

## 6 Governance and Funding

This chapter presents the proposed governance structure of IMI, which has been prepared by the key IMI stakeholders: representatives of the European Commission, academia, biopharmaceutical companies and EFPIA. The recommendations on the IMI governance structure have also been reviewed by representatives from the Member States.

The following principles of governance are part of the proposal to grant Joint Technology Initiative (JTI) status to IMI, and will be implemented as soon as this status has been granted by the European Council.

### 6.1 Legal Status

The European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA) will hold joint responsibility for creating and operating a JTI that will implement the recommendations of the IMI Strategic Research Agenda.

IMI will be established based on article 171 of the Treaty establishing the European Community ('The Community may set up joint undertakings or any other structure necessary for the efficient execution of Community research, technological development and demonstration programme'). The IMI legal entity will be an international not-for-profit organisation.

JTI status represents the highest level of pan-European public and private sector collaboration and coordination. This is needed because the scientific challenges addressed by IMI are too complex for organisations and/or nations to address in isolation. For IMI to succeed, it is essential that it is granted JTI status by the European Competitiveness Council after consultation of the European Parliament.

### 6.2 Structure

The IMI Joint Undertaking will have a legal mandate to award research grants to European Public–Private Collaborations. This organisation will have the responsibility of managing the involvement of stakeholders, as well as the operations required to support the implementation of the SRA. To fund, implement and operate IMI successfully, it is important that the structure of the IMI Joint Undertaking is flat and highly efficient. To support this objective, the organisational structure described in Figure 31 below is proposed for the IMI Joint Undertaking.

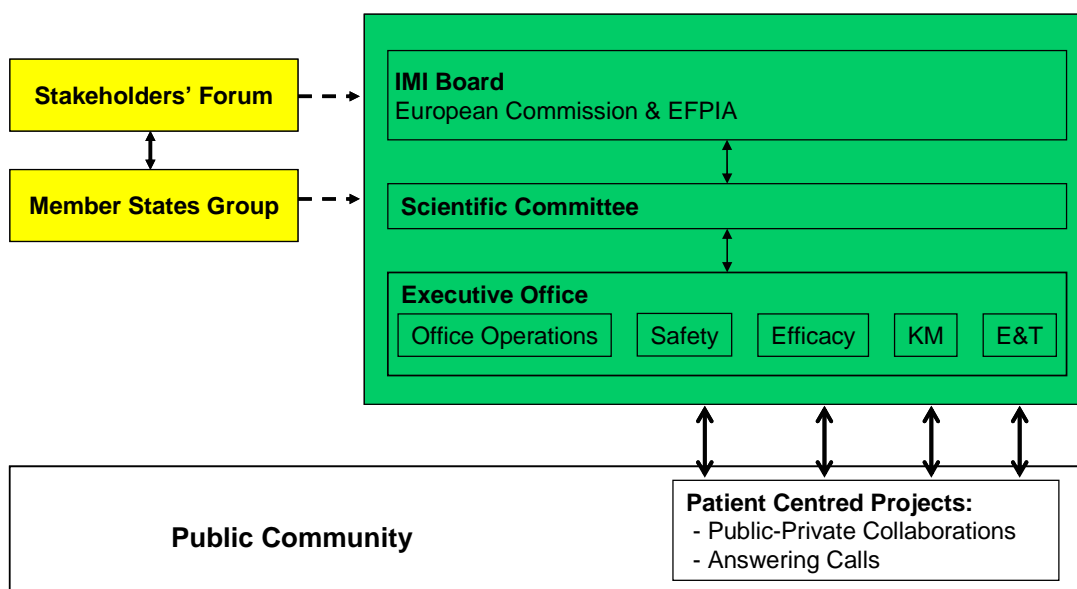


Figure 31 : Proposed IMI Implementation Structure

All stakeholders are eligible to participate in IMI projects, the only condition being that the research is performed in Europe. Therefore, there is no official membership of IMI.

The IMI Joint Undertaking will comprise the following bodies:

- The Member States Group, with nominees from all Member States and Associated Countries, 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 SRA, such as Education & Training;
- The Stakeholders' Forum will be open to all stakeholders. It will convene annually at the General Assembly, where IMI activities will be presented and discussed to ensure openness and transparency to all stakeholders. In addition, the Stakeholders' Forum will be invited to provide advice to the Board on the orientation of IMI activities.
- The Board will be responsible for directing the operations of the IMI Joint Undertaking. The Board will oversee the implementation of the SRA by the Executive Office. Initially, the Board will be composed of representatives from the European Commission and EFPIA. However, based on future expressions of interest, new Board members representing other stakeholders may join;
- The Executive Office will be responsible for the overall operational and communication activities of IMI. It will develop a document termed 'Internal Regulation' which outlines the activities of the three IMI bodies, and how IMI will conduct its operations;
- The Scientific Committee will be an advisory body to the Board. It will conduct its activities in close liaison with, and with the support of, the Executive Office. It will consist of 15 members who reflect a balanced representation of both public and private stakeholders, including: academia, patients, industry and regulators. Collectively, its members will represent expertise from across the entire drug discovery and development process, and be expected to provide scientific recommendations on the scientific strategy of IMI.

Based on the recommendations presented in the SRA, the Executive Office will publish calls for research proposals that address the topics described in the SRA. Groups of partners (for example, academic institutions, SMEs, biopharmaceutical and healthcare companies, regulatory authorities and patients) will then form Public-Private Collaborations (PPCs) to propose research projects that address the topic of the respective call, and apply to IMI for funding. Each proposal will be prioritised and approved via a peer review process, on the basis of stringent scientific criteria and its potential impact on the IMI bottlenecks. The review and approval process will be developed by the Executive Office to ensure rapidity and transparency in the system. Academic institutions and SMEs within the PPC whose proposal has been approved will then receive funding from the IMI Joint Undertaking for the duration of the research project. As a guideline, a Public-Private Collaboration will consist of a minimum of one academic institution and/or one SME, plus one biopharmaceutical company which is a member of EFPIA.

Two contracts shall be signed to implement such a Public-Private Collaboration:

- The IMI Grant Agreement: the legal document that will govern the relationship between the partners and the IMI Joint Undertaking. The IMI Grant Agreement will be a high-level agreement that defines the specific project and the financing, as well as the application of the IMI Intellectual Property Policy;
- The Project Agreement: the legal document that will govern the relationship between the project partners, including detailed Intellectual Property Rights based on the IMI Intellectual Property Rights Policy (see Chapter 7). This system allows flexibility so that contractual obligations can be based on the project specifics, and so that the project agreement fairly reflects the scientific and commercial interests of all partners.

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 mn<sup>65</sup>. The IMI will apply the same definition.

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<sup>65</sup> Article 2 of the Annex of the Recommendation 2003/361/EC

### 6.3 Funding

To implement fully the recommendations of the SRA will require about €460 mn per year for seven years starting in 2007 equally shared between FP7 and the EFPIA member companies.

FP7 will fund academic participants and support SMEs while biopharmaceutical companies will fund their own contributions to 100%. Other or non-biopharmaceutical companies participating in Public-Private Collaborations will be supported on a case-by-case basis. 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. The funding mechanism of IMI is described below in Figure 32.

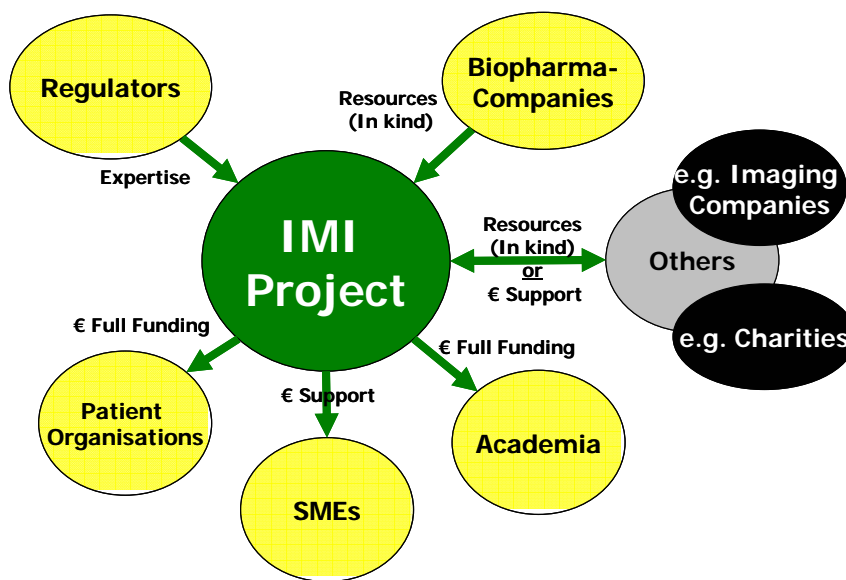


Figure 32 : IMI Funding Model

It is envisaged that the initial public funding could be about €50 mn (subject to yearly evaluation) and, therefore, the amounts shown below represent an estimated range of financial resources becoming available over the next seven years.

Source of funding	Recipient of funding	Estimated Costs Per Year (€mn)	
		2007	2013
European Union	Executive office	0.5	3
	IMI Project Participants: public institutions, patients organisations & SMEs	50	250
EFPIA	Executive office	0.5	3
Biopharmaceutical companies matching EU funds	IMI Projects Participants: biopharmaceutical companies	50	250

Figure 33 : IMI Funding Sources

Co-ordination of the IMI activities with the EU infrastructure funds is important, and therefore two representatives from IMI have been nominated for the committee responsible for the co-ordination of EU infrastructure funds in DG Research.

EU structural funds can also be used to establish R&D infrastructures; IMI will be in a unique situation to advise on how such infrastructures will best benefit the public–private biomedical community. To achieve this, IMI proposes to participate in committees responsible for the co-ordination of EU structural funds at the EU and/or national level.

## 6.4 Overview of IMI Costs by Pillar

The levels of investment required to support the recommendations related to each of the SRA Pillars have been estimated, and are summarised in Figure 34 below. These estimates are to be considered as preliminary estimates and subject to revision once the IMI is implemented. The duration of adopting the majority of the recommendations is between five and seven years, i.e. 2007–13.

<b>Activities</b>	<b>Costs per year (€mn)</b>
<b>Improve Predictivity of Safety Evaluation</b>	<b>165.4</b>
European Centre of Drug Safety Research	36.7
Biomarker development	22.5
Relevance of rodent non-genotoxic carcinogenicity	22.5
Clinical safety and pharmacovigilance	68.7
IT infrastructure support	15.0
<b>Improve Predictivity of Efficacy Evaluation</b>	<b>236.7</b>
Cancer	66.7
Brain Disorders	62.3
Inflammatory Diseases	60.0
Diabetes	37.7
Infectious Diseases	10.0
<b>Improved Knowledge Management for Better Decision Making</b>	<b>38.6</b>
Running the KM Teams	3.3
KM Platform Infrastructure	8.4
KM Platform Research Projects	2.2
Translational KM Joint Projects	1.0
Translational KM Efficacy Support	23.7
<b>Improve Education &amp; Training to Develop the Talent Base</b>	<b>14.5</b>
Create and run European Medicines Research Academy (3 FTEs)	0.4
Running of training programmes	3.8
PhD grants	10.3
<b>Implementation: IMI Executive Office</b>	<b>6.0</b>
<b>GRAND TOTAL/YEAR</b>	<b>€0.46 bn</b>
<b>GRAND TOTAL IMI (2007–2013)</b>	<b>€3.23 bn</b>

Figure 34 : Estimated Annual Costs of Implementation of the SRA

Figure 35 below shows that more than 50% of the proposed IMI budget is dedicated to improving the predictability of efficacy evaluation.

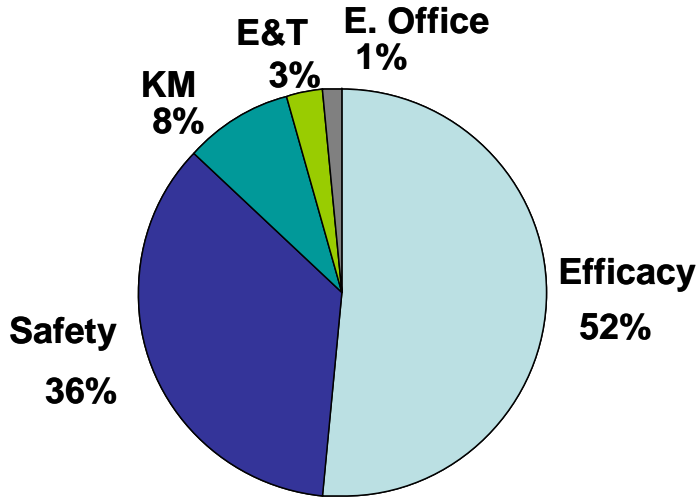


Figure 35 : Distribution of the SRA Total Yearly Costs (€0.46 bn)

### 6.5 Overview of IMI Costs by Type

General and Administration (G&A) costs are defined as general, administration and infrastructure costs. These include the costs of the Executive Office, of the overheads of the European Center of Drug Safety Research as well as the KM platform infrastructure and various co-ordinating activities such as communities of experts (CoEs). G&A costs represent a total of €33 mn per year or 7% of the total SRA budget the remaining being allocated to research projects. For comparison, InnoMed, the project of the 6<sup>th</sup> framework programme also have G&A costs of 7% of the total budget. IMI's total G&A costs of €33 mn per year are evenly distributed amongst the: Efficacy, Safety and KM Pillars of the SRA as described in Figure 36 below.

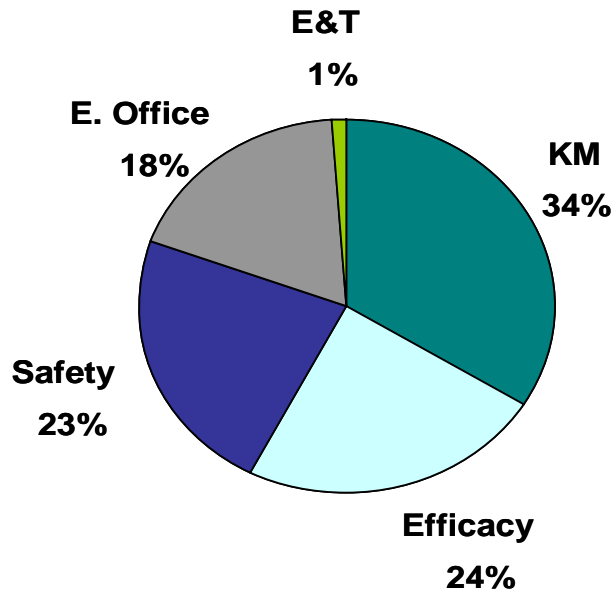


Figure 36 : SRA G&A Budget Cost Drivers

## 6.6 Communication

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The future success of IMI depends on creating a high-performance collaborative culture, based on objective and transparent communications between all public and private stakeholders across Europe. To achieve this objective, effective communication is an important success factor for IMI.

To support this approach, the following communication tools and approaches will be implemented:

- IMI website with up-to-date information on the progress of the initiative;
- Annual General Assembly of the Stakeholders' Forum;
- Continuously updated material on IMI;
- Annual report;
- Introduction pack for the partners in Public–Private Collaborations;
- Press releases;
- Press conferences, when appropriate;
- The organisation of information days with Member States;
- Yearly status reports from Public–Private Collaborations;
- Final reports from Public–Private Collaborations to ensure a large dissemination of the results and of the potential application of these results to the biomedical R&D process;
- English as the official language to be used for all IMI communications.

## 6.7 List of Contributors

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