Almirall experience at IMI

Almirall

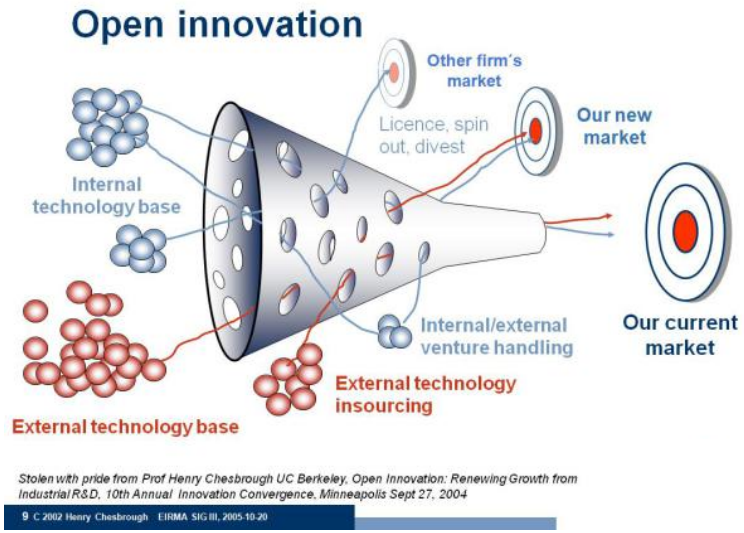
Soluciones pensando en ti

Thomas Eichholtz, R&D Director, CSO

Why join IMI? – Some initial hurdles

- In 2008 we had no experience in international consortia

- The concept of pre-competitive collaboration and open innovation much less developed than nowadays



- Legal concerns in terms of liabilities, IP, governance, finance, etc. had to be addressed

- It meant a first exposure to dealing with EU-like bureaucracy, too…

Why join IMI? – some quick wins too!

- Joining IMI opened the way to consider collaboration through the participation in consortia:

- Strengthened the participation and visibility of Almirall at the RDG

efpia

- Taught us how to deal with EU standards for funding

EUROPEAN COMMISSION

Projects joined in initially - safety and efficacy pillars

- **Definition of different sub-groups of patients with severe asthma to help the prediction of response to treatments and the design of better, more targeted ones**
- Duration: October 2009-June 2015
- Partners: 11 pharma companies, 26 University, Research Organizations, Public Bodies and Non-Profit, 4 SME and other industries

- **Development, validation and use of patient reported outcome (PRO) tools to investigate dimensions of physical activity that are judged as being essential by patients living with COPD**
- Duration: September 2009 – October 2015
- Partners: 8 pharma companies, 10 University, Research Organizations, Public Bodies and Non-Profit, 1 SME

- **Developing improved tools for prediction, detection, and monitoring of drug-induced injuries to the kidney, the liver, and the vascular system, using markers in patients blood and/or urine**
- Duration:
- Partners: : 11 pharma companies, 5 University, Research Organizations, Public Bodies and Non-Profit, 4 SME

Projects joined in initially – educational calls

Develop and establish of a comprehensive modular education and training programme in safety sciences for medicines

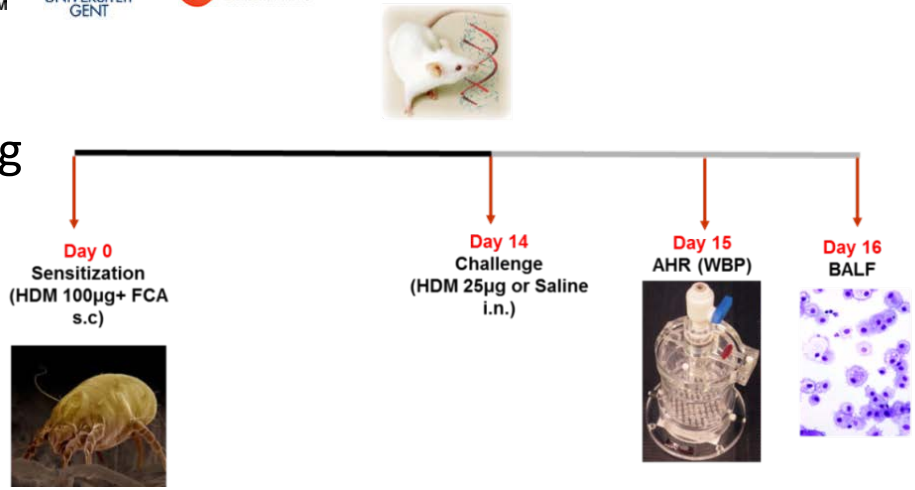
Develop a European training and education platform in pharmacovigilance and pharmacoepidemiology.

Build and implement a new modular Master level programme for advanced studies in Pharmaceutical Medicine and Drug Development Sciences

Establish of a sustainable, pan-European platform for education and training (E&T) covering the whole life-cycle of medicines research

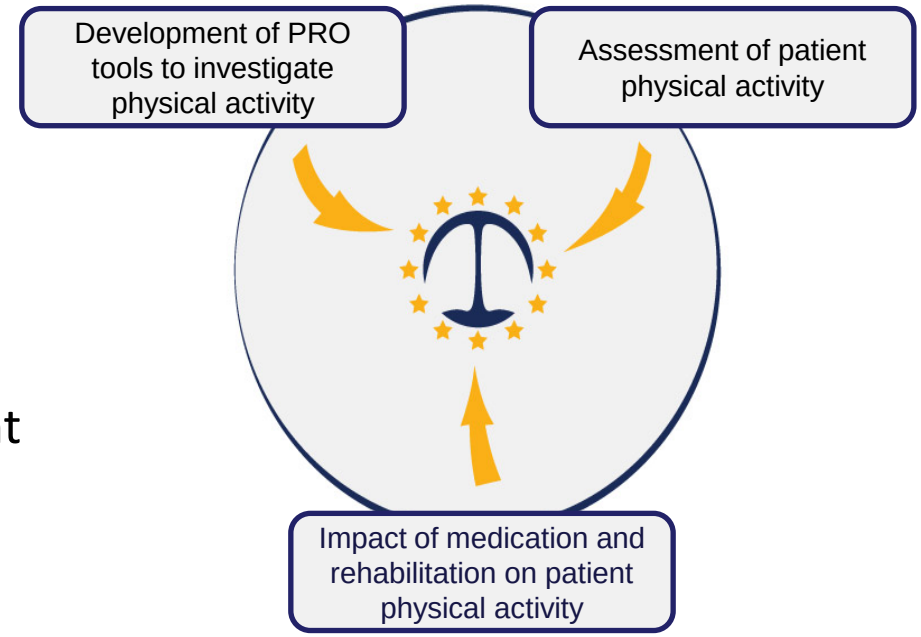
Almirall at U-BIOPRED

- Almirall contribution consists in the establishment of new animal severe asthma and of viral exacerbation
- These are being used to generate a ‘paw print’ that could be compared to the human ‘handprint’ in order to find translatable biomarkers
- **Results obtained so far:**
- Models set up and characterized in collaboration with UCB and Imperial College. Alternative models developed by The Fraunhofer institute, U. of Ghent, GSK, etc.
- Transcriptomics have been carried out in samples from these models and along with collected readouts
- Several communications to congresses, with manuscripts in collaboration with partners being submitted
- Other academic and SME partners:



Almirall at PROactive

Current status:
Hybrid instrument in validation, combining short patient-reported outcome questionnaire and two activity monitor variables: daily version and clinical visit version

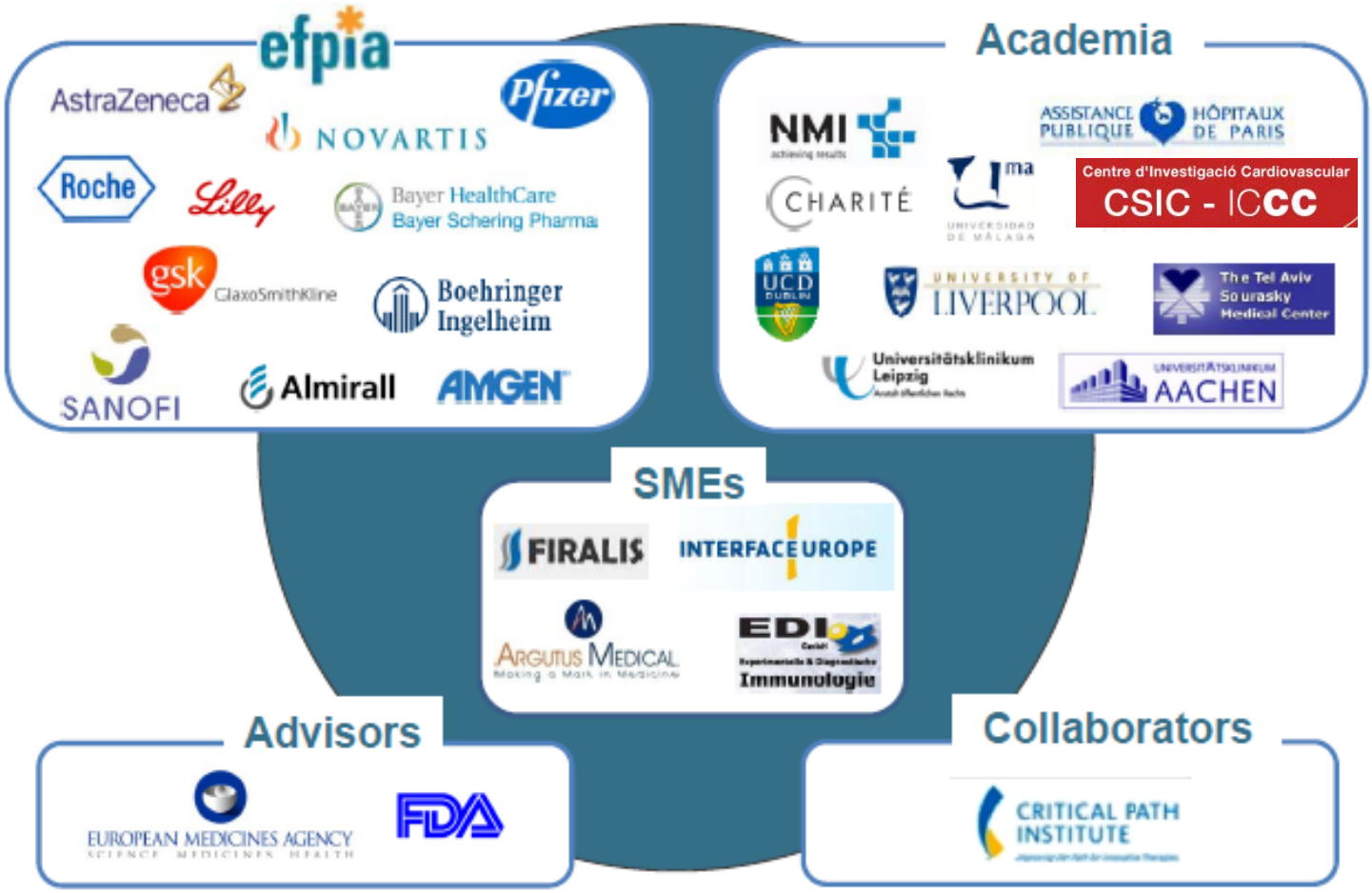


Almirall contributed to data management and clinical input into initial validation study, Co-organisation of training meetings/general assembly meetings

Other academic and SME partners:

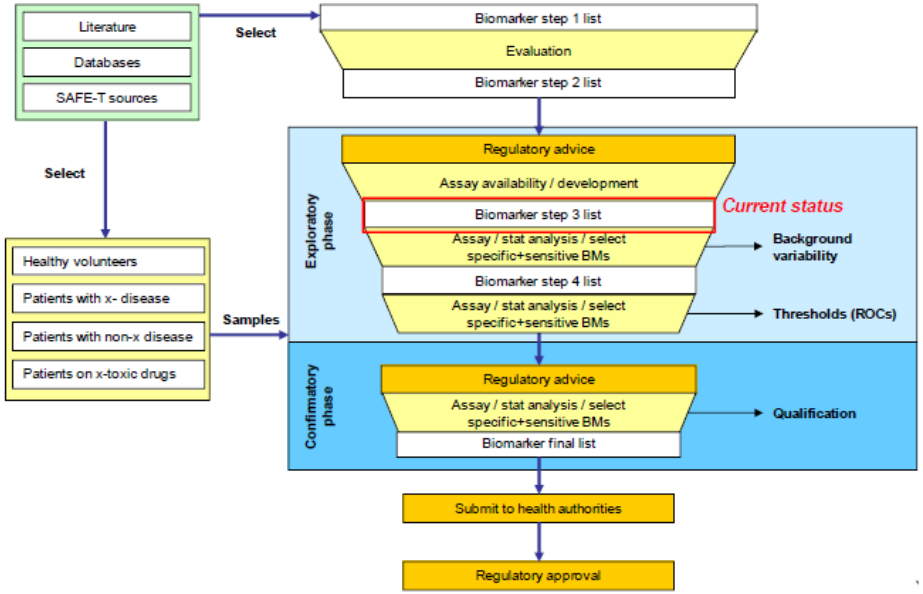
CREAL centre de recerca en epidemiologia ambiental
Choice Healthcare Solutions
LONG FONDS Voorheen Astma Fonds
BRITISH LUNG FOUNDATION
THE UNIVERSITY OF EDINBURGH
KATHOLIEKE UNIVERSITEIT LEUVEN
Universität Zürich
umcg
European Respiratory Society
Royal Brompton & Harefield NHS Foundation Trust

SAFE-T participants

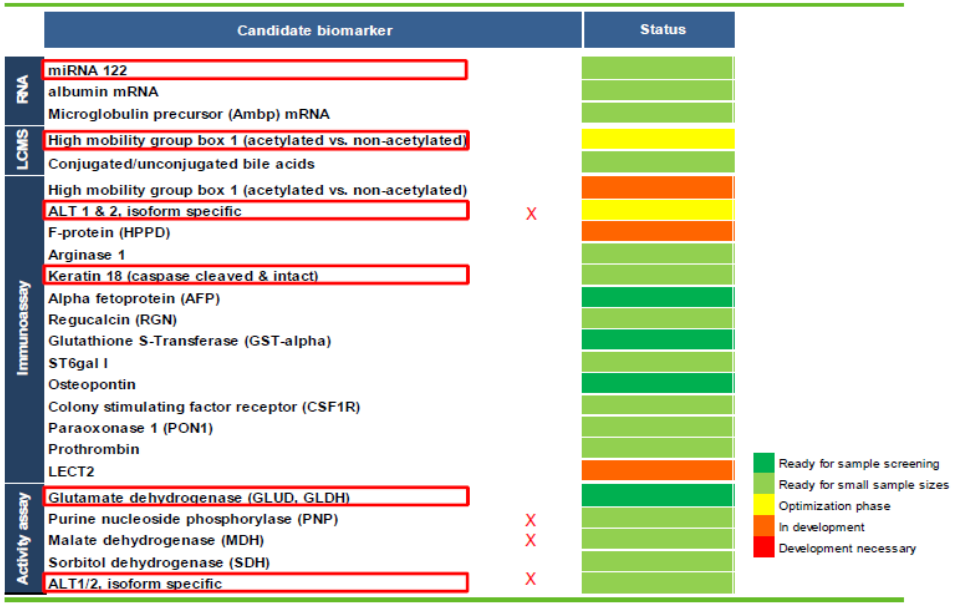


Almirall at SAFE-T

Biomarker Qualification Process



DILI Potential Biomarkers



- Qualification of translational Drug Induced Liver Injury (DILI) biomarkers
- Glutamate dehydrogenase and miRNA-122 are more sensitive liver injury markers than alanine aminotransferase
- Hepatoproteome studies to assess adaptation of liver to repeated acetaminophen exposure *manuscript submitted to Hepatology*

Almirall participation after call 1 much more limited – Why?

- Saturation of the capability to participate, given our size
- Specific topic suitability – two respiratory projects in the first call
- Changes in our own focus prevented additional entries being considered
- Initial perceptions on the time taken for very large projects to reach cruise speed…
- So, better see how the initial wave of projects matures and delivers before committing further

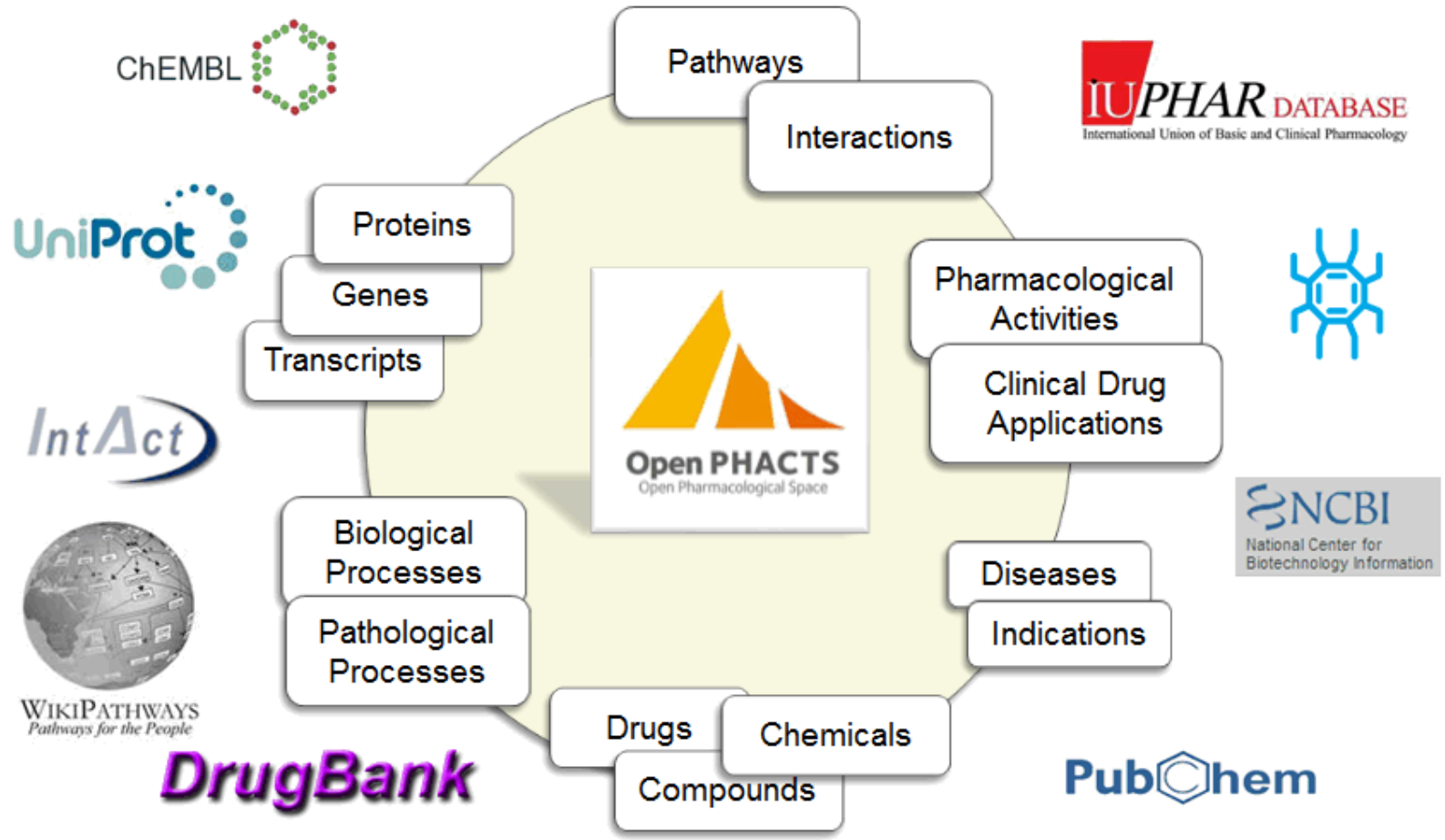
OpenPHACTS – a late entry

- Computational extraction, integration and exploitation of the open source knowledge in order to facilitate pharmaceutical R&D.
- Budget: 20.9 M€ (6.5 M€ of industrial contribution).
- Duration: February 2011 – February 2016 (3 years plus 2 years through an ENSO extension).
- Partners: 10 pharma companies, 6 SMEs and 15 academic institutions.

- Almirall joins-in during 2014, as part of the project transition into the ENSO (Explore New Sicientific Opportunities) extension
- Fit found with our interest in taking advantage of the data available to simplify the R&D cycle in terms of time, risk and cost
- Almirall contributing to testing and technical implementation o ChemBio Navigator, the application defined by the consortium to access and mix public and private data at specific settings

Open PHACTS

Open Pharmacological Space



Good things we would like to keep

- Sharing of pre-competitive knowledge between the different groups, particularly EFPIA members, was unthinkable at the start
  - Re-defining what is competitive and what is not
- Working together with Academia and Biotech towards common goals
  - The specific deliverables developed couldn't have been obtained in isolation
- Interaction with collectives such as patient organizations, through patients panel and ethics board, or students and teachers for the educational calls, regulators, etc. found very enriching

Challenges encountered

- Specific contribution from partners not fully defined at the start: everybody brought what they wanted – *hard to make a paella if nobody brings the rice…*

- It's increasingly difficult for pharma partners to maintain interest and focus on specific disease areas for the duration of the project – *drop-outs have been hard to manage*

- Still hard for some academic partners to see industry being more than just a source for funds – *not everyone has the same mindset*

Overall, the best possible recommendation is that we are contributing to IMI2 from the start…

The right prevention and treatment for the right patient at the right time

Strategic Research Agenda for Innovative Medicines Initiative 2