## Event Report: How can digitalising health services reduce the societal impact of pain?

On 31st March 2022, the **Societal Impact of Pain (SIP) Platform,** hosted a multi-stakeholder virtual event with over 100 registrants entitled "How can digitalising health services reduce the societal impact of pain?" The event was supported by MEP Cyrus Engerer (S&D, Malta); MEP Sirpa Pietikäinen (EPP, Finland); and MEP Susana Solís Pérez (Renew, Spain).

This event built on the **SIP position paper on Digital Health: Pain Assessment and Quality Indicators,** highlighting the importance of European institutions and national governments taking appropriate actions in the area of digital health and pain. The aim of this event was to identify gaps in digital health policies for people living with pain, and to provide recommendations for an effective implementation.

I. Introduction
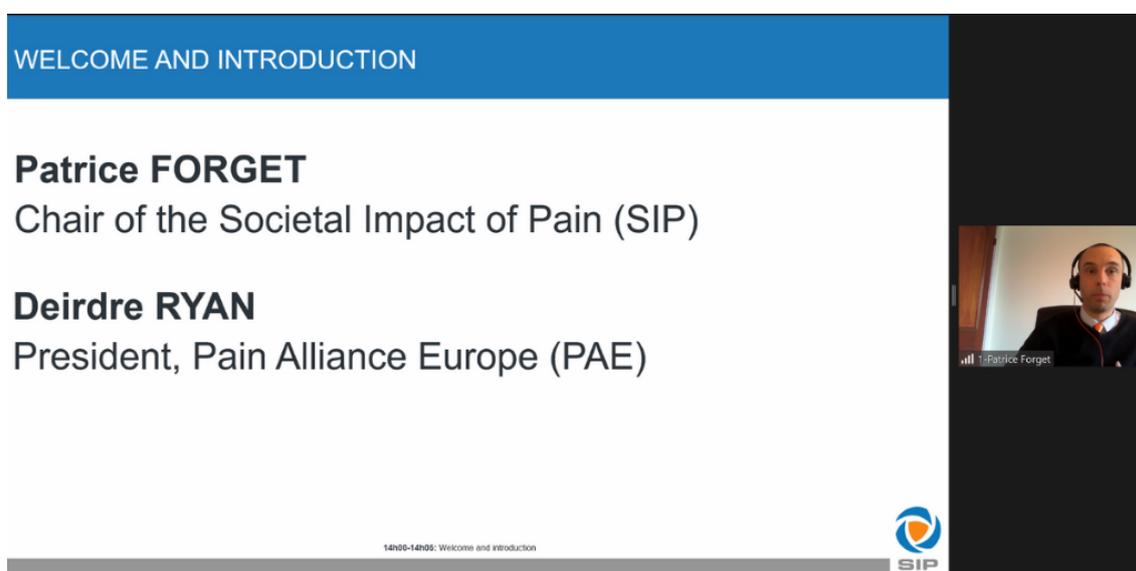
Patrice Forget, Chair of SIP, and **Deirdre Ryan**, President of Pain Alliance Europe (PAE), opened the event welcoming the audience and panellists, and presented the SIP Position paper on Digital Health: Pain Assessment and Quality Indicators, which was being launched on the day.

Jamie Wilkinson, SIP Project Manager, conducted a live digital health and pain policy quiz.

II. State of the art: digital health, pain assessment, and quality indicators

Esther Pogatzki-Zahn, European Pain Federation (EFIC), and Department of Anaesthesiology & Intensive Care at University of Münster, presented the state of the art with regards to Patient Reported Outcomes (PROs) and their uptake by the European Medicines Agency (EMA), as well as presenting the IMI-PainCare Initiative. Some studies, (such as 'Assessing outcome in postoperative pain trials: are we missing the point? A systematic review of pain-related outcome domains reported in studies early after total knee arthroplasty'), recognise the need for harmonising outcome domains. Esther also discussed the consensus of PROs to be assessed in clinical trials after surgery, and the core outcome set recommendations for PROs and PROMs for chronic pain trials. She concluded by suggesting next steps, in the form of the operationalisation of PROMs and the alignment and acceptance of PROs and PROMs for their use in clinical trials (EMA/FDA) and the real world.
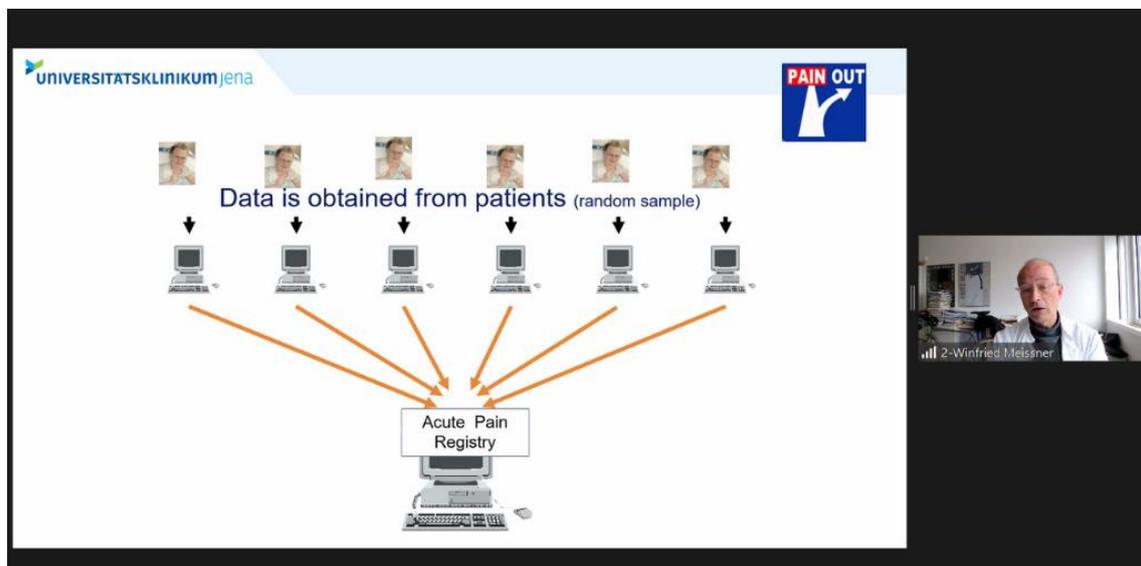
Winfried Meissner, European Pain Federation (EFIC), and Department of Anaesthesiology & Intensive Care at University Hospital FSU Jena, presented PROs as quality indicators, and best practices from PAIN OUT, (an international quality improvement and registry project that

provides a unique and user-friendly web-based information system to improve treatment of patients with post-operative pain, funded by the European Union). Winfried gave an overview of the project and explained how data is obtained from patients, and mentioned the different networks PAIN OUT works with. PRO-based feedback on quality is positive and effective, since it is the patient's voice, and that whilst digital tools are helpful in quality improvement efforts, personal contact remains just as important. Finally, Winfried acknowledged that composite scores, functional interference, and intensity of treatment, amongst others, can also be good quality indicators.

III. Patient perspectives on digital health

Deirdre Ryan, President of PAE, highlighted the important role health literacy, as well as digital health literacy, plays nowadays. Deirdre explained how vital it is to make sure patients understand how digital health tools work, so they are well informed and able to make appropriate health choices. It is important to learn from the past and to look back at what COVID-19 has taught society in terms of digital health literacy. It is imperative for Member States (MS) to standardise their health practices and health systems, to tackle the challenges of outdated systems and the use of ICD-11 and reported outcome measures, as well as the use of e-health records and telemedicine. Therefore, involving patients at every level is key to transform everything in the health sphere into the digital health sphere.

IV. Perspectives from MEPs

MEP Sirpa Pietikäinen (EPP, Finland), co-chair of the MEP Interest Group on Brain, Mind and Pain (BMP), stated that around 150 million people suffer chronic pain in Europe. She acknowledged the importance of providing all the necessary tools to healthcare professionals and patients in order to properly tackle this phenomenon. Additionally, the need to establish pain and pain-related functioning as a quality indicator in the development of instruments of pain assessment via the use of pain reported outcome measures (PROMs), was highlighted, as they are currently being underused. The subjective experience of pain must always be considered when discussing pain assessment and pain treatment. Finally, Sirpa acknowledged the importance of enhancing the availability of, and equal access to hybrid formats of pain management.

MEP Susana Solís Perez (RE, Spain), member of the European Parliament Special Committee on Artificial Intelligence in a Digital Age (AIDA), and Panel for the Future of Science and Technology (STOA), congratulated SIP on the launch of the new Digital Health Position Paper. Susana stated that 1 in 5 Europeans experience chronic pain, and acknowledged that the COVID-19 pandemic

has transformed health systems, shifting the way MS deliver medical treatment, and leading to an acceleration of the digitalisation of the health sector. Chronic pain patients are now able to access health services digitally, and this offers a unique opportunity to ensure better access and availability of diagnosis and treatment. Susana emphasised the importance of ensuring that these new services and infrastructures are complementary to, and support existing services. Susana also noted the important role the European Health Data Space (EHDS) will play in the exchange of health data and health delivery purposes. The EHDS will pave the way for more successful research, innovation, and policy making environment across Europe, ensuring that data is well protected, standardised, and interoperable, and it should be the European Parliament's main priority in the subject.

V. <u>Perspectives from Member States, Stakeholders, and the Commission</u>

Jerome de Barros, Policy Officer, Unit B3 – European Reference Networks and Digital Health, DG SANTE, European Commission, presented the European Health Data Space and gave an overview of the primary and secondary used of health data. The EHDS objectives are the timely and simplified exchange of, and access to health data for different use cases. For example, healthcare provision, access and control of patients over their data, cross-border exchange of health data, digital health services (including e-health and m-health), research, pharmacovigilance, public health, and policy making. Jerome also explained the legal basis for the EHDS, such as the Cross-Border Healthcare Directive, the GDPR, the Data Governance Act, the AI Act, the Data Act, the MDR and the eIDAS. Furthermore, Jerome highlighted that the EHDS is also being drafted to take into account input from different stakeholders, following a public consultation in 2021. The EHDS aims to allow patients to control their health data, unleash the data economy, ensure the interoperability and security of health data, as well as allowing the re-use the data for research, innovation, and regulatory decisions. Some of the main problems associated with the EHDS include the fact that individuals, as well as healthcare professionals, may have difficulties accessing and controlling health data, and that policy makers and regulators may not always easily access health data. Jerome also explained the 'MyHealth@EU' Initiative, (an online health portal currently active in 10 MS), is expected to grow rapidly in the years to come. There are two services available at the moment: patient summaries and e-prescriptions. However, this will be expanded to medical images, lab results, discharge letters

and other health information categories, and a pilot will explore the possibility of patient access to their health data within this portal.

Gertrude Buttigieg, SIP Malta, and Chair of the Malta Health Network offered the MS and patient perspective on digital health. Gertrude explained the benefits and the challenges of digital health in this regard. Telehealth facilitates access to health, for example, when it comes to long-distance healthcare, or when face-to-face encounters are difficult to arrange (i.e. people living in rural areas). Additionally, e-prescriptions have proven to be useful to save time and to facilitate cross-border healthcare, as well wearable devices, to help in self-management by tracking temperatures, glucose levels, and pain intensity for instance. E-prescriptions may not always work everywhere and different levels of digital and digital health literacy may also be a disadvantage for some. Additionally, it is important to understand who has access to such data. Digital innovations can help improve diagnosis, therapeutic and intervention options, as well as research. Digital health may provide a more sustainable healthcare in an era of growing demand and shortages of funds, time and healthcare professionals. The example of Jacqueline Sperling (Faculty of Harvard Medical School, McLean Hospital) was provided, where a clinical psychologist proved that online intensive group therapy for children with anxiety and OCD was just as effective as face-to-face sessions. Finally, Gertrude highlighted the importance of taking advantage of what the digital era has to offer, without losing site of important and relevant topics such as, digital health literacy, digital health, and health ethics, amongst others.

Andy Bleaden, Community Director, ECHAlliance, presented the European Connected Health Alliance (ECHAlliance), a global connector for digital health. Andy explained the role of their ecosystems, which bring together a permanent community of stakeholders to develop a joint health agenda, aiming to address and find common solutions to regional health challenges. The main benefit of working together in one of these ecosystems is the multiplier effect of collaborating in their International Network of Ecosystems, since they break down silos, transform healthcare delivery, and create economic growth.

VI. Breakout sessions – Recommendations

Session 1 – Uptake of patient reported outcomes by regulators

The session '**Uptake of patient reported outcomes by regulators'** was chaired by Esther Pogatzki-Zahn, EFIC, and Nadia Malliou, Board Member, PAE, and Hellenic League Against Rheumatism (ELEANA), and adopted the following conclusions and recommendations:

1. Implementation of ICD-11 & ICF by all EU MS for the digitalisation of healthcare services
2. PROMs need to be related to the ICD-11 diagnosis/condition - like disease specific PROMs (if available) and be validated
3. Pain as a quality indicator assessment by the use of PROMs, e.g., pain intensity and functioning as a COS (pain is subjective) to be used in clinical trials and real life
4. Patient- and clinician-friendly digital tools for health services and health and digital literacy – participation of patients at every step

Session 2 – Learning from each other and exchanging of best practices in digital health

The session '**Learning from each other and exchanging of best practices in digital health**' was chaired by Ruth Zaslansky, EFIC, and Winfried Meissner, EFIC, and Deirdre Ryan, PAE, and adopted the following conclusions and recommendations:

1. Promote the alignment of best practices for assessment and management from in-person care to digital health spaces (e.g., interdisciplinary and multimodal)
2. Establish standardised measurements throughout electronic medical recording and patient reported outcomes
3. Accommodate patients' expectations, assess patients' needs, plan proper and timely treatment plan to inform different stages of digital care

Session 3 – Digital Health Literacy

The session '**Digital Health Literacy'** was chaired by Nadja Nestler, EFIC, Harriet Wittink, EFIC, and Liisa Jutila SIP, Finland and Suomen Kipu Ry (Finnish Pain Association), and adopted the following conclusions and recommendations:

1. Foster the infrastructure for digital health literacy for all, including patients and HCPs, by including them in the development process of the systems, to ensure it covers their needs
2. Support the training and education of HCPs and patients and organisations, in order to contribute to the continued development of digitalisation of healthcare services/systems
3. Allocate adequate resources and funding for digital health literacy, to close the digital skills gap, and to address the importance of early and late learning
4. Ensure plain language, appropriate media, and that all materials are reviewed by patient groups

VII. Conclusions

Deirdre Ryan, President of Pain Alliance Europe (PAE), concluded the meeting by summarising the previously discussed topics and by thanking both participants and speakers, and inviting them to share and follow-up on the recommendations through their communications and social media channels. Deirdre restated the value of digital health and of ensuring Europe moves towards this new era without leaving anything, or anyone behind.
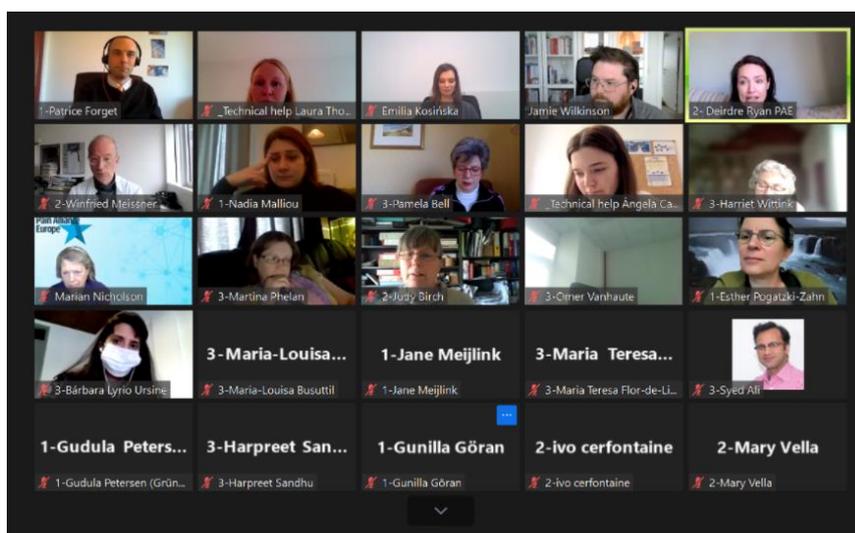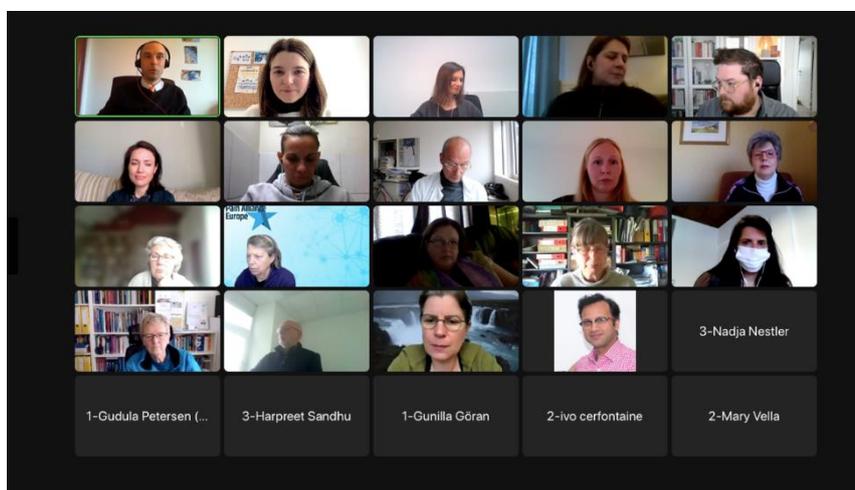
IX. About SIP

The 'Societal Impact of Pain' (SIP) platform is a multi-stakeholder partnership led by the European Pain Federation (EFIC) and Pain Alliance Europe (PAE). SIP aims to raise awareness of pain and to change pain policies. The platform provides opportunities for discussion for health care professionals, pain advocacy groups, politicians, healthcare insurance providers, representatives of health authorities, regulators, and budget holders.

X. Contacts

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