



## Press release

### **IMI invests €17.4 million to develop new biomarkers for vaccine immunosafety.**

Brussels, June 18, 2012

On March 1, 2012 the IMI-JU funded project – Biomarkers for Enhanced Vaccine Safety (BioVacSafe) – initiated its collaborative work to develop new tools that will improve the evaluation and monitoring of vaccine immunosafety.

BioVacSafe is a public-private consortium of 19 partners involving three of Europe's leading vaccine producing companies, experts from major academic institutions, small- and medium-sized enterprises (SMEs), and non-governmental organization (NGO) actors.

The project has a total budget of 30.2 million Euros and covers a five-year period.

BioVacSafe aims at establishing tools, methods and guidelines for the evaluation of vaccine reactogenicity and enhancing immunosafety of novel vaccines. In this context, BioVacSafe partners have a unique opportunity to tackle the urgent need to establish new collaborative networks among industry, academia, biotech companies, regulators and patients' organizations to promote and support R&D for safer vaccines.

#### **A new approach to vaccine safety**

Vaccines are widely acknowledged as one of the cheapest and most efficient ways to combat infectious diseases in both developed and developing countries. With billions of doses of vaccines administered globally every year, vaccine safety has always been a top priority for pharmaceutical companies, regulators and the public alike. The need for new approaches, methods and tools, is a priority.

The BioVacSafe project will draw on the latest life science research findings to profile how individuals respond to the different components of vaccines at cellular, genetic and molecular levels. This will allow the Consortium to identify and characterize new biomarkers useful to identify warning signs that a candidate vaccine may be reactogenic. Meanwhile, the Consortium will develop new ways to identify, classify and record adverse reactions to vaccines. Furthermore, the BioVacSafe team will probe how natural illnesses and infections, particularly diseases of the immune system, interact with vaccines.

By discovering novel ways to identify and better understand the mechanisms of adverse reactions to vaccines, at all stages of development, BioVacSafe will accelerate the development and introduction of a new generation of safer, more effective vaccines. Moreover, the new, more accurate tools developed by BioVacSafe should help to boost public confidence in vaccine safety.

*The Max Planck Institute for Infection Biology (MPIIB)*, one of the major contributors to the BioVacSafe project, will compare gene expression profiles induced by the different types of vaccines. Stefan Kaufmann, Director at the MPIIB, says: "I am convinced that this will allow the design of response profiles that predict safety and efficacy of current and novel vaccines and provide guidelines for greater cost efficiency in the development of future vaccines".

#### **BioVacSafe details:**

Grant Agreement n. 115308

Start date: 01/03/2012

Duration: 60 months

Total cost: €30 .2 million

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**Project Partners****EFPIA member companies**

- Novartis Vaccines and Diagnostics, Siena, Italy
- GlaxoSmithKline Vaccines, Rixensart, Belgium
- Sanofi Pasteur, Lyon, France

**Universities, research organisations, public bodies, non-governmental organizations**

- University of Surrey, Guildford, UK
- Chalmers University of Technology, Göteborg, Sweden
- Charité Universitätsmedizin Berlin, Berlin, Germany
- Commissariat à l'énergie atomique et aux énergies alternatives, Paris, France
- Göteborgs universitet, Göteborg, Sweden
- Health Protection Agency, London, United Kingdom
- Imperial College London of Science, Technology, Medicine, London, UK
- Liverpool School of Tropical Medicine, Liverpool, UK
- Max-Planck-Gesellschaft zur Förderung der Wissenschaften, Berlin, Germany
- Statens Serum Institut, Copenhagen, Denmark
- Università degli Studi di Siena, Siena, Italy
- Universiteit Gent, Ghent, Belgium
- Universiteit Utrecht, Utrecht, Netherlands

**Small- and medium-sized enterprises (SMEs)**

- CDISC European Foundation, Woluwe-Saint Lambert, Belgium
- ImmunArrray, Rehovot, Israel
- deCODE genetics (Isensk Erfdagreining ehf), Reykjavik, Iceland

