Innovative Medicines Initiative

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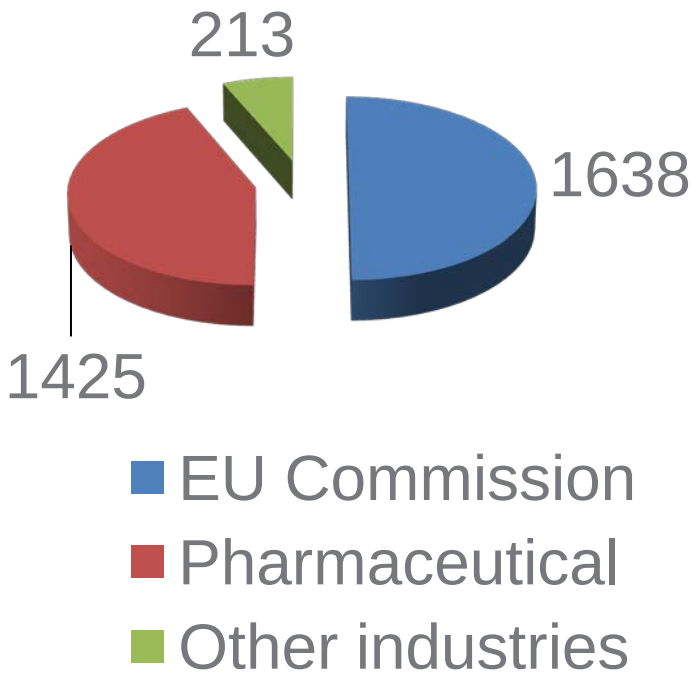
Global External Innovation and Alliances
Bayer HealthCare Pharmaceuticals, Wuppertal

farmaindustria, 22.06.2015, Madrid

Largest Public Private Partnership for Health R&D



- 1:1 funding, joint decision making
- EU funds to SMEs & academia
- Industry contribution in-kind
- 3.400 Billion € in IMI-2
- Ideas from industry & academia

The Agenda for this talk is our Vision

- Addressing healthcare priorities (WHO)
- Fostering open innovation pooling of research assets
- Promoting stratified medicines
- Encompassing the entire product cycle beyond R&D
- Promoting stratified medicines
- Accelerating access to novel drugs: regulatory impact?

➢ **And some words about the call generation process**

59 projects covering wide spectrum of topics

http://www.imi.europa.eu/content/ongoing-projects

Fostering Open Innovation

Unprecedented pooling of industrial research assets

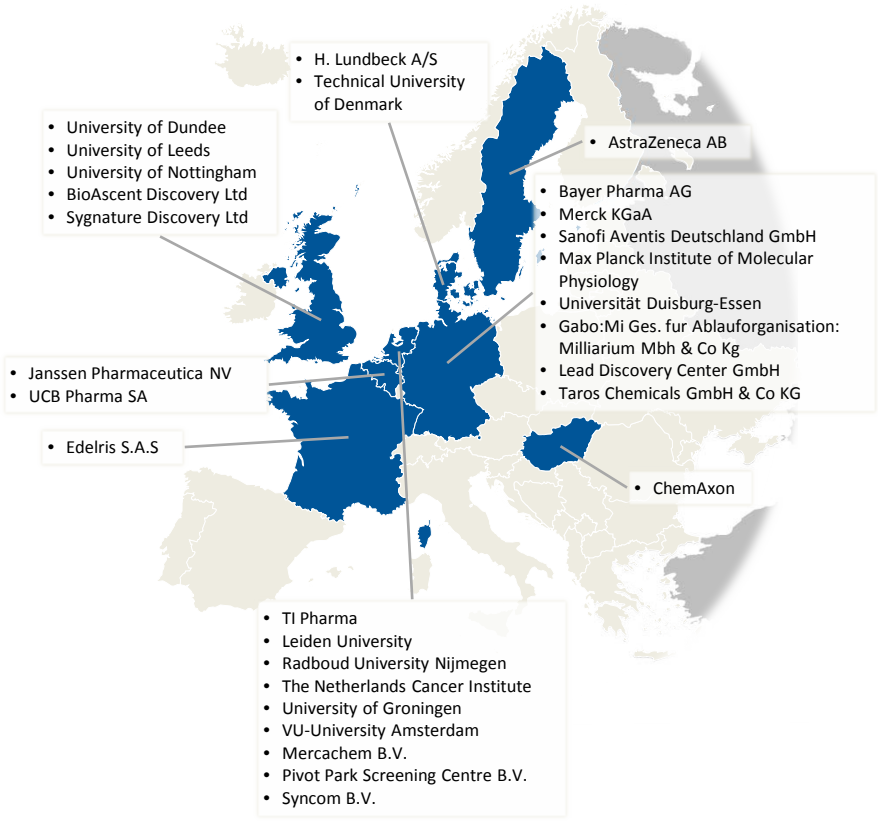
EUROPEAN LEAD FACTORY
Game changing for innovative medicine

Goal

- A highly diverse Joint European Compound Collection with ~500.000 compounds from public and private institutions
- Establish of a screening platform available to researchers in universities, SMEs and pharma industry

Status / Achievements

- High quality compound collection (~320.000)
- European Screening Center with state-of-the-art facilities
- 11 public target programs give option for companies to gain access to novel targets by partnering with 3rd parties
- Numerous company target programs running with the option for generation of proprietary novel lead structures



Total Budget:	196 539 059 €
Start of Project:	01/01/2013

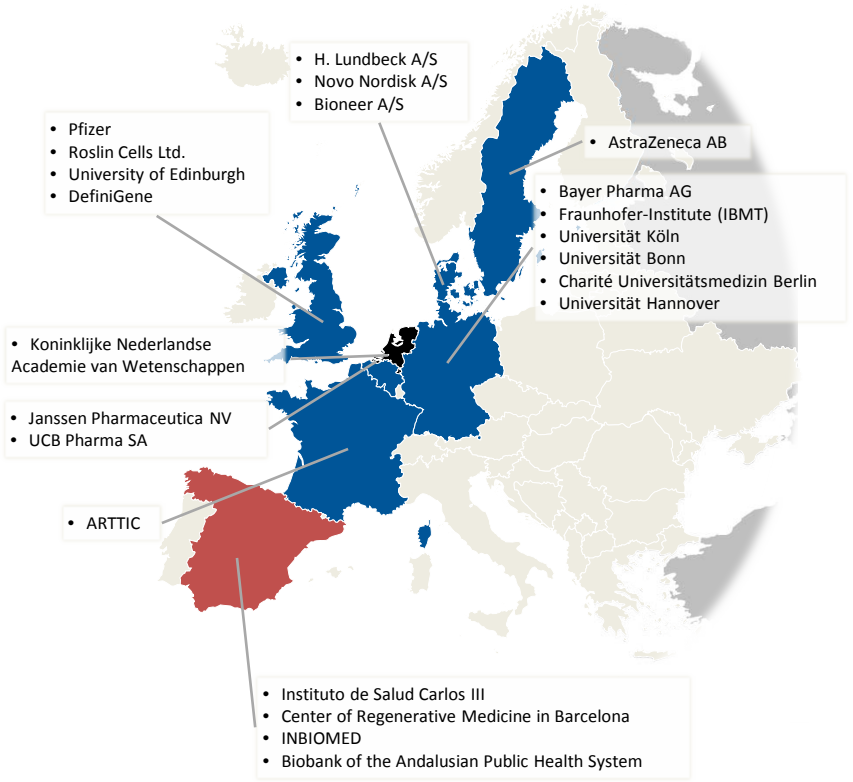
Unprecedented pooling of industrial research assets

Goal

- Establish a self-financing European Bank for induced pluripotent Stem Cells (iPSC)
- Share iPSC lines, generated with validated protocols and characterized according to high quality standards

Status / Achievements

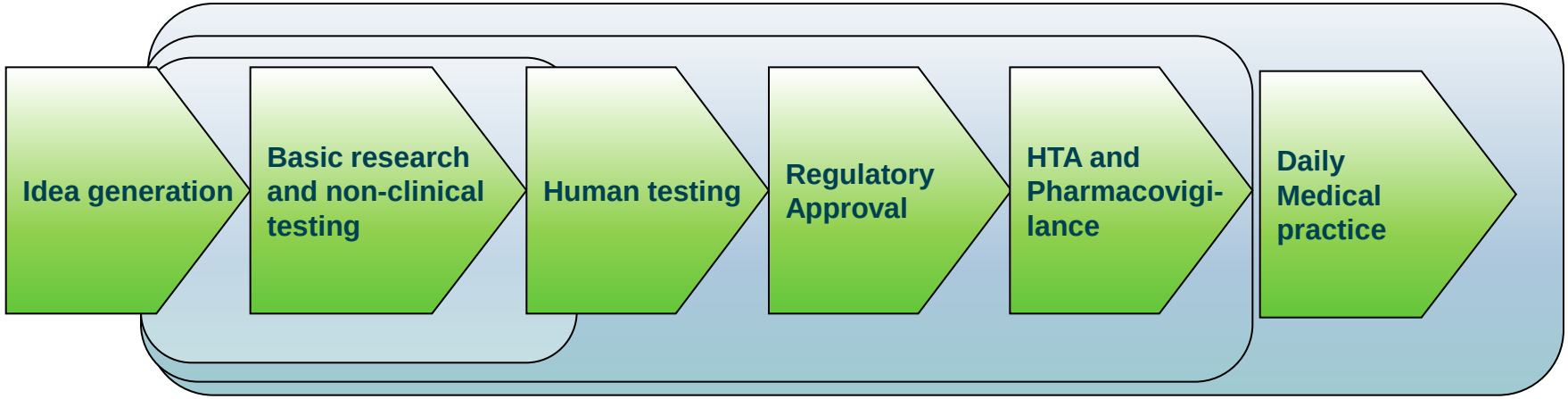
- Design & implementation of bio-engineering and quality control testing technologies
- Harmonization of standards, policies, procedures and legal instruments
- Collaboration with other iPSC global projects
- Provides access to more cell lines and data than any other cell banks,



Total Budget:	36 M€
Start of Project:	04/02/2014

Encompasing the entire product cycle

Increasing the efficiency of the complete pharmaceutical R&D Process



2007 SRA: initial focus of early IMI calls

2011 SRA: now addressing societal challenges and healthcare

2013 SRA: IMI 2 includes real life medical practice

SRA – Strategic Research Agenda

Promoting Stratified Medicine

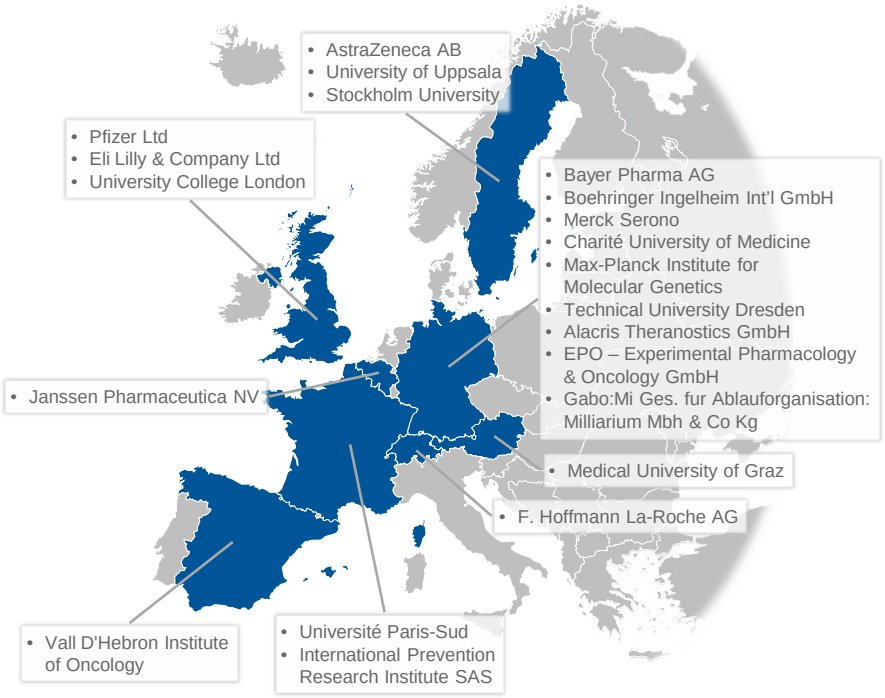
Promoting stratified medicine

Goal

- Validation of systems biology approach: *in silico* prediction of treatment response in colon cancer patients to address tumour heterogeneity

Status

- patient-derived models for colon cancer established (cell lines, xenografts)
- Tool for in silico prediction of drug response developed (ModCell™)
- Negotiation with EMA on validation of ModCell™ initiated



Total Budget: 30 Mio €

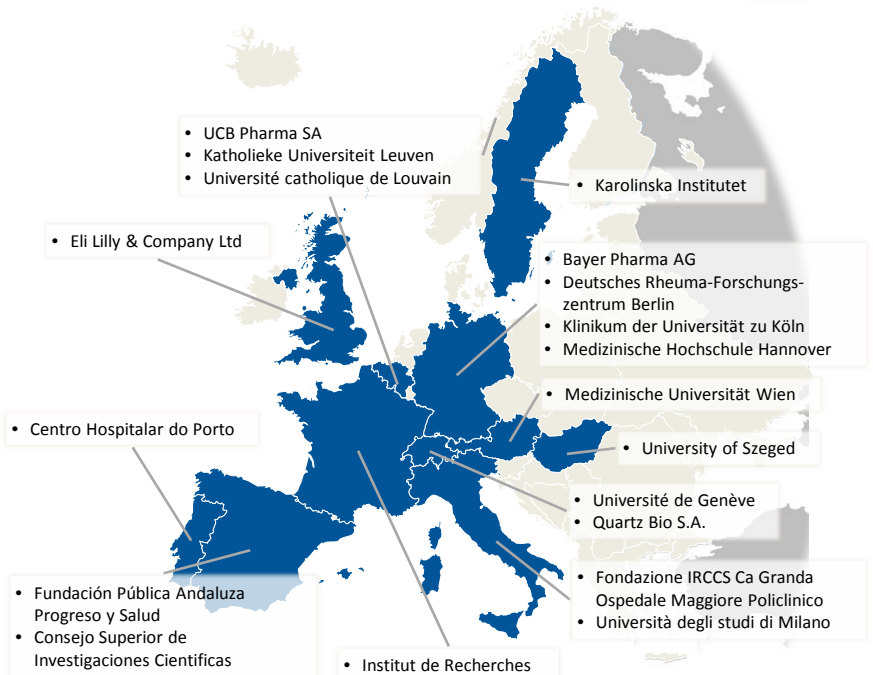
Start of Project: 01/01/2011

Understanding the molecular basis of SAD*

PRECISESADS

Objectives

- Develop molecular diagnostic signatures of SADs using multiple “omics” technologies and bioinformatics, for better patient stratification and tailored therapies



Total Budget: 22 733 839 €

Start of Project: 01/02/2014

*) systemic autoimmune diseases

"The rationale for the FDA's rigid standards is to avoid the sale of a drug like thalidomide……We count and recount the costs of such side-effects. We do not count the costs of not allowing new drugs to be made available."

— **Niall Ferguson**, The Great Degeneration: How Institutions Decay and Economies Die

Will IMI have an impact on the Regulatory Framework?

Medicines Adaptive Pathways to Patients

OBJECTIVE

to maximize the positive impact of new drugs on public health by balancing timely access for patients with provision of adequate information on risk/ benefits

MAPPs will focus on targeted, stratified medicines with clear biomarkers, well-defined populations, available diagnostics, and high level of efficacy and safety

Improved transparency & harmonization of Pharmaco-vigilance and -epidemiology

PROTECT

Objective

- Develop and validate tools & methods to improve early detection and assessment of ADRs from spontaneous reports, electronic health records, clinical trials, and observational studies

Status / Achievements

- Inventory of the drug consumption in Europe provided (Drug Consumption Database in Europe)
- PROTECT ADR database compiled with all ADRs listed in the Summary of Product Characteristics of medicinal products authorized in the EU
- Recommendations on current methods to assess and visualize risks and benefits of medicinal products
- Active involvement of regulators, EMA is coordinator

Total Budget: 27 738 885 €

Start Date – End Date: 01/09/2009 – 28/02/2015

How calls are concieved…

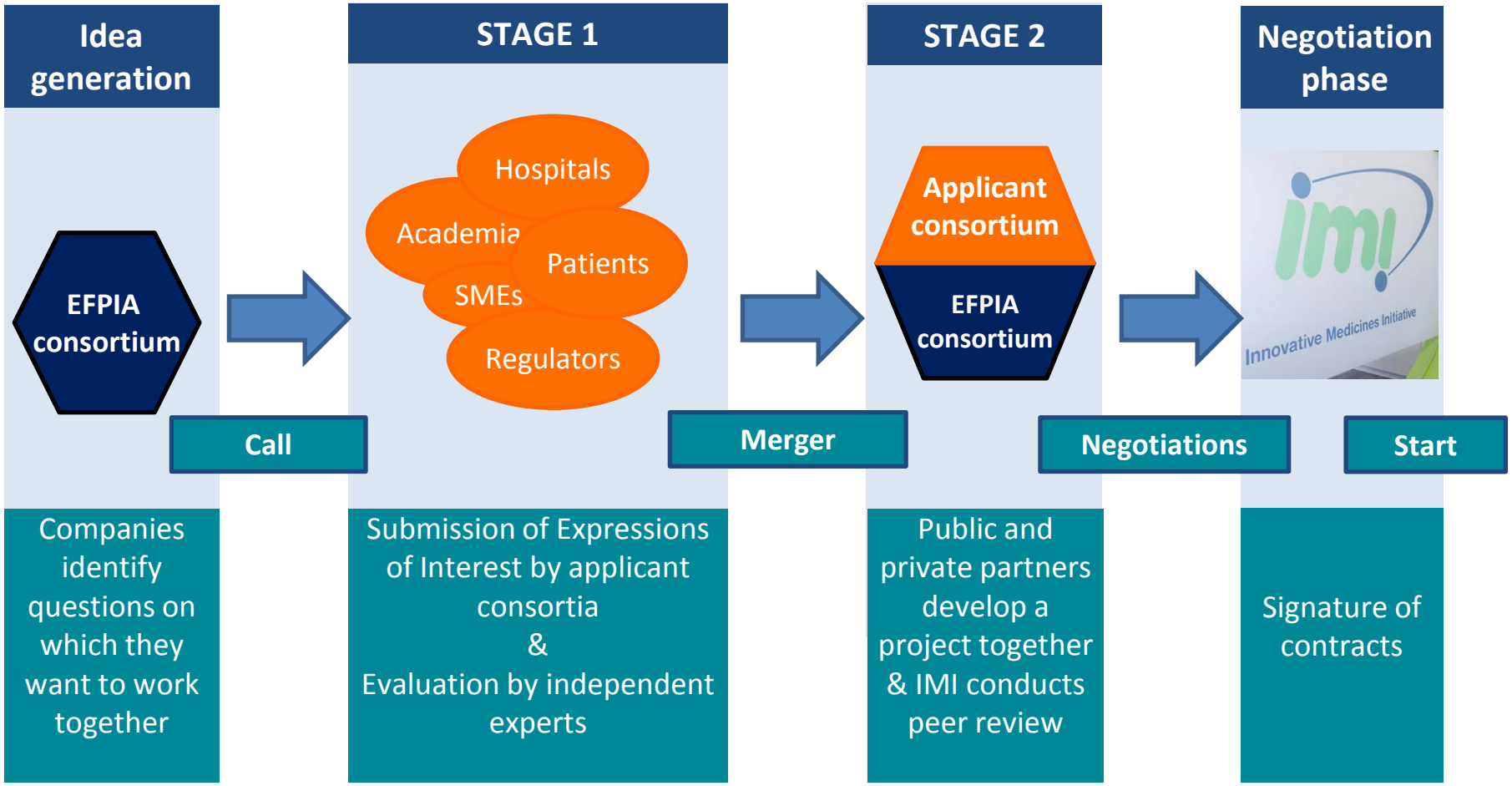
Goals of the IMI 2 programme

- Increase the success rate of clinical trials
- Speed up the earlier stages of drug development
- Develop new treatments for areas of unmet need
- Develop new diagnostic and predictive biomarkers
- Improve tools to assess the efficacy & safety of drugs

- Open to other industries, **not limited to EFPIA members**
- **Better inclusion of SMEs** : eligible if revenues < 500 M €

From topic definition to project start

Two-stage process (incl. fast track)



Prioritization & selection criteria

- Field of unmet need
- Patient-centric approach
- Science ready to “shift the paradigm” in this decade
- Added value of PPP (incl. other industry sectors)
- Synergies/complementarity with similar EU initiatives

Summary

- IMI is a PPP success story addressing major challenges in pharmaceutical R&D
- With IMI2 the partnership has been renewed until 2024
- Focus: Stratified medicine and healthcare priorities
- Impact on R&D, Regulatory, Market Access & Practice
- Room for win-win collaborations beyond big pharma

From science to the patient…together.

Science For A Better Life