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.

Expected outcomes:

(1) Alignment on outcomes in acute post-operative and chronic pain (follow-up of treatment success in clinical practice, clinical trials for drug development)

(2) Refining preclinical pain models and enhancing their translation into the clinic

(3) Providing new approaches for patient stratification in clinical trials

(4) Identification of translatable pharmacodynamic biomarkers to prove target engagement in the clinical development of new analgesics

(5) Supporting decision making in clinical practice

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

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The public-private consortium

The IMI-PainCare Consortium is composed of 40 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
Foundation for the Research of the Hospital Clínico Universitario of Valencia	SP
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
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Sapienza University Rome	IT
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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
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IMI-PainCare

Improving the care of patients suffering from acute or chronic pain

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imi innovative medicines initiative efpia

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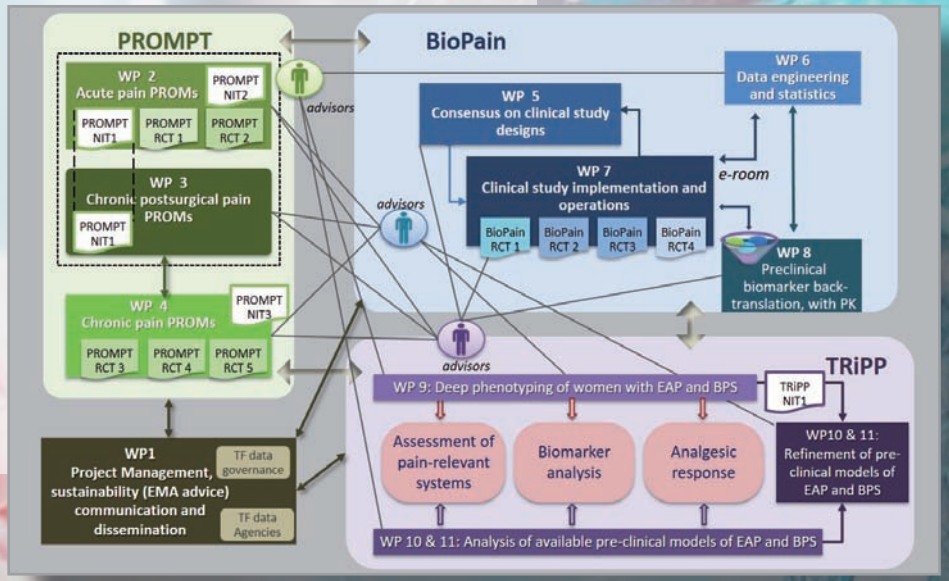
PROMPT: Providing Standardized Patient Reported Outcome Measures for Improving Pain Treatment

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.

Expected outcomes:

Improvement of pain management by use of consented, standardized PROMs that are accepted around the world.



BioPain: Improving translatability of functional biomarkers in pain pathways

Chronic pain is a major cause of years lived with disabilities and loss of productive work time. Analgesic drug development has been stagnant in the past decades because results of preclinical studies often fail to predict those of clinical trials. BioPain aims to close this translation gap by standardizing and pharmacologically validating objective measures of nociceptive signalling that translate between animals and humans. We will

a) perform RCTs in healthy subjects and parallel trials in rats using electrophysiological and imaging biomarkers of peripheral, spinal and brain signal processing,
b) use PK/PD modelling to delineate the actions of standard-of-care drugs in these neural compartments,
c) record pain intensity, distress and anxiety.

This way we will provide tools necessary to implement patient stratification and enrichment as encouraged by the EMA/CHMP/970057/2011 guideline.

Expected outcomes:

- Refining preclinical pain models and enhancing their translation into the clinic
- Identification of translatable pharmacodynamic biomarkers to prove target engagement in the clinical development of new analgesics

Summary statement: standardization and pharmacological validation towards accelerated translation in analgesic drug development

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