



Innovative Medicines Initiative

# What IMI means to Poland?

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# IMI – What is it?

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## THE INNOVATIVE MEDICINES INITIATIVE

The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients.

IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe. IMI is a joint undertaking between the European Union and the pharmaceutical industry association EFPIA.

IMI has a budget of 2 mld euro.

IMI stems from European Technological Platform in the area of innovative drugs which was found in 6FP. As Joint Undertaking initiative IMI was lunched in 7FP (2008-2017).

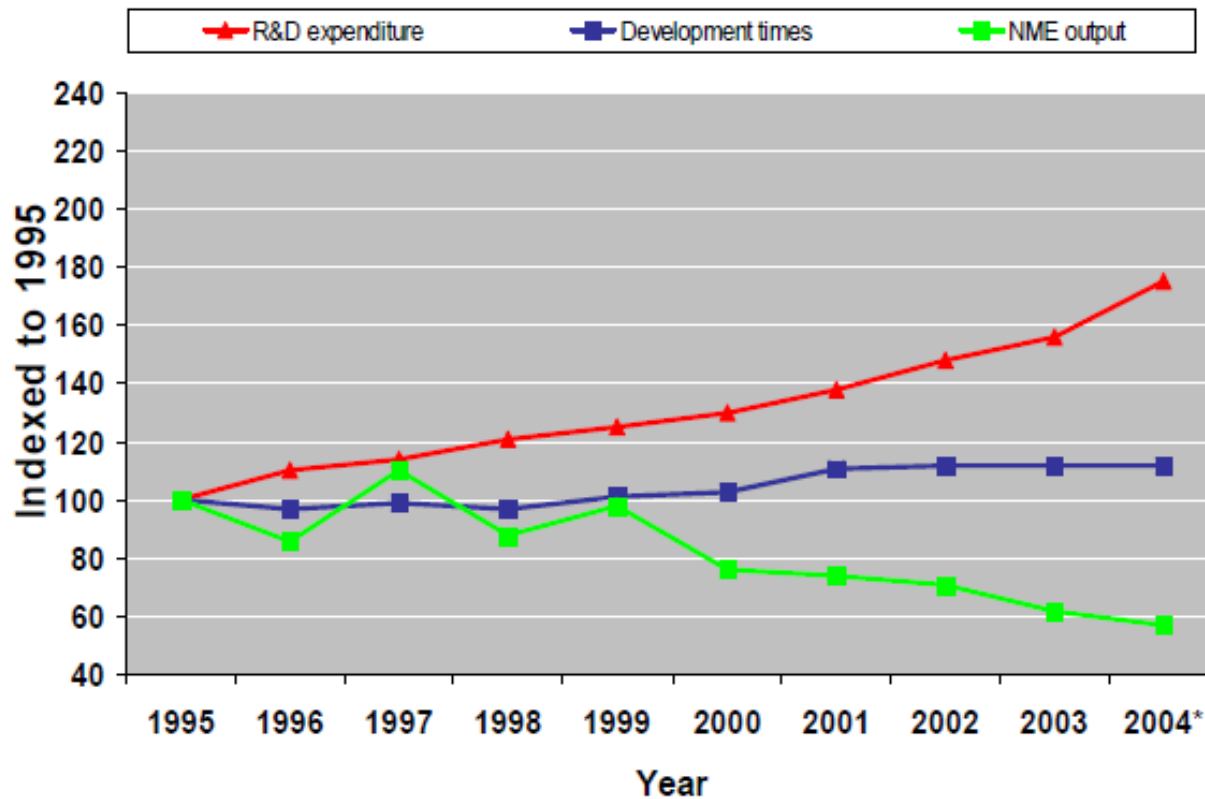
<http://www.imi.europa.eu>



# Problems in drug development process



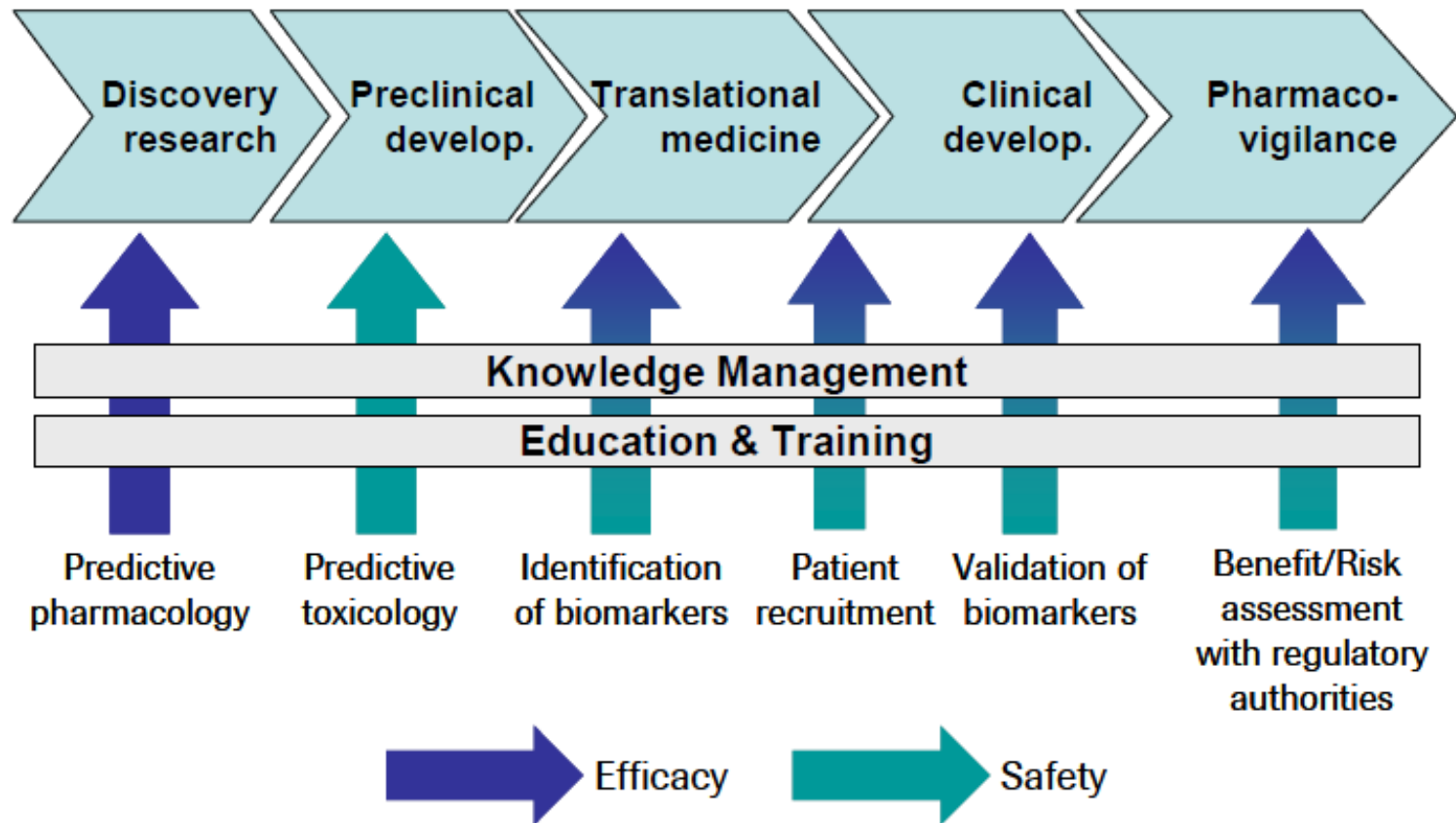
Global expenditure for R&D, development time and NME (new molecule entities)



# Why IMI was launched?



Crutial bottlenecks in R&D of drug development



# How IMI works?



IMI supports projects prepared by consortia and it builds network of expert groups which cover industry and academia in Europe. All these activities are aimed at precompetitive drug development methodology.

IMI activity is based on „Strategic Research Agenda” which covers four main research areas:

- Predictivity of Safety Evaluation (Pillar I) **more accurately evaluating the safety of a compound during the pre-clinical phase of the development process and the later phases in clinical development.**
- Predictivity of Efficacy Evaluation (Pillar II) **improving the ability to predict how a drug will interact in humans and how it may produce a change in function.**
- Knowledge Management (Pillar III) **more effective utilisation of information and data for predicting safety and efficacy.**
- Education and Training (Pillar IV) **closing existing training gaps in the drug development process.**

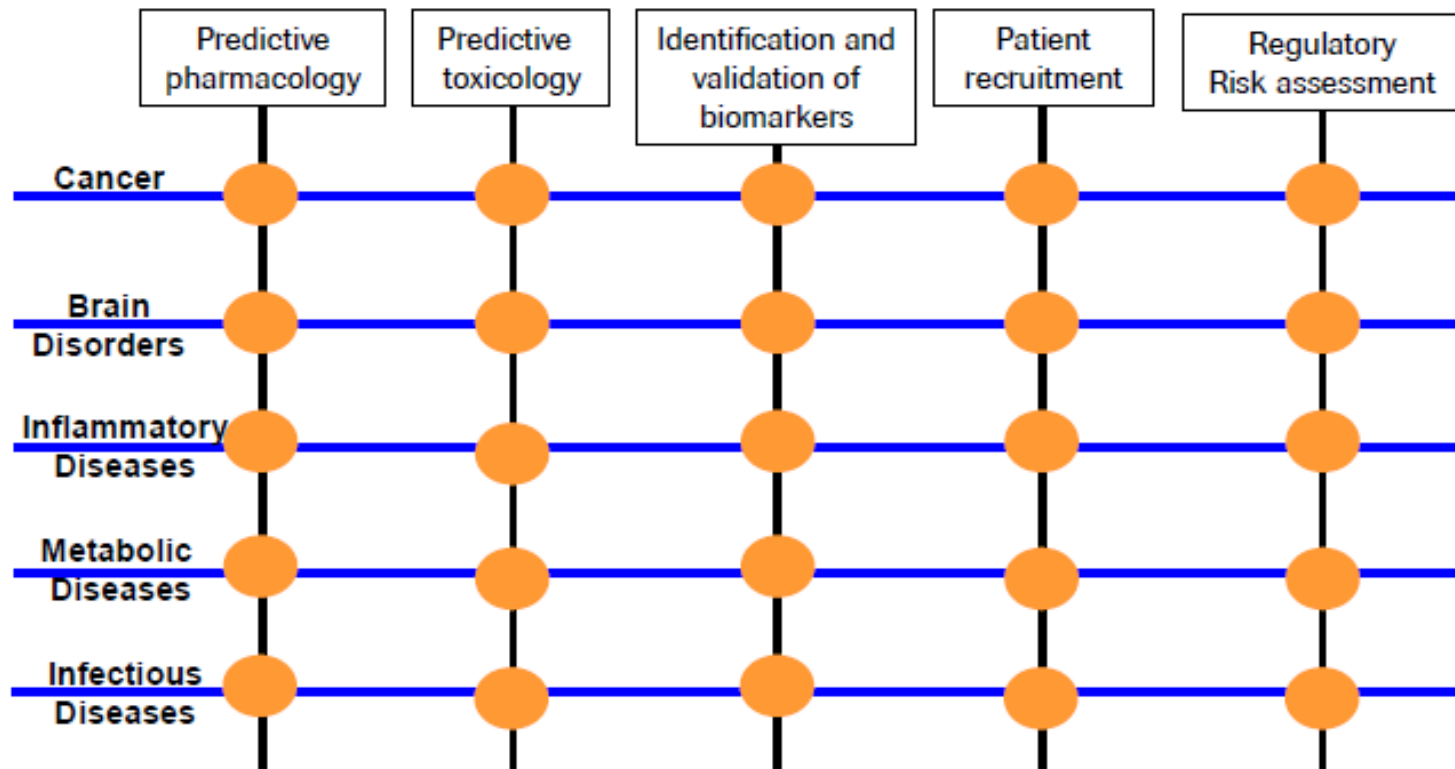
Every year basing on SRA „annual calls for proposals” is prepared and it contains indication for each call.



# Areas of activity of IMI?



Areas of activity in II pillar – efficacy



# History of calls

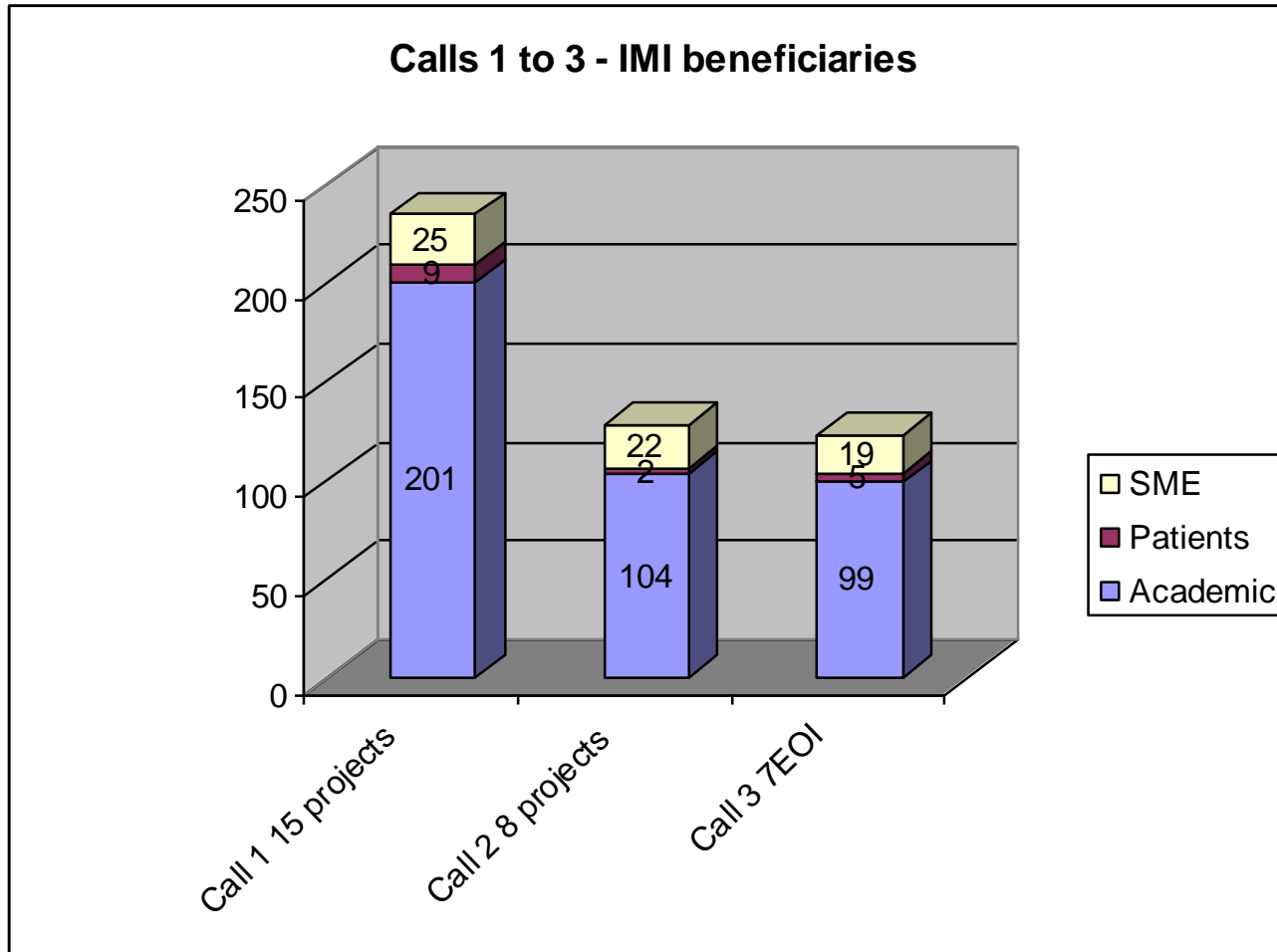
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1 <sup>st</sup> call	– 15 projects (395 teams)	€281 mln
2 <sup>nd</sup> call	– 8 projects (193 teams)	€171 mln
3 <sup>rd</sup> call	– 7 projects (123 teams)	€215 mln
4 <sup>th</sup> call	– closed stage II (9 projects selected)	
5 <sup>th</sup> call	– closed II stage (evaluation)	
6 <sup>th</sup> call	– closed I stage (6 projects selected for stage II)	
7 <sup>th</sup> call	– launched stage I	



# Statistical data about calls

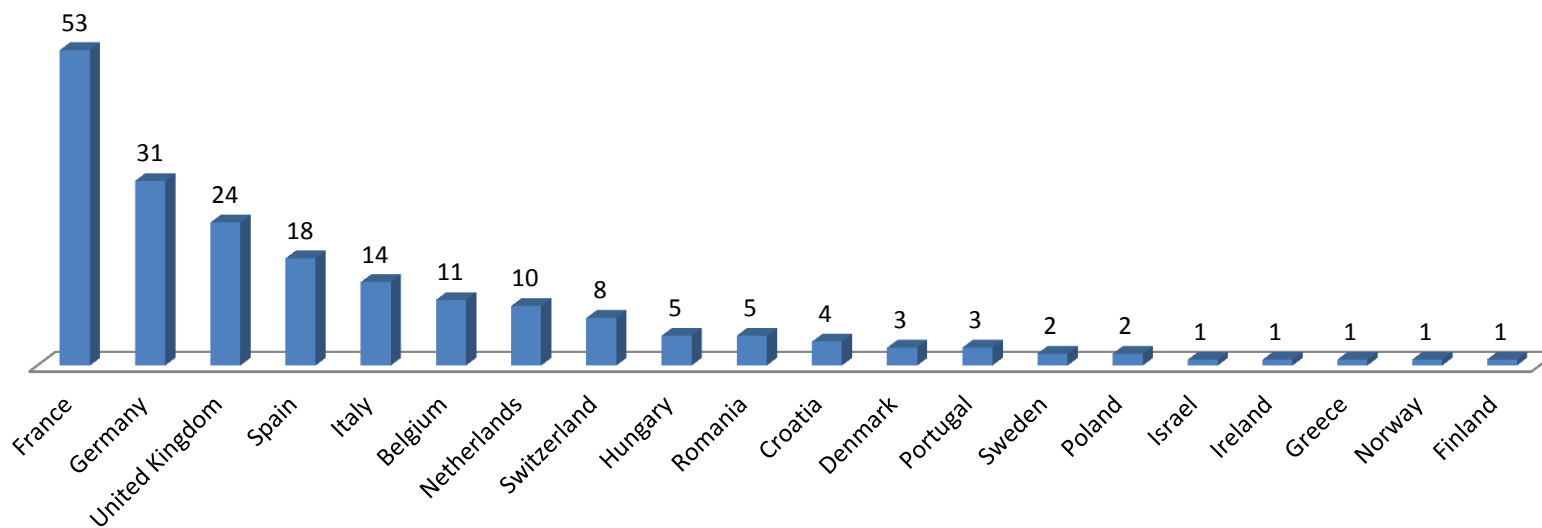




# Statistical data about call 6



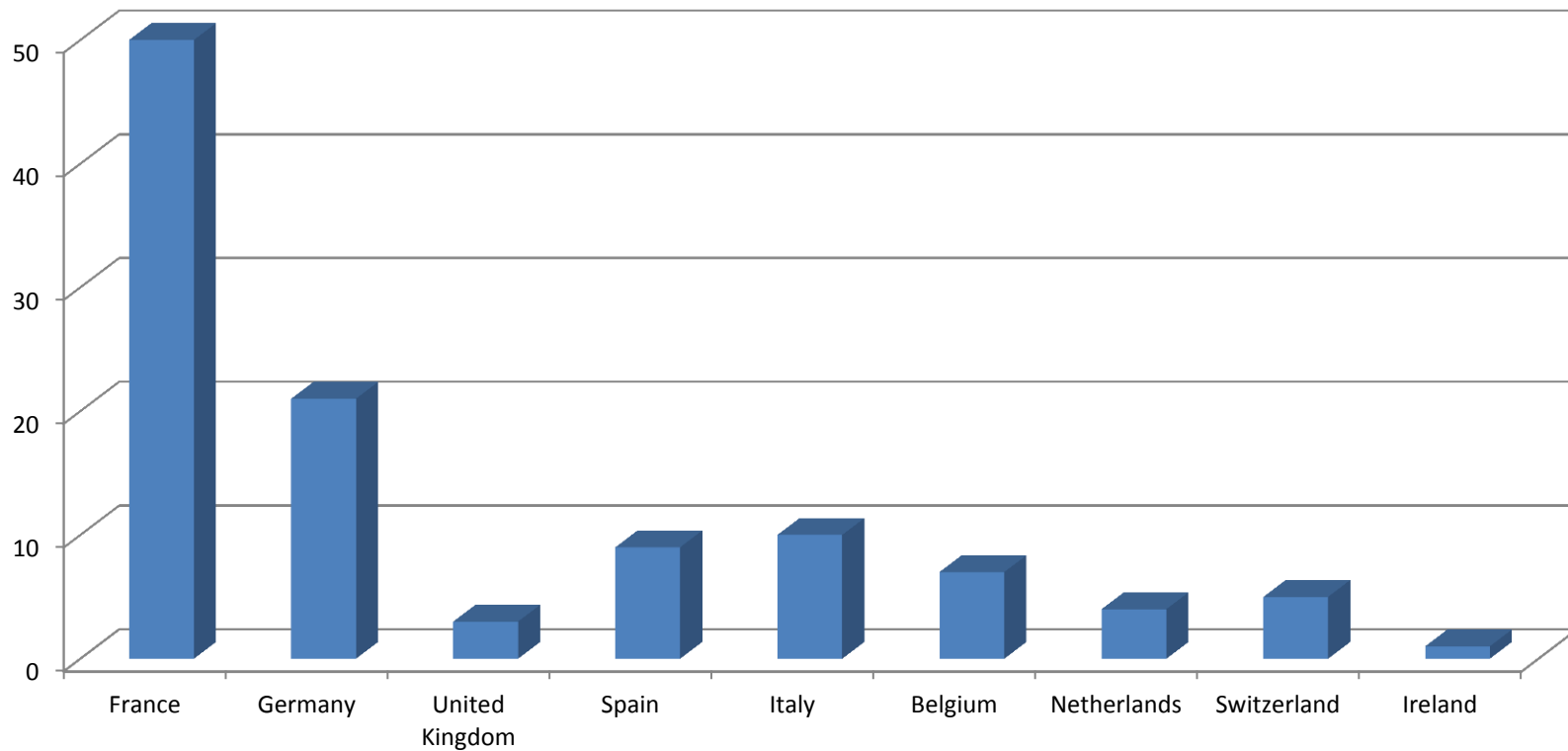
**Call 6**  
**Number of Applicants by Country**  
**(Eligible Eols)**



# Statistical data about call 6



Successful Eols by country



# POLISH SUCCESSFUL STORIES

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**1st call - UBIOPRED - UNBIASED BIOMARKERS FOR THE PREDICTION OF RESPIRATORY DISEASE OUTCOMES**

**€ 20.685.241 (26 public partners)**

The Jagiellonian University Medical College, Krakow, Poland

**2nd call - EHR4CR - ELECTRONIC HEALTH RECORDS SYSTEMS FOR CLINICAL RESEARCH**

**€ 16.051.514 (21 public partners)**

Medical University of Warsaw, Poland

- In total three participants – 0,4 mln euro



# 7th call – call themes

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The 7th Call for proposals has two topics:

- Developing a framework for rapid assessment of vaccination benefit/risk in Europe
- Incorporating real-life clinical data into drug development

The IMI JU applies a two-stage Call process. In the first stage, 'Applicant Consortia' (i.e. formed by academia, small and medium-sized enterprises (SMEs), patient organisations, non-EFPIA companies, etc.) are invited to submit, to the IMI JU, an Expression of Interest (EoI) in response to a Call topic.

**Submissions deadline (for submitting Eols):** October 9, 2012 - 23:55:00 Brussels time (CEST)



# Financial rules



The IMI JU financial contribution will be based on the reimbursement of the eligible costs. The following funding rates apply to the legal entities eligible for funding: **For research and technological development activities, up to 75%** of the eligible costs are eligible for funding. For other activities (**including management and training activities**), **up to 100%** of the eligible costs charged to the project are eligible for funding. For indirect costs (overheads), the legal entities eligible for funding may opt for one of the following indirect costs methods: the actual indirect costs; or the simplified method which is a modality of the actual indirect costs for organisations which do not aggregate their indirect costs at a detailed level, but can aggregate them at the level of the legal entity; or **a flat rate of 20% of total eligible direct costs** (excluding subcontracting costs and the costs of resources made available by third parties which are not used on the premises of the beneficiary).



# Future topics (2012)



- **NewDrugs4BadBugs (ND4BB)**  
**Tackling resistance to antibiotics: building partnerships to progress the discovery and development of novel antibiotic drugs to treat the most urgent infections.**  
**This topic will be launched in a future Call for proposals.**

## PROBLEM STATEMENT

Despite the recognised need for new antimicrobials, only two new classes of antibiotics have been brought to patients in the last 30 years and many drug developers have left the field.

Key barriers to the development and delivery of effective antibiotics are:

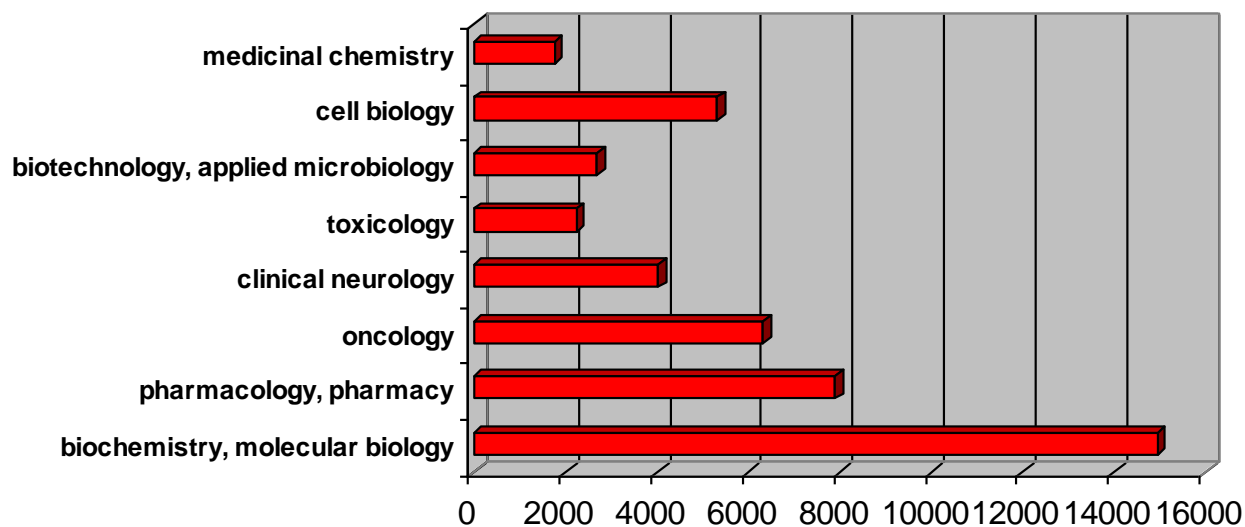
1. discovery and development of novel antibacterial agents is scientifically challenging;
2. there are substantial regulatory challenges to the introduction of novel antibacterial agents;
3. antibiotics have a low return on investment (ROI) relative to other medicines.



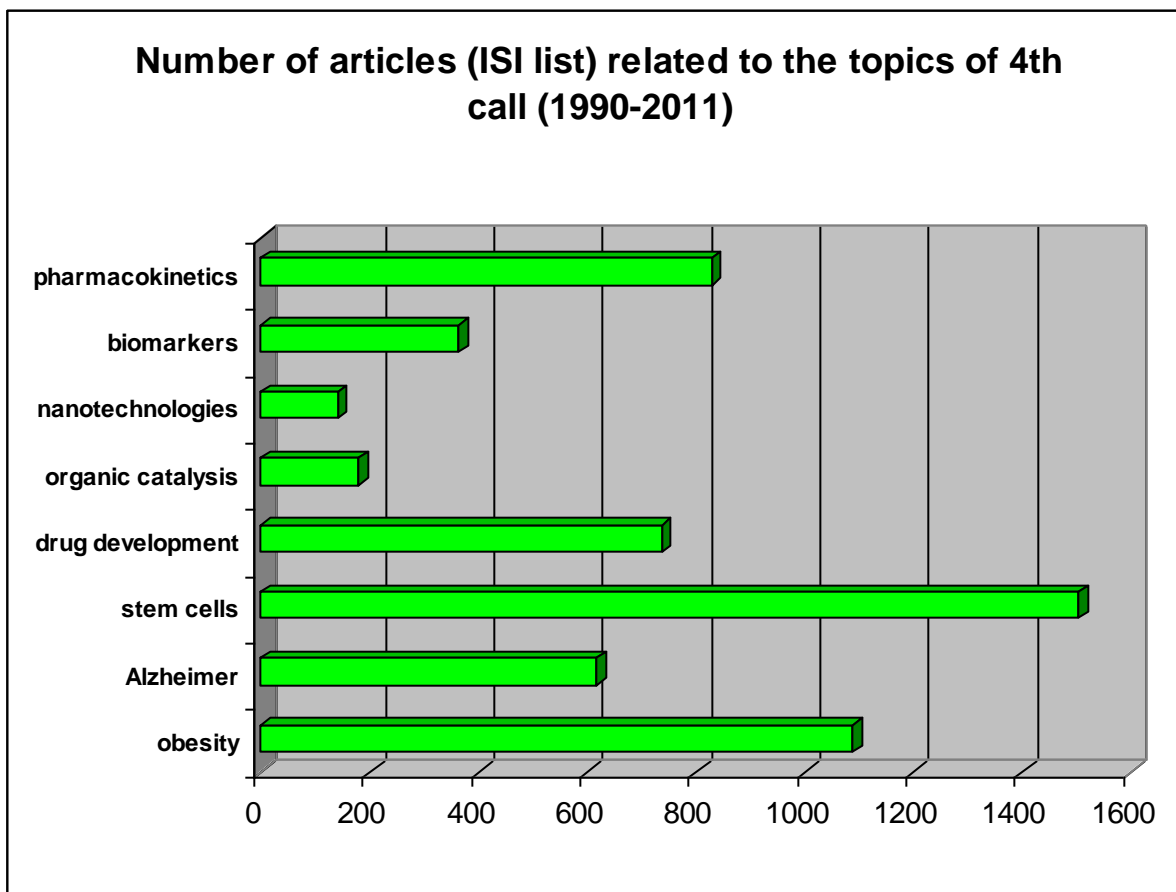
# Polish expertise



**Number of articles (ISI list) with Polish affiliation  
(1990-2011) according to the research field**



# Opportunities in 4th call





# IMI matters to new member states. Why?

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- 1. The new member states have excellent scientists who are fully able to compete for and win funds from IMI for research collaborations.**
- 2. IMI will support new member states in developing clinical research capability and capacity via networks of clinical centres that will allow local hospitals to take part in clinical trials, which in turn will attract investment to the country.**
- 3. IMI's member state group will allow for greater dissemination and coordination of national research efforts and will help scientists from new member states participate in international collaborations.**
- 4. Patients in new member states will benefit both from early access to innovative medicines as well as through exposure to patient organisations.**



# Opportunities for Polish researchers and Poland

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1. Direct participation of Polish research groups in IMI projects
2. Creation of international networks of collaboration – even without financial support from IMI
3. Participation in post IMI projects – namely drug development projects based on IMI achievements
4. Involvement of Polish SMEs – especially from biotechnology sector.

**IMI coordination in Poland: NCBiR (The National Centre for Research and Development) dr Izabela Rzepczyńska and dr Aleksandra Mościcka-Studzińska**

