



Innovative Medicines Initiative

Europain

Understanding Chronic Pain and Improving Its Treatment



efpia

Three partners – one problem



- **Patients need better and safer treatments for pain**
- **The socio-economic burden on society of chronic pain is great**
- **EFPIA members have not been successful in developing new analgesics**



Patients need better pain treatments



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- On average, one out of every five Europeans suffer from chronic pain, a devastating and widespread problem.
 - Existing drug therapies are insufficient, a majority of patients stop treatment due to lack of efficacy or side effects.
 - In spite of major scientific advances in understanding the mechanisms of pain, treatment options have not improved
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Untreated pain - a problem in Europe



- The socio-economic burden of chronic pain is great, both on the individual and on society.
 - Europeans with chronic pain suffer on average for 7 years and the costs to society are huge, estimated at €34 billion a year (<http://www.europeanpainnetwork.com>) .
 - Indirect costs are several-fold.
 - The ultimate goal of the project is to improve the pharmacological treatments against pain and to reduce the burden of illness of very large groups of the European population.
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New analgesics – a challenge for EFPIA members



- Developing new drugs is complex, resource demanding and time consuming
 - Today, overall, only 4% of CNS drug projects who reach into man will reach the market.
 - Improved early predictions in order to spend resources on the most likely successful drug candidates is key
 - In order to succeed in providing better medicines to patients we need to collaborate closely between Academic partners, Biotech SMEs and EFPIA members
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Major reasons why developing new analgesics is difficult



- Pain experience and pain-related problems are not always predictably related to the underlying cause
 - Different forms of chronic pain have different underlying mechanisms.
 - Personalised health care – identifying the right patient segment
 - RATS DO NOT TALK! The gap between animal behavioural models and humans has not been overcome
 - Only recently has identification of novel targets and genes important in chronic pain become fairly easy
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What we will do about it – step 1



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- Looking back at previous draw-backs and use learnings as a platform to go forward.
 - We will identify common mechanisms that can be translated from animals to humans
 - Improve understanding of clinical findings to sensitivity to existing analgesics
 - We will determine psychosocial and clinical risk factors for development of chronic pain
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What we will do about it - step 2



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- Improve and refine animal models of chronic pain so that they will be more relevant to humans
 - Establish and validate mechanism-based human pain models.
 - Find objective measures of spontaneous pain using advanced technologies
 - Identify novel pain mediators important in chronic pain
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How we will go about it



- Use of advanced technologies, e.g. nerve function and new imaging techniques
 - Explore new biochemical biomarkers
 - Develop disease specific animal models of pain, including related symptoms
 - Develop target specific models of pain in human volunteers
 - Define disease specific patient characteristics
 - Prospectively study the development of chronic pain after surgery
 - Analyse and study the placebo effect
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We apply new integrated ways of working



- All partners will perform experimental assessments in exactly the same way
 - Protocols are aligned across all activities
 - All data from consortium will be integrated in a common database
 - We have a Training Center for advanced clinical examinations to ensure high quality
 - We will develop common consensus guidelines for experimental models
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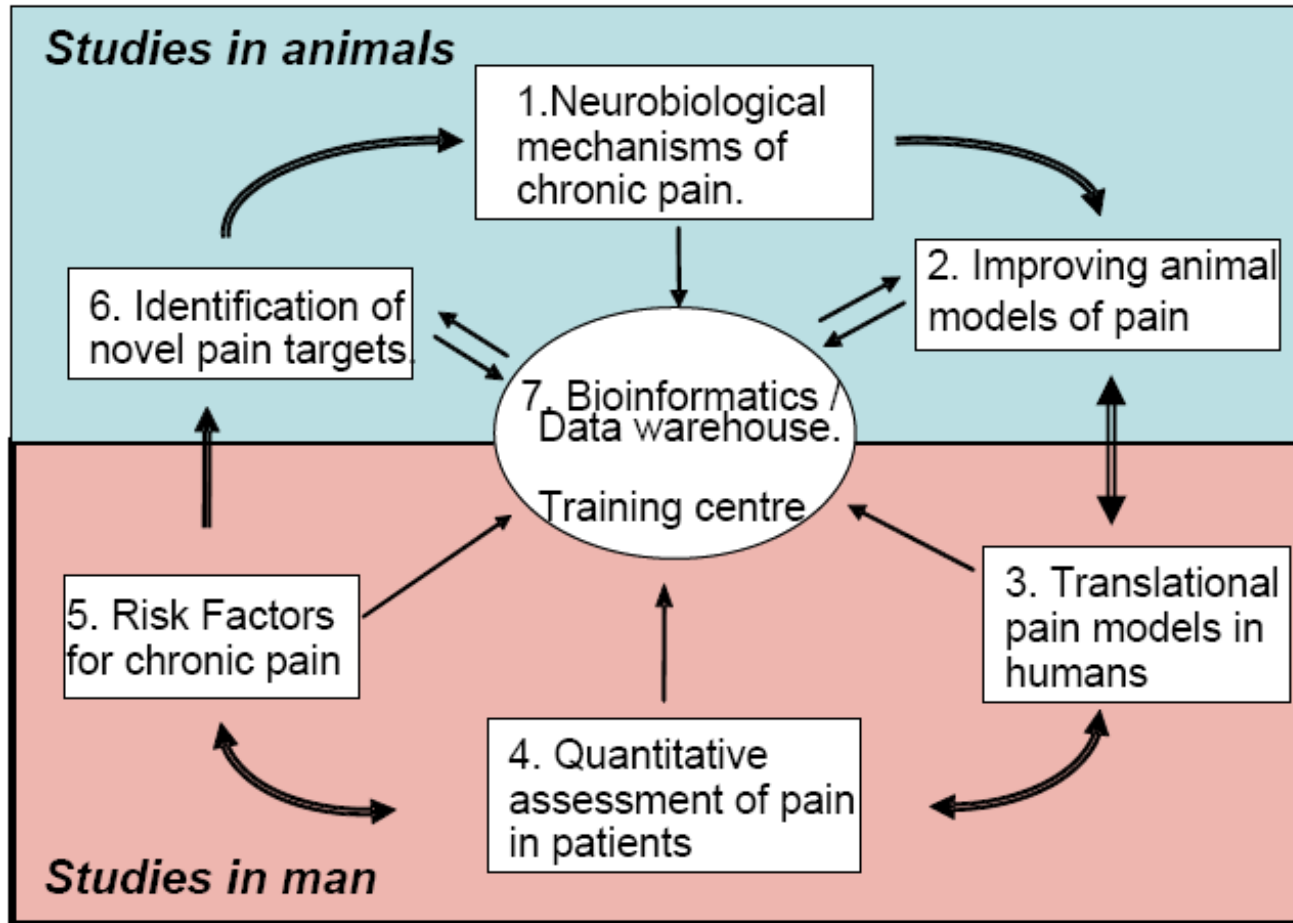
Innovative approach



- Twenty partners and more than a hundred scientists from eight countries
- Never before have so many partners from Academia, SME and EFPIA members collaborated so closely together to overcome the present hurdles
- We will systematically integrate advanced technology with animal data and clinical signs and symptoms from more than 65 study activities
- Sharing knowledge, resources and time will benefit the European partners and the pain patients of Europe.



An all-integrative approach



Expected outcome



- We will have identified factors predicting development of chronic pain
 - We will have identified important mechanisms behind chronic pain
 - We will be able to predict better from animal data which drugs will actually work in humans
 - This will improve the drug development process by addressing the relevant mechanisms
 - Improved treatments for pain will reduce costs for society and reduce suffering for the individual
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Expected benefit to patients



- The results will help to improve success in bringing new and better treatments for pain patients
 - It will be possible to identify individuals at risk for developing chronic neuropathic pain and thereby treatment could be intensified for these patients at an early stage
 - Improved success rate in drug development will give EFPIA members and Biotech SMEs better treatment options.
 - Shortened development times for new analgesics will bring benefit to patients sooner
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Expected benefit to Europe



- Better pain treatment will reduce the socio-economic burden for patients and society
- Improved success rate in drug development will give EFPIA members and Biotech SMEs better possibility to contribute to economic growth in Europe.

Added value of the consortium



- All partners openly share data, knowledge and techniques
 - All results will be shared in a large database so that results can be directly compared
 - EFPIA partners will contribute with knowledge in study design, database handling, trial performance
 - Academic and EFPIA partners will join in performing scientific work
 - The SMEs will contribute with their specific advanced methodology of measuring activity in pain nerves
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Achievements after 6 months



- Post docs have been employed
 - The common results database is set up.
 - EFPIA partner data mining is ongoing
 - Study protocols are ready
 - All investigators have undergone education and have been certified to do patient examinations will be performed in exactly the same way.
 - Some of the substudies have already started

 - The first very preliminary results will soon be coming in.
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Time and money

Financing

- IMI funding: 6 MEUR
- EFPIA contribution, mainly in kind: 12.5 MEUR
- Total project cost: 18.5 MEUR

Timing:

- Starting date: October 1, 2009
- Duration: 60 months, ending Sept 30, 2014



Participants



EFPIA

- AstraZeneca
- Boehringer Ingelheim
- Pfizer Limited
- Eli Lilly and Company Ltd
- Esteve S.A.
- UCB Pharma
- Sanofi-Aventis R&D

Academia

- King's College London
- University College London
- University of Oxford
- Imperial College London
- Christian-Albrechts-Universitaet zu Kiel
- Ruprecht-Karls Universitaet Heidelberg
- Technische Universitaet Muenchen
- BG Universitätsklinikum Bergmannsheil GmbH
- Klinikum der Johann Wolfgang Goethe-Universitaet
- Aarhus University Hospital
- Region Hovedstaden
- University of Southern Denmark

SME

- Neurosciences Technologies S.L.



Further information



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 - Project website under construction
- Press release available from all partners

www.imi.europa.eu

