



# Innovative Medicines Initiative:

## "lessons learnt from IMI 1"

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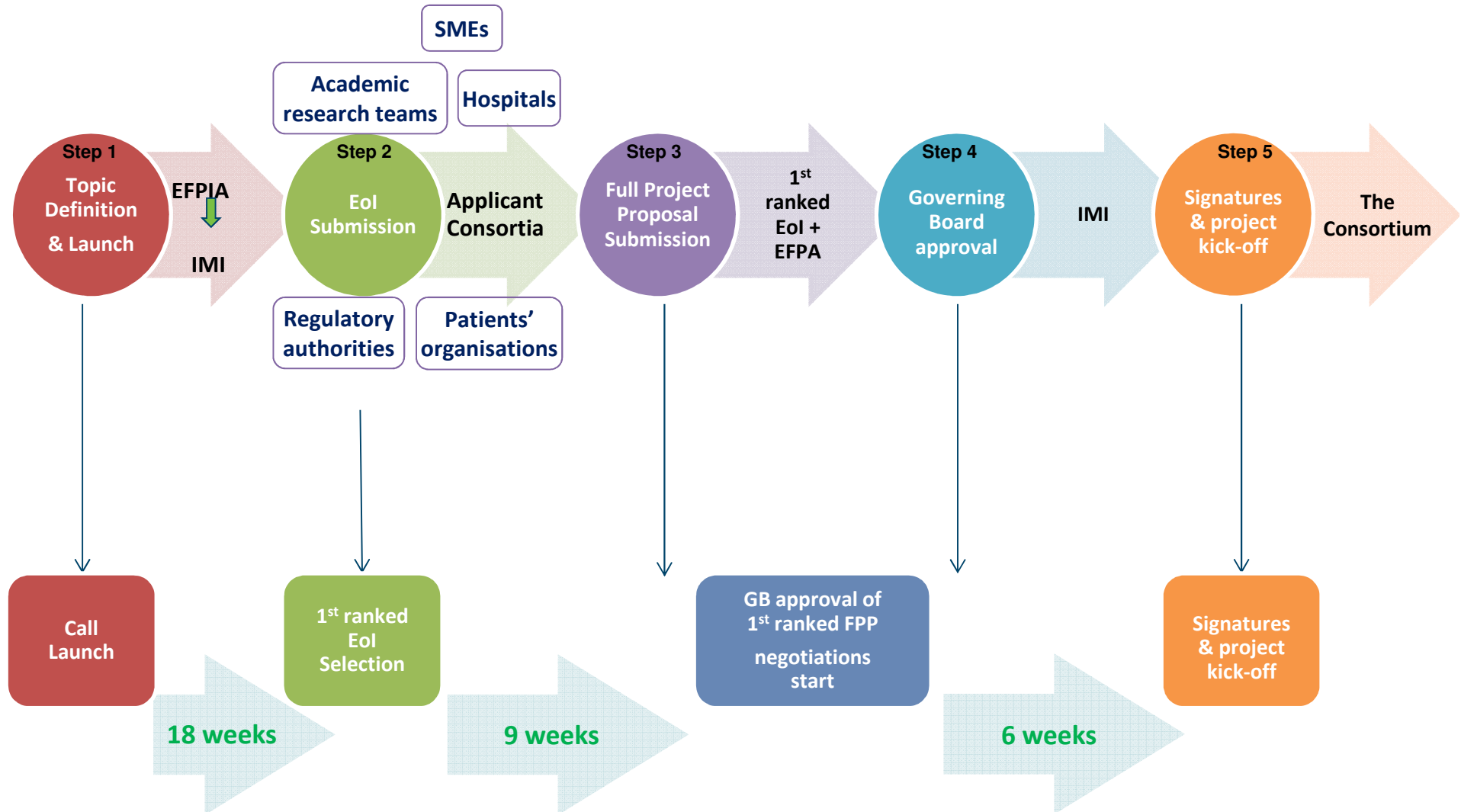
# IMI focus - Hurdles to better healthcare



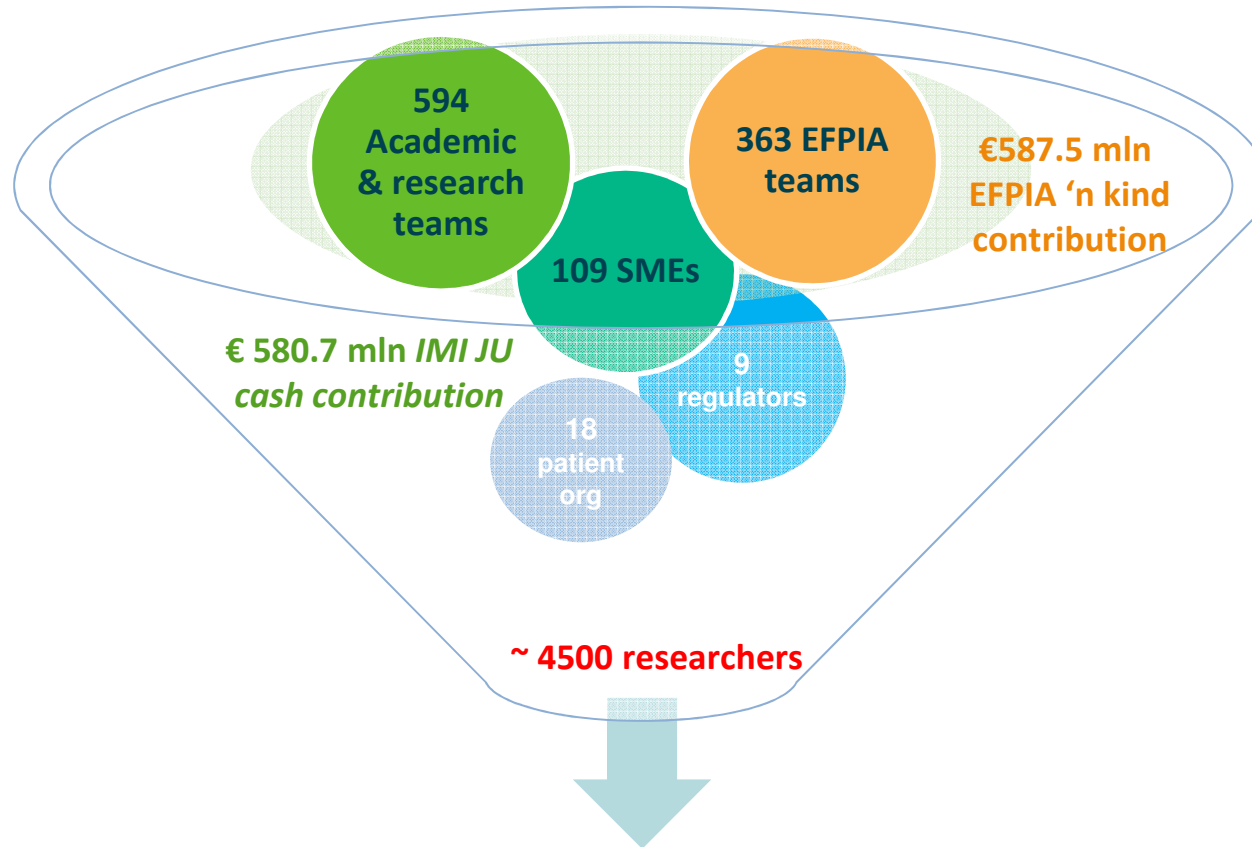
- Disease heterogeneity
- Lack of predictive biomarkers for drug efficacy and safety
- Insufficient pharmacovigilance tools
- Outdated clinical designs
- Socio-economic approaches not adapted to tailored therapies
- Insufficient incentives to develop drugs for rare or complex diseases
- Lack of training programmes focusing on collaborative approaches



# How it works - Optimized timelines



# Key Figures from 40 on-going Projects



Improved R&D productivity of pharma industries  
Innovative approaches for unmet public health needs



# The IMI Family



COMBACTE

TRANSLOCATION

[www.imi.europa.eu/content/ongoing-projects](http://www.imi.europa.eu/content/ongoing-projects)



# IMI projects are delivering:

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- ✓ Robust validated models for drug development
- ✓ Biomarkers and tools predictive of clinical outcomes - efficacy and safety
- ✓ Potential new drug targets
- ✓ Improving the design and process of clinical trials
- ✓ “Big Data” solutions to leverage knowledge
- ✓ Education and Training for new generation R&D scientists

# Achievement highlights

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Generated and patented the 1<sup>st</sup> human  $\beta$ -cell line and its performance has been confirmed by 3 pharma partners



EU-AIMS collaboration with EMA triggered drafting the guidelines for the treatment of autism



Evaluated 153 potential biomarker candidates for drug-induced injury of the kidney, liver and vascular system - validation ongoing in 17 exploratory clinical studies



Proposed optimization of schizophrenia trials - reduction in number of patients required from 79 to 46, reduction of the trial duration from 6 to 4 weeks

# IMI - The Neutral Trusted Party

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**Fosters large scale industry collaboration and engagement  
with scientific community**

**Promotes active involvement of patients, regulators and  
payers**

**Enables innovation via join effort where singular  
approach has failed so far**

**Facilitates Intellectual Property agreements**





# One IMI IP policy, multiple interests

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**Flexible Intellectual Property Rights policy allows to accommodate the interests of all stakeholders**

**Promotes knowledge creation, exploitation and disclosure → open innovation, open access**

**Ensures fair allocation of rights**

**Rewards innovation**

# Lessons learned

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**Neutral trusted party**

**IPR Policy**

**Communication**

**Flexible and adaptable approach**

**Planning**

**Simplification**

**Speed**

# Future Calls: Call 9

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Four topics under consideration:

- Real life data in medicines R&D and pharmacovigilance
- Correlates of protection for influenza vaccines
- Geriatric indications: Sacropenia
- Addressing antimicrobial resistance and reinvestment  
in AMR field (part of ND4BB programme)

Call Launch: **end of June 2013**

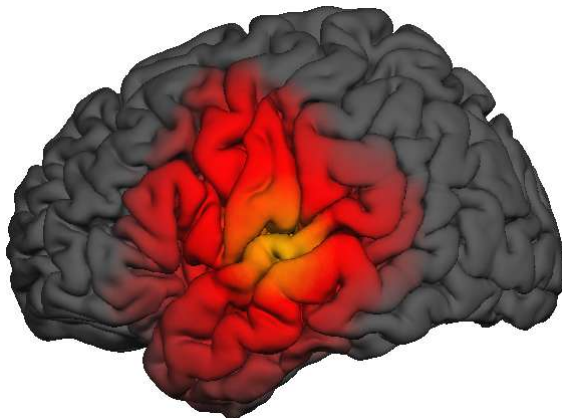


# IMI Stakeholder Forum

## 13 May, Brussels



### Brain disorders



- Affect **1 in 3 Europeans**
  - Cost the economy **€798 bn/yr**
- IMI projects** – PPPs tackling the challenges in drug R&D

### IMI & the European Research Area



- High level speakers from industry & EU institutions
- Nobel laureate Rolf Zinkernagel

**Registration:** via [www.imi.europa.eu](http://www.imi.europa.eu)



Innovative Medicines Initiative

[www.imi.europa.eu](http://www.imi.europa.eu)

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**THANK YOU !**



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