The Project

IMI-PainCare comprises three sub-projects:

PROMPT:
Providing standardized patient reported outcome measures for improving pain treatment

BioPain:
Improving translatability of functional biomarkers in pain pathways

TRiPP:
Improving translation in chronic pelvic pain.

These three sub-projects address distinct aspects and scientific challenges. Bringing them together into one project creates the opportunity for valuable cross-fertilization.

Objectives of IMI-PainCare

- Align on outcomes in acute postoperative and chronic pain
- Foster the use of PROMs in real world to enable clinicians to follow-up treatment success and with this improve pain relief for patients
- Refine preclinical pain models and enhance their translation into the clinic
- Identify translatable pharmacodynamic biomarkers to prove target engagement in the clinical development of new analgesics
- Provide new approaches for patient stratification in clinical trials
- Support decision making in clinical practice
- Disseminate the findings broadly, including to decision makers

Overall, IMI-PainCare will increase the health and well-being of citizens by improving the management of pain and will strengthen leadership and competitiveness of European industries
Project duration: 1.4.2018 -31.3.2023

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The public-private consortium

The IMI-PainCare Consortium is composed of 41 participants from14 countries; 6 are EFPIA members (European Federation of Pharmaceutical Industries and Associations) with strong traditions in pain research and development, 23 are internationally renowned academic and clinical institutions, 5 are specialist SMEs with cutting-edge technologies, 3 are patient organizations and 3 are professional pain/anesthesia societies.

Heidelberg University	DE
Actual Analytics LTD	UK
University of Aalborg	DK
Aarhus University	DK
Boston Children's Hospital	US
Christian-Albrechts-University Kiel	DE
ConsulTech GmbH	DE
European Pain Federation	BE
Endometriosis.org LTD	UK
European Society of Anaesthesiology	BE
European Society of Regional Anesthesia and Pain Therapy	CH
Public Assistance Hospital of Paris	FR
Hospital District of Helsinki and Uusimaa	FI
Institute of Molecular and Cell Biology in Porto	PT
INCLIVIA, Valencia	ES
National Institute of Health and Medical Research	FR
International Painful Bladder Foundation	NL
King's College London	UK
MRC Systems GmbH	DE
Michigan State University	US
Neuroscience Technologies SLP	ES
Pelvic Pain Support Network	UK
PROMPTLY - Software Solutions for Health Measures	PT
Queen Mary's University London	UK
Region Hovedstaden	DK
Sapienza University Rome	IT
University of Cork	IR
Cliniques Universitaires St. Luc	BE
University of Edinburgh	UK
Jena University Hospital	DE
University of Louvain	BE
University of Navarra	ES
University of Oxford	UK
University of Münster	DE
Grünenthal GmbH	DE
Bayer AG	DE
Eli Lilly and Company LTD	UK
Esteve Pharmaceuticals SA	ES
Novartis Pharma AG	CH
Teva Pharmaceutical Industries LTD	IL
Endodiag	FR

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IMI-PainCare

Improving the care of patients suffering from acute or chronic pain

www.imi-paincare.eu

imi innovative medicines initiative efpia

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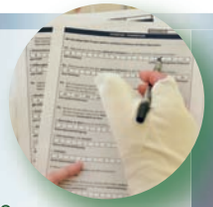
IMI-PainCare



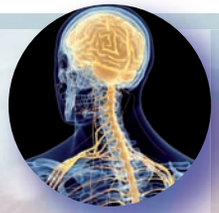
PROMPT: Providing Standardized Patient Reported Outcome Measures for Improving Pain Treatment

PROMPT seeks to improve the management of acute and chronic pain by identifying a core set of Patient Reported Outcome Measures (PROMs) which are predictive indicators of treatment success in clinical practice and controlled trials. These will address pain intensities as well as the functional consequences of pain for individuals, and identify patients at risk of experiencing chronification of acute post-operative pain. This will help health care professionals to individualize pain management, and thus improve the quality of life of pain patients. Furthermore, the correlation of baseline characteristics and a selection of PROMs for specific chronic pain conditions will identify which parameter(s) most reliably predict treatment success.

Major achievements and ongoing work:

- Consensus on a core outcome set of domains for assessing effectiveness of acute pain management after surgery
- Identification of measurement instruments for assessing effectiveness in perioperative pain management after sternotomy, breast cancer surgery, TKA and endometriosis-related surgery
- Identification of PROMs measures related to previously published domains for assessment of treatment efficacy in chronic neuropathic and pelvic pain
- Inclusion of more than 3,300 patients in a prospective data collection on PROMs, including data on physical activity from ca. 400 pts
- Systematic literature reviews on CPSP risk factors after total knee arthroplasty and breast cancer surgery and on chronic neuropathic and pelvic pain

device for tracking physical activity



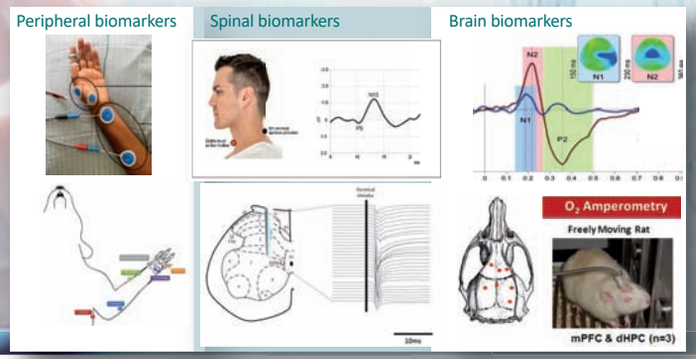
BioPain: Improving translatability of functional biomarkers in pain pathways

Development of medications for the treatment of chronic pain has been stagnant in the past decades, although chronic pain is a major cause of years lived with disabilities and loss of productive work time. BioPain is contributing to close the translation gap between preclinical studies and clinical trials by standardizing and pharmacologically validating objective measures of nociceptive signalling that translate between rodents and humans.

Major achievements and ongoing work:

- Developed two instruments for general use (electrode forfor pain-LTP, pinprick with trigger output)
- Initiated parallel pairs of RCTs in rodents and humans using electrophysiological and imaging biomarkers of peripheral, spinal and brain signal processing
- Developed PK-PD models for analgesic actions of lacosamide, pregabalin and tapentadol that currently undergo validation in rodents and humans
- Analyses predictive value of expectation, catastrophizing and anxiety on pain and analgesia

This way we will provide tools necessary to implement patient stratification and enrichment as encouraged by the EMA/CHMP/970057/2011 guideline.
Contacts with EMA, FDA and NIH have been established.



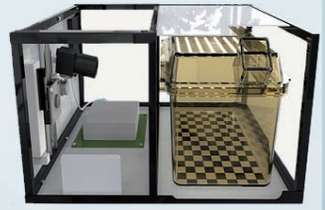
TRiPP: Improving translation in chronic pelvic pain

Chronic pelvic pain (CPP) is common, yet remains a neglected field of research. Endometriosis associated pain (EAP) is particularly prevalent (~10% women), whilst interstitial cystitis/bladder pain syndrome (IC/BPS) although less common (ca. 0.06%) is associated with significantly reduced quality of life and psychological distress. Current treatments for both conditions focus on the pelvis with limited success, ignoring the fact that comorbidities such as autoimmune, endocrine and other pain conditions are common amongst sufferers.
Development of novel effective therapies has, however, been hindered by the lack of preclinical models reflecting the full clinical picture. TRiPP will adopt new approaches to stratify patients with EAP and IC/BPS by underlying mechanistic pathways, leveraging cross-disciplinary knowledge of pain mechanisms with state-of-the-art biomarker discovery, and then back-translate these findings to refine preclinical models.

Expected outcomes:

- Provide deeper understanding of the pathological conditions which lead to pelvic pain
- Deep phenotyping of women with these two CPP-syndromes will be performed.
- Existing pre-clinical models will be assessed and then refined in line with the clinical phenotypes aiming for better mechanistic and predictive validity.

Summary statement:
Increase disease understanding of EAP and BPS leading to patient stratification and improvement of preclinical model validity



Actual Analytics Home Cage Analyser (HCA)