



The Innovative Medicines Initiative
Keys for Success – Industry Input

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1. Executive Summary

The pharmaceutical industry represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA) is convinced that the Innovative Medicines Initiative (IMI) will help create an environment, which will lead to additional private investment in pharmaceutical and biotechnology R&D across Europe.

This initiative is a unique public private partnership in which the key stakeholders in health care will work together to create an environment in which academic groups, SMEs regulators, diagnostic and pharmaceutical companies can be increasingly effective in their different roles. The leadership provided by the Commission is essential to facilitate effective partnerships between the different stakeholders that will participate in IMI.

The creation of IMI will help to develop expertise, skills and know-how in Europe, which will attract additional non-clinical and clinical research in the EU by small and large enterprises. The innovation of IMI lies in the way IMI will facilitate the collaboration at the EU level between all the stakeholders in biomedical research such as academia, governmental institutions, small and large enterprises, regulators and patients. The IMI Strategic Research Agenda has been created in full partnership with the key stakeholders in healthcare, they are fully supportive and eager to participate in IMI collaborative research projects.

In the short term, IMI itself will leverage investment because the industry will match the European Commission's investment in IMI in common public private research programs. Long term, IMI will play a role in increasing private R&D investment in Europe by helping to create a biomedical research environment that enables and fosters innovation and collaboration.

Action is essential at the European level to harness the scientific know-how and expertise that exists across the European Union. Action is also needed at this level to partner with European regulators in order for the research to be applied to regulation and guidance in drug discovery and development as rapidly as possible. For example this approach if applied nationally would lack co-ordination and risk duplication. Moreover, the majority of medicines are approved through the centralised European procedure therefore application to European rather than national regulation and guidance is essential if the IMI is to impact drug discovery and development.

The research projects proposed by IMI are broad and multi-disciplinary and cannot be carried out effectively by one company or one within one member state. The IMI projects are also 'pre-competitive' for the pharmaceutical industry i.e. in areas where competitive advantage cannot be gained for a single R&D based pharmaceutical company and the knowledge and capabilities gained from performing such projects are made available to the entire public and private sector. There is therefore no market incentive for a single company to invest in this type of research. Companies (including SMEs), academics, regulators and patients need to come together to share resources and expertise to address the challenges of drug discovery and development. Pharmaceutical companies are focussed on competitive research (e.g. research to discover and develop new medicines) and can find it difficult to share data and expertise in non-competitive areas. The establishment of the IMI will provide a mechanism to do this in an effective and efficient manner. Without the IMI inter-company collaboration will be slow and difficult – if not impossible.

IMI will benefit the European science base and attract further investment by generating academic know-how and expertise in new technologies as well as an environment in which collaborative research can flourish. There are also significant benefits to the SME sector through full participation in the IMI projects and access to resources and know how which can be applied to a new technology A stronger European biomedical R&D base will also facilitate the expansion of other sectors e.g. Clinical Research Organisations, telecoms, Information Technology, nanotechnologies, diagnostics and biomedical engineering (e.g. remote data capture, novel administration devices, telemetry, bioprocessing).

The benefits to the European-based industry **and** the European science base warrant private **and** public investment. Initiatives in other countries in health care also utilise very significant public funding and for Europe to attract private investment in pre-competitive research public investment is required.

If the EU does not support the creation of IMI, such pre-competitive projects (and the associated pharmaceutical R&D investment) are very likely to take place outside Europe through initiatives in the US and Asia. Europe's biomedical R&D base will decline as will the attractiveness of Europe as a place for the pharmaceutical industry to invest. This is likely to result in further re-location of the pharmaceutical industry's R&D capabilities outside Europe. This in turn will decrease Europe's ability to sustain a competitive infrastructure to support cutting edge academic and clinical research.

IMI will help to anchor R&D investment in Europe by making large EU Public-Private Collaborations attractive to the pharmaceutical industry. No prior European Commission funding instruments have achieved this to date. One of the factors guiding investment by the biopharmaceutical industry is access to the right skills and the right partners, i.e. a strong knowledge base. Implementation of IMI will develop a stronger knowledge base within the public and private sectors in Europe, knowledge that will be relevant to address the challenges of the industry. This knowledge will enable public institutions and academia to target their activities for better partnerships with the pharmaceutical and biotechnology sectors. As they become stronger and better partners, they will attract industry to establish collaborations in competitive areas, thus leveraging the IMI investment.

The proposed IMI governance is also novel and designed to accelerate decision taking and implementation of IMI while emphasising the basic IMI principles of scientific excellence, transparency, collaboration and efficiency. The IMI governance structure consists of the IMI Board, the IMI Scientific committee and the IMI Executive Office, the Member States Group and the Stakeholders' Forum. The IMI board consists of the European Commission and EFPIA and will be accountable for the overall efficient implementation of IMI and the scientific excellence of the research performed.

Outstanding biomedical R&D leadership for Europe to benefit patients and society is the vision of this powerful partnership between the European Commission and the European Federation of Pharmaceutical Industries and Associations, who are supporting the Innovative Medicines Initiative with strategic and financial resources.

2. Introduction

The level of R&D expenditure in the pharmaceutical and biotechnology sectors has always been high and is one of the highest compared with other industrial sectors. In Europe, creating IMI will facilitate the integration of the pharmaceutical R&D effort, it will re-establish and support a closer collaboration with academia, regulators and SMEs and therefore leverage the level of individual investments. The Strategic Research Agenda of IMI has been created in full partnership with the key stakeholders in healthcare. These stakeholders are fully supportive and eager to participate in IMI collaborative research projects.

The Innovative Medicines Initiative (IMI) aims to build and exploit new scientific knowledge and technologies through pan-European Public-Private Collaborations to better enable the discovery and development of new medicines. IMI will make the process of developing new medicines more efficient by conducting research to apply new technologies to drug discovery and development. This will be done by combining resources, expertise and know-how, that exist within Europe's biomedical R&D base, in a coordinated way. Potential participants include academia, R&D based pharmaceutical companies, small and medium-sized enterprises (SMEs), regulators and patient organisations. The type of research projects proposed by IMI are 'pre-competitive' for the pharmaceutical industry i.e. in areas where competitive advantage cannot be gained for a single R&D based pharmaceutical company and the knowledge and capabilities gained from performing such projects are made available to the entire public and private sector. For the remainder of this document 'pre-competitive research' shall be referred to as 'pre-competitive pharmaceutical research'. The biopharmaceutical industry means the pharmaceutical and the biotechnology sectors.

The 24 companies represented on the Research Directors Group of the European Federation of Pharmaceutical Industries and Associations (EFPIA) are committed to engage in the Innovative Medicines Initiative (IMI). These companies represent Europe's biopharmaceutical industry from large global companies to relatively small and predominantly national enterprises. All of the companies represented on the Research Directors' Group of EFPIA are engaged in projects with a focus on scientific excellence irrespective of their size. The biopharmaceutical industry has made a number of public commitments to match the level of public investment by the European Commission. These commitments in the form of press releases and presentations at biomedical conferences are in the public domain. The pharmaceutical industry has also given statements of support to Heads of State and senior members of government of Member States as well as at the highest levels of the European Commission.

In a letter dated November 28th 2006, the European Commission formally requested that the industrial leaders of the Innovative Medicines Initiative analyse the impact of the IMI Joint Undertaking in terms of additionality, market failure, governance and role of the Member States.

This document in response to that request has been prepared by the pharmaceutical industry represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and released to the European Commission by the EFPIA Research Directors Group on February 20, 2007.

The EFPIA Research Directors Group consists of representatives from 24 pharmaceutical companies: AstraZeneca, Bayer-Schering Pharma, Boehringer Ingelheim, Chiesi, Eli Lilly, Esteve, Genzyme, GSK, Johnson & Johnson, Lundbeck, Merck, MSD, Novartis, Novo-Nordisk, Organon, Pierre Fabre, Pfizer, Roche, Sanofi-Aventis, Serono, Servier, Solvay, UCB and Wyeth.

3. Market Failure

Market failure is defined by the European Commission in the document “Roadmap for Joint Technology Initiatives” (www.imi-europe.org/NewsAndEvents.aspx?subpage=news) as follows:

Each JTI is expected to provide details of the nature and extent of market failure in the areas it is addressing and to demonstrate how public intervention through a Public-Private Partnership will overcome the market failure effectively and will achieve the desired economic and social effects.

3.1 Market Failure in the Biopharmaceutical Sector

The challenges facing biopharmaceutical research and development are significant. The development of a new drug is a long, complex and resource-intensive and highly uncertain process. Various estimates have placed the costs between \$400 million and \$900 million during the period 1994 to 2000 and the current trend is for the cost to increase further, as the drug development process becomes increasingly complex and resource intensive. As illustrated in Figure 1, during the previous 10 years, global R&D expenditure in the pharmaceuticals and biotechnology sector has steadily increased, without a corresponding increase in new medicines reaching the market and patients.

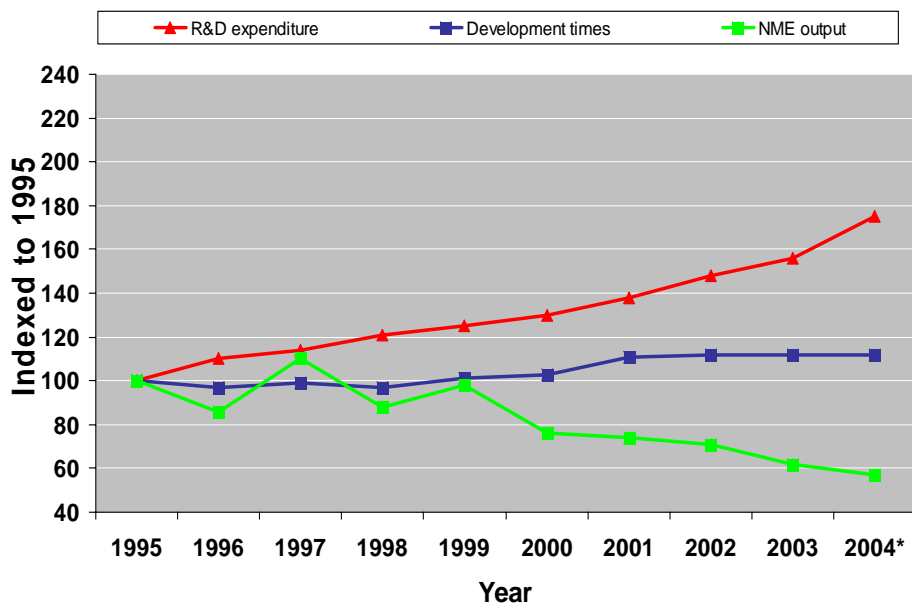


Figure 1 : Global R&D Expenditure, Development Times and NMEs 1995–2004¹

Increasing clinical development times and investment in medicines that fail to make it to market drives the high cost of developing a new medicine. High attrition (where compounds are dropped from development) is linked to the challenges of optimally predicting safety and efficacy early in the R&D process i.e. making sure that successful medicines can be identified with greater certainty early in the drug discovery and development process. Reducing attrition in late stage development will allow for more resources to be directed at early stage development, with the aim of increasing the number of promising candidates entering into clinical trials. Increasing the number of promising candidates depends on having better tools for predicting safety and efficacy as early as possible. By improving predictivity of safety and efficacy evaluation, IMI will increase the productivity of R&D investments and the number of innovative medicines available to society. This is why the

¹ Centre for Medicines Research International Ltd. CMR International 2005/2006 Pharmaceutical R&D Factbook (2005).

biopharmaceutical sector supports the implementation of IMI and EFPIA declared IMI its top R&D initiative for 2007.

As IMI projects are highly targeted applied research projects, the benefits of IMI to the process of developing new medicines will be evident in a timely fashion. The areas of research to be covered by IMI projects are described in the IMI Strategic Research Agenda (<http://www.imi-europe.org>). Projects requiring to build-up new infrastructures and networks between different participants in IMI, concrete impact will be seen after 4 to 6 years. However the launch of the IMI will have an immediate effect on the desirability of Europe for biomedical research so making it easier to attract world class talent. The scientific outcomes of IMI projects will be publicly reported by the IMI executive office in order to monitor timely progress.

3.2 The European Union

Due to changes in demographics which will impact Europe before other parts of the world, chronic diseases and diseases of the elderly – which have been difficult to address- are likely to exacerbate the need for a better biopharmaceutical R&D processes.

In terms of Research policy, the US government has established a system of dialogue with the private sector about what is truly needed to drive economic growth and to improve access to innovative treatments. This has translated into massive public investment in health R&D in comparison to Europe and the rest of the world (Figure 2). This, in combination with very attractive market conditions (one patent, free pricing, etc.), has made the US the most attractive location for the biopharmaceutical companies. While it is unlikely that European countries will ever completely emulate the US market conditions, research investment is an area where Europe can truly improve to maintain private pharmaceutical and biotechnology investments.

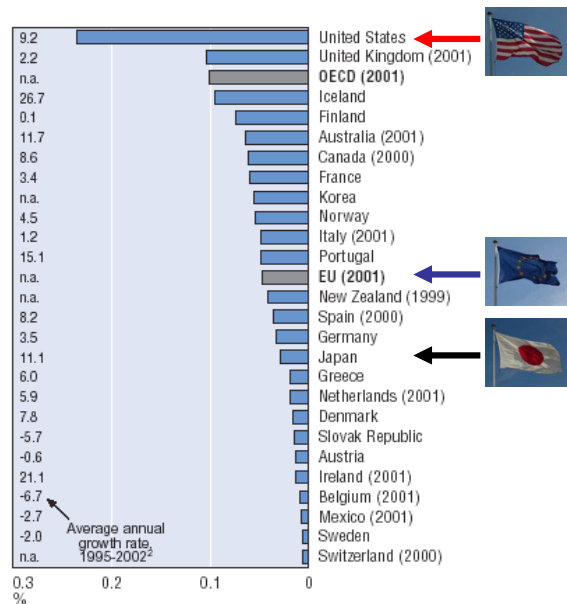


Figure 2 : Health R&D in Government Budgets as a Percentage of GDP, 2002²

Another distinct challenge that Europe faces is the ability to achieve critical mass. While there are currently interesting research projects ongoing in various Member States they are fragmented compared to the US. The impact of such projects could be much larger if they are coordinated at the European level. In this context it is important to remember that while governments mostly plan

² OECD (2003). R&D Database, Paris.

nationally, industry plans globally, as a result of this any larger region of the world that can coordinate its efforts is interesting to the pharmaceutical industry.

In Europe it is necessary to duplicate a lot of work and use a lot of resources on coordination due to the fact that Member States do not operate as one on their R&D investment. Large countries such as the US and China have a unified investment strategy that allows the biopharmaceutical industry to better plan and leverage its resources.

Europe has a real opportunity to capitalise on previous national investments in genomics, in bioinformatics, in electronic health records etc to implement IMI and to reap the benefits not only in terms of the information generated but also the resulting infrastructure (IT, physical) that will be created.

Action is required at the European level to harness the scientific know-how and expertise that exists across the European Union. The findings from such Public-Private Collaborations (e.g. the validation of a biomarker) are of value to the biomedical community as a whole, and the information generated must be shared as widely as possible to facilitate the development of new regulatory processes and standards. As the majority of medicines are approved through the centralised European procedure application to European rather than national regulation and guidance is essential if the IMI is to impact drug discovery and development. Action at a national level would be limited in terms of the industrial and academic scientific expertise available in any one country. This approach would also lack co-ordination and risk duplication. The development of the IMI strategic research agenda by scientists from many Member States have shown that there is a broad agreement on the research topics to be addressed. It is therefore necessary to establish IMI as a pan European mechanism to co-ordinate and to leverage national efforts in the interest of all stakeholders. It is for these reasons that the European representatives of the research-based biopharmaceutical industry, small and medium enterprises (SMEs), regulators, patients and universities want to cooperate in IMI projects.

3.3 Need for Collaboration

The application of genomics and other technologies offers a real opportunity to address the challenges of drug development. Better prediction of safety and efficacy of an investigational compound as early as possible in the drug development process can be delivered, for example, by applying advances in predictive toxicology (toxicogenomics, toxicoproteomics and metabonomics), or by developing a better understanding of disease mechanisms through the use of approaches such as system biology, modelling, improved animal models and experimental medicine. Such cross disciplinary efforts can only be done in collaboration with all stakeholders in society i.e. academia, regulators, governmental institutions, companies and patients.

The amount of research needed to apply and validate new technologies successfully is very substantial. Therefore no single pharmaceutical company can fund the hugely expensive and extensive research that is needed. In addition, individual companies normally do not invest in research that benefits the whole sector. There is no market incentive for a single company to invest in generating knowledge that will benefit the entire pharmaceutical and biotechnology sector. In other words there is no commercial advantage for a single company to invest in this type of research, this is why public intervention is required.

Companies small and large, regulators, governmental institutions, academics and patients need to come together to share resources and expertise to address the challenges of drug discovery and development. Access to knowledge from other organisations/stakeholders other than the industry itself is a key factor as is the cooperation with regulators. Companies mostly focus on competitive research (e.g. research to deliver a new medicine) and are not used to sharing data and expertise in non-competitive areas. The establishment of the IMI will provide a mechanism to do this in an effective and efficient manner. The innovation of IMI is in the way IMI will permit companies to collaborate between themselves and to collaborate with other stakeholders in the biomedical world

for the benefit of patients. Without IMI and the facilitator role of the European Union, this type of collaboration will be slow and difficult.

Currently the biopharmaceutical industry does not have a culture of sharing information generated from their research activities. Thus data from failed trials are often not optimally used to improve the overall process. With IMI, companies will be able to share and leverage knowledge by discussing it with other stakeholders and to apply this newly generated data to the R&D process. Thus saving resources that could be invested in compounds less likely to fail. The 6th Framework project InnoMed is an example of such an approach, which demonstrates that companies could work together to leverage data from their own company when public intervention is applied. If implemented, IMI will apply the same approach to the entire R&D process from discovery to pharmacovigilance.

In summary, Public-Private Collaborations across Europe are required to:

- Create new and more effective networks between pharmaceutical companies and their public partners (universities and hospitals)
- Mobilise knowledge and share previously unobtainable information
- Stimulate creativity by involving the entire biomedical R&D sector in Europe
- Achieve a critical mass required to solve the complex questions of biology
- Create innovation through partnerships
- Increase dialogue with regulators and drive rapid application of scientific findings
- Help change the public perception of pharmaceutical research in Europe.

Advances via collaboration in biomedical science within the entire European research community will make a significant contribution to improving the productivity of the biomedical R&D process. This will then be translated into the timely discovery, development and delivery of new medicines to meet patients' and societies' needs.

The IMI must be funded, co-ordinated and administered efficiently to have the maximum impact. This is where the creation of a Joint Technology Initiative (JTI) to manage the projects is both important and relevant. The JTI structure, by enabling focus on delivering the SRA, will ensure effective and streamlined administration, which is unlikely to be achievable through Framework 7 that has a broader research agenda. The Strategic Research Agenda is an ongoing programme, it will need to be updated, adjusted and monitored in the light of new information to ensure the relevance of the proposed projects. The interaction and synergies between the cornerstones of the SRA (education, knowledge management, safety and efficacy assessment) are unlikely to be well managed in the larger and less focussed structure of the Framework Programme. Moreover the JTI structure enables strong industry involvement at a strategic level, which is vital if IMI is to be successful. This would not be possible under the Framework Programme.

3.4 Need for Public Intervention

Pre-competitive pharmaceutical research is extremely important, as the biopharmaceutical industry recognised that the challenge of applying new science to the pharmaceutical R&D process is too complex for any single company to tackle alone. However, overcoming a culture of competitive drug development is difficult. This is where a Public-Private Partnership is extremely interesting to the biopharmaceutical industry, as the public partner does not develop drugs it brings a degree of neutrality to the table that would be difficult to achieve otherwise. Additionally having a public partner funding the other participants in IMI projects i.e. academics, patients and SMEs allows the involvement of the public sector with its specific expertise. It also maximises the potential benefits of the knowledge generated by IMI projects. This is why a public intervention is necessary.

The result of this public intervention is that IMI will deliver benefits to the research based biopharmaceutical sector as a whole and to society at large. The societal benefits include:

- Strengthening the EU science base and the EU knowledge-based economy, for example by enabling academics to participate in public-private research projects enabling academic scientists to have access to resources and technologies that would otherwise not be readily available;
- Encouraging the development of a vibrant EU R&D based pharmaceutical industry that delivers economic and healthcare benefits to EU citizens; this could be especially beneficial in the new Member States;
- Attracting additional biotechnology investment to the EU; as SMEs will be able to access resources that would otherwise be unavailable;
- Reducing emigration of highly qualified personnel from the EU, a phenomenon also known as brain drain, and attracting more of such personnel from outside the EU (including from the USA);
- Giving patients earlier access to new innovative medicines;
- Allowing a focus for pre-competitive pharmaceutical research on diseases important to European citizens.

Public participation is critical to the success of IMI. Public-Private Collaborations will guarantee a high scientific level, efficiency and sustainability. They are key to fostering the inter-industry cooperation by focusing on the pre-competitive topics. Public participation is important, working together for appropriate and cost-effective ways to address the needs of the growing number of European citizens with chronic health conditions.

Initiatives similar to IMI in other parts of the world will also utilise public funding and for Europe to attract private investment in pre-competitive research, public investment is required. Moreover, the funding model proposed through the IMI is particularly attractive to the EU, as industry will match public funds, nowhere else do public funds create such a direct leverage.

IMI is about improving our understanding of the human body to support the faster discovery and development of better medicines. It will use the latest knowledge and technologies to facilitate and accelerate the development of new medicines. This task responds to a societal need that the private sector cannot address alone.

3.5 Need for Public Intervention at the EU Level

The challenges in biomedical sciences have become so complex and expensive that international multi-disciplinary collaborations are needed between scientists from different Member States. Academia and SMEs need funding to participate in such collaborations and the European Commission is the only funding agency experienced in supporting and co-ordinating pan-European research collaborations for the best interest of the European scientific environment.

For the knowledge generated by IMI to have a real business impact, a strong link between IMI and the regulatory authorities at the EU level is needed. The European Union plays a critical role in ensuring EMEA support to IMI.

The European Union is playing a key facilitator role to encourage companies to collaborate on pre-competitive research topics, and for companies to collaborate with the other stakeholders in a co-ordinated pan-European manner.

3.6 Risk of Doing Nothing

The need to collaborate to address the bottlenecks in the biomedical R&D process has been recognised globally. Moreover the topics of research have been agreed upon globally i.e. improving the prediction of safety and efficacy evaluation. This situation has created a global competition to attract private investment in pre-competitive frameworks that are taking place across the world. The main initiatives competing with IMI for private investment are:

- The Predictive Safety Testing Consortium from the C-Path initiative led by the FDA in the US;
- Severe Adverse Events Consortium in the US;
- The Biomarkers Consortium led by PhRMA and the Foundation for the NIH (FNIH) in the US;
- The Alzheimer's Disease Neuroimaging Initiative (ADNI) from the NIH in the US;
- The Center for Biomedical Innovation in the US,
- The Toxicogenomics Initiative in Japan,
- The Translational Medicine Initiative in Kobe, Japan.

As the biopharmaceutical industry has recognised the need to invest more in pre-competitive pharmaceutical research, if IMI is not implemented in Europe the biopharmaceutical industry will participate in the non-European initiatives to fulfil its need to innovate. This does not mean that the establishment of a Joint Technology Initiative (JTI) will keep industry from investing outside Europe, as the very attractive market conditions in the US will always have a positive impact on investment decisions. Rather it means that as long as Europe is a market with highly controlled market access and pricing, the IMI JTI is an opportunity to increase Europe's attractiveness, and build up a specialised capability in pre-competitive pharmaceutical research. The biopharmaceutical industry is global and will conduct and invest in this research wherever there are favourable conditions and frameworks that can deliver. With the implementation of IMI, it is likely that the biopharmaceutical investment in R&D will increase in the EU. Without the implementation of IMI, it is likely that the investment in R&D will significantly decline in the EU.

IMI has the potential for being a 'one-stop-shop', providing that the governance structure of IMI is lean and focused on scientific excellence, collaboration, efficiency, transparency and performance, and that the European Commission invests €1 billion of public funding, IMI could become more attractive than other initiatives.

Should Europe decide not to invest in IMI, such pre-competitive pharmaceutical research projects (and the associated pharmaceutical R&D investment) are very likely to take place outside Europe through other initiatives in the US and Asia. Europe's biomedical R&D base will decline as will the attractiveness of Europe as a place for the biopharmaceutical industry to invest. This is likely to result in further re-location of the biopharmaceutical industry's R&D capabilities outside Europe. This in turn will decrease Europe's ability to sustain a competitive infrastructure to support cutting edge academic and clinical research. Ultimately innovative medicines will be discovered and developed outside of Europe. Long term this may result in delayed access to innovative medicines for European patients.

4. Additionality

Additionality is defined by the European Commission in the document “Roadmap for Joint Technology Initiatives” (www.imi-europe.org/NewsAndEvents.aspx?subpage=news) as follows:

Each JTI must be able to demonstrate how its establishment will lead to additional research being undertaken by industry. In this regard, an evaluation of the contribution of the industrial participants in the JTI is required, or at a minimum, an agreed way to measure the additionality of the R&D investments by industrial partners during the lifetime of the JTI.

4.1 Additional Private Investment: Short-Term

The pharmaceutical industry currently invests in Europe around 20 Billion euros a year in R&D the majority spent in European clinics and hospitals. This investment is placed in Europe because of the expertise in Europe to carry out scientific medical research relative to other parts of the world. The IMI program will significantly enhance the likelihood that Industry investment in R&D will increase over time. What is clear today is that in the absence of IMI, industry investment in Europe will not increase and indeed may decline. In a number of EFPIA companies, funds that could have been spent in Europe are now committed in other parts of the world, notably the USA and Asia.

Globally collaborative, pre-competitive pharmaceutical research is a novel concept. While various companies may have ongoing projects, these do not even begin to reflect the scale necessary to have real impact on the drug development process (see Market failure chapter). There is at this point in time no consolidated data showing the amount of this type of research undertaken, but it is minimal.

The R&D based pharmaceutical companies involved in the creation of IMI are committed to match the public resources invested by the European Commission in IMI by in-kind contributions. This type and level of private investment in IMI is unprecedented and not simply a re-direction of existing R&D resources, because currently the participation of the industry in pre-competitive pharmaceutical collaborative research is marginal. IMI will create a new type of research project for Europe that will be jointly supported on equal terms by the European Commission and Europe’s R&D based pharmaceutical industry. This new approach has the potential to help bind together Europe’s fragmented biomedical R&D environment.

Every Euro invested in IMI by the European Union will be matched by the same investment by the pharmaceutical industry through contributions of resources, equipment, and expertise. It is estimated that the EU will invest €1 billion in IMI from 2008 to 2013. This will leverage €1 billion of investment from the pharmaceutical industry leading to a total of €2 billion of investment in Europe’s biomedical R&D sector focussed on delivering the SRA.

This investment would not have taken place through the Framework Programme even if it were suitable. In the 6th framework programme, each Euro of public investment is not matched by industry investment. In fact in the 6th framework programme the biopharmaceutical industry receives public investment, the proportion of the industry contribution is approximately one-third.

4.2 Additional Private Investment: Medium–Long Term

The pharmaceutical industry is global and seeks to invest in research and development where the highest return on investment can be obtained. The Industry currently spends over 20 Billion euros in Europe on R&D. Costs, availability of trained scientists, scientific excellence and an environment in which innovation can flourish are key factors. With the emergence of low-cost economies (e.g. in India and China), Europe must look to attract investment through scientific excellence, know-how and effective collaborations.

IMI projects will focus on new technologies. The expertise and know-how developed by European stakeholders, in particular academics, will attract investment. The best translational medicine

physicians and clinical trials experts will attract clinical trials to Europe along with investment in competitive pharmaceutical research.

The new type of Public-Private Partnership proposed by IMI in which academic, SME, patient, regulatory and industry expertise is brought together will help foster an environment in Europe in which further collaborative research can flourish as the networks created will form the basis for this. This is a key element in attracting investment.

IMI aims to work closely with regulators so that the research outputs of IMI can be applied as quickly as possible to improve the process of discovering and developing new medicines. The collaboration with regulators in setting research priorities and project design in IMI is a key factor for the industry to invest in research in Europe. This also provides an excellent opportunity for EU regulators to demonstrate leadership in applying new technologies and contributing to the International Conference on Harmonization (ICH). This in turn will help attract pharmaceutical industry investment in the EU. If successful this could be one of the major differentiators between IMI and initiatives in other parts of the world.

IMI will help to reverse the emigration of highly qualified personnel from the EU, a phenomenon also known as 'brain drain', and attracting more of such personnel from outside the EU (including from the USA) by making excellent collaboration and funding opportunities more available, reversing the trend from a 'brain drain' to a 'brain gain' for Europe.

IMI will foster collaboration and risk sharing activities between SMEs and larger companies. By collaborating with the pharmaceutical industry SMEs will be able to overcome complex scientific, technical and operational issues faster than by working alone as they will gain access to significant knowledge and capabilities that are currently unavailable and deeply embedded within the biopharmaceutical industry. This should attract further biotech investment from within and outside Europe, as the experts needed by biotech firms to develop their products will be available in Europe. This will also encourage venture capital funds to flow back into Europe. Improving the productivity of the R&D process and decreasing the risks in drug development are key elements, which will attract additional biotechnology activities in Europe. Another advantage of IMI for SMEs is that by collaborating with biopharmaceutical companies SMEs will be more attractive for venture capital investment as the peer review process of IMI will provide rigorous scientific due diligence. Venture capital companies could consider this as an important risk management instrument in their investment decision making. As venture capital financing is critical for SMEs to develop products and particularly therapeutics, IMI can be expected to boost the injection of venture capital into SMEs. Further, through its participation in an IMI project an SME may become attractive to a biopharmaceutical company and commercial agreements may develop.

A stronger European biomedical R&D base will facilitate the expansion of other sectors e.g. Clinical Research Organisations (CROs), telecoms, Information Technology (IT), nanotechnologies, diagnostics, imaging and biomedical engineering (e.g. remote data capture, novel administration devices, telemetry, bioprocessing). Representatives from all these sectors have contacted the pharmaceutical industry to explore how to participate in IMI. They realise the potential long-term impact of working today together on the standards of tomorrow.

In the long-term IMI will contribute to the level and performance of biomedical research performed in Europe. IMI will facilitate the development of new technologies and ensure they are applied to business needs more rapidly. As a result companies will be attracted to perform R&D in Europe where the best science is conducted by the best trained experts.

IMI will not only generate data for better decision making, it will also invest in establishing networks and infrastructures for Communities of Experts. These investments will make better facilities available for public partners, and as such for future R&D conducted outside the context of IMI, in the long term.

4.3 IMI Impact on EU Competitiveness

4.3.1 Impact on EU Competitiveness

According to the 2005 EU Industrial R&D Investment Scoreboard³ the pharmaceuticals and biotechnology sector invested a total of €17.7 billion in R&D in 2004, making it Europe's second-highest R&D investing sector after Automobiles and Parts. However it is the leading sector in terms of R&D investment growth, which reached 11.9% between 2001 and 2004 (3Y CAGR). Over the same period, employment in the pharmaceuticals and biotechnology sector grew by 7.8% (3Y CAGR 2001–2004). These statistics demonstrate that the biopharmaceutical industry is Europe's most dynamic R&D sector, and a key contributor to the Lisbon Agenda. However, in the last few years some companies have started to reduce R&D activities in the EU to increase those activities in the US or in Asia. Five European and American pharmaceutical companies have already opened new R&D centres in China for example.

These investments in China are mostly driven by costs but also by the availability of a large population of very talented scientists. IMI will contribute to reverse this trend because it will:

- Facilitate collaboration between industry and academia on topics relevant to the biopharmaceutical R&D process;
- Increase the European level of expertise and know-how in technologies relevant to the biopharmaceutical R&D process; such technologies could be in electronic health records or in imaging.
- Accelerate the application of scientific innovation to the regulatory process through collaborations with the regulatory authorities;
- Improve the professional environment for scientists, by improving the infrastructure and by fostering collaborations across sectors.

Currently Europe has limited structured outlets for Public-Private Collaborations. Many scientists have few opportunities to participate in these types of projects and thus are attracted to go and work where such opportunities are more readily available e.g. the USA. IMI will provide more university-based scientists with the opportunity to strengthen their ability to work in partnership with the private sector, which in turn may lead to greater entrepreneurship and the creation of more spin-offs from academia. In addition IMI offers the opportunity to coordinate European investment in research, this will mean that the individual companies can better leverage the resources they spend on coordinating European research effort.

For SMEs participating in IMI, an additional benefit will come from the potential to leverage their assets through collaboration with the pharmaceutical industry. Thus validating or discovering new application for biotechnologies will offer an important incentive for SMEs to participate in IMI projects. It will also facilitate the commercial development of these assets.

IMI is expected to have a positive impact on the way biomedical R&D is conducted in Europe and on European competitiveness. This expectation is supported by the fact that IMI addresses key R&D recommendations for European R&D competitiveness that have been outlined in major reports concerning Europe's biomedical R&D sector e.g. Aho Report⁴ and the recent Cooksey Report⁵.

³ European Commission (2006). The 2005 EU Industrial R&D Investment Scoreboard, Luxembourg

⁴ Aho, E. (2006). Creating an Innovative Europe. Report of the independent expert group on RTD and innovation appointed by the Hampton Court Summit and chaired by Mr. Esko Aho. EUR 22005. Brussels: European Commission.

⁵ Cooksey D (2006). A Review of UK Health Research Funding. HMSO. London.

The 'Aho Report' calls for a pact for research and innovation to drive the agenda for an innovative Europe based on three areas:

Need for Europe to provide an innovation-friendly market through actions on regulation, standards, public procurement, intellectual property and fostering a culture, which celebrates innovation: IMI supports the creation of an innovation-friendly market because it will facilitate a smooth transition of new basic scientific knowledge into regulatory standards. In addition, innovation has been recognised as a core value for pharmaceutical companies as illustrated by the high investment in R&D made by this sector.

Measures are needed to increase resources for excellence science, industrial R&D and the science-industry nexus: IMI governance structure has been designed to support scientific excellence through its Scientific Committee and competitive call process. IMI will support projects addressing R&D bottlenecks in the pharmaceutical process through Public-Private Collaborations targeting the science-industry nexus on an unprecedented scale.

Cutting across established structures to allow new linkages to be made through the instruments of European technology platforms and clusters: IMI governance structure specify that all IMI projects must have as a minimum one academic or SME organisation and a pharmaceutical company. The knowledge management and Education and Training pillars of IMI will also contribute to increase linkage between different established structures.

The following recommendation quoted from the recently published A Review of UK Health Research Funding by Sir David Cooksey illustrates the attractiveness of IMI:

The Office for Strategic Co-ordination of Health Research and the Translational Medicines Funding Board should work with the healthcare industries and other interested stakeholders (e.g. the medical charities) to develop proposals for joint public and private investment in new technologies for medicines discovery, along the lines laid out in the FDA's Critical Path programme and the European Innovative Medicines Initiative.

If implementation is started rapidly, IMI will provide the EU with a real opportunity to compete effectively with the US and Asia. It will not only attract companies and venture capitalists to invest in Europe but is also expected to help create additional jobs and reverse the brain drain.

4.3.2 Performance Indicators for the Impact on EU Competitiveness

The proposed metrics to measure the impact of IMI on EU competitiveness are:

- The number of pre-competitive pharmaceutical collaborative research projects established in the EU as a proportion of those established globally;
- The investment in EU pre-competitive pharmaceutical collaborative research projects as a proportion of the investment in these projects globally;
- Number (and/or budget) of clinical projects performed in the EU: e.g. conduct phase I, II and III clinical studies in Europe required to support safety and efficacy projects;
- Number of EU subjects enrolled in phase I-IV trials;
- Number (and/or budget) of IMI projects involving the Health Information Technology industry: IMI will boost this sector through their participation in the Knowledge Management and imaging projects;

In addition, the following metrics are proposed to measure the impact of IMI on private investment in the EU:

- Per year, the number of pre-competitive pharmaceutical collaborative research projects established in the EU;

- Per year, private investment in pre-competitive pharmaceutical collaborative research projects in the EU;
- Over the duration of IMI, evolution of the private investment in pre-competitive pharmaceutical collaborative research projects in the EU;
- Over the duration of IMI, evolution of the investment of the biopharmaceutical industry in R&D in the EU in comparison with the rest of the world;

4.4 IMI Impact on EU Scientific Environment

4.4.1 Impact on EU Scientific Environment

IMI will benefit the European science base and attract further investment by generating academic know-how and expertise in new technologies as well as an environment in which collaborative research can flourish. There are also benefits to the SME sector through access to resources and know how which can be applied to new technologies.

4.4.2 Performance Indicators for Impact on EU Scientific Environment

The proposed metrics to measure the impact of IMI on the EU scientific environment are:

- Per year, the number of patents generated by IMI projects;
- Per year, the number of publications generated by IMI projects;
- Per year, the number of validated biomarkers including chemical, toxicological and imaging that have been established and used in clinical trials;

In addition, it should be considered to discuss the following metrics concerning the regulatory impact of IMI with the EMEA:

- Per year, the number of new or amended EMEA guidelines related to the use of new technologies in drug discovery and development;
- Per year, the number of new EMEA guidelines including surrogate end points;
- Per year the number of recalls and restrictions in use due to safety reasons
- The change in median time to approval by therapeutic area.

4.5 Developing Performance Indicators

IMI will encourage R&D expenditure in Europe but it will be difficult to assess with accuracy what the investment would have been in 2014 without IMI. The biopharmaceutical industry proposes to measure performance using the metrics listed above. However, these metrics need to be defined more precisely, measured and validated. Some metrics may be discarded, others added. Metrics from the 7th Framework Programme could also be considered for IMI.

Deciding what performance measures to apply to IMI is an important decision, the following questions will be used to determine that the right measures have been selected:

- Is the measure directly linked to the expected outcome?
- Can it be easily related to the activities undertaken in IMI?
- Is the measure objective and independently verifiable?
- Is the measure understandable?
- Is the measure sensitive enough to provide timely indications of performance changes?
- Does the measure negatively impact IMI?

- Does tracking the measure require reasonable resource expenditures?

For each proposed metric, the answer to these questions will be reviewed as well as the projected timescale to measure impact on these metrics. The performance metrics, their definitions and qualifications should be attached to the IMI Internal Regulation as soon as the EU approves IMI. It would be desirable to do this via pilot study, starting with a selection of the indicators.

4.6 Commitment from Europe's Biopharmaceutical Industry

All 24 companies represented on the Research Directors Group of EFPIA are committed to engaging in IMI. These companies represent the entire spectrum of Europe's biopharmaceutical industry from 'big pharma' to relatively small and predominantly national enterprises. Big pharma companies are expected to take the lead and act as Project Co-ordinators extending best practices across the entire sector. All of the companies represented on the Research Directors' Group of EFPIA are engaged in conducting projects with a focus on scientific excellence irrespective of their size. The biopharmaceutical industry has made a number of concrete commitments to match the level of public investment by the European Commission. These commitments in the form of press releases and presentations at biomedical conferences are in the public domain. Privately the biopharmaceutical industry has made commitments to Heads of State and senior members of government of Member States and at the highest levels of the European Commission.

To date the biopharmaceutical industry has demonstrated its commitment to IMI via an investment of an estimated €5 million in IMI. Every year IMI's annual accounts and balance sheets for the preceding year shall be submitted for audit to the Court of Auditors of the European Communities. The Court of Auditors in accordance with its current procedures shall execute the audit. Should the biopharmaceutical industry not meet its commitment to match EU funds, this will be detected quickly and the impact on the image of the pharmaceutical industry would be devastating. This is a serious deterrent and industry is determined that this will not happen.

The level of R&D expenditure of the Pharma industry has always be high and one of the highest within the various industrial sectors. IMI will facilitate the integration of the pharmaceutical R&D effort in EU, re-establish and support a closer collaboration with academia and SMEs and will leverage the level of individual investment.

4.7 Impact on the Image of the Industry

To date IMI has already contributed to transforming the perception of pharmaceutical R&D in Europe following a series of thematic workshops to develop the Strategic Research Agenda organised by the European Commission and EFPIA. Since January 2005, a diverse and balanced group of over 350 stakeholders, including R&D experts, regulators and patient group representatives from across Europe, have been consulted in the development of the Strategic Research Agenda and contributed to its recommendations. The InnoMed integrated project under FP6 has already shown that large collaborative projects can be implemented in Europe as 16 biopharmaceutical companies are working with 13 Universities and 7 small and medium-sized enterprises (SMEs) to address some of the bottlenecks identified in IMI.

This has shown to the public i.e. governmental bodies, patients and taxpayers, that the industry does not only talk about developing efficient, innovative and safe drugs and place patients and health care at the centre of the stage, but is also actively doing so.

In addition the biopharmaceutical industry expects IMI will have a significant positive impact on the perception of the industry in Europe through building trust arising through new levels of public-private collaboration that increase mutual understanding. More open and transparent collaborations with stakeholders such as patient groups, regulators and clinicians will help to improve the image of the industry in the public community.

Furthermore a more positive public opinion of the pharmaceutical industry is likely to be developed from IMI because IMI will demonstrate to the general public that the biopharmaceutical industry is:

- Committed to patients through the faster discovery and development of better medicines.
- Committed to and actively investing in innovation.
- Committed to investing in Europe.
- Aware of the need to reduce, refine and replace animal experimentation.

In summary, IMI is an initiative that will contribute in a positive way, demonstrating the capacity, willingness and openness of the pharmaceutical industry towards working together with other scientists and experts on a common goal of improving health among citizens.

5. Governance

Governance is defined by the European Commission in the document “Roadmap for Joint Technology Initiatives” (www.imi-europe.org/NewsAndEvents.aspx?subpage=news) as follows:

Each JTI must describe the decision-making and management bodies of the legal entity and how these bodies will operate to ensure achievement of the objectives.

5.1 Introduction

For the IMI to be effectively implemented it is essential that there is an effective and open governance structure. Industry will fully participate if the simplicity, speed and coherence of decision taking are appropriate to the investment of time and resources. The governance structure is lean and efficient and involves the minimum number of steps to ensure efficient and effective decisions. All decisions will be completely transparent and therefore this proposal combines effectiveness and transparency. The industry believes that the governance structure proposed is optimal for IMI.

The IMI governance structure was developed by a governance taskforce comprising representatives of the Commission and EFPIA was established in the beginning of 2006. The objective of this taskforce was to ensure that the two partners funding IMI were satisfied with the way that IMI will achieve its objective of implementing the Strategic Research Agenda. The work of the governance taskforce has resulted in the following documents:

The IMI Statutes, to be approved by the EU Member States as part of the IMI approval process;

The IMI Internal Regulation outlines the activities of the three IMI bodies, and how IMI will conduct its day-to-day operations. The IMI Board will formally approve it once IMI is established.

The key guiding principles for the development of the IMI governance are:

- Ensuring scientific excellence and relevance of the Strategic Research Agenda;
- Streamlined governance/management with as little bureaucracy as possible;
- Foster collaborative behaviour: call and evaluation processes must secure workable partnerships;
- Ensuring transparency.

5.2 Objectives

The objectives of IMI Joint Undertaking (JU) are:

- to ensure the efficiency and sustainability of the Joint Undertaking,
- to ensure the successful implementation of the Strategic Research Agenda,
- to ensure the pooling of the necessary resources and their efficient management,
- to ensure transparency and openness to all stakeholders.
- to ensure the right level of industry influence to maintain industry commitment.

IMI ensures intra-industry cooperation because it focuses on pre-competitive pharmaceutical research projects for which extensive public-private and intra-industry collaboration is essential.

The governance structure of IMI has been designed so that the biopharmaceutical industry matches the resources contributed by the European Commission to stakeholders participating in projects. A diverse and balanced group of more than 350 stakeholders, including R&D experts, regulators and patient group representatives from across Europe, have been consulted in the development of the SRA and contributed to its recommendations.

An Executive Office led by an Executive Director will manage the day-to-day operations of IMI. The Executive office will play a key role in ensuring that the relevant stakeholders participate in IMI, by, among other things, planning outreach and communication activities to build awareness of IMI.

The Intellectual Property Rights (IPR) policy of IMI ensures that the results of IMI projects are widely disseminated in a timely manner and shared appropriately across Europe's biomedical sector. They have been written by a multi stakeholder group to encourage collaboration between all the actors in Europe's biomedical sector. The IPR Policy is part the internal regulation document for IMI and can be found at: <http://www.imi-europe.org>. The IMI Board will formally approve it once IMI is established.

5.3 Decision-Making and Management Bodies

The IMI Joint Undertaking will have a legal mandate to award research grants to European Public–Private Collaborations. The organisation will have the responsibility of managing the involvement of stakeholders, as well as the operations required to support the implementation of the Strategic Research Agenda. To fund, implement and operate IMI successfully, it is important that the structure of the IMI Joint Undertaking is efficient and non-bureaucratic. All stakeholders will be eligible to participate in IMI projects, the only condition being that the research is performed in Europe. Therefore, there will be no official membership of IMI. The IMI governance structure of the Joint Undertaking consists of one decision making body - the IMI Board, a management body - the Executive Office, and an advisory body - the Scientific Committee. In addition, a Member States Group and Stakeholders' Forum will ensure co-ordination with national activities and transparency of IMI activities.

5.3.1 The IMI Board

The IMI Board will be composed initially of the Founding Members of IMI, i.e. the European Commission and the European Federation of Pharmaceutical Industries and Associations. The Board will be responsible for the overall operations of IMI and implementation of the Strategic Research Agenda. To prevent potential conflicts of interest, Board Members cannot participate in Projects. The Board will be composed of five representatives of the European Commission and five representatives of EFPIA. Five Board Member representatives will be appointed by the Commissioner for Science and Research of the EC, and five by the President of EFPIA in conjunction with the Chairperson of EFPIA's Research Directors' Group. To ensure an equal partnership, all Board decisions will be made by consensus and its Chairperson will rotate on an annual basis between the Founding Members. Companies that are representing EFPIA on the Board shall be permitted to participate in Projects. New Board members representing other stakeholders may join based on future expressions of interest and meeting appropriate membership criteria.

The tasks and responsibilities of the IMI Board are set out in the IMI Internal Regulation.

5.3.2 The Scientific Committee

The Scientific Committee will be an advisory body to the Board and it shall conduct its activities in close liaison and with the support of the Executive Office.

The Scientific Committee is composed of a maximum of fifteen members selected by the Member States Group from a shortlist of nominations from the IMI Board. When members complete their term or resign, the Member States Group, working with the Scientific Committee, will be asked to produce a shortlist of replacements. After approval of the shortlist by the Board, final selection will be made by the Member States Group⁶. The Member States Group then makes the final selection, in accordance with specific selection criteria approved by the Board. This is to ensure a balanced

⁶ Initially forty prospective members are short-listed by the Board

representation of expertise across the IMI stakeholders e.g. academics, patients, regulatory authorities and industry. The chairperson of the Scientific Committee is elected from within the Scientific Committee and serves for a non-renewable 2 year term. The other members serve for a 3 year term, which is, subject to approval by the Member States Group, renewable once for an additional term of 2 years. The chairperson of the Scientific Committee may attend the Board meetings at the invitation of the Board.

The tasks and responsibilities of the IMI Board are set out in the IMI Internal Regulation.

5.3.3 The Executive Office

The Executive Office will be responsible for the overall operation and communication activities of IMI. It will consist of an Executive Director and supporting staff. Its activities will be set out in the 'Internal Regulation' document, which is approved by the IMI Board.

5.3.4 The Member States Group

The Member States Group will consist of nominees from all Member States and Associated Countries, and it will approve the composition of the Scientific Committee. It will facilitate rapid dissemination of information between IMI and Member State activities, and ensure co-ordination with Member State activities. In addition, it will play a leading role in the implementation of certain strategic parts of the Strategic Research Agenda, such as Education & Training.

A key role of the Member States Group acting on behalf of Member States will be to facilitate communication between IMI and the EU Member States and Associated Countries. It shall in particular be invited to ensure the dissemination of information in their respective countries regarding calls for proposals, calls for experts or meetings organised by IMI.

In addition, the Member States Group shall be responsible for the implementation of some specific areas and/or topics of the Strategic Research Agenda, in particular concerning Education & Training, which falls within the rules for subsidiarity. It is envisaged that the Member States Group will contribute to the Implementation of the Education and Training activities of IMI via the European Medical Research Academy (EMRA).

5.3.5 The Stakeholders' Forum

The Stakeholders' Forum will be an important communication channel to the European IMI stakeholders to ensure transparency and openness of IMI activities. Its role will not only be to ensure that the activities of IMI are disseminated and communicated in the scientific and public Communities, but also to provide independent commentary on the progress of the implementation of the Strategic Research Agenda to the Board and Executive Office. Additionally the Stakeholders' Forum will be able to suggest proposals on the way forward for IMI.

The Stakeholders' Forum will meet once a year at the Stakeholders' Forum Meeting where IMI activities will be presented and discussed. As a guiding principle, representation should aim at reaching the following proportions:

Universities, hospitals, public research:	25%
Large industry:	25%
SMEs ⁷ :	25%
Regulatory Authorities:	10%
European Commission:	5%
Patient organizations:	10%

⁷ Micro, small and medium-sized enterprises or SMEs are defined by the European Commission as: enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding €50 mn, and/or have an annual balance sheet total less than €43 million⁷. IMI will apply the same definition.

Member States Group Representatives

All Members

The tasks and responsibilities of the Stakeholders' Forum are set out in the IMI Internal Regulation.

5.3.6 Proposed Role of the Regulators in the IMI Governance

Regulators should be represented on the IMI Board, on the Scientific Committee and on the Stakeholders' forum. In addition, EMEA representatives should be directly involved in IMI Projects as projects participants when relevant. In this manner regulators will become directly involved in IMI and will therefore be in a good position to put the outcomes of IMI into regulatory practice rapidly.

Therefore the regulators will have a direct impact on IMI decisions through participation in the IMI Board, the Scientific Committee and Stakeholders Forum. The EMEA will provide regulatory expertise to help identify needs and solutions. It is also very important to ensure co-ordination with other regulatory initiatives.

5.4 Funding Process

The proposed EC contribution to the IMI Joint Technology Initiative is €1 billion for the period of the 7th Framework Programme (FP7 2007-2013). The annual contribution from the EC will start in the range of €100 million and gradually increase to reach €300 million. This investment will be matched in kind by the EFPIA member companies to reach a total of €2 billion for the FP7 period.

FP7 will fund academic participants and support SMEs while biopharmaceutical companies will fund their own contributions to 100%. With this structure, public money will therefore go exclusively to public sector participants and SMEs, and not to biopharmaceutical companies. The biopharmaceutical industry partner(s) will provide R&D resources such as staff, laboratory facilities, materials and clinical research, which will match the FP7 funds.

For all participants in a Project, public and private, financial reporting to IMI shall:

- Be performed on an annual basis;
- Include a Cost Statement related to the Project, as well as Audit Certificates.

The Cost Statement will describe costs incurred by the Project Audit Certificates will be obtained from participants' appointed auditors, certifying the cost statement.

The funding mechanisms of IMI are described in the Figure 3 below.

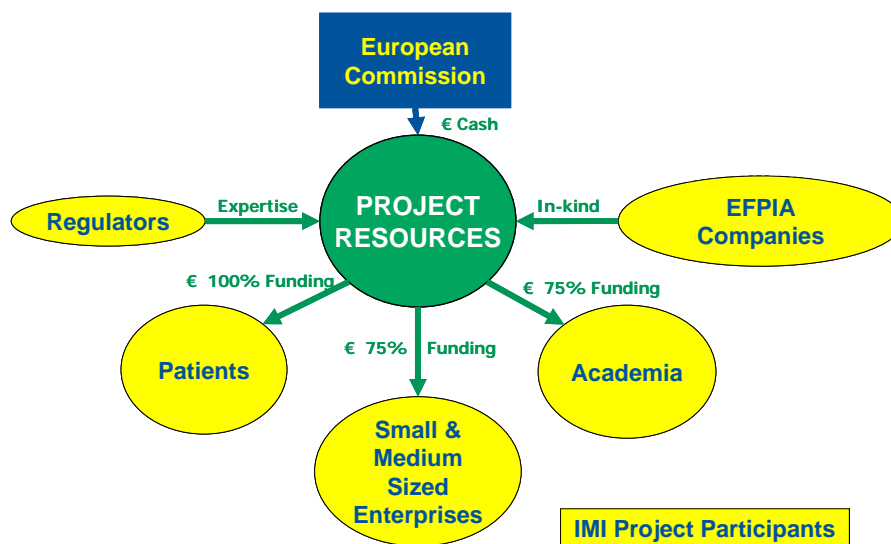


Figure 3 : Funding of IMI Projects

Keys for Success – Industry Input

In order to ensure total transparency on the IMI costs, every year IMI's annual accounts and balance sheets for the preceding year shall be submitted for audit to the Court of Auditors of the European Communities. The Court of Auditors in accordance with its current procedures shall execute the audit. Should the biopharmaceutical industry not meet its commitment to match EU funds, this will be detected quickly and the impact on the image of the pharmaceutical industry would be devastating. This is a powerful deterrent not to be underestimated, industry is determined that this will not happen.

6. Role of Member States

Role of Member States is defined by the European Commission in the document “Roadmap for Joint Technology Initiatives” (www.imi-europe.org/NewsAndEvents.aspx?subpage=news) as follows:

For those JTIs which foresee the involvement of Member States as founding fathers, the role of Member States in the JTI decision-making process must be clarified so that national financial contributions enhance the impact of the JTI and reinforce the principles of scientific excellence and industrial relevance without regard to national financial return in relation to the FP7 financial contribution. This concerns notably the two JTIs in the field of information and communication technologies (ARTEMIS and ENIAC).

IMI will be funded by the Seventh Framework Programme and by the Industry and should not induce any extra costs to the Member States. However the role of the Member States in IMI is essential for the successful implementation of IMI. In addition, IMI will give the Member States the opportunity to leverage national research investments through better co-ordination and connectivity with the other European countries.

Members States drive the EU focus on building the most competitive knowledge-based economy:

- Maintaining and expanding national (and/or regional) public research infrastructure in biomedical science;
- Maintaining the national education systems to participate fully in European collaborations, in particular IMI;
- Working with national funding agencies to identify areas of pre-competitive collaborative research that can be funded nationally;
- Leveraging the collaborative philosophy created by IMI in biomedical research.

These activities are pre-requisite to the creation of IMI. Concerning the practicalities of the implementation of IMI, the Member States also have a key role to play. Member States will have a direct input to IMI to ensure its successful implementation by:

- Appointing a national representative to IMI Member States Group;
- Nominating the members of IMI’s Scientific Committee based on a proposal from IMI Board
- Mobilising national stakeholders’ awareness of IMI;
- Proactively communicating and discussing the benefits of IMI within the national biomedical R&D community;
- Developing initiatives to help public and private researchers participate in IMI;
- Liaising with IMI management through IMI Member State Group to co-ordinate national biomedical R&D priorities with IMI, and identifying areas of potential synergy.

IMI will use resources effectively and Member States will have access to the information documenting the efficient use of EU resources.

1. IMI governance structure and processes are defined in order to combine the EU rules for control of public funds with the industry requirements for performance and agility;
2. To ensure the appropriate use of resources in IMI, quality control measures will be implemented at both IMI project level and IMI management level;
3. For IMI projects reporting procedures and rules for advances of project funds will be established to ensure that the IMI projects deliver with a minimum of risk to Community funds;

4. Every year IMI's annual accounts and balance sheets for the preceding year shall be submitted for audit to the Court of Auditors of the European Communities. The Court of Auditors in accordance with its current procedures shall execute the audit.

7. Abbreviations Used

CRO	Contract Research Organisation
DB	Database
EC	European Commission
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
FP	Framework Programme
FP6	6 th Framework Programme
FP7	7 th Framework Programme
ICH	International Conference on Harmonisation
IMI	Innovative Medicines Initiative
IP	Integrated Project
IPRs	Intellectual Property Rights
IT	Information Technology
JTI	Joint Technology Initiative
JU	Joint Undertaking
KM	Knowledge Management
NCE	New Chemical Entity
NME	New Molecular Entity
PPPs	Public–Private Partnerships
R&D	Research and Development
RDG	Research Directors Group
SME	Small and Medium-sized Enterprise
SRA	Strategic Research Agenda