BIOVACSAFE
Biomarkers for enhanced Vaccine immunoSafety

Vaccine safety: the next generation

Since their discovery, vaccines have protected millions of people worldwide from a broad range of infectious diseases, making them one of the most effective public health interventions out. New and better vaccines are still urgently needed, yet their introduction is hampered by lengthy and expensive vaccine safety testing procedures. The aim of the IMI-funded BIOVACSAFE project is to develop cutting edge tools to speed up and improve the testing and monitoring of vaccine safety, both before and after release to the market. By bringing together Europe's top industrial and academic teams for the first time, the project will ultimately usher in a new generation of safer, more effective vaccines.

Vaccines are widely acknowledged to be 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 is a top priority for pharmaceutical companies, regulators and the public alike. The problem is that testing and monitoring new vaccines for safety is a slow, cumbersome and extremely expensive process; the development of a new vaccine costs millions of euros, and less than 1 vaccine in 10 makes it through clinical testing.

As companies add new components to vaccines to make them more effective, testing them for safety becomes even more challenging. And, while severe adverse reactions to vaccines are rare, predicting who is at risk of a severe reaction is extremely difficult; this problem will be further complicated by the ageing of the population and the growing burden of chronic conditions and diseases of the immune system.

A new approach to vaccine safety

The BIOVACSAFE project will draw on the latest life science research findings to profile, in great detail, how individuals respond to the different components of vaccines at the cellular, genetic and molecular level. This will allow the project team to develop tools that can rapidly and accurately identify warning signs that a potential vaccine may be reactogenic. The tools could be employed early on in vaccine development, before vast amounts of time and money have been spent.

Meanwhile, the team will develop new ways to identify, classify and record adverse reactions to vaccines; this should also boost researchers' ability to pick up on problems early in vaccine development. Finally, the team will probe how natural illnesses and infections, particularly diseases of the immune system, interact with vaccines. By identifying these interactions, the team hopes to find ways of preventing them occurring in the first place. Finally, the team will create databases that can be used to store information on and explore reactions to vaccines.

BIOVACSAFE at a glance

Full project title:
Biomarkers For Enhanced Vaccine Safety

Start date: 01/03/2012

Duration: 60 months

Total cost: €30.2 million

Project coordinator & **Managing entity:**
University of Surrey

EFPIA coordinator: Novartis Vaccines

Project website: www.biovacsafe.eu

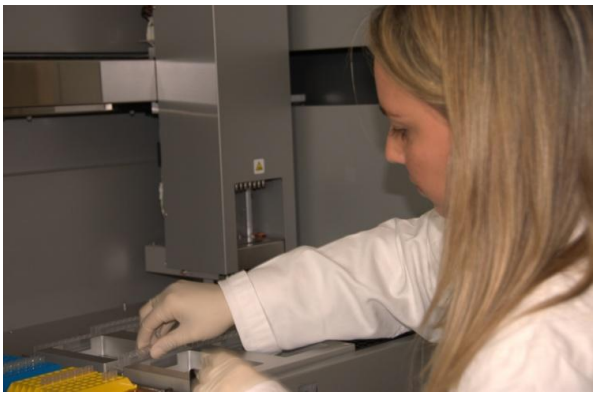
Towards the next generation of vaccines

By coming up with novel ways to identify and better understand the cause 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 to combat infectious diseases, cancer and chronic diseases. As well as speeding up vaccine development, the new, more accurate tools developed by BIOVACSAFE should help to boost public confidence in vaccine safety. Furthermore, because the project includes studies of populations in both developed and developing countries, its findings should be of global relevance.

An injection of health for Europe's vaccine development sector

BIOVACSAFE brings together for the first time three of Europe's leading vaccine development and manufacture companies as well as top experts from academic institutions and small and medium-sized enterprises (SMEs). By sharing their expertise as well as access to data and patient groups, all project partners will see their knowledge base and their competitiveness grow. Crucially, by pooling their expertise, the BIOVACSAFE partners have a unique opportunity to make progress in this important area.



Contacts

Project Coordinator & Managing Entity of EU funds

University of Surrey
Representative: Professor David Lewis

EFPIA Coordinator

Novartis Vaccines
Representative: Giuseppe del Giudice

Contact:
Email: biovacsafe_projectmanagement@surrey.ac.uk

Press Contact

Mike Findlay
University of Surrey
Tel.: +44 1483 689314
E-mail: mediarelations@surrey.ac.uk

Project Partners

EFPIA Member Companies

- Novartis Vaccines, Siena, Italy
- GlaxoSmithKline Biologicals, Rixensart, Belgium
- Sanofi Pasteur, Lyon, France
- Islensk Erfdagreining ehf, Reykjavik, Iceland

Universities, Research Institutions, Public Bodies, non-profit Organisations

- University of Surrey, Guildford, UK
- Chalmers University of Technology, Göteborg, Sweden
- Charité Universitätsmedizin, Berlin, Germany
- Commissariat à l'énergie atomique et aux énergies alternatives, Paris, France
- Göteborgs universitet, Göteborg, Sweden
- Imperial College London of Science, Technology, Medicine, London, 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
- CDISC European Foundation, Woluwe-Saint Lambert, Belgium
- St George's University of London, London, UK
- Department of Health, London, UK

Small and Medium-sized Enterprises (SMEs)

- ImmunArrray, Rehovot, Israel
- VisMederi, Siena, Italy

Financing

IMI funding	€17.4 million
EFPIA in kind contribution	€7.6 million
Other contributions	€5.2 million
Total project cost	**€30.2 million**

This project is funded by the Innovative Medicines Initiative (IMI), a public-private partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA), under Grant Agreement 115308.

Last update: March 2015