



Innovative Medicines Initiative

# The Innovative Medicines Initiative (IMI) a spotlight on successes

## Michel Goldman, Executive Director of the Innovative Medicines Initiative (IMI), highlights some of the initiative's biggest achievements so far, and looks towards the next IMI public-private partnership (PPP)

On 10 July, the European Commission released its proposals for a second Innovative Medicines Initiative ('IMI 2'), a public private partnership (PPP) with a budget of €3.45bn and the goal of delivering new breakthroughs that will help to tackle Europe's biggest health challenges. The new PPP will build on the successes that the current IMI has achieved so far.

The IMI was set up in 2008 with a €2bn budget and the goals of speeding up the development of safer and more effective medicines for patients and boosting the competitiveness of Europe's pharmaceutical sector.

Today, the initiative has 40 projects up and running and more are in the pipeline. IMI is widely recognised as a pioneer of open collaboration, a novel way of working that is radically changing the shape of the pharmaceutical research and development (R&D) landscape.

### **An evolving story**

Over the years, IMI has learnt a lot about how to set up and run large scale projects in which partners from industry, academia, small businesses, patient groups and others join forces to tackle some of the biggest challenges in drug research and development. In response to feedback from project participants, we changed our funding rules and simplified our procedures; as a result, our time to grant (i.e. the time from the deadline for submitting applications to the signature of the grant agreement) has fallen to below 200 days, and all application and reporting is done via our online tool. IMI has also evolved scientifically. The first IMI projects focused primarily on the early stages of drug development. In 2011, an update of the Scientific Research Agenda extended the scope of IMI's work to cover issues such as regulatory approval, pharmacovigilance, and health technology assessments. As a result, IMI now has projects covering the entire drug development cycle.

Significantly, IMI has demonstrated the success of the PPP model in health research, most notably in disease areas where treatments are currently lacking and where the research and innovation challenges are simply too great for any single organisation or company to tackle alone.



Professor Michel Goldman, Executive Director, IMI

### **Action on autism**

For example, one of our most successful projects, European Autism Interventions – A Multicentre Study for Developing New Medications (EU-AIMS), is working on autism spectrum disorders (ASD). People with ASD experience difficulties in social interaction and communication, and often have unusual repetitive behaviours. Yet although ASD affects one child in 110 and is a lifelong condition, there are currently no drugs designed specifically to treat the main symptoms. The goal of EU-AIMS is to generate tools that will enhance our understanding of ASD, and ultimately pave the way for the development of new, safe and effective treatments for use in both children and adults.

EU-AIMS has already made a number of important discoveries. Amongst other things, it has found that some of the brain changes associated with autism could be reversible, even once brain development is completed. Elsewhere, the project is also contributing to new treatment guidelines being compiled by the European Medicines Agency (EMA), and setting up two of the largest ever clinical studies of ASD.

The first of these will look at the risk of autism in a younger brother or sister of a child with autism, while the second will track how symptoms change with age. These will involve around 1 000 patients and will begin in 2014.

### **Tackling diabetes**

Another project delivering groundbreaking results is IMIDIA (Improving Beta-Cell Function and Identification of Diagnostic Biomarkers for Treatment Monitoring in Diabetes), which is one of three IMI

projects focusing on diabetes. Diabetes is a chronic disease in which patients' blood sugar levels are elevated because the beta cells in the pancreas fail to produce enough insulin. It is estimated that diabetes affects round 366 million people worldwide, and that figure is likely to rise to 552 million by 2030. Patients are at risk of a number of serious complications, including heart disease and stroke, and damage to the blood vessels, kidneys, and eyes. Diabetes therefore has a major impact on sufferers' quality of life.

Currently there is no cure for diabetes, and treatment options are limited. For many years, a major challenge for diabetes researchers was the lack of a human pancreatic beta cell line that survived (and so could be studied) in the lab; instead, scientists had to use rodent beta cell lines.

Now, IMIDIA researchers, including scientists from the French SME Endocells, have developed a human pancreatic beta cell line that not only survives in the lab, but also behaves in much the same way as beta cells in the body. The result has been hailed as a breakthrough for diabetes research.



### Spotlight on safety

A major challenge in drug development is identifying potential drugs that may have unintended and harmful side effects by damaging vital organs such as the heart, liver, or kidneys.

All too often, toxicity issues are picked up very late

in development, when vast amounts of time and money have been spent on a potential drug. With this in mind, many IMI projects are developing tools and methodologies to detect drug safety issues much earlier in drug development.

For example, the eTOX project has developed a computer model to test whether potential medicines could be harmful to the heart. Users simply have to enter the molecular formula of the compound into the tool, and the system generates a simulated ECG (electrocardiogram).

Clinicians routinely use ECGs to diagnose heart problems in their patients; in the same way, users can study the simulated ECG generated by the eTOX system to determine whether or not a compound is toxic to the heart. According to the project team, it provides better results than the currently-used computational systems.

### Focus on the future

IMI has achieved much in its short existence. As well as delivering scientifically excellent results that are set to improve the drug development process, it is provoking a revolution in the way pharmaceutical R&D is carried out and is injecting new life into Europe's pharmaceutical sector.

Meanwhile, IMI is still launching new calls for proposals; our ninth call, launched in July, featured topics on frailty and the use of social media to monitor drug safety and also builds on our antimicrobial resistance programme.

Further calls for proposals are in the pipeline. As the achievements of IMI's ongoing projects demonstrate, PPPs have a clear role to play in health research and innovation. We are confident that IMI 2 will build on the successes and lessons learnt in the current programme.

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## About IMI

With a €2bn budget, the Innovative Medicines Initiative (IMI) is the world's largest public private partnership in life sciences. Through its collaborative projects that bring together experts from industry, academia, small and medium-sized enterprises (SMEs), patient groups, and regulators, IMI aims to develop tools and technologies that will speed up the development of safer and better drugs for patients. IMI has launched 40 projects to date. Some projects focus on specific health issues such as neurological conditions (Alzheimer's disease, schizophrenia, depression, chronic pain, autism), diabetes, lung disease, oncology, inflammation and infection, tuberculosis, and obesity. Others focus on broader challenges in drug development like drug and vaccine safety, knowledge management, the sustainability of chemical drug production, the use of stem cells for drug discovery, drug behaviour in the body, the creation of a European platform to discover novel medicines, and tackling antimicrobial resistance. In addition to its research projects, IMI supports a number of education and training projects. [www.imi.europa.eu](http://www.imi.europa.eu)