The Innovative Medicines Initiative – fiction vs facts
Setting the record straight

The Innovative Medicines Initiative (IMI) is a partnership between the European Union and the European pharmaceutical industry that is working to improve the drug development process and so accelerate the development of better, safer medicines for patients. IMI works by forging collaborative partnerships involving all stakeholders in medical research, including the pharmaceutical industry, universities, small and medium-sized enterprises (SMEs), patient groups, and regulatory agencies. Since its creation in 2008, it has established itself as a pioneer of open collaboration, and the impressive results of IMI's projects amply demonstrate the success of the public-private partnership model.

In 2015, certain organisations and outlets have published articles and reports on the Innovative Medicines Initiative (IMI) which include a number of misconceptions and inaccuracies. This factsheet sets out and corrects some of the most commonly-repeated misunderstandings about IMI.

For more information or clarifications on any of these points, contact IMI via press@imi.europa.eu.

What they say	The reality
Through IMI, taxpayers' money is being used to subsidise the pharmaceutical industry.	IMI funds are used exclusively to support the participation in projects of 'public' partners like universities, SMEs and patient organisations. The pharmaceutical industry does not receive any money through IMI, but contributes its own resources (personnel, access to facilities, infrastructures and materials) to the initiative. This means that for every euro invested in IMI by the European Commission, an additional euro is leveraged through the pharmaceutical companies' contribution to IMI. Moreover, the results of IMI projects benefit the wider research community, and not just the pharmaceutical industry. In the long term, IMI's results will ultimately impact on public health through the faster and more efficient development of safer, better medicines.
IMI's intellectual property (IP) regime was designed by and favours industry.	IMI's IP regime was designed in collaboration with both the European Commission and EFPIA. It aims to promote the creation and exploitation of knowledge generated and reward innovation, while respecting the assets and interests of all project partners. The regime applies equally to all partners in IMI projects, industry or otherwise, and it allows project partners to share data and test each other's findings in unprecedented ways. All IP and governance issues are agreed on by all partners before projects start, with discussions and agreements being checked by IMI staff to ensure all partners' interests are respected.
EFPIA drove the creation of IMI.	The seeds of IMI were sown in the EU-funded INNOMED project, which ran from 2005 to 2009, and demonstrated the feasibility of bringing together multiple pharmaceutical companies as well as other partners in collaborative projects with common objectives. From its inception, IMI was a joint initiative of the European Commission and EFPIA, born out of the shared realisation that action was needed to re-establish Europe as an attractive place for pharmaceutical research; to reverse the brain drain; and to improve

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	the medicines development process. Underpinning this was an understanding that these challenges could only be overcome by creating an initiative to support cross-sector, pan-European collaboration.
EFPIA is in the driving seat, deciding on research topics and grants.	IMI is a public private partnership between the European Union and the pharmaceutical industry represented by its industry association EFPIA. As a founding member of IMI and source of half the funding, it is natural that EFPIA has an influence on IMI's activities. However, EFPIA's input on research topics is balanced by input from the European Commission as well as the scientific community and Member States. As to decisions on grants, all funding decisions are based on the outcome of open, competitive Calls where proposals are evaluated and ranked by independent experts.
IMI's research is not aligned with the World Health Organization's priority areas and does not focus on unmet needs.	The first IMI research agenda of 2008 focused on identifying key bottlenecks in how medicines are developed, not on the development of medicines as such. It was updated in 2011 to take account of new developments in medicines research and drug discovery. It was only with the launch of the 2014 research agenda for IMI 2 that an explicit link was made with the WHO's 2013 report on Priority Medicines for Europe and the World. An analysis of IMI's projects does however reveal a strong focus on areas of unmet medical need; infectious disease (including antimicrobial resistance) takes around a third of the budget. Other priority areas include brain disorders, diabetes and cancer. In addition, many IMI projects do not focus on a specific disease area but are tackling cross-cutting issues in drug development such as medicines and vaccines safety, benefit-risk assessment techniques, clinical trial design, and the environmental impacts of medicines and medicines development. IMI also supports a number of education projects. It is also important to bear in mind that IMI's strength lies in tackling very specific issues which can only be solved through collaboration between industry, academia and others. IMI is just one part of the wider research landscape, and some health issues identified by the WHO are better tackled through other research programmes.
IMI's original purpose was to develop treatments but in practical terms it is conducting research in areas that benefit the pharmaceutical industry.	As set out in Article 2 of the legislation creating IMI 1, the objective was to improve 'the efficiency and effectiveness of the drug development process with the long-term aim that the pharmaceutical sector produce more effective and safer innovative medicines'. In other words, IMI's original purpose was never to develop new treatments directly. The results of the projects are beneficial not only to the pharmaceutical industry, but to all partners in the projects, including academics, SMEs, patient groups, etc. Furthermore, many projects are delivering resources, infrastructures, knowledge and tools that are available to the entire medical research community.
Participating universities and research institutions have little	The scientific community is well represented in IMI through the Scientific Committee, which brings together leading scientists from

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influence over what happens at IMI.	different fields and backgrounds from across Europe. The Scientific Committee provides high-level advice to the Governing Board and to the Strategic Governing Groups. All stakeholders in medicines research are also welcome to provide feedback via IMI events, particularly the Stakeholder Forum. Within projects, governance is typically shared by representatives of the industry and academia (or SMEs or patient groups).
Researchers and SMEs only have a voice in the evaluation of submitted evaluations.	Through the Scientific Committee and States Representatives Group, the wider scientific community (including academia, SMEs, patient groups, and regulatory authorities) is consulted on IMI Call topics under development. Evaluations are carried out by independent experts, mainly (but not exclusively) from academia.
IMI offers cost savings to the industry, as IMI projects replicate work that individual companies would have had to do anyway.	IMI projects specifically focus on areas where progress relies on the input of diverse partners, and not the pharmaceutical companies alone. Furthermore, IMI works to address bottlenecks that are shared by many in medical research (not just companies), and reducing duplication of effort cuts costs and saves time for all.
EFPIA was tasked with setting up IMI.	In its early days, IMI was run by the European Commission's Directorate-General for Research and Innovation. Once sufficient staff had been hired, management and implementation of IMI transferred to the IMI Executive Office, which is an autonomous, neutral body.
In IMI, risks are carried by the taxpayer while results are privatised.	Firstly, IMI's main goal is to improve the drug development process in general to make it faster and more efficient (and not to deliver new medicines directly). The rules regarding access to and use of the results of IMI's projects are set out in IMI's intellectual property policy, which applies equally to all partners in projects. This means that the benefits of projects are also enjoyed by all partners in the projects, including academics, SMEs, etc. Secondly, the question of pricing is way outside the scope of IMI's activities and is in fact a Member State competency.
The public is not informed about individual companies' contributions to individual IMI projects and the European Court of Auditors (ECA) cannot audit payments made by industry partners.	EFPIA is a member of IMI, and not the individual companies. EFPIA's total contribution is reported transparently both as a total and per project. In addition, IMI now publishes a breakdown of EFPIA's total contribution to IMI, by company and by cost category, in its Annual Activity Reports. The role of the ECA is to verify if EU funds are being used appropriately, yet large pharmaceutical companies do not receive any EU funding through IMI. Nevertheless, as pharmaceutical companies' contribution is an essential element of IMI, they are checked thoroughly by both IMI staff and external auditor firms. The work of these firms is itself subject to ECA audits.
The control mechanisms lack transparency / audit results are not made public.	IMI is audited regularly by the European Court of Auditors. The ECA's findings, and IMI's responses to them, are published on the ECA website. IMI also provides detailed information on its audit activities

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	and outcomes in its Annual Work Plans and Annual Activity Reports, all of which are published online.
Many leading European research institutes stay away from IMI.	A good measure of the participation of leading European research institutes is the involvement in IMI projects of members of the League of European Research Universities (LERU). In fact, almost all LERU members are involved in IMI, with some participating in several projects.
The funds provided to universities and SMEs etc. are insufficient.	Under both IMI 1 and IMI 2, IMI's funding rates have been in line with those of the European Commission's wider research programmes. In practice, for IMI 2, this means that these organisations receive 100% reimbursement of direct eligible costs and a flat rate of 25% of this for indirect costs.
The EUPATI project is training patients to lobby in favour of the pharmaceutical industry.	The goal of the EUPATI project is to teach patients how medicines are developed so that they can make meaningful contributions to medicines research. There is now broad recognition that patients can and should be involved in research and medicines development, and they are increasingly invited to take part in various committees and projects. However, if patients are not familiar with the jargon or the process, there is a risk that their involvement would be largely tokenistic.
IMI does not focus on European priorities.	IMI's research agenda and Call topics have always been subject to consultation with the European Commission, EU Member States, and the European scientific community. Among other things, this ensures that there is a European interest in all IMI projects. This incorrect statement appears to be based solely on one potential medicine that was proposed for testing in one of IMI's 60+ projects. In fact, a breakdown of IMI's projects by research area reveals a strong alignment with issues that are important for Europeans, such as infectious disease (antimicrobial resistance kills 25 000 Europeans annually), brain disorders (affect 1 in 3 Europeans), and diabetes (affects 33 million people in Europe). More recently, IMI has demonstrated its ability to mount a rapid, coordinated response to a major epidemic with the launch of its Ebola+ programme.