

## Reflections on the Innovative Medicines Initiative

Michel Goldman

The pharmaceutical industry is developing new collaborative models for drug development. This article discusses the experience so far of the Innovative Medicines Initiative, which is currently the largest public–private partnership that is dedicated to pharmaceutical innovation, highlighting lessons learned for the success of precompetitive consortia.

Public–private partnerships (PPPs) are increasingly being established to reinvigorate research and development (R&D) of innovative medicines. In parallel with the creation of US-based PPPs, the Innovative Medicines Initiative (IMI) was set up to enhance the competitiveness of the pharmaceutical sector in Europe for the benefit of both patients and scientists. To this end, the European Federation of Pharmaceutical Industries and Associations (EFPIA) was invited by the European Commission (EC) to develop a series of recommendations to address major bottlenecks in the drug development process. Following the establishment of a research agenda in consultation with various stakeholders, the IMI was launched in 2008 by the European Union and EFPIA, as a Joint Undertaking with a total budget of €2 billion to be spent over a 10-year period, making the IMI the largest PPP in R&D in the field of life sciences. Both of the IMI's founding members — the EFPIA and the EC — are equal in terms of their level of investment and their rights.

To fulfil its mission, the IMI implements R&D programmes that are focused on the development of new tools and methods for the prediction of drug safety or efficacy and more efficient knowledge management. Furthermore, it supports education and training projects on the same topics. IMI-sponsored activities are conducted by consortia that bring together pharmaceutical companies, small- and medium-sized enterprises (SMEs) and partners from the public sector. EFPIA-affiliated pharmaceutical companies invest in the form of 'in kind' contributions by committing human resources, providing access to data sets and infrastructures, and sometimes through direct monetary contribution. This industry investment is matched by funds from the EC's Seventh Framework Programme to other consortium members, including academic teams, SMEs, patients' organizations, regulatory agencies and other non-profit institutions.

The first two calls for proposals launched by the IMI in 2008 and 2009 resulted in 23 ongoing projects, which were established in a three-step process. First, the research

topics were developed, primarily by 23 EFPIA-affiliated companies, with input from the IMI Scientific Committee and from a States Representatives Group. Second, following a call for proposals, consortia that were eligible to receive public funding from the EC competed through the submission of expressions of interest, and the best-ranked consortium, selected by independent experts, was invited to join EFPIA-affiliated companies in the next stage. Third, they formed the final consortium, which developed a full project proposal that was submitted for peer review.

The resulting 23 consortia involve 221 R&D teams from EFPIA-affiliated companies, 298 academic institutions, 47 SMEs, 11 patients' organizations and 7 regulatory agencies, with a total budget of €453 million. The number of partners per consortium ranges from 12 to 50 (the median is 23). The projects, which will typically run over a 5-year period, are listed in [Supplementary information S1](#) (table). Several projects aim to identify novel biomarkers or improve understanding of disease mechanisms, as well as beneficial or unwanted effects of drugs. Furthermore, many projects are based on sharing of data sets that already exist or that will be assembled.

Concrete results have already been achieved and publicly reported. For example, the NEWMEDS project has assembled the largest database so far on schizophrenia, with more than 10,000 patients, and initiated pioneering mechanistic studies combining genetic and imaging approaches through the participation of nine pharmaceutical companies, seven academic teams and several SMEs<sup>1</sup>. In parallel, the U-BIOPRED project has developed an international consensus statement on the classification of patients with severe asthma and produced a new algorithm for use in clinical research<sup>2</sup>. Furthermore, in several projects the IMI provides a new forum for dialogue between regulatory agencies and other stakeholders, including industry and patients' organizations. One example is the PROTECT consortium, in which the European Medicines Agency coordinates a project that aims to develop innovative pharmacovigilance tools based on patient-reported outcomes.

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doi:10.1038/nrd3434

### Key challenges

Although these initial achievements are encouraging, the long-term success of the IMI will depend on its capacity to meet several challenges that are common to PPPs dedicated to precompetitive research. Lessons learned from the IMI with respect to these challenges are presented here.

**Management of projects.** Most IMI consortia are led by scientists from EFPIA-affiliated companies, which greatly helps in keeping projects on track according to defined milestones and deliverables. Special attention should be paid to the composition of the consortia, as it is clear that the management complexity increases with the number of partners. It is therefore important to carefully consider the added value of each academic or SME partner, bearing in mind that a critical mass is necessary to ensure the competitiveness of the consortium. Depending on the nature of the project, regulatory institutions might participate as observers, members of advisory boards or as full partners. The involvement of patients' associations should also be taken into account, especially for projects that are related to drug safety and pharmacovigilance or based on patient-reported outcomes. Indeed, these consortia offer unique possibilities to take patients' views into consideration during drug development.

**Research topics.** The selection of research topics should take into consideration that the boundaries of precompetitive research can evolve. In a consortium focusing on the identification of new drug targets for a given disease, a company leaving the corresponding disease area might decide to withdraw, as has been the case in some IMI projects. In the IMI's experience, projects on drug safety are less subject to changes in their precompetitive nature from the perspective of large pharmaceutical companies. However, what is precompetitive for large companies might be competitive for SMEs or academic teams; for example, a biomarker for preclinical safety might become a commercial product for a small company that is developing diagnostic tests. Indeed, the IMI is currently reflecting on how to provide the flexibility required to cope with the evolving needs of industry without jeopardizing the interests of academic teams. One approach would be to facilitate budget reallocations and inclusion of new partners in the course of the projects.

**Intellectual property.** A significant challenge for the IMI and similar PPPs is the management of intellectual property (IP) rights given the multiple and sometimes divergent interests of consortium partners. When difficulties arise, the IMI Executive Office, which operates autonomously from the EFPIA and the EC, acts as an 'honest broker' to facilitate arrangements that preserve the interests of all parties. This is especially important when partners from non-profit institutions do not have the facilities and expertise required for a balanced negotiation with the legal services from large pharmaceutical companies. In order to provide a framework for consortium agreements, the IMI established a policy that provides the flexibility to adapt the management of IP rights

to the needs of each project ([Supplementary information S2](#) (box)). Although this pragmatic approach has allowed the conclusion of the necessary agreements, it is likely that the question of IP management will remain a matter of debate for PPPs in the pharmaceutical sector.

**Potential overlap between consortia.** Considering the large number of PPPs that are currently flourishing globally, some overlap between their activities is inevitable. Obviously, this might result in fragmentation of the knowledge created and dissipation of resources; indeed, several pharmaceutical companies have reported that they are suffering from 'consortium fatigue' owing to the number of PPPs they are involved in and the many solicitations they receive to join new ones. Within the IMI, an emphasis is made on establishing links and synergies, not only between IMI-sponsored consortia but also with similar PPPs. For example, a memorandum of understanding is under negotiation between the IMI and the Critical Path Institute in the United States, which might help to reconcile the global nature of the IMI's objectives with its specific European-centred mission.

**Performance indicators and rewards.** To ensure the sustainability of the IMI and similar PPPs, there must be evidence that they are beneficial for large pharmaceutical companies as well as for SMEs, academic institutions and other non-profit organizations engaged in the pharmaceutical sector. It is therefore important to establish a methodology to measure the global impact of such initiatives in addition to the performance of the individual projects they support. Another important challenge is to ensure that individuals who are responsible for the success of precompetitive projects are rewarded, as their contributions do not always result in publications in which they are the main authors (which is a major criterion for promotion in academia) and, from an industry standpoint, do not necessarily create value in the short term.

### Concluding remarks

With the advent of therapies tailored further to patients' individual needs and the increased attention given to rigorous evaluation of the benefit–risk balance of new drugs, medical advances are likely to be increasingly dependent on collaborative networks such as those established through the IMI. The first lessons learned from the IMI indicate that if research programmes are carefully selected and issues related to IP properly addressed, PPPs that are dedicated to precompetitive R&D can offer the appropriate instruments to enable this approach to shape the future of medicine.

1. Abbott, A. The drug deadlock. *Nature* **468**, 158–159 (2010).
2. Bel, E. H. *et al.* Diagnosis and definition of severe refractory asthma: an international consensus statement from the Innovative Medicine Initiative (IMI). *Thorax* 23 Nov 2010 (doi:10.1136/thx.2010.153643).

### Competing financial interests

The author declares [competing financial interests](#): see Web version for details.

### Acknowledgements

I would like to thank S. Black, K. De Rijck, A. Juliens and M. Poinot for their valuable assistance in the preparation of the paper, and A. Smith for his critical reading of the manuscript and useful suggestions.

### Disclaimer

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