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The Innovative Medicines Initiative: A European Response to the Innovation Challenge

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The Innovative Medicines Initiative (IMI) was launched in 2008 as a large-scale public–private partnership between the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA). With a total budget of €2 billion, the IMI aims to boost the development of new medicines across Europe by implementing new collaborative endeavors between large pharmaceutical companies and other key actors in the health-care ecosystem, i.e., academic institutions, small and medium enterprises, patients, and regulatory authorities. Projects conducted by IMI consortia have already delivered meaningful results, providing proof-of-concept evidence for the efficiency of this new model of collaboration. In this article we review recent achievements of the IMI consortia and discuss the growing interest in the IMI as a best-practice model to reinvigorate drug development.

The health-care sector is facing unprecedented challenges in ensuring the translation of biomedical advances into efficient, safe, and affordable new therapies for the benefit of patients worldwide. First and foremost, large pharmaceutical companies realize that their classical business models are obsolete in an era in which several of their major patents are expiring and their research and development (R&D) productivity is declining.[1] Second, biotech companies, which are a key source of new drugs,[2] are finding it increasingly difficult to acquire venture-capital funding. Third, regulatory authorities are looking for new methods to assess the benefit–risk profiles of new medicines[3] and to bridge the gap between efficacy in clinical trials and efficiency in usual care.[4] Last, but not least, patients are keen to play a more active role in the assessment of the efficacy and safety of new drugs.[5,6] Indeed, the level of trust between the different actors in drug development needs to be urgently restored following the disillusionment felt by many that the sequencing of the human genome did not deliver the expected therapeutic breakthroughs and in view of the growing number of conflict-of-interest cases.[7,8]

While the economic crisis is increasing the pressure to reduce costs related to health care in general and drug development in particular, there is now a unique window of opportunity to tackle these challenges. In fact, a large consensus exists among the different stakeholders on the urgent need to establish new modes of collaboration among industry, academia, biotech companies, regulators, and patients' organizations.[9–13] Public–private partnerships (PPPs) involving both private for-profit companies and publicly funded nonprofit institutions are the natural instruments to implement these collaborative efforts.

A CONSTELLATION OF PPPs

Until recently, PPPs in the biomedical sector were mostly bilateral agreements, typically between a pharmaceutical company and an academic institution. Yet it is clear that larger consortia have to be built to tackle the major challenges that the health-care system faces. As far as pharmaceutical R&D is concerned, a number of large PPPs have been developed to support drug discovery and development with respect to hitherto neglected infectious disorders in developing countries, with the goal of filling the dramatic gap between the global disease burden and the corresponding investment in pharmaceutical R&D.[14] These PPPs tackle tropical diseases such as malaria (e.g., the Medicine for Malaria Venture), tuberculosis (e.g., the Global Alliance for Tuberculosis Drug Development), and other endemic infections through the identification, screening, and evaluation of existing and novel compounds. The ultimate objective is the development of efficient, safe, and affordable therapies by promoting and supporting R&D for new drugs, vaccines, and diagnostics. Pioneered by the United Nations Development Programme/World Bank/World Health Organization Special Programme for Research and Training in Tropical Diseases, which was launched in 1975,[15] PPPs for neglected diseases are funded through a variety of sources, including philanthropic organizations such as the Bill and Melinda Gates Foundation, which played a key role in their expansion. Other PPPs—for example,

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Sage Bionetworks and the European Bioinformatics Institute Industry Programme—were specifically built for sharing bioinformatics platforms and resources dedicated to chemoinformatics, computational chemistry, or computational biology, often on the model of the open-source systems pioneered in the computer software industry.[16–18]

The Critical Path Initiative, launched by the US Food and Drug administration (FDA) in 2004, has been critical to the emergence of several PPPs that aim to improve drug development through the use of new scientific tools and methods.[19] Key actions recommended by the Critical Path Initiative include the development of qualified biomarkers for drug efficacy and safety, the modernization of clinical trials, the development of novel bioinformatic approaches to facilitate data exploitation, and the revision of drug manufacturing processes.[19] The Critical Path Institute was created to support such projects. Since its incorporation in 2005, the Critical Path Institute has launched several PPPs, including the Predictive Safety Testing Consortium and the Coalition Against Major Diseases, which is focused on Parkinson's and Alzheimer's diseases.[20] The Predictive Safety Testing Consortium, which comprises 15 pharmaceutical companies along with the FDA, the European Medicines Agency (EMA), and several academic institutions, aims to identify, validate, and qualify new biomarkers for drug safety. An important first achievement for this consortium was qualification by the FDA and the EMA of seven biomarkers for preclinical assessment of kidney safety.[21] Launched in 2006, the Biomarkers Consortium, managed by the Foundation for the National Institutes of Health, is another United States–based PPP working on the development of biomarkers.[22] The first project completed by this consortium provided evidence that adiponectin measurement predicts glucose tolerance in patients with type 2 diabetes.[22]

In parallel with the creation of United States–based PPPs, the Innovative Medicines Initiative (IMI) was set up to enhance the competitiveness of the pharmaceutical sector in Europe for the benefit of patients and scientists.[23] To this end, the European Federation of Pharmaceutical Industries and Associations (EFPIA) was invited by the European Commission to develop a series of recommendations in order to address major bottlenecks in the drug development process. After consultation with various stakeholders, a research agenda was established to serve as a basis for an ambitious initiative to promote innovation and investment in the biopharmaceutical sector across Europe. On this basis, the IMI was launched in 2008 by the European Union and the EFPIA, with a total budget of €2 billion to be spent over a 10-year period, making the IMI the largest PPP in life sciences R&D. The IMI's two founding members, the EFPIA and the European Union, have equal investment and rights in the IMI. To fulfill its mission, the IMI implements R&D programs focused on developing new tools and methods for predicting drug safety and efficacy as well as for more efficient knowledge management. Furthermore, the IMI supports education and training projects on these topics. EFPIA pharmaceutical companies invest in the IMI in the form of in-kind contributions by committing internal human resources or providing access to data sets and infrastructure and sometimes in the form of direct monetary contributions. This industry investment is matched by funds from the European Union; the funds support other consortium members, including academic teams, small and medium-sized enterprises (SMEs), patients' organizations, regulatory agencies, and relevant not-for-profit institutions.

PRECOMPETITIVE RESEARCH AND COLLABORATIVE INNOVATION AS CORNERSTONES OF THE IMI

Precompetitive research is a cornerstone of the IMI in Europe. Precompetitive pharmaceutical R&D is defined primarily as a field of activity in which large companies agree to collaborate and invest jointly (despite the fact that they compete in the drug market) because these precompetitive activities do not provide a direct commercial advantage. Indeed, pharmaceutical companies realize the benefit of pooling resources for projects to develop new tools and standards for drug development. The development and qualification of biomarkers for drug efficacy or drug safety and of new knowledge-management strategies to exploit large data sets are typical examples of precompetitive R&D. As precompetitive activities are progressively integrated into novel R&D models, pharmaceutical companies are increasingly keen to promote public domain drug discovery systems involving open-access tools for computational biology and chemistry.[16–18] Accordingly, they are revising their intellectual property policies, which now have a greater focus on key elements of the value chain.

This new mindset paves the way for novel modes of collaboration with partners outside industry, especially with academic teams and small biotech companies. For their part, academic scientists are actively seeking help to turn their ideas into reality and are no longer as fearful of developing partnerships with large pharmaceutical companies. In fact, collaborative or open innovation models are progressively replacing the vertically integrated models that characterized large pharmaceutical companies in the past.[9]

Before reviewing concrete achievements of the IMI consortia, we summarize the governance structure of the IMI and the process through which the IMI fosters collaborative projects in R&D and in education and training.

IMI GOVERNANCE AND IMPLEMENTATION OF IMI PROJECTS

The chief decision-making body in the IMI is the Governing Board, which is made up of equal numbers of representatives of the IMI's founding members, i.e., the European Commission and the EFPIA. The Governing Board carries the overall responsibility for the operations of the IMI and oversees the implementation of its activities. It therefore commits itself to the fulfillment of the IMI's objectives, namely, overcoming challenges in European pharmaceutical R&D and supporting biomedical research for the benefit of patients. The IMI Scientific Committee, which brings together 15 experts in pharmaceutical and biomedical sciences, provides strategic science-based recommendations to the IMI's Governing Board as well as advice on the scientific priorities that form the basis for the topics of the IMI's calls for proposals. Representatives of the EMA are regularly invited as observers to the Scientific Committee meetings. Additional

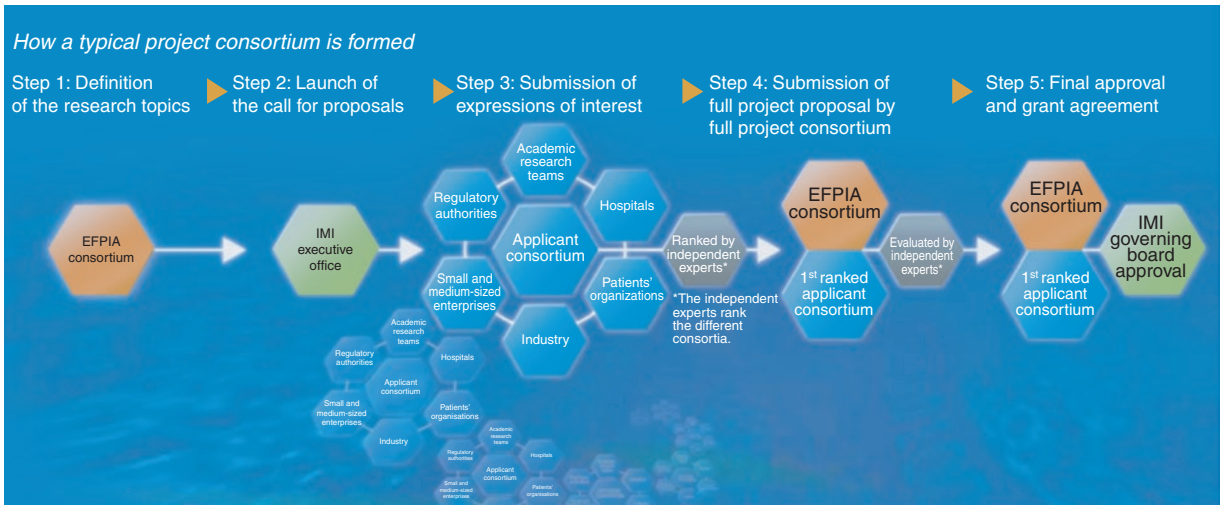

Figure 1 The multistep process leading to the launch of IMI projects. EFPIA, European Federation of Pharmaceutical Industries and Associations; IMI, Innovative Medicines Initiative.

guidance comes from the States Representatives Group, which comprises representatives from the EU Member States and other countries associated with the Seventh Framework Programme. The day-to-day management of the IMI is the task of the IMI Executive Office, which is responsible for the organization of regular calls for proposals, the management of public and private funding, and the communication of the IMI's activities to key groups. Importantly, the Executive Office acts as a neutral platform to facilitate dialogue between the industry and other stakeholders in the health-care sector on various matters, including the management of intellectual property rights.

A LEADING ROLE FOR INDUSTRY IN THE IMPLEMENTATION OF IMI PROJECTS

A key difference between the IMI and other public–private initiatives in the health-care area is that IMI projects stem primarily from pharmaceutical companies. This ensures that the IMI efficiently addresses gaps and bottlenecks in the drug development process by combining the traditional strengths of industry (management organization and technology) with those of academia and small businesses (creativity, innovation, and entrepreneurship).

As illustrated in **Figure 1**, the first step in defining IMI projects is for EFPIA companies to specify the topics on which they wish to collaborate and invest resources together. The topics are further refined through consultation with the European Commission, the IMI Scientific Committee, and the IMI States Representatives Group. The IMI Executive Office then organizes a competitive call for proposals that attracts applications from consortia comprising groups that are eligible to receive EU funding; these may include academic teams, SMEs, patients' organizations, and regulatory authorities. For each topic, independent experts are invited to identify the applicant consortium that is best able to address the objectives of the project in collaboration with the EFPIA companies. The winning applicants' consortium then works together with the EFPIA companies committed to that specific topic to develop a full project proposal. This proposal

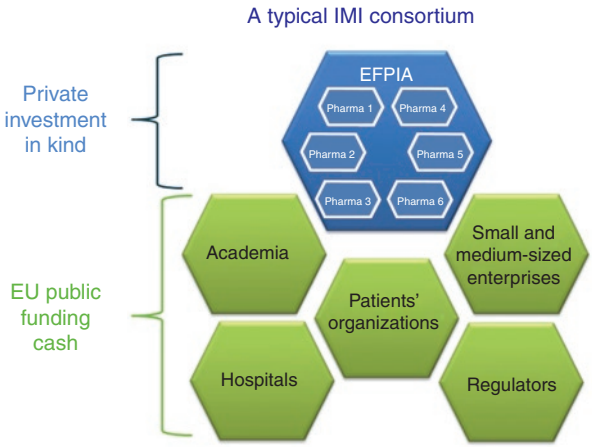

Figure 2 IMI projects are conducted jointly by large pharmaceutical companies that are members of EFPIA (which provide in-kind contributions) and nonprofit organizations and small businesses supported by EU funding. EFPIA, European Federation of Pharmaceutical Industries and Associations; IMI, Innovative Medicines Initiative.

is subjected to a final peer review that considers all aspects of the project, including potential ethical issues. Final approval of the full project proposals comes from the IMI Governing Board. In the spirit of the PPP, EFPIA companies finance their own participation in the projects, while their partners are supported by European public funding (**Figure 2**).

Lessons learned from the first IMI projects

The first three calls for proposals, launched by the IMI in 2008, 2009, and 2010, resulted in 30 projects. Altogether, the resulting 30 consortia involve 25 EFPIA companies, 350 academic institutions, 55 SMEs, 11 patients' organizations, and 10 regulatory agencies; the projects have a total budget of around €600 million. The number of partners per consortium ranges from 12 to 50 (median: 23). The projects, which typically run over a five-year period, are listed in **Table 1**. Several of them aim to identify novel biomarkers for drug efficacy or safety or to enhance our understanding

Table 1 Ongoing projects of the Innovative Medicine Initiative

Consortium	Launch	Overall coordination	Managing entity for EC funds[a]	Budget (million €)[b]	Key objectives
1st call					
SAFE-T (http://www.imi-safe-t.eu)	2009	Novartis	University of Tübingen	35.9	Identification of sensitive and predictive biomarkers for liver, kidney, and vascular system toxicity for use in clinical drug development
PROTECT (http://www.imi-protect.eu)	2009	European Medicines Agency		29.8	Enhancement of safety monitoring through new tools and methodologies to evaluate risk–benefit profiles of drugs
SUMMIT (http://www.imi-summit.eu)	2009	Boehringer Ingelheim	Lund University	28.4	Identification of biomarkers to identify high risk of cardiovascular complications in diabetes
PHARMACOG (http://www.alzheimer-europe.org/pharmacog)	2010	GSK	Mediterranean University	27.7	Development and validation of new tools for testing of candidate drugs to treat Alzheimer's disease
IMIDIA (http://www.imidia.org)	2009	Sanofi-Aventis	Lausanne University	25.4	Generation of novel tools and fundamental knowledge on β-cell organization to accelerate the path to improved diabetes management
NEWMEDS (http://www.newmeds-europe.com)	2009	Lundbeck	King's College London	24.0	Identification of biomarkers to allow more targeted treatments for schizophrenia and depression
U-BIOPRED (http://www.ubiopred.eu)	2009	University of Amsterdam		20.6	New classification of severe asthma
EUROPAIN	2010	AstraZeneca	King's College London	18.2	Better understanding of chronic pain mechanisms to aid the development novel analgesics
PROACTIVE (http://www.proactivecopd.com)	2009	Chiesi Farmaceutici	Catholic University of Leuven	16.7	Production of a user-friendly electronic tool to assess chronic obstructive pulmonary disease
MARCAR (http://www.imi-marcar.eu)	2009	Novartis	University of Dundee	13.3	Identification of new biomarkers for drug-induced tumor formation
E-TOX (http://www.etoxproject.eu)	2009	Novartis	IMIM Foundation, Barcelona	12.9	Development of novel strategies and software tools for better prediction of drug side effects
EMTRAIN (http://www.emtrain.eu)	2010	AstraZeneca	Medical University of Vienna	7.7	Establishment of a pan-European platform for higher education/training to cover the life cycles of medicines
EU2P (http://www.eu2p.org)	2009	Roche	University of Bordeaux	7.2	Establishment of a pan-European training and education platform in pharmacovigilance and pharmacoepidemiology
PHARMATRAIN (http://www.pharmatrain.eu)	2009	European Federation of Courses		6.6	Establishment of a modular master's program on pharmaceutical medicine and drug development
2nd call					
BTCURE (http://www.btcure.eu)	2011	UCB	Karolinska Institute	38.1	Development of future curative treatments for early intervention against rheumatoid arthritis
ONCOTRACK (http://www.oncotrack.org)	2011	Bayer Schering	Max Planck Gesselschaft	30.7	Identification of new models to predict side effects of cancer treatments in defined groups of patients
DDMORE (http://www.ddmore.eu)	2011	Pfizer	University of Uppsala	21.2	Establishment of standards for common tools to enhance modeling and simulation technologies

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Table 1 Continued

Consortium	Launch	Overall coordination	Managing entity for EC funds[a]	Budget (million €)[b]	Key objectives
PREDECT (http://www.predect.eu)	2011	Servier/ AstraZeneca	University of Helsinki	17.7	Development of new models for novel treatments for cancers of the breast, prostate, and lung
QUIC-CONCEPT	2011	AstraZeneca	EORTC	17.1	Identification of specific imaging biomarkers to improve cancer drug development
RAPP-ID (http://www.rapp-id.eu)	2011	Johnson & Johnson	University of Amsterdam	14.4	Development of a point-of-care test for rapid detection of microbes
OPEN-PHACTS (http://www.openphacts.org)	2011	Pfizer	University of Vienna	16.4	Development of an open access innovation platform using a semantic Web approach
EHR4CR (http://www.ehr4cr.eu)	2011	AstraZeneca	European Institute for Health Records	16.1	Construction of an electronic-health-records platform to support IMI projects ethically and cost-effectively
3rd call					
MIP-DILI		AstraZeneca	University of Liverpool	32.3	Improving the early prediction of drug-induced liver injury in humans
ABIRISK		GlaxoSmithKline	INSERM	TBD	Immunogenicity: assessing the clinical relevance and risk minimization of antibodies to biopharmaceuticals
BIOVACSAFE		Novartis Pharma	St George's Hospital Medical School	30.2	Immunosafety of vaccines—new biomarkers associated with adverse events (early inflammation, autoimmune diseases, and allergy)
PREDICT-TB		GlaxoSmithKline	University of Liverpool	TBD	Improving the preclinical models and tools for tuberculosis medicines research
EU-AIMS		Roche	King's College, London	35.8	Translational end points in autism
DIRECT		Sanofi-Aventis	University of Dundee	43.0	Development of personalized medicine approaches in diabetes
EUPATI		Roche	European Patients' Forum	10.0	Fostering patient awareness about pharmaceutical innovation

EC, European Commission; IMI, Innovative Medicines Initiative; TBD, to be defined.

[a]Institution responsible for the coordination of partners receiving public funds originating from the European Commission. [b]Includes public funds from the European Commission and in-kind contributions from pharmaceutical companies that are members of the European Federation of Pharmaceutical Industries and Associations.

of the mechanisms underlying disease processes and elucidate both the beneficial and the unwanted effects of drugs. This is in line with the recognized need to gain in-depth insight into the genetic and molecular bases of the modes of action of medicines to increase the chances for drug approval.[24] Furthermore, many projects are based on the sharing of existing data sets that will be assembled through collaborative efforts. Several of these data-sharing projects are based on patient-reported outcomes and rely on the active involvement of patients' organizations.

Early achievements

Although the first IMI projects were initiated only two years ago, significant results have already been obtained. For instance, the NEWMEDS consortium has created the largest known database of studies on schizophrenia, gathering information on >20,000 patients in >25 countries.[25] This consortium, which brings together thirteen pharmaceutical companies, seven academic teams, and three SMEs, offers the industry and the academic community unique opportunities to develop tools, methods, and models to discover innovative treatments for schizophrenia. The consortium has also assembled a database on 2,500 patients with major depression, and this database has already yielded new clues to predict therapeutic responses. Researchers in the PHARMACOG consortium dedicated to neurodegenerative diseases have proven that sleep deprivation in human volunteers induces cognitive impairment similar to that in patients with Alzheimer's disease. They have shown that commercially available drugs for Alzheimer's disease can reverse this cognitive impairment, thereby suggesting that the model of sleep deprivation could be useful in the assessment of new candidate drugs for Alzheimer's disease. In the same vein, the EUROPAIN consortium established the potential usefulness of a model of ultraviolet B irradiation to simulate chronic abnormal sensitivity to pain. This model allowed the team to demonstrate that CXCL5 is a peripheral mediator of ultraviolet B irradiation–induced inflammatory pain in humans and

therefore represents a potential target for the development of a new class of analgesics.[26]

In the area of pulmonary diseases, the U-BIOPRED consortium produced a consensus statement on the definition of severe asthma[27] as a first step toward a new stratification of patients with asthma. This stratification will be on the basis of an integrative systems biology approach, combining genome, transcriptome, proteome, and metabolome data[28] as well as patient-reported outcomes, with the ultimate goal of tailoring therapies according to this handprint. Patient-reported outcomes are also at the core of the project conducted by the PROACTIVE consortium, which aims to develop validated methods to assess physical activity in patients with chronic obstructive pulmonary disease.

Diabetes is a field of intense investigation in the IMI. The IMIDIA consortium generated the first human β-cell line suitable for the evaluation of drugs targeting β-cell function[29]; this has been recognized as a major advance.[30] Interestingly, this cell line, which was generated in an academic laboratory, will be commercially exploited by an SME that will offer services to large pharmaceutical companies. This is an example of the collaborative innovation networks fostered by the IMI. The cell line will be used not only for drug screening but also as a tool to produce monoclonal antibodies suitable for the imaging of pancreatic islets. The SUMMIT consortium is developing methods to identify patients at high risk of developing complications of diabetes. The researchers have prepared a new computer model that will help with that prediction. They have also started clinical studies to identify noninvasive markers of vascular complications. A third project will be launched soon to develop personalized medicine approaches in type 2 diabetes.

Several IMI projects are developing and validating new methods to identify potential unwanted drug effects more rapidly and more accurately during the course of drug development. The SAFE-T consortium has already identified 153 potential biomarker candidates for drug-induced injury to the kidney, liver, and vascular system, and has entered into a dialogue with the FDA and EMA about a generic strategy to qualify biomarkers for clinical use.[31] Also in the area of drug safety, the eTOX consortium is in the process of establishing the biggest shared database of preclinical drug safety from the legacy data of various companies. As can be expected, companies had to devote considerable effort to reaching legal and terminology agreements to enable the sharing of their data sets. Furthermore, the eTOX researchers developed an innovative multiscale computer model that allows *in silico* prediction of the impact of a given compound on the electrical activity of the heart by simulating its action on potassium channels, a model that might be more reliable than current methods for anticipating potential side effects at the cardiac level.[32] The critical role of SMEs in this consortium was recently underscored.[33] In parallel, the MARCAR project produced an efficient method to identify epigenetic changes causing nongenotoxic carcinogenesis.[34] In the area of pharmacovigilance, the PROTECT consortium coordinated by the EMA is developing innovative tools based on patient-reported outcomes collected through modern means of communication.

EDUCATION AND TRAINING PROJECTS

Innovative tools and models will not be sufficient to boost drug development. The reinvigoration of innovation in the pharmaceutical sector requires highly skilled, experienced researchers in industry, academia, and regulatory institutions. A major mission of the IMI is therefore to train a new generation of scientists who will be fully acquainted with the complexity of pharmaceutical R&D and open to collaboration across conventional boundaries. Currently, 85 private and public partners are collaborating to implement the IMI's education and training programs. The SAFESCIMET consortium has launched a course, "Drug Discovery and Development," that is the introductory course to a new European master's degree in advanced safety sciences for medicines. The PHARMATRAIN consortium has developed a syllabus for pharmaceutical sciences that is the basis for new European programs on integrated drug development. The EU2P project has launched online interactive courses in pharmacovigilance and pharmacoepidemiology that have evoked high levels of interest, especially among those who are interested in regulatory sciences. Furthermore, the EMTRAIN consortium has mapped more than 700 master's courses in pharmaceutical medicine and developed a framework for continuing professional development that will help scientists working in the field to maintain their professional skills and knowledge and adapt to changes in the sector. There will soon be an additional educational project coordinated by a patients' organization to raise awareness among patients and caregivers about the different aspects of drug development.

A CRITICAL NEED FOR INDICATORS OF PERFORMANCE

The experience gained from ongoing IMI projects provides evidence that the sharing of know-how and data sets among pharmaceutical companies, academic teams, and small businesses delivers results that could not have not been obtained otherwise. This has been possible because of the climate of trust and mutual respect that prevails in IMI consortia. Indeed, by providing a neutral platform for a healthy dialogue among the various partners, the IMI fosters the emergence of new mindsets, both in industry and in publicly funded organizations, especially academic institutions. This role of "honest broker" proved to be essential in facilitating agreements on intellectual property rights and ensuring a balanced communication on IMI projects.[35]

Although the IMI appears to be moving the pharmaceutical ecosystem in the right direction, it will be essential to monitor its performance to convince decision makers in pharmaceutical companies and public research policy makers that their investments are worthwhile. This is not a trivial task, because there is currently no established consensus on a method for assessing the added value of PPPs. However, several recent publications provide useful guidance for the development of key performance indicators.[36–39] As a whole, these indicators should measure the ability of the partnership to mobilize funds, attract the best talents within and outside industry, promote collaborative research activities, generate game-changing results relevant to industrial R&D, ensure the standardization and qualification of novel assays, and disseminate the new knowledge that has been created.

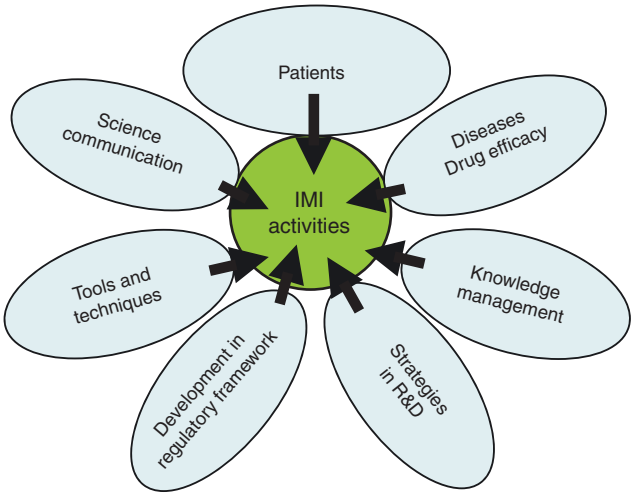

Figure 3 Key concepts and priorities integrated into the revised research agenda, which represents the basis for future calls for proposals. IMI, Innovative Medicines Initiative.

FUTURE DIRECTIONS OF THE IMI

The overall strategy of the IMI has recently been revisited to take into account scientific advances and changes in the health-care environment that have occurred since the preparation of the initial research agenda in 2005. As shown in **Figure 3**, the revised agenda remains "patient-centric" and includes topics with a high potential for translation into the clinic in a reasonable time frame. Priority is to be given to ambitious "game-changing" projects that tackle major public health issues through collaborative innovative approaches. Knowledge management will be an essential component of the new projects, which will be based on the sharing of patient-level data, including classic clinical information, results of assays based on "omics" technologies, and patient-reported outcomes. Electronic health records and innovative software solutions will be used to collect and analyze the data sets. A new framework will be established for the study of rare "extreme phenotypes" as human models for common disorders (e.g. obesity and Alzheimer's disease). A large-scale project will explore the potential of induced pluripotent stem cells generated from patients with neurodegenerative diseases or diabetes as new tools to assess candidate drugs against these disorders. Furthermore, the IMI is currently preparing an ambitious project to tackle antimicrobial resistance, with the objective of restoring industrial investment in the development of novel antibiotics. The building of a Joint European Compound Library and Screening Centre is another important IMI project to be launched in the coming months. The IMI is also planning to address the challenges represented by the development of combination therapies[40] and innovative medicines for pediatric disorders.[41]

Extending the boundaries of precompetitive research

The first successes of PPPs dedicated to drug research prompted the pharmaceutical industry to extend the boundaries of the precompetitive space to include proof-of-concept clinical investigations, as proposed by the ARCH2POCM initiative.[42] The EFPIA companies committed to the IMI project on antimicrobial resistance are ready even to extend the concept further by investing jointly in phase II or phase III trials.

Toward more global approaches

Although the IMI was created to reinvigorate the pharmaceutical sector specifically in Europe, the scope of the partnership is clearly global and should benefit industry and patients worldwide. To take advantage of the industrial expertise present outside Europe, the IMI is currently considering accepting that, under well-defined limits, in-kind contributions from outside Europe will also be taken into account in the calculation of matching public funds. Furthermore, the IMI is partnering with two United States–based institutions: (i) the Critical Path Institute, which promotes exchanges in the field of drug safety, and (ii) the Clinical Data Interchange Standards Consortium, which provides training to scientists of IMI consortia on standards for sharing and pooling clinical data sets.

Promoting regulatory science

Both industry and regulatory agencies recognize the IMI to be a neutral platform that facilitates their dialogue. During a recent meeting, the FDA, the EMA, the EFPIA, and the European Commission agreed to involve regulatory agencies more closely in the generation of ideas for future IMI programs and in the monitoring of advances that could facilitate regulatory approval for drugs. In addition, IMI education and training programs will consult with the EMA and the FDA to promote regulatory science,[43] with the ultimate objective of enhancing access to innovative medicines for patients.

Cutting the red tape

As in any PPP, it is essential for management processes to ensure that the public money is wisely spent, while the industrial partners can fulfill their commitments in a flexible way. After two years of experience, the IMI recently modified its rules to better accommodate the expectations of all partners. For instance, actual indirect costs can now be fully reimbursed, and reporting procedures have been simplified.

CONCLUSION

The IMI offers unique opportunities to foster collaborative innovation in the pharmaceutical sector. Besides its role as a funding source, the IMI provides the neutral platform that is essential for fruitful and transparent exchanges between the various stakeholders who can then combine their efforts to reinvigorate the development of innovative therapies. Further developments of the IMI model will depend on objective assessment of its added value in the health-care environment. It is also desirable that the European dimension of the IMI be reconciled with its global mission to implement a game-changing dynamic based on noncompetitive research and open innovation, for the benefit of both industry and society.

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CONFLICT OF INTEREST

M.G. is Executive Director of the Innovative Medicines Initiative.

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