



Innovative Medicines Initiative

Health Research at a Crossroads – Are Public-Private Partnerships the Way Forward?

European Parliament – Brussels – Belgium

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Executive Summary

Health research is at a crossroads. Developing new drugs for the many diseases and conditions that still lack a cure or effective treatment is proving extremely difficult, leading some pharmaceutical companies to give up on entire disease areas. Meanwhile, budgets for drug research and development are tighter than ever.

This event, organised by the **Innovative Medicines Initiative (IMI)** and hosted by **Amalia Sartori MEP**, aimed to present **IMI's achievements** and activities and promote a **discussion** on the **role of public-private partnerships (PPPs) in health research**. The stakeholders agreed that:

- IMI enables **unique, open collaboration** between public and private partners in a way that was not possible before.
- IMI has delivered **significant research achievements**.
- A **PPP in innovative health research** under Horizon 2020 would be a way of **tackling remaining challenges** in health research.
- This new PPP should **build on IMI's achievements** and learn from its successes and difficulties.
- The new PPP should have an **appropriate budget** and a **flexible structure** built on existing **simplified rules**, as in IMI.
- The new PPP should bring together **all relevant stakeholders** to jointly address they key challenges in health research for the **benefit of society and industry**.

Event webpage: www.imi.europa.eu/events/2012/09/07/health-research-crossroads

Goal of the event

- To have a debate on the future of health research in Europe and the role of public-private partnership in the context of a period of economic crisis.

Key questions

The debate takes place at a time when important decisions on EU health research are being taken and against the backdrop of profound changes and challenges in pharmaceutical research & development (R&D).





Key issues in this context are:

- Developing innovative drugs is proving increasingly difficult and costly. Some pharmaceutical companies are giving up on entire disease areas, while many diseases and conditions still lack effective treatments. Is there a way out of this innovation crisis?
- Budgets for pharmaceutical R&D are tighter than ever. Which new business models are needed?
- Are public-private partnerships the way forward? What are the lessons learnt from the IMI experience for Horizon 2020? Would other models offer a better solution?

Speakers & Panellists

- Amalia Sartori MEP
- Roch Doliveux, Chief Executive Officer, UCB & Chair of the IMI Governing Board
- Ruxandra Draghia-Akli, Director, DG Research & Innovation, European Commission & Member of the IMI Governing Board
- Andrew Jack, Journalist, Financial Times
- Michel Goldman, Executive Director, IMI
- Magda Chlebus, Director, EFPIA
- Mary Baker, President, European Brain Council & Member of the IMI Scientific Committee
- Rolf-Detlef Treede, Chair of Neurophysiology, University of Heidelberg
- Tine Bryan Stensbøl, Divisional Director, Synaptic Transmission Research, Lundbeck
- Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency
- Scott Wagers, Chief Executive Officer, BioSci Consulting

Participants

The event attracted around 150 attendees, including:

- Policy makers (including MEPs and their assistants)
- Representatives of the Member States
- European Commission staff
- Pharmaceutical companies
- Universities
- Research organisations
- Patients' organisations
- Journalists

Summary of the presentations and discussions

Opening remarks – Amalia Sartori MEP

In her opening statement, Ms Sartori recognised the contribution of IMI, as an honest broker, to improving drug research and development in Europe. Many IMI projects have already delivered unexpected results that would not have been possible without IMI.

She considered it important to invest in all stages of the research cycle with all stakeholders concerned.

Ms Sartori also stated that she will defend the multi-annual framework budget proposed by the European Commission in spite the difficult economic context.



Ms Sartori asked participants to have a closer look at IMI deliverables not only for industry, but for small companies, regulators, patients and other groups and contribute to the discussion on whether this type of public-private partnership is the way forward for health research in Europe.

She noted the importance of the subject for the stakeholders, as testified by the number of participants at the event.

IMI - the story so far – Ruxandra Draghia-Akli, European Commission

Dr Draghia-Akli described how IMI was first set up due to the difficulties industry faced applying to take part in framework programme projects; this led to the idea of setting up a European Technology Initiative.

She also highlighted the process of setting out the strategic research agenda and explained that IMI was founded with €1 billion in funding from each partner with joint decision making. The IMI Council Regulation process had strong support from the European Parliament and in particular from Françoise Grossetête MEP.

IMI has launched seven Calls for proposals so far and the first projects, which have been running for around three years, are already delivering exciting results that go beyond the state of the art. It also had success in increasing levels of trust between the EU, pharmaceutical industry, academia and patients. IMI's goal is to improve the drug development process by addressing major hurdles in the drug research process from knowledge fragmentation to data pooling, etc.

One of the goals that was not clearly stated at the beginning was to ensure the greater involvement of regulators and patients.

Dr Draghia-Akli also highlighted the successes of some of IMI's 37 ongoing projects, such as EUROPAIN (chronic pain), and PharmaCog (Alzheimer's disease).

Dr Draghia-Akli invited participants to have a look at lessons learned from IMI and bring up essential elements to develop further this partnership.

IMI's added value to the pharmaceutical industry – Roch Doliveux, UCB

Dr Doliveux stressed that science has never provided us with so many opportunities to innovate, yet it is so complex that no-one can do it on their own, as demonstrated by the Nobel Prize for medicine which was awarded to two researchers involved in stem cell research.

He also underlined the importance of healthcare innovation in Europe and spotlighted IMI as an open innovation model.

Dr Doliveux addressed four key issues during his speech:

- The importance of healthcare innovation in Europe

Europe cannot get out of the economic crisis without innovation. The biopharmaceutical and health industries are the most strategic industries in Europe to help cope with the ageing population in Europe and around the world.

- The challenges around innovation in healthcare in Europe

Complex science: it is proven that the business model does not work and needs to be changed. A new paradigm shift requires new models to understand the phenotypes of individuals with shared technology and collaboration.

Disconnect between innovation and access to innovation: Who will pay for innovation? Governments' cost-saving measures should target off-patent medicines and not innovative medicine e.g. difficulties with German reimbursement systems.

Education: Need for more science students and to maintain European universities leadership.



- How IMI became a role model for open innovation

The first of its kind and with an unprecedented scale, IMI is the largest PPP in life sciences in the world. It manages to raise interest around the world and effectively solves the bottleneck of the discovery of new medicines. IMI is a neutral platform which seeks real collaboration between public and private partners where the best potential and intellectual input throughout Europe is combined.

- Why the public-private partnership should continue under Horizon 2020

Horizon 2020 should build on IMI's achievements and lessons learnt to take IMI to the next level.

Debate

Moderated by Andrew Jack, Financial Times

Tine Bryan Stensbøl, Lundbeck

The involvement of Lundbeck in the IMI project NEWMEDS was described as a fantastic collaboration experience and game-changing. Participating organisations are fully committed and engaged to work together as one team on the NEWMEDS project. The project has brought together data from over 23 000 patients, something which would not have been possible without IMI. She is in favour of a more flexible approach for companies' management of project investments. Intellectual property (IP) is working well.

Scott Wagers, BioSci Consulting

The role of the consulting organisation in IMI projects is to get people to innovate. Diversity delivers good innovation and should be carried on under Horizon 2020. IMI projects are changing the way people are working, and collecting data is delivering good results e.g. U-BIOPRED, BT-CURE and eTRIKS. In his view there is no way for a single organisation or company to achieve this alone.

Magda Chlebus, EFPIA

The way research teams in IMI projects work together is constantly evolving and now covers more aspects of the research chain. We need to find innovative ways of moving research results forward. As large-scale collaborations are complex, a new structure should be flexible. EFPIA has been working with the European Commission and IMI for two years to simplify procedures.

Rolf-Detlef Treede, University of Heidelberg

EUROPAIN is an umbrella project which is completely open. In spite his university's scepticism about participating in the project, he does not regret joining the project, as academic people could never do the work alone. The sustainability of the project beyond its initial five years is a concern for the consortium as pre-competitive work on humans is longer than in animals. Regarding working with big companies, he mentioned some difficulties, such as the governance in companies (e.g. financial decisions being made on a quarterly basis), and the loss of an industrial partner and its intellectual know-how which was key for the project. Intellectual property is working well.

Mary Baker, European Brain Council

Dr Baker expressed her concern about the ageing population, pointing out that it requires six tax payers to pay for one pensioner. How can we continue to improve quality of life, especially in old age, and reduce the burden of disease for society? She highlighted IMI's EU-PATI project which is



training patients in the drug development process. These topics are particularly important as we are moving to the sphere of personalised medicine. In the view of Dr Baker, IMI has to go on with an extension and budgetary support.

Hans-Georg Eichler, European Medicines Agency

Dr Eichler noted discussed the importance of regulators engaging in IMI and reflected on how to do this while remaining unbiased. IMI is moving forward and expanding to address the entire life cycle of a medicine which pleases Dr Eichler. His recommendation for Horizon 2020 is to make more use of IMI as an instrument and to involve payers' organisations.

Michel Goldman, IMI

The IMI Executive Director highlighted some key achievements:

- Change in mind set and trust where IMI plays the role of honest broker
- A major strength of IMI is having industry leading the process with a vision to move along the value chain
- On intellectual property, one size does not fit all. In 37 IMI projects, IP is not an issue.

For the future we need to empower patients and to involve further regulators.

Roch Doliveux, UCB

Regarding the management of the consortia, Dr Doliveux considers that people should not feel dominated. Some projects may benefit from management by a member of the consortium, others from management by an external consultancy. Nonetheless, industry intellectual know-how is needed in the projects.

Ruxandra Draghia-Akli, European Commission

Dr Draghia-Akli stressed that a public-private partnership is the way forward. It should ensure that real public health issues are addressed; that other industries can join at both the programme and project level; that contributions both in cash and in-kind from industry are accepted to tackle different types of challenges.

Questions from other attendees

Participants questioned the sustainability and reward of team work in academia. Here panellists agreed that sustainability and reward for team work in academia and industry are critical. IMI is developing metrics to measure networks and collaboration. Sustainability should be looked at in a broader way in the future.

There were also questions on the proposed scope for a future public-private partnership in life sciences. Will it be only pre-competitive? And will it allow the participation of medium-sized companies that are not EFPIA members? Panellists clarified that pre-competitive means different things but the idea is that future public-private partnership will cover the entire research cycle including pharmacovigilance. Panellists also agreed that any company should be able to participate in IMI projects.



Questions were also asked on how IMI will operate as from 2014 if its first mandate will finish in 2017. Regarding the mandate, the new public-private partnership should start operation as from the approval of a legislative act and in the terms included therein.

Conclusions

- IMI enables open collaboration between public and private partners in a way that project partners perceive to be unique and was not possible before.
- IMI has delivered significant research achievements – this was acknowledged by all participants including Members of the European Parliament.
- Looking to the future, Europe should build on IMI's work, learning from both its achievements and difficulties to ensure that all stakeholders continue to benefit from this innovative and successful way of working.
- The participants agreed that a renewed public-private partnership in innovative health research under Horizon 2020 should be the way to tackle remaining challenges. It should however be allocated an appropriate budget.
- All stakeholders showed willingness to work together to address remaining challenges to restore competitiveness in the health sector in Europe for the benefit of society and industry.
- Among other things, speakers proposed:
 - moving further on clinical research;
 - having a simple and flexible structure built on existing simplified rules;
 - optimising the use of patients' information from clinical trials;
 - developing methodologies to carry out clinical trials in a better way;
 - addressing key biological goals;
 - jointly addressing challenges with all stakeholders including with additional stakeholders affected by or involved in this area;
 - participation of industry know-how should be kept in the projects;
 - personalised medicine should also be addressed.

More information on the event

More information on the event, including the agenda and the presentations of Ruxandra Draghia-Akli and Roch Doliveux, can be found online at:

www.imi.europa.eu/events/2012/09/07/health-research-crossroads

About IMI

IMI is the world's largest public-private partnership in health. 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 37 projects, many of which are already producing impressive results. The projects all address major bottlenecks which will accelerate the development of safer and more effective treatments for patients.

More info: www.imi.europa.eu

Disclaimer: This report is entirely the responsibility of IMI JU. It is not intended to be a transcript of the debate, but to provide an overview of the key points made that are, in the author's opinion, most relevant to the subject in hand.