

## SIP response to the European Commission's Roadmap for A European Health Data Space

### Background

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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 scientific framework of the SIP platform is under the responsibility of EFIC, and the strategic direction of the project is defined by both partners.

**In Europe<sup>1</sup> there are approximately 740 million people<sup>2</sup>, most of whom experience an episode of severe pain at some point in their life.** For approximately 20 percent, that pain is chronic pain. In other words, 150 million people are experiencing pain across Europe, approximately equal to the population of France and Germany combined. In 2018, SIP published its Joint Statement<sup>3</sup> which includes recommendations for policy action highlighting opportunities for action and collaboration by the European Commission, Member States, and civil society to reduce the societal impact of pain. These recommendations are based on the findings of the SIP Framing Paper<sup>3</sup>. These recommendations form the over-arching and guiding principles for SIP, and are divided into four categories: **health indicators, research, employment, and education**. Regarding health indicators, one of SIP's key 2021 priorities is to explore the possibilities **for recording and measuring pain**, particularly in the context of the **digitisation of health services and systems**.

SIP welcomes the European Commission's Roadmap for A European Health Data Space, and below we have outlined several points for the Commission to consider for inclusion in future iterations of the initiative. We hope that these recommendations are seen by policymakers as useful to the development of the European Health Data Space initiative.

### A European Health Data Space: Opportunities to reduce the societal impact of pain

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SIP notes the following key goals of the initiative:

- To use digital health to provide high-quality care and to use digital health to reduce inequalities
- To promote access to health data, and movement of data with patients
- That citizens control their personal data

SIP takes particular note of the following objective:

*Objective 1: Ensuring access, sharing and use of health data for healthcare delivery purposes as well as re-use for research and innovation, policy-making and regulatory activities, in a privacy-preserving, secure, transparent and trustworthy way:*

*a) Establishing an appropriate legal and governance framework to cover the access to and exchange of health data for healthcare provision, research, policy-making and regulatory activities.*

*b) Lowering technical barriers hindering data use and re-use, in particular those related to infrastructure, interoperability, data quality and standards in the health field.*

In terms of **exchange of health data, interoperability, and health systems performance** and improvement, SIP asks the Commission to ensure that the future policy and regulatory environment permits and promotes tools to develop, share, and measure data on pain and its societal impact.

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<sup>1</sup> Note: data taking from 37 countries, absent in Andorra, Armenia, Azerbaijan, Belarus, Georgia, Iceland, Liechtenstein, Luxembourg, Malta, Monaco, and the Vatican City.

<sup>2</sup> Eccleston, C., Wells, C., & Morlion, B. (2017). European Pain Management. Oxford, UK: Oxford University Press, ISBN: 9780198785750 Available at: <http://oxfordmedicine.com/view/10.1093/med/9780198785750.001.0001/med-9780198785750-chapter-1>

<sup>3</sup> SIP Thematic Network – SIP Thematic Network 2018 – Joint Statement now available in several languages. Available at: <https://www.sip-platform.eu/resources/details/sip-thematic-network-2018-joint-statement-now-available-in-several-languages> Last accessed November 2020

## Pain as an indicator in digital health infrastructure

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***Recommendation: Ensure the initiative includes provisions to allow development of instruments to assess the societal impact of pain (pain as a quality indicator)<sup>4,5</sup>***

We ask to explore opportunities to build on existing instruments which are available to define, establish and/or use pain as an indicator in the assessment of healthcare systems' quality, and thus contribute to assessing the societal impact of pain. This will build on existing initiatives and opportunities to fill the data gap on the societal impact of pain.

Scientists, healthcare professionals, and patients in the pain field have identified various measurements and quality indicators which can help us better understand the societal impact of pain, including **patient reported outcome measurements (PROMs)**. Pain is ultimately a subjective experience, though as we move towards consensus on pain measurement via certain PROMs, this could become a realistic aspect of **electronic health records (EHRs)**. These tools should eventually become a standard part of health care systems organisation and could help us better implement patient mobility and the digitalisation of healthcare systems through EHRs. Additionally, pain as an indicator should be integrated in existing registries and prospective projects whether they are disease, exposure, treatment, or procedure focussed.

The most crucial recent development on pain as an indicator relates to the classification of diseases under the World Health Organisation (WHO) 11th revision of the **International Classification of Diseases (ICD-11)**. The new codification relating to pain, and especially chronic pain states, should be implemented throughout healthcare systems to improve analysis of performance, and provide the research community with data to facilitate further clinical research. It is only through a clear understanding of pain (acute, subacute, and chronic) and its management that the reintegration of people with disabling chronic pain conditions, into the workplace can be achieved as well as preventive strategies including in the early acute and subacute phases. Moreover, according to experts in the field, ICD-11 and ICF will not only contribute to the transformation of healthcare in the context of the Digital Single Market, but it will also be an important first step towards the practical roll out of the classification of chronic pain for morbidity documentation and health policy purposes (as embedded in ICD-11). Furthermore, it will enhance reporting in research by providing more precise definitions and would facilitate patient management through standardisation using these WHO classifications. Finally, it will promote patient-oriented pain management by employing the ICF<sup>6</sup>.

## Cross border exchange of pain measurement

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***Recommendation: Ensure the European Health Data Space initiative includes provisions to allow European health systems to exchange cross border data on pain measurement (via standardised EHRs and/or common tools).***

As we transition to digital medicine, considering how its infrastructure could benefit chronic pain patients is a key question. EHRs, for example, if standardised, should consider pain measurement. This is key to achieve comprehensive and resilient health systems. Digital technologies in health should be better prepared to provide remote care when and where needed in case of a crisis (such as COVID-19). This preparation will, in turn, help clinicians and other healthcare professionals work more efficiently to deliver patient care, to conduct comparable quality improvement programmes, service evaluations, and research projects. This will allow the variability of problems and practice to be assessed in prospective, disease, or exposure focused analyses, as well as to share best practices.

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<sup>4</sup> SIP 2018 Joint Statement <https://www.sip-platform.eu/resources>

<sup>5</sup> <https://www.sip-platform.eu/resources/details/sip-response-to-the-exph-draft-opinion-on-the-organisation-of-resilient-health-and-social-care-following-the-covid-19-pandemic>

<sup>6</sup> <https://www.sip-platform.eu/resources/details/icd-11-and-icf-workshop-in-brussels>

As stated in Article 8 of Directive 2011/24/EU, prior authorisation of cross-border healthcare should be based upon the degree of the patient's pain. Pain measurement is therefore a legal imperative as defined in EU law. Cross-border healthcare may become increasingly important as Europe seeks ways to manage the burden upon their health systems caused by shocks such as COVID-19.

### **Education and training for digital technologies for health**

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***Recommendation: Ensure the European Health Data Space initiative includes provisions for healthcare professionals and patients to receive education and training on digital technologies for health.***

As we transition to more digitalised healthcare systems, the healthcare sector (professionals and patients alike) will need to acquire new skills to use emerging digital health technologies. Member States should have access to the necessary education and training resources to establish state of the art, integrated models of care and interdisciplinary teams<sup>7</sup> that are known to aid treatment of conditions such as chronic pain. Promoting wider access to education and training on digital health technologies for healthcare professionals and patients will broaden competencies of healthcare professionals and increase the digital health literacy of patients. This will in turn enhance the effectiveness of the health system and the quality of care.

Therefore, based on the aforementioned, SIP calls on the Commission to ensure that the initiative includes:

- 1) Provisions to permit EU institutions and national governments to develop, share, and implement instruments to assess the societal impact of pain, namely, **instruments to assess pain as a quality indicator** within European health systems;
- 2) Provisions to allow European health systems to **exchange cross border data on pain measurement** (via standardised EHRs and/or common tools);
- 3) Provisions to **ensure healthcare professionals and patients receive education and training on digital technologies** as part of the educational curricula and training (via promoting access to education).

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<sup>7</sup> SIP 2018 Joint Statement <https://www.sip-platform.eu/resources>