



Innovative Medicines Initiative

For immediate release

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PRESS RELEASE

NEW CALL FOR PROPOSALS MOBILISES STAKEHOLDERS IN EU-WIDE JOINT EFFORT

IMI BUILDS COLLABORATIONS TO MONITOR VACCINE SAFETY AND DRUG EFFECTIVENESS

- In some cases, concerns regarding vaccine side effects have led to lower vaccination rates and subsequent disease outbreaks. Large-scale, coordinated monitoring of vaccine benefits and risks is needed to prevent future outbreaks.
- There is a growing need to gather information on the effectiveness of new drugs in the real-world setting earlier in the development process.
- The Innovative Medicines Initiative will support experts to tackle these issues in public-private collaborations.

BRUSSELS, 17 July 2012 – Today the Innovative Medicines Initiative (IMI) is calling experts to join forces and tackle two challenges which are of major importance to public health. Measuring the combined benefits and risks of vaccines and assessing the effectiveness of new medications in the real world setting are the focus of the Call for proposals that IMI is launching today.

For both topics, the challenge is so big and complex, that it can only be tackled by a multidisciplinary consortium including academic researchers in a wide range of areas, as well as representatives from regulatory agencies, manufacturers, healthcare organisations, small- and medium sized enterprises (SMEs), patients' organisations and public health institutes, together with experts in governance, ethics and communication. Therefore, IMI will support public-private partnerships to pave the way towards a solution.

Michel Goldman, IMI's Executive Director commented: 'Gaining more insight into the real-world benefits and risks and effectiveness of vaccines and drugs will help health authorities and companies to make better informed decisions about new and existing products. But foremost, it will result in getting better medicines to the patients in a faster way.'

Topic 1: Developing a framework for rapid assessment of vaccination benefits and risks in Europe:

Vaccines are one of the most effective preventive public health measures, with millions of people vaccinated every year. However public distrust has been growing in recent years, fuelled by fear of safety issues and the ever fading personal knowledge of the potential detrimental effects of the prevented diseases. In some cases this has led to a decrease in vaccination uptake and subsequent outbreaks of diseases previously under control.

The ability to rapidly access and evaluate information regarding both the actual benefits and risks of vaccines is needed to maintain trust from the public and to allow the regulators and physicians to make appropriate decisions regarding vaccination strategies. However, since adverse reactions to vaccinations are rare, data from large numbers of patients is required to accurately assess both the benefits and risks of vaccines. Although there are efforts underway to support such efforts, with encouraging results, there is clear need in Europe for a larger and more sustainable framework based on standardised and validated processes.

Therefore, IMI is calling experts in the field to join their skills and expertise in order to prepare the implementation of an efficient and sustainable infrastructure for rapid assessment of benefits and risks of vaccines that are already on the market. The public-private consortium will have to set out governance rules, explore synergies with existing projects, perform proof of concept studies and deliver an action plan for the implementation of a sustainable framework for benefit/risk monitoring of vaccines.

The European Union's Seventh Framework Programme will provide, through IMI, up to €5 million in funding to the public partners in the consortium. The participating pharmaceutical companies that are members of EFPIA will provide €5 million in in-kind contributions.





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Topic 2: Incorporating real-life clinical data into drug development:

The safety and efficacy of a new medicine is extensively tested during the development phase in accordance with strict regulatory guidelines. However, the assessment of the benefit/risk and value of new medicines continues beyond initial market approval. Recently there has been a rapid growth in real world studies to complement clinical trial data and support Health Technology Assessment (HTA) evaluation. These studies draw on data from clinical practice and so provide information on how medication performs in real life. In conjunction with clinical trial data, they offer evidence for reimbursement and funding decisions at national and local levels. This affects the speed and level of patient access to new medicines.

It is in the interest of patients, doctors, public authorities and drug developers to obtain this real-world information on the effectiveness and benefit/risk of a drug as soon as possible and in a systematic way. Therefore, IMI calls on public and private experts, including patients' organisations, to join forces. The consortium that will be selected through the Call process will investigate how this type of research can be best incorporated in the development plans and trial designs of drugs. New and open tools will be developed to assess the value of new medicines for public health, which will help governance bodies to make informed decisions about new drugs.

In particular in the areas of **diabetes, cardiovascular disease, lung disease, cancer and nerve/brain disorders**, the consortium will develop guidance on how to implement the methods for effectiveness research. In addition, IMI is asking the experts to develop training activities, for a better understanding and awareness of relative effectiveness research.

The European Union's Seventh Framework Programme will provide, through IMI, up to €8 million in funding to the public partners in the consortium. The participating pharmaceutical companies that are members of EFPIA will provide €8 million in in-kind contributions.

More information:

- IMI 7th Call for proposals: www.imi.europa.eu/content/7th-call-2012

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About IMI

IMI is the world's largest public-private partnership in health care. IMI is improving the environment for pharmaceutical innovation in Europe by engaging and supporting networks of industrial and academic experts in collaborative research projects. The European Union contributes €1 billion to the IMI research programme, which is matched by in kind contributions worth at least another €1 billion from the member companies of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The Innovative Medicines Initiative is currently funding 30 projects, many of which are already producing impressive results. The projects all address major bottlenecks which will lead to accelerate the development of safer and more effective treatments for patients.

More info: www.imi.europa.eu

