous successful projects for example the StigmApp from the second edition needs to be converted from android to iOS and could be made available in other languages. This would mean allocating funding towards an extension or expansion grant only available to previous winners.

Further development of the dissemination of final project outcomes is also desirable. There is the opportunity for example to present posters(s) on the Pain Patient-Centered Innovation Grant (PPCIG) at EFIC's biennial Pain Congress and other significant pain academic and networking platforms. This could be achieved through the application of the grant secretariat or the specific project leaders



This new opportunity will require input from all the grant stakeholders, gathering feedback from previous applicants, juries, steering committees, winners and sponsors. The grant secretariat will be coordinating this in the interim year before the 4th edition starts.

3. Research Collaborations

New Research Projects:

PAE Europe-wide annual surveys

PAE has been conducting annual surveys since 2017. The response has grown each year. The topics addressed thus far are diagnosis and treatment, pain and working life, stigma, and digital health (e-health and m-health). In 2021 we repeated the diagnosis and treatment survey to compare the 2017 results. There was also 2 surveys on the impact of Covid-19 on Pain Patients. Due to survey saturation and decline in respondent numbers PAE did not conduct a patient survey in 2022. The 2023 survey will explore self-management of chronic pain in line with our over-arching focus on self-management in common years. The results of previous surveys can be found at www.pae-eu.eu/surveys.

Continuing Research Projects:

ITN ETUDE:

ETUDE stands for "Encompassing Training in fUnctional Disorders across Europe". This programme aims to identify underlying mechanisms, improve diagnosis and treatment and reduce stigma for patients with functional disorders. Functional Disorders (FD) are clusters of chronic somatic symptoms that currently cannot be linked to reproducibly observable pathophysiological mechanisms, such as Fibromyalgia. Functional limitations are as severe in FD as in well-defined chronic physical illnesses. Direct medical costs and indirect costs as a consequence of sick leave and work disability are high.

ETUDE recruited 15 Early Stage Researchers (ESRs) in the 10 academic and 1 non-academic institutions that make up the network, spread across six countries (Netherlands, Germany, UK, Denmark, Poland, and Italy). In addition, 19 academic and non-academic partner organisations will support the training and secondment of ESRs. PAE hosted 2 of these researchers in a 4-month secondment. They have recently launched their research call for participants. The projects aim to learn more about people with fibromyalgia's experience of stigma in healthcare and the impact of a fibromyalgia diagnosis. We continue to work closely with the project and the ESRs and will be part of the dissemination plan in 2023.

QSPainRelief:

QSPainRelief is an international collaborative research project funded by the European Commission that brings together 10 partner institutions from 5 European countries and the United States of America. The 5-year project started in January 2020 and uses an innovative



quantitative systems pharmacology (QSP) approach to pain relief to developing an effective combination treatment for chronic pain in individual patients. We PAE are part of the scientific and Ethical Advisory Board of the QSPainRelief project and are advising on certain work packages including the patient survey which will be launched in 2023.

European Brain Council (EBC) Value of Treatment (VoT):

The EBC VoT case study on Chronic Pain started on December 2, 2020, with the first meeting of the working group composed of experts from the European Academy Neurology (EAN), European Pain Federation (EFIC) and patient experts from Pain Alliance Europe (PAE).

The project involved developing a cost model for direct and indirect costs of three pain conditions: fibromyalgia, low back pain, and diabetic related neuropathic pain. PAE was instrumental in designing care pathways and ensuring the patient's reality was considered. We also developed patient narratives to accompany the pathways to show the real-life impact of pain and what effective treatment can look like.

INTEGRATE-Pain:

INTEGRATE-Pain, the "IMI-NIH Transatlantic Emphasis Group on Research And Translation-to-care Efforts for Pain," was established by the NIH HEAL initiative and IMI-PainCare to foster cooperation and consensus in the field of pain research.

Of the opportunities and priorities that INTEGRATE-Pain has established in recent years, a current area of focus is developing a consensus on a core set of patient-reported outcomes (PROs) for pain conditions (accounting for co-morbidities) because both NIH and EU pain leadership realised that they were independently working on selecting and implementing Core Outcome Sets (COS) for pain. Members of INTEGRATE-Pain believe that a consensus on common PROs and Patient-Reported Outcome Measures (PROMs) in clinical trials and clinical practice would enhance the pain management field. A consensus on PROs and PROMs between the U.S. and EU would allow for the comparison of quality and meaningful data in acute and chronic pain conditions, and across diverse populations (e.g. adult and paediatric). NIH and EU leadership have therefore asked the INTEGRATE-Pain Consortium to begin working on identifying and establishing a COS that could be used in both the U.S. and E.U. and ideally utilised around the globe.

Since the August 2020 virtual workshops, leaders from INTEGRATE-Pain have been collaborating on a [systematic literature review](#) to identify and examine pain-domain COS initiatives around the world. Initiatives and stakeholders came together on June 14, 2022, for a [virtual meeting](#) to discuss the results of the literature review and the possibility of launching a Delphi process for pain domains. INTEGRATE-Pain is also working on writing a paper that captures the discussions from the August 2020 meeting and explores the following areas of potential future collaboration: harmonisation of common data elements (CDEs); alignment across preclinical and clinical domains of disease models, co-morbidities,



and pain-specific outcomes; expansion and validation of biomarkers of nociceptive signal processing; and integration of preclinical and clinical studies to enhance therapy development.

In July 2022 the Delphi process began, and PAE recruited European patients to participate. The Delphi process is an iterative consensus method involving a series of questionnaires that are sent to relevant stakeholder participants (generally experts for a specific health condition). Participants in the INTEGRATE-Pain core outcome set (COS) development Delphi process will be asked to rate the importance of outcome domains on a questionnaire created by our steering committee. The goal of the process is to reach a consensus on the most important domains for all forms of acute pain, the transition from acute to chronic pain, episodic/breakthrough pain, and chronic pain. Most Delphi studies involve two-to-three rounds of voting. The Delphi technique is the most common method for rating the importance of outcomes and outcome measures for inclusion into a COS. This process and the project overall will continue into 2023.

OECD PaRIS Knee and Hip Replacement Project:

The project began in 2017 with a mandate from the Organisation for Economic Co-Operation and Development (OECD) Health ministers to make health systems more patient-centered. Previous president Joop Van Griensven was instrumental in representing the patient voice in establishing the patient advisory panel and guidelines. At the core of making health systems, more people-centered is our ability to systematically collect data on what matters most to patients. PaRIS is doing that in 2 ways:

First, PaRIS helps to accelerate and standardise the international monitoring of patient-reported indicators in areas where such indicators of health care quality and outcomes are already used. Countries within and beyond OECD collaborated to develop patient-reported indicators with 3 working groups focusing on hip and knee replacements, breast cancer, and mental health care

Second, PaRIS is developing a new international survey of outcomes and experiences for patients with chronic conditions who are treated in primary care or other ambulatory healthcare settings, where little is being measured at the present.

Currently, several registries have been established internationally to measure Patient-Reported Indicators Surveys (PaRIS) for patients who undergo a knee or hip replacement. There have been publications of the initial clinical findings from data derived from the registries. PAE is in discussion with the working group on how the patients' experience can be better represented - the human face to the data. We would like an analysis of the information materials provided to patients, and how were the questionnaires explained. An opportunity to highlight best international practices. In line with our agenda through SIP, we would also like to see registries adopt the ICD-11 coding and an implementation plan for the change. Work will continue into 2023.

New Research Project Proposals:

EU SafePolyMed <https://www.safepolymed.eu/>

Towards Safer Drug Treatment and Enhanced Patient Empowerment

The International research team sets out to provide physicians and pharmacists with innovative tools to increase drug treatment safety and educate patients on how to actively manage their own healthcare.

Adverse drug reactions (ADRs) are a major burden to our healthcare and economic systems. In Europe alone, approximately 197,000 deaths per year can be attributed to ADRs according to an assessment by the [European Commission](#). The regular use of five or more medications concomitantly (polypharmacy), the coexistence of two or more long-term medical conditions diseases (comorbidity), and genetic diversity have a major effect on drug efficacy and consequently, raise the incidence and severity of ADRs. Although drug-drug interactions (DDIs) and drug-gene interactions (DGIs) are highly interconnected, in clinical practice, they are still considered separate entities. Hence, a more holistic approach taking into account individual disease states and drug-drug-gene interactions (DDGIs) is needed.

Aiming to increase overall patient safety, the new research project “SafePolyMed – Improving Safety in Polymedication by Managing Drug-Drug-Gene Interactions” seeks to develop innovative tools to define, assess and manage DDGIs for physicians and individual patients promoting enhanced citizen education and empowerment. Bringing together twelve partner institutions from across Europe, SafePolyMed receives total funding of 5.6 Million euros under the European Union’s “Horizon Europe” Framework Programme for Research and Innovation.

The project has identified PAE as a key stakeholder in pain patient representation and has invited us to represent pain patients on the advisory committee and be part of the Patient Organisation Hub.

BrainStimPain

The BrainStimPain project aims to install ten early-stage researchers (ESRs) in a Doctoral Network doing frontline research on pain mechanisms in the brain and how they may be modulated towards normality by non-invasive brain stimulation. Beneficiaries and partners involved in the network are highly internationally renowned. Through an ambitious and interdisciplinary training programme, joint supervision of the ESRs, and secondments to non-academic settings, this project will deliver ESRs who can serve as first movers in a new generation of researchers capable of exploiting the synergies between different research disciplines and technologies to optimise and boost innovation, and advance pain neuroscience. The long-term perspective of the research, therefore, forms a basis for the next generation of pain management and is thus important for reducing the burden of pain on a personal and societal level.

The network includes eight academic beneficiaries within pre-clinical and clinical research, aiming at translational pain research within non-invasive brain stimulation, as well as non-academic partners (e.g. industry (TMS) and research associations).



DAHLIA Project COST Grant

The overall aim of the DAHLIA project is to develop, evaluate and implement a widely accessible digital behavioural health treatment to improve well-being in individuals with chronic pain. This project has already been established in Sweden and it would like to expand to other regions in the EU.

COST (European Cooperation in Science and Technology) <https://www.cost.eu/> is a funding organisation for research and innovation networks. Their Actions help connect research initiatives across Europe and beyond and enable researchers and innovators to grow their ideas in any science and technology field by sharing them with their peers. COST Actions are bottom-up networks with a duration of four years that boost research, innovation, and careers.

The DAHLIA project has approached PAE to make a joint application to COST to develop a network of all pain stakeholders to expand the project. If successful PAE will be instrumental in establishing this network at keeping the patient-voice central to all activity in 2023.

Conclusion

As described, the Board intends to take advantage of the reputation we have earned in the past and accomplish as much as possible for the benefit of people with chronic pain. We realise that we have set ambitious goals, but with everyone's support, funding, and the Board's determination, we believe we will have every chance of making this a success.