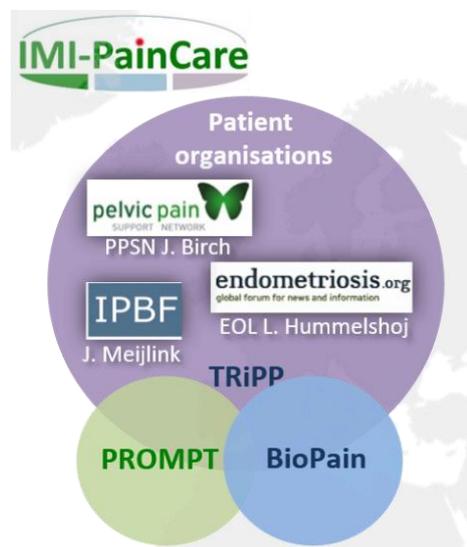


## Pan-European Pain Project IMI-PainCare – Review of 2020 and Engagement of Patient Organisations

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IMI-PainCare is an international consortium of 40 partners from academia, biotech companies, pharmaceutical industry, pain societies, and the three patient organisations International Painful Bladder Foundation (IPBF), Pelvic Pain Support Network (PPSN), and Endometriosis.org Ltd (EOL). The lead is shared by Prof. Rolf-Detlef Treede, University of Heidelberg, and Dr. Marcel Froehlich, Grünenthal. Set within the framework of the European Innovative Medicine Initiative (IMI) ([www.imi.europa.eu](http://www.imi.europa.eu)), the largest public-private partnership for health research worldwide, it was launched on April 01, 2018 to improve the care of patients with acute or chronic pain ([www.imi-paincare.eu](http://www.imi-paincare.eu)). The consortium strives to streamline the research and development process for novel analgesic drugs and improve treatment quality in clinical practice.



The main interest of the IPBF is in the subproject TRiPP - “Translational research in pelvic pain” which has a special focus on improving the management of pain related to endometriosis (EAP) and interstitial cystitis/bladder pain syndrome (IC/BPS).

TRiPP intends to adopt new approaches to stratify patients by identifying underlying mechanistic pathways, leveraging cross-disciplinary knowledge of pain mechanisms, utilize input from patient organisations in improved research concepts and develop and optimise preclinical disease models and endpoints for pelvic pain conditions. The strategy is based on obtaining information, including biomarkers, directly from patients in order to identify the relevant biological pathways affected in these disorders. The project also aims to establish whether women with EAP and IC/BPS can be stratified into subgroups and to explore whether these subgroups relate to treatment response. In a non-interventional clinical trial, about 800 previously documented EAP patients and control volunteers, as well as new patients with IC/BPS will be enrolled. In 2018, the consensus and approval of study protocol design took full advantage of the significant advice from the patient organisations. The clinical trial is ongoing and results are expected in 2021.

Two additional subprojects belong to IMI-PainCare: PROMPT: “Providing Standardized Patient Reported Outcome Measures for Improving Pain Treatment” aiming at alignment on outcomes in acute postoperative and chronic pain to enable follow-up of treatment success in clinical practice as well as in controlled trials; and BioPain: “Improving translatability of pharmacodynamic biomarkers in pain pathways”, the main objective of which is to validate various measures of nociceptive functions and their modulation by administration of analgesic drugs in humans and animals, ultimately enabling better decision making and drug selection in the early phase of development, reducing attrition rates in the translation of new analgesics from preclinic to clinic.

The year 2020 began with the IMI-PainCare General Assembly (GA) of all project partners on 15-16<sup>th</sup> January, hosted by Lilly at their Research Centre in the UK. A major discussion topic was the controversial Draft Guidance of the U.S. Food and Drug Administration (FDA) entitled “Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS): Establishing Effectiveness of Drugs for Treatment” as issued on December 5<sup>th</sup>, 2019. With strong support from Jane Meijlink, IPBF chair, the IMI-PainCare consortium provided official comments on the Draft Guidance, which were complementary to those sent by Jane on behalf of the IPBF and together speaking with a firm voice (<https://beta.regulations.gov/document/FDA-2019-D-4656-0001/comment>).



Main joint comments were (i) to consider enrollment of subpopulations in clinical trials reflecting the high diversity of patients suffering from IC/BPS and paving the way to more individualized treatments as this is being done in other indications based on genetic or pathological markers, (ii) to avoid combination of the two core symptoms of pain/discomfort, urgency and frequency in one single endpoint (e.g. in a single Patient Reported Outcome instrument) taking into account that patients may experience different degrees of bother from the two core symptoms, and (iii) to acknowledge that Hunner lesions (HL) and non-lesion IC/BPS have long been recognized as potentially different entities and that these should be separated and not combined in future studies. Of course, documentation of the lesions will be critical. We will keep you updated whether and which of our comments will be accepted in the final Guidance.

Moreover, the patient organisations have had a strong impact on the IMI-PainCare Research. Jane Meijlink (IPBF) and Judy Birch (PPSN) provided advice on the study protocol design of the four multi-centre BioPain trials in healthy human volunteers (BioPain RCT1-4) and carefully reviewed the recently submitted manuscript about the trial BioPain-RCT3, which is documented in the acknowledgement (TRIALS: IMI2-PainCare-BioPain-RCT3: A randomized, double-blind, placebo-controlled, cross-over, multi-center trial in healthy subjects to investigate the effects of lacosamide, pregabalin and tapentadol on biomarkers of pain processing observed by electro-encephalography (EEG)). Thanks to the IPBF chair’s advice, the abstract became more understandable to patients and suitable to reach a broad public. In the

subproject TRiPP, all three patient advocates, Jane Meijlink (IPBF), Judy Birch (PPSN) and Lone Hummelshoj (EOL) contributed to and are co-authors of the literature review submitted for publication recently (PAIN: Preclinical Models of Endometriosis and Interstitial Cystitis/Bladder Pain Syndrome: An IMI-PainCare Initiative to Improve their Value for Translational Research in Pelvic Pain).

Overall, IMI-PainCare is an excellent example to show how patient organisations can impact on and provide considerable benefit to scientific research projects. We are looking forward to the evolving research results of IMI-PainCare and continuing this very fruitful collaboration!



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