Innovative Medicines Initiative

Innovative Medicines Initiative
Annual Implementation Plan
2013

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1 FOREWORD

The Innovative Medicines Initiative Joint Undertaking (IMI JU) is at a crossroads. After three years of operation as an autonomous community body, IMI JU is recognised as an efficient public-private partnership that fosters high quality collaborative projects bringing together the different stakeholders involved in drug development. By consistently ensuring a fair selection of applicant consortia and facilitating agreements between the different partners, IMI JU has come to be appreciated as an effective neutral platform. Stakeholders have also welcomed the simplification and streamlining of procedures that were implemented in 2012.

At the same time, the new challenges faced by the pharmaceutical industry and the healthcare sector at large have led IMI JU to revisit its priorities for the future. The current objective is to address the needs common to industry and society by focusing on major public health issues and ensuring a permanent dialogue with regulatory authorities and patient organisations. The series of Calls for proposals to be launched in 2013 will reflect this significant evolution.

In order to accommodate the fast-growing workload and ensure the delivery of high-quality work according to strict ethical standards, administrative and financial processes will be continuously reviewed and adapted as needed.

As IMI JU projects move along with often impressive achievements, it will be critical to continue to document and monitor progress using key performance indicators. In parallel, IMI JU's communication activities will be further expanded by conducting outreach campaigns targeting different audiences. Raising awareness of IMI JU to facilitate the establishment of a new public-private partnership in innovative health research under Horizon 2020 will indeed represent a top priority in 2013.

By doing so, IMI JU will ensure that it transitions smoothly and successfully into the future.

Michel Goldman
Executive Director

2 SCIENTIFIC PRIORITIES FOR 2013

The Scientific Priorities for 2013 are derived from the revised Scientific Research Agenda (SRA) which has been drafted by the IMI Scientific Committee (SC) in consultation with the State Representative Group (SRG), and adopted by the IMI Governing Board on July 2011. Furthermore, the Scientific Priorities below were subject to a specific consultation with SC and SRG in November 2012.

The 2013 Priorities for the design of new Call topics have been selected on the basis of the following underlying criteria:

- potential to foster strategic initiatives targeted on 'game changing' ideas;
- areas where the maximum number of companies can join forces. To maintain focus, these priorities will address one or more of the 7 Areas of Research Interest defined in the revised SRA;
- areas addressing the scientific, societal, and regulatory challenges that hold up the translation of the newest sciences and technologies into efficient healthcare with the ultimate aim of speeding up patient access to the most effective therapies and disease-prevention treatments.

EFPIA may propose new priorities based on emerging needs which are identified in the Scientific Research Agenda.

Projects will deliver data, tools and methodologies, as well as processes for sharing information and learning from the whole healthcare ecosystem in real time. They will also contribute to creating:

- strong networks of scientific excellence across Europe;
- comprehensive stakeholder networks including regulators, payers, consumer advocates, and patient associations alongside academics, SMEs and pharmaceutical companies.

In this context, particular attention will be given to enhance patient involvement both at Call text elaboration and evaluation stage.

IMI will also look into the sustainability and implementation of tools, methods and infrastructures created within ongoing IMI projects.

The topics derived from the 2013 Priorities are implemented through Calls for proposals where selection is based on evaluation criteria defined in the relevant Call documents.

2.1 Pharmacogenetics and Taxonomy of Human Disease

Towards an unbiased redefinition of disease: In 2013 IMI will further expand on the initiative started in 2012 on a redefined taxonomy of disease based on molecular/genetic/proteomic and other markers in order to reduce complexity and cost of clinical trials and aid medical practice with better treatment paradigms.

This would include for example:

- Analysis of additional heterogeneous diseases, for example in the field of brain and immunological disorders;
- Creation of biology-based objective end points for treatment, leveraging the new disease classification.

The IMI initiative will build on relevant FP7 projects (especially from the 2012 Health Work-Programme and ESFRI) to ensure synergy and avoid overlaps.

2.2 Infectious Diseases

Antimicrobial resistance: 2012 saw the launch of the first topics part of the 'New drugs for Bad Bugs' (ND4BB) platform. Projects in this field to be launched in 2013 will complement the comprehensive approach/European Union strategy to combat antimicrobial resistance across the entire innovation cycle.

This would include for example:

- Clinical studies to deliver new innovative treatments, especially against Gram negative agents;
- Generating data to support the setting up of new business models which would attract further R&D investments in AMR in Europe;
- Any other topic which will address a scientific, technological or regulatory challenge which holds up investment in R&D into novel antibiotics and other methods to combat antimicrobial resistance.

Effectiveness of influenza vaccines: To progress in this area of high unmet need, this initiative will build on results obtained in previous European projects and will take advantage of recently launched projects in the 7th Framework Programme to boost R&D on vaccines across Europe by joining private and public forces. Major aims will include accurate evaluation of new and improved vaccines using standardised and validated assays and relevant surrogate markers of protection.

The maturation of topics derived from this priority will include a careful consideration of previous and planned FP7 topics and funded projects (for example topics and projects generated from Topics FP7-HEALTH.2007.2.3.1-1, 2011.2.3.1-1, 2011.2.3.1-3 and 2013.2.3.1-1 as well as FP7 HEALTH.2013.2.3.0-1) in order to insure synergy and complementarity and avoid overlapping. In addition IPR issue will be also carefully considered to allow for maximal synergy, especially in the area of vaccine development.

2.3 Other Priorities included in the Areas of Research Interest: Diseases - Drug Efficacy

In the contexts of the changes faced by the pharmaceutical industry and the evolving health care ecosystem, demonstrating both measurable medical benefits and positive health-economic effects, represent a significant challenge. As well as developing new interventions with enhanced drug efficacy, projects will aim to develop new methods to evaluate this drug efficacy.

Projects under consideration for 2013 would include for example:

- Drug repurposing in neurology, e.g. terminated compounds which did not show a negative safety profile and could be studied for their potential in different indications;
- Integrating molecular pathology and treatment as the standard of care in oncology;
- Validation and optimisation of models set for efficient clinical trial access in advanced cancer. This initiative will build and expand on achievements of already ongoing activities for colorectal cancer, in order to allow application to other cancer types;
- A systems biology approach to human immunology to establish a comprehensive understanding of the functioning of a healthy human immune system. And, subsequently, to understand the deviations linked to disease conditions and their aetiology. A similar approach could be extended to the understanding of human metabolism. In the maturation of the topics derived from this scientific area synergies will be sought with already running FP7 projects and initiatives (e.g. projects derived from FP7 HEALTH CALL 2012 and ESFRI) in order to avoid duplications of efforts.

2.4 Coping with Regulatory and Legal Hurdles

In line with the SRA recommendations and R&D productivity needs, IMI projects will endeavour to provide data and tools for the rationalization of R&D models and regulatory pathways in order to make R&D faster, iterative and adaptive.

Clinical trials design: The scope of this initiative would be to understand and apply the advances in mathematical, statistical and computing science to the rationalization of clinical trial design. This should allow earlier access to medicines and better response rates in target groups, while avoiding unnecessary treatment in patients who are unlikely to benefit.

This would include the design of innovative clinical trials adapted to personalized/stratified medicine, some of them involving companion diagnostics. Corresponding topics will be developed taking into considerations the lessons learned from past and ongoing projects in the 7th Framework Programme, including those derived from interactions with regulatory bodies.

Strengthening the role of patients in regulatory benefit assessment**:** To complement the above, IMI will look into the development of methods and tools for the patient-centric harmonization of risk-benefit evaluation.

This will include the development of methodology for the inclusion of real life data on patient/citizen preferences into company, regulatory, and payer decision making processes. By engaging with patients and producing a deeper understanding of patients' real-world experiences with their conditions and medications, such initiatives will provide key new insights for the drug development process. These initiatives have the potential to enable better health outcomes and to substantially speed up clinical trial enrolment.

This would include for example:

- Development of a harmonized methodology for holistic value assessment to facilitate alignment around a comparative "cost-benefit" evaluation;
- Gathering of data to provide evidence of different responses in sub-populations;
- Mechanisms for cross industry/regulator data sharing.

Other potential initiatives involving key aspects of regulatory science would include the study of the impact of intrinsic (genetic) variations in efficacy and safety of medicines.

2.5 Knowledge Management

IMI will continue to focus on knowledge management. In particular, the emphasis will be on the development of models to ensure the sustainability of the generated assets beyond the life span of a single project. The initiatives will aim at integrating tools, methodologies and infrastructures between various IMI projects with similar or complementary focusses to create a new value and allow application of information in new areas, such as regulatory sciences. The final goal will be to move the tools generated to the next application stage to harvest their entire potential.

This would include for example:

- Development of standards to allow harmonization, integration and linking of smaller data sets to create real 'big data';
- Development of tools for data mining and analysis;
- Linking data bases, bio-banks etc. within, and potentially outside IMI;
- Expansion of existing infrastructural projects to new therapeutic areas and applications (e.g. EMIF, ELF, Taxonomy).

2.6 Possible emerging scientific needs proposed by EFPIA companies and that are included in the revised Scientific Research Agenda

EFPIA may propose further additional priorities based on emerging needs which have been identified in the revised Scientific Research Agenda and are still not addressed by IMI projects. Such projects could address long-term trials to study prevention in Alzheimer's disease.

As in the past, particular attention will be paid to avoid overlap and establish synergies with activities launched outside IMI, i.e. under the umbrella of the Cooperation, Ideas, People and Capacities sections of the 7th Framework Programme.

Additional projects under programmes launched in earlier calls could be envisaged to provide further proof of concept.

3 IMPLEMENTING THE SCIENTIFIC RESEARCH AGENDA

2013 will represent a key year for the implementation of the SRA and the IMI Public Private Partnership (PPP) model.

The last batch of IMI Calls for Proposals will be launched, based on the 2013 scientific priorities set out in the previous section.

As in the previous years, high level independent scientific panels will be engaged for the selection of top quality public consortia that, together with the EFPIA teams, will execute projects derived from the Call Topics.

Grant agreement negotiations will be carried out with the challenge of striking the right balance between maintaining tight timelines and ensuring the best end-product, both from an operational, and an intellectual property rights point of view.

2013 will mark the implementation of the first 'Think big' initiatives, including the launch of the New Drugs for Bad Bugs (ND4BB) research platform, the European Medical Information Framework (EMIF) platform, the European Lead Factory (ELF) and the Stem Cell initiatives.

In addition, the first projects generated from the new SRA scientific priorities will kick off their activities in 2013. These projects will represent a significant enhancement and broadening of the R&D value chain challenges addressed by the IMI, in line with its adjustment to the evolving needs of industry and society.

With as many as 47 projects running their activities at different stages, from early implementation to round up and closure of their final year, project management and monitoring will also be a major endeavour.

A key activity will be to communicate the success stories and the learning generated by the implementation of the SRA in the IMI projects launched so far. Of crucial importance will be to continue working on the key performance indicators, and to extract messages to support and shape the future of IMI. The IMI will continue to gather evidence on R&D bottlenecks, medical needs, barriers to medical innovation, and other factors delaying progress in healthcare.

3.1 Activities related to the Launch of new Calls for Proposals and to Proposals Evaluation and Grant Negotiation

In 2013, the IMI JU will launch its last batch of Calls for Proposals to implement the 2013 scientific priorities. The consultation on the proposed topics will be streamlined and will include workshop(s) with the Scientific Committee, experts, and the States Representatives Group. It is expected that at least 3 Calls for Proposals will be launched covering at least 8 Topics.

The ENSO Call for proposals launched in the last quarter of 2012 will also continue in 2013 with 2 cut-off dates at the end of Q2 and Q4 respectively.
In addition to the evaluation of Expressions of Interest submitted for new topics and to the evaluation of the proposals submitted to the ENSO Call, 2013 will mark the preparation, submission, evaluation of the Full Project Proposals (FPPs) generated from Call 7, and of the Expressions of Interest and FPPs from Call 8. The evaluation of the proposals will be based on criteria of scientific and/or technological excellence; quality of the project plan, strength of the partnership, including merging EFPIA and public consortium; budget; and ethical issues.

In order to enhance and improve the ethical review of projects and avoid the additional review of ethical sections of projects during negotiation, the use of an ethical screening between Stage 1 and Stage 2 evaluation, as utilised in the last Calls of 2012, will continue to be applied.

Due to simplification and streamlining of the process from idea generation to conclusion of the Grant Agreement, timelines will be significantly shortened. The target will be to complete the signature of the Grant Agreements for Calls 7 in May 2013 and Call 8 projects by Q3 2013, and of further projects generated by Calls launched in Q1 & Q2 of 2013 by the end of the year.

To maximise efficiency of the calls management, the IMI JU will continuously explore and implement process simplification and process improvements while maintaining the highest standards of the 2-stage evaluation process.

3.2 Activities to support and monitor on-going projects

A total of 47 projects generated from Call 1 to Call 8 will be running at different stages of their life cycle in 2013. IMI JU will continue to provide support and advice to the consortia, including on amendments to Grant Agreements. The latest modifications of the model Grant Agreement reflected in an updated version of the financial guidelines, including non EU in-kind contributions, will be implemented.

An overview of the project support and monitoring activities for 2013 is provided in the table below.

IMI Calls	Number of IMI projects						
	ongoing	starting in 2013	1st year	interim reviews	post-interim review phase	final year	submitting annual reports & financial statements
1	15				15		15
2	8			6	1	1	8
3	7						7
4	7		7				7
5	1		1				
6	2	2	2				
7	2	2	2				
8	5 (6*)	5	5				
Total	47	9	17	6	16	1	37

**project generated from Topic1c will be part of Topic 1*

All 15 projects generated from Call 1 and one project of Call 2 underwent interim reviews in 2012, and will enter the final phase of their life cycle in 2013. This will include the optimization of their work-plan based on the feedback received from interim reviews.

In 2013, the 8 projects generated from Call 2 will enter their third year of activities; 67 of which will undergo interim reviews. For one project (OpenPHACTS), 2013 will also be the final year of activities. IMI JU will endeavour to run these reviews effectively, via the identification of suitable experts and with good collaboration with the project consortia.

In 2013, the 7 projects generated from Call 3 will be in their 2nd year of activities and the 7 projects generated from Call 4 will be in their 1st year of activities.

In 2013, for the 37 projects from Call 1 to 4, 37 annual periodic reports and corresponding financial statements will be submitted and processed.

A large number of projects will start their activities during 2013 as set out below:

- The project generated from the merging of the two topics of the Call 5: Lead Factory;
- The first two projects (AMR1 and AMR2) of the ND4BB research platform, generated from Call 6;
- The two projects generated from the two Topics of Call 7;
- The projects generated from Call 8.

A key task for the IMI JU will be to continue maximizing efficiency by implementing the remaining simplified process developed during 2012; facilitating, optimizing, and monitoring the running of the projects and seeking user feedback for further improvement.

To this end, the positive experience of the workshop with the project coordinators to provide guidance on the financial and administrative aspects of the projects will be renewed in 2013. Furthermore, interactions between projects and sharing of lessons learnt will be promoted using various other channels (e.g. the IMI Group on LinkedIn).

Based on the previous positive experience, “cross project” meetings will be organized to identify synergies and avoid duplication between projects with common objectives or focusing on closely related fields. Furthermore, the IMI JU will continue to support and provide the necessary assistance to increase research collaborations amongst the projects.

In particular, collaborative activities are expected in the areas of:

- Diabetes research: A memorandum of understanding is already in place, with a more specific agreement being developed for SUMMIT, IMIDIA and later DIRECT.
- CNS disorders:
  - A collaboration between NEWMEDS and PharmaCog on touch-screen preclinical testing which could be extended to EU-AIMS;
  - A collaboration between PharmaCog and EMIF-AD;
  - Further opportunities for increasing interactions will be created by taking advantage of the “Month of the Brain” organized by the European Commission.
- Knowledge Management projects.

Furthermore, 2013 should mark the implementation of a memorandum of understanding to facilitate data sharing and collaboration between the following projects:

- E-Tox and MIP-DILI in the area of text-mining information on hepatotoxic compounds and generation of in vitro and in vivo foreground data to validate hypotheses generated by in silico modelling approaches.
- eTOX and Open PHACTS in the area of preclinical data sharing.
- eTRIKS and IMI-Projects wishing to adopt the transMART platform for the Knowledge Management needs.

3.3 Knowledge Management

In 2013, the following activities with respect to Knowledge Management (KM) are planned:

- Renewal of the Clinical Data Interchange Standards Consortium (CDISC) membership including a CDISC overview course for new IMI projects of Calls 5, 6, 7;
- Continued facilitation of the implementation of data standards on a need basis;
- Assistance with the implementation and use of the ETRIKS platform for all projects within the frame of IMI legal and financial rules;
- E-collaboration will be optimized through the development of a new platform by Q2 2013.

3.4 Call to Explore New Scientific Opportunities (ENSO)

A number of important achievements by IMI consortia have already been acknowledged particularly following project mid-term reviews.
IMI JU will ensure the follow-up of the continuous Call for proposals to explore new scientific opportunities for on-going and new projects, demonstrating the added value of IMI JU in the context of the EC framework programme.

The maximum IMI JU contribution available for 2013 is EUR 7,525,335 shared equally between the 2 cut-off-dates along which proposals will be evaluated and selected. Lessons will be drawn from the 2012 ENSO exercise, which may lead to an increase in the number of cut off dates for the ENSO Call in 2013.

3.5 Monitoring the Performance of IMI JU

The main focus of IMI in 2013 will continue to be on two strategic overarching priorities that have been identified as critical for overall success, namely:

- The **strategic** relevance and added value of IMI as a public-private partnership (*Reinforcing pharma R&D in Europe by addressing bottlenecks and gaps in drug research)*;

- The **operational** performance of the Executive Office (*Maximising the efficiency and effectiveness of the Executive Office)*.

The twelve Key Performance Indicators (KPIs) that have been identified as critical for providing both internal and external stakeholders with a clear and consistent view of the Joint Undertaking's performance and achievement of strategic objectives will be maintained. These KPIs and other supporting metrics will be used to measure, track and report progress during 2013, both on an annual basis as part of the Annual Implementation Plan and Annual Activity Report and regular basis through periodic scoreboards.

The relevant data generation established in 2012 on the basis of project interim reviews and project annual reporting, as well as other project-related meetings, will continue in 2013. The output together with analysis of project achievements will be made available to IMI stakeholders and also used for external communication purposes.

The extracted information will continue to be used to generate key messages in particular on how IMI is improving R&D productivity, along the following framework:

(1) Establishment of robust validated models for drug development and elimination of poorly predictive ones;
(2) Development of novel biomarkers for drug development;
(3) Identification of new drug targets;
(4) More effective approaches to predict adverse drug effects and late attrition (discussed at early stages with regulators);
(5) Exploitation of pooled data from multiple sources;
(6) Agreeing development and regulatory submission of key standards for drug development;
(7) Optimizing clinical trials.

The key messages will be periodically updated as the achievement extraction from projects continues. In addition bibliometric analysis of project publications will be undertaken with the assistance of an external provider, Thomson Reuters. Two reports analysing the bibliometric output of IMI projects will be delivered in 2013.

No.	KPI	
Reinforce Pharma R&D in Europe by addressing bottlenecks and gaps in drug research		Target 2013
1	The extent to which IMI JU projects cover the value chain of drug development	Qualitative Assessment
2	Percentage of projects achieving 75% of pre-set milestones within the first two years from the launch of the projects	≥90%
3	Measurable outputs in terms of: • Biomarkers, tools and models qualified for use in drug development • Validated standards, measurements, methodologies, models, simulation technologies, tools and platforms successfully integrated in the R&D process • Students/scientists enrolled in education and training activities	Quantitative and qualitative assessment
4	Bibliometric indicator: Citation scores of project publications	Quantitative and qualitative assessment
5	• Percentage of participants in signed grant agreements that are SMEs • Percentage of overall budget for projects allocated to SMEs	≥13% ≥15%
6	Number of new ventures/collaborations, business activity, patents and licenses resulting from projects	Quantitative and qualitative assessment
7	Impact on societal and healthcare challenges	Collect preliminary indications on the impact on society and healthcare from launched projects

No.	KPI	
Maximise the Efficiency and Effectiveness of the Executive Office		Target 2013
8	Average Time to Pay (TTP)	• Pre-financing payments: ≤15 days • Interim payments to beneficiaries: ≤45 days
9	Average Time to Grant (TTG)	≤290 days
10	Average monthly visits to the IMI website	≥7000 unique users
11	Percentage of filled positions	100%
12	Annual budget execution	Running costs: 100% commitment and payment appropriations Operational costs: • commitment appropriations as close as possible to 100% but ≥95% • payment appropriations as close as possible to 100% but ≥90%

3.6 Support to Small and Medium Size Entreprises

Based on past activities IMI JU has been successful in encouraging SME participation in IMI Calls. This is particularly apparent in the Call 5 in which 49% of all eligible applicants and 41% of the successful applicants were SMEs. SMEs involved in the Call 5 have been allocated 68% of the IMI budget for the Call 5. To build on this success IMI JU will continue to work with its founding members and other stakeholders and partners to increase support for SMEs and increase SME participation in its projects. IMI JU will achieve this through the preparation of new materials targeted at the SME sector as well as the provision of targeted support notably through the dedicated helpdesk. The IMI Executive Office will host and attend meetings specifically aimed at involving the SME sector. It will also undertake activities to increase liaison with both individual SMEs and European umbrella organisations that support the SME sector at the regional, national and international level. These activities cover co-operation and co-ordination in areas that can best contribute to fulfilling IMI JU objectives, in particular with a view to:

- Promote and communicate the activities of IMI;
- Encourage increased engagement of SMEs with IMI;
- Share knowledge and data that advance the mutual interest of the parties in accordance with policies and procedures for each party.

3.7 Cooperation with external bodies

A key priority for 2013 will be to strengthen the relations with regulatory agencies including EMA, FDA and PDMA in order to ensure that the projects benefit from the input of regulators. For this purpose, joint meetings and teleconferences will be organized in conjunction with EFPIA and the EC. A meeting is already planned in Q1 2013 in Brussels together with the Critical Path (C-Path) Institute, focusing on drug development in Alzheimer's disease and tuberculosis and the related regulatory challenges.

We will continue to share experience on the management of Public-Private Partnerships with C-Path and with the NHIF Biomarkers Consortium[1]; regarding the latter, discussions will progress on potential collaboration in the areas of kidney safety markers and Autism Spectrum Disorders and a legal framework will be established to facilitate this collaboration.

The collaboration with the Clinical Data Interchange Standards Consortium (CDISC[2]) will be continued in 2013 for the benefit of IMI JU beneficiaries. Training activities by C-DISC will be offered to partners of IMI consortia and standards developed during IMI projects will be discussed in the context of C-CDISC standards.

Collaborations involving specific projects in 2013:

- PreDiCT-TB project (Tuberculosis) - IMI JU will facilitate and promote the creation of a legal framework for information sharing of the IMI PreDi-CT-TB project and the CPTR initiative from C-Path, and pay particular attention to promote synergy between the two initiatives both from the industrial and academic sides.
- EU-AIMS project (Autism Spectrum Disorders (ASD) - The project will enhance its work on developing databases and biobanks for ASD R&D by linking into the AGRE Biobank run by Autism Speaks[3], the NDA[4] run by NIH, and the Infant sibs network (IBIS[5]) funded by NIH and led by University of North Carolina (UNC).
- EUROPAIN project (chronic pain) - EUROPAIN will continue its collaboration with the C-Path initiative ACTTION[6] and define a strategy for exchange of information, especially in the critical area of placebo effect.
- IMIDIA and SUMMIT projects (diabetes) - The diabetes project IMIDIA will continue the successful collaboration with the Juvenile Diabetes Research Foundation (JDRF[7]) and discussion will be started for a possible collaboration of JDRF with the IMI project SUMMIT.

3.8 Intellectual Property

The Executive Office will continue providing information and guidance on the handling of IP-related issues as well as pitfalls that applicants and participants may encounter during the submission, negotiations and implementation phases of IMI proposals and projects.
To that end, the Executive Office will:

- enhance communication in order to further improve knowledge and understanding of IMI IP Policy to stakeholders;
- provide SMEs with simple and practical information through the dedicated webpage;
- maintain its IP Helpdesk;
- get feedback from participants and stakeholders on the implementation of the IP policy;
- participate in events organised at European level on IP management and best practices.

[1] http://biomarkersconsortium.org/
[2] http://www.cdisc.org/

[3] http://research.agre.org/program/descr.cfm?do=program
[4] http://ndar.nih.gov/
[5] http://www.ibisnetwork.org/index.html
[6] http://www.acttion.org/home
[7] http://www.jdrf.org/ and http://www.jdrf.org/index.cfm?page_id=117103

4 COMMUNICATION AND EVENTS

The IMI Communication and External Relation strategy will focus on the following four key objectives:

1. Gain support for IMI from EU policy makers;
2. Mobilise applicants for IMI Calls across Europe;
3. Enhance the wider visibility of IMI and its success;
4. Strengthen the commitment of top-managers of the pharmaceutical companies.

For each of the objectives, the corresponding messages, means, target groups and events are detailed in the sections below.

4.1 Objective 1: Promotion of IMI JU in the EU Institutional arena

This objective consists of gaining support for IMI from the EU institutions and EU Member States through the promotion of IMI JU, its objectives and achievements.

Target audience for this objective includes the European Parliament and Council and Policy makers in EU Member States.

The communication strategy in essence consists of demonstrating that IMI is on track in delivering its objectives and that with projects already reporting important achievements, IMI, by acting as a neutral platform under high professional and ethical standards, is a credible model for the future of public private partnership in innovative health research.

To implement these objectives the following actions will be undertaken:

- Translate key achievements (from project interim review) into lay language, include them in key messages and promote them in publications, presentations and other communications;
- Translate project achievements in overall IMI achievements;
- Promote and support IMI project participants and other stakeholders as speakers and ambassadors representing the success of IMI;
- Collaborate and coordinate with other multipliers, including EFPIA and EC, to promote the success of IMI towards key stakeholders;
- Further improve advocacy and public relations strategy and implementation through advice and collaboration with a PR-agency to provide strategic advice and assistance on a number of areas that include relations with press and stakeholders, media training, media monitoring as well as preparation, running and follow up to press events.

Alongside the staff in the Executive Office, the following groups will be mobilised for implementing this objective:

- Members of the IMI Governing Board and IMI project participants will be further encouraged to act as ambassadors and multipliers for communicating IMI's success;

- States Representatives Group members and Health National Contact Points will be further encouraged to act as ambassadors towards policy makers in the Member States. For certain topics, National Focal Points for Public Health at DG SANCO will be mobilised as well.

The above objective will have particular significance at times of political discussions and decisions on **Horizon 2020** and the possible launch of a new public-private partnership to tackle important health challenges. This would build on IMI successes and lessons learned.

4.2 Objective 2: Mobilise applicants

This objective aims at expanding the population of applicants for future IMI calls in order to reinforce truly pan-European research networks.

In this context, the key message will evolve around the unique opportunities for participating in pharmaceutical research, development & training with IMI, as the world's leading public private partnership in health research.

- Based on past experience, particular attention will be paid to:
- Development of webinars and local events;
- Step up engagement of multipliers, in order to improve outreach in particular in Central, Eastern and Southern Member States;
- Facilitate networking among potential applicants, for instance by improving the IMI Partner Search Tool.

4.3 Objective 3: Enhance IMI's wider visibility

This objective consists of enhancing the visibility of IMI towards other stakeholders, including the general public and patients, through media-activities focusing on IMI success stories.

Key messages will evolve around the following themes:

- IMI success stories demonstrate that IMI is speeding up the development of better and safer drugs for patients.
- IMI offers a successful model for reinvigorating pharmaceutical R&D in Europe.

Actions will include the following, with the input from the EC and EFPIA as amplifiers and multipliers of success stories:

- Press releases/media campaign on success stories;
- Stepping up media activity with a PR-agency and through increased direct contacts with journalists;
- Promoting success stories via social media;
- Regular contacts with editors of major scientific journals (i.e. Nature, Science, Lancet, New England Journal of Medicine), economical journals (i.e. Financial Times), and EU press (i.e. Parliament magazine, European Voice) will be continued in order to maintain IMI visibility in those publications.

4.4 Objective 4: Strengthen industry commitment in the context of competing initiatives worldwide

This objective aims at reinforcing and increasing the commitment of industry decision-makers towards IMI. Different channels of communication will be used to demonstrate how IMI already improved R&D productivity and to underline that even more will be achieved in the future with the recent changes in the research agenda and the new topics recently launched. The European Lead Factory, the Anti-microbial resistance programme, the iPS stem cells projects and the "new taxonomy" projects will be used as examples of this new strategy.

4.5 Key events

Event	Date – Place	Target Audience	Objective (s)
Call launches: Webinars, Info sessions	in function of the Calls Brussels & Member States	Potential applicants	*2, 3*
EU's Irish and Lithuanian Presidencies Key events to be selected	Q1-2/2013*	Policy makers	*1*
	Q3-4/2013*	Policy makers	
Key steps in the EU legislative process for Horizon 2020 and the future of IMI	March 2013*	Policy makers	*1*
	Autumn 2013*	Policy makers	
IMI Stakeholder Forum	tbc*	IMI stakeholders	*1, 4*
DIA Annual EuroMeeting	4-6 March 2013 Amsterdam	Policy makers SMEs Industry	*1, 2, 3, 4*
Joint IMI-C-Path meeting	7 March 2013 Brussels	Policy makers Industry	*1, 4*
BIO International Convention Session on IMI	22-25 April 2013 Chicago	IMI stakeholders Policy makers	*1, 4*
Month of the Brain	May 2013	Policy makers Patients Potential Applicants	*1, 2, 3*
Congress of the European Associations for Clinical Pharmacology and Therapeutics (EACPT)	August 2013 Geneva	Potential applicants	*2, 3*

* These events could be linked/merged, timing and content will be aligned to forthcoming EU Presidencies' agenda.

5 MANAGEMENT OF THE EXECUTIVE OFFICE

Building on from 2012 achievements, a key strategic action for 2013 will be to further consolidate IMI JU's Executive Office as a strong, vibrant and creative organisation, notably in preparation for the transition to the future.

The assumptions below are based on the current legal framework under which IMI JU operates and is without prejudice to changes which could result from the outcome of Horizon 2020 or any transition measure in preparation thereof.

5.1 Horizontal Support Activities

The IMI JU will continue to provide support in 2013 to its Governing Board, the Scientific Committee, the States Representatives Group and the Stakeholders' Forum and their working groups.

The Governing Board gathers representatives of IMI JU founding members. It has the responsibility for overseeing the operations of the IMI JU and the implementation of its activities. It will meet at least twice in 2013, in addition to monthly teleconferences.

The Scientific Committee is an advisory body to the Governing Board. It will meet at least twice during the year 2013. The IMI States Representatives Group (SRG) will be consulted on the Call texts and will receive the evaluation outputs. At least two meetings of the SRG are foreseen for 2013. Continuous attention will be given to enhance communication with these bodies and seek and feedback on any significant IMI activities and developments, including on the future of IMI.

One year after their set up, the collaborative platforms for supporting the Governing Board, the Scientific Committee and the States Representatives Group will be reviewed both from a content and operations point of view. This will be based on user feedback and satisfaction collected through a questionnaire.

Through an annual Stakeholders Forum, IMI aims to engage key stakeholders in discussions about the activities and the future of IMI. The 2013 Stakeholder Forum will offer IMI the opportunity to present achievements and success stories from on-going IMI projects and to preview upcoming Calls. The 2013 meeting is scheduled to take place in Q2.

5.2 Budget

5.2.1 Draft Budget for 2013

The claims put forward in the preliminary draft annual budget plan for 2013 approved by the Governing Board in December 2011, as part of the Annual Implementation Plan for 2012, were re-evaluated in Q1 2012 prior to the launch of the formal budgetary procedure.

A table overview of the 2013 draft budget is set out in Annex A to this report together with the staff establishment plan. It forms the basis of the on-going procedure with the Budgetary Authority (European Parliament, Council) and is without prejudice to its final outcome, which is expected to be known in December 2012.

Commitment appropriations (in EUR)	
Running costs	8,400,000
*Operational costs	204,654,541

*The amount of commitment appropriations for operational costs is provisional as the final figure depends on the amount carried over from previous year. The amount will be modified at the beginning of 2013 based on the Governing Board decision.

Payment appropriations (in EUR)	
Running costs	8,400,000
Operational costs	126,150,000

	Budget for **running costs** (in EUR)
Title 1 – costs related to IMI staff	4,541,000
Salaries, missions, training and recruitment costs	
Title 2 – running costs of the IMI JU office	3,859,000
Office equipment, IT and telecommunications, external communication and events, audit, formal meetings and expenditure in connection with research activities (experts, workshops, meetings and events targeting the IMI projects).	

It should be noted that budget for running costs decreased overall by EUR 300,000 compared to the draft annual budget for 2013. Several cuts were operated based on historical data (real past consumption) and re-evaluation of current and foreseeable needs. Cuts relate to staff missions, office equipment, telecommunications and postal expenses and external communication, item for which an over-budgeting had been observed. Some increases have been introduced for formal meetings as more meeting are being organised outside Belgium and for staff training.

		Budget for **operational costs** – Title 3 (in EUR)
Commitment appropriations		204,654,541
2013 commitment appropriations	196,029,206	
Interest generated on IMI bank account	350,000	
Carried over appropriations	8,275,335	
Unused appropriation from running costs 2012 (EU contribution) estimated	750,000	
Cancelled appropriations Call 3 and Call 4	7,490,335	
Cancelled appropriation from 2011 estimated	35,000	
Payment appropriations		126,150,000
2013 payment appropriations	125,800,000	
Interest generated on IMI bank account which has increased from EUR 5,000 based on the analysis of 2011.	350,000	

These payment appropriations will be used for intermediate payments for projects of Calls 1, 2, 3 and 4 and for pre-financing payments for projects of Call 6 (outstanding payments not executed in 2012), Call 7 and Call 8.

IMI JU foresees to execute the commitment appropriation through launch of new Calls for proposal. The amount of carry-over is reserved for ENSO Call 2013 for an amount of EUR 7,525,335.

5.2.2 Preliminary Budget for 2014

The preliminary annual budget plan for 2014, together with the staff establishment plan, is set out in Annex B. It should be noted that these preliminary figures will be revised following the results of 2014 budgetary hearings and approval of 2014 Draft budget by the EU budgetary authority.

In a nutshell, the driving elements are the following:

- As regards operational costs, no commitment appropriation is foreseen. This is based on the understanding that 2013 should mark the launch of final Calls. However, should the launch of Calls be envisaged in 2014, commitment appropriations not used in 2013 could be carried over to 2014. In this context, consideration may be given to earmark funds for so-called bridging calls between IMI and its successor.
- A total of EUR 198,000,000 in payment appropriations is planned to cover payments of cost claims of Calls 1 to 7 and pre-financing of Calls 8 and all Calls launched in 2013.
- A further reduction of running costs is foreseen, with total appropriations of EUR 7,900,000, i.e. a reduction of EUR 500,000 from 2013 level. The reduction will affect activities expected to scale down, that is costs linked to evaluations, IT development costs and audit and studies.

5.3 Financial Management

During 2013, the finance team will continue with its day to day activities of initiation, verification and payments of invoices and cost claims, creation of commitments, recovery orders, and analysis of periodic reports and negotiations of financial and administrative parts of projects. These activities will be conducted in a timely manner that will be monitored through corporate KPIs, in particular payment times and budget execution.

Best practice and highest quality standards will be ensured through the availability of a Manual of Financial Procedures developed and updated during 2012. In addition, knowledge dissemination will be further developed through the development of further guidance and the tenure of several financial workshops, in particular targeting beneficiaries, with the aim to reduce errors in financial reporting. Finally, the finance team will oversee a smooth implementation of the revised EU Financial Regulation due to enter into force in Q1.

5.4 Ex-post audits

The Executive Office will carry on with the implementation of the Ex-post Audit Strategy adopted in 2010 and harmonised with the EC's FP7 to ensure the legality and regularity of the operational expenditure on a multiannual basis by systematically detecting and correcting errors. This strategy also complements ex-ante controls embedded in IMI JUs management processes and will eventually include the recovery of any amounts found to have been paid in excess.

The ex-post control of operational expenditure is a critical element of IMI's Internal Control Framework as it is one of the key building blocks leading to the assurance required for the Executive Director's Annual Statement of Reasonable Assurance, and to key stakeholders including

the Governing Board, the European Court of Auditors (ECA), the Budgetary Authority and the Internal Audit Service of the European Commission (IAS).

The first sixty ex-post audit engagements covering the claims of final beneficiaries that were validated by 30 June 2011 were launched in November 2011, following the conclusion of a framework contract with three external audit contractors. These audits are expected to be completed by November 2012 and shall be followed up during 2013 with the analytical, extrapolative and reporting work related to the closure of each audit. The appropriate measures to correct any detected errors shall be therefore taken.

In parallel, on completion and approval of an Audit Plan for the next representative sample, a second set of ex-post audits will be launched by Q4 2012 to be implemented during 2013 to cover new cost claims received and validated by IMI JU since the last audited period, which is between 1 July 2011 and 31 August 2012. These cover new claims from Call 1 projects, the first claims from Call 2 projects and declarations of in-kind contributions by EFPIA companies.

Based on lessons learned the process will be streamlined and targeted to cope with the challenges and risk identified, namely an "error rate" that appears to be higher than 2% target defined in the Ex-Post Audit Strategy, postponement of audits due to clashes with EC's audits of same beneficiaries (which impinged in 2012 on the overall sampling approach as envisaged in the Strategy), delays in the delivery of audit reports by external contractors and limited resources to handle the workload.

To cope with this risk the following actions will be planned:

- Actions to correct errors through extrapolation of systematic errors and implementation of audit results;
- Preventive actions to address identified causes of errors through periodic guidance and training to beneficiaries and dissemination of audit results to IMI JU scientific and financial officers;
- Liaison with the EC's Coordination group for external audit in the Research family (CAR) for the application of the agreed exception from the planning constraints conditions, early booking of audits in SAR-PAA, the IT tool enabling the above group to share its audit work, and updating of the Strategic Audit Plan;
- Rigorous monitoring and enforcement of contract conditions (Conflict of interests checks, timely delivery, and quality);
- Additional resources to be assigned to ex-post audit activities also to cope with the increasing demands for frequent coordination with the European Commission's ex-post audit units, the regular audits of this process by the ECA, and the planned IAS audit in 2013-2014 of this key control.

5.5 Information and Communications Technology (ICT)

IMI ICT strategic objective is to deliver value to the business and to be a key enabler of new business initiatives with the goal of supporting and shaping the present and future of IMI. ICT applications and infrastructure aim at making all IMI processes simpler and more efficient.

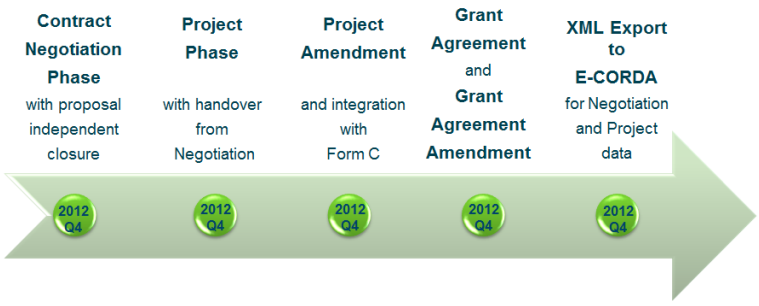
The following table sets out an overview of ICT developments planned in 2013.

IMI Core Business	
SOFIA (Submission OF Information Application)	• ENSO Call (Q2) • Enhanced Form C (Q2) • Scientific Annual Report (Q2) • Contract Management and Project Reporting phase (Q2) • Audit Implementation Statistics and Monitoring Module (Q2)
Business support tools	
Support to Governance Bodies (GB, SC, SRG)	• Survey on usability and further improvements (Q3)
Knowledge Management	• New collaborative platform (Q2)
PST (Partner Search Tool)	• Improvements (continuous)
Events Registration Tool	• Networking module (Q3)
IMI website	• Migration (Q2)
ICT Internal Support	
DORA (Document Repository Application)	• Document approval flow (Q3)
ISA (Information System for Absences)	• Appraisal (Q1)
IMI Intranet	• Improvements (continuous)

5.5.1 Support to IMI core business

In view of the increase in workload, a fully integrated application to support the management of the Call and project –related processes and of the projects life cycle is of vital importance. This will continue to be done through SOFIA (Submission OF Information Application), IMI core business application.

The following graph illustrates the on-going developments of SOFIA:



To achieve completion of the application, 2013 developments will be as follows:

ENSO Call
This new Call for proposal has specific requirements for the submission and evaluation stages, which imply the development of a new and tailored-made module in the SOFIA application to accommodate the peculiarities of this Call type.

Enhanced Form C
An Activity Report detailing the use of resources is needed to clarify the eligibility of the costs. Each participant will need to detail the costs incurred providing the cost type and unit of measure, amount, equipment and depreciation method, explanation on the cost (e.g consumables, travels) and under which work package the costs were incurred.
This detailed cost breakdown will help IMI to examine acceptability of costs, saving clarification delays and therefore facilitating and speeding payment.

Scientific Annual Report
The progress of work packages implemented throughout the project life will be recorded in SOFIA via web forms. Work packages are the basis for detailed annual reporting, whether financial or scientific.

Following the Work packages web forms SOFIA will make available the upload of the deliverables produced per work package.

Contract Management and Project Reporting phase
A module to manage the steps from reception of the annual project reporting until payments will be developed. Timers and triggers will be in place to manage the grant in a timely manner.
With this module it is envisaged to integrate the Enhanced Form C with the scientific annual reporting bringing into completion the management of the Call Process.

Audit Implementation
A module will be developed to support the ex-post audit planning, sampling, implementation, analysis and follow-up.

Statistics and Monitoring Module
A module to enable the analysis of scientific and financial data available in SOFIA will be developed. A web access will enable users to drill through the data and generate a variety of tailor-made dashboards.

The above developments are illustrated below.

In addition, optimal support will be provided to maintain and further enhance the technical interface through XML Export of SOFIA data with CORDA and E-CORDA.

5.5.2 Other ICT Support Tools

a. Knowledge Management

During 2012 CIRCABC[8] started to be used for exchanging documentation in progress and final one regarding Project Interim Reviews. CIRCABC has increased efficiency by reducing exchange time and e-mail traffic between IMI Scientific Project Managers and Project Coordinators but nevertheless has performance issues with file management.

It is envisaged during 2013 to create an IMI collaborative platform to integrate with the IMI ICT architecture and with better performance for file management.This platform goes in line with the IMI project integration strategy and plans for capturing the output from project activities and creating a mechanism for current and future IMI projects into Horizon 2020.

b. Partner Search Tool (PST)

As part of the unification of IMI ICT architecture initiated in 2012, the PST has been migrated and incorporates an administration module that facilitates the update and insertion of new keywords, thereby enabling to maintain the PST updated in view of the fast pace of launch of new Calls. In 2013 it is envisaged to enhance the PST's usability, enabling coordinators and partners to team up more easily.

5.5.3 Events Registration Tool

In mid-2012, the events registration tool has been upgraded with the implementation of a web tool in line with the core image of IMI. Further improvements will be implemented in 2013, in particular with a networking module that will enable participants to events to interact ahead of and around the event.

5.5.4 IMI website

During 2013 it is envisaged to migrate the IMI website in order to unify and streamline the IMI ICT architecture.

5.5.5 ICT Internal Support

Infrastructure

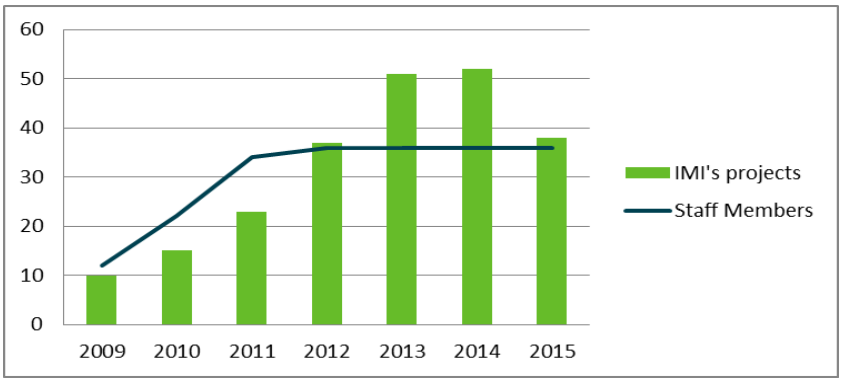
Due to the increasing number of evaluations a new multifunction printer shall be leased to facilitate the Call coordination process.

Other highlights in 2013 include upgrade of staff portable laptops, improvements to common file and email servers with other Joint Undertakings, assessment of security and performance of Office 365 in view of increased usage of Office Online Services hosted in the Cloud. In addition, in 2013 will mark the full scale implementation of **DORA** (DOcument Repository Application), IMI JU's electronic document management system enabling full electronic processing, storage and fast retrieval of all official IMI documents.

[8] Communication and Information Resource Centre for Administrations, Businesses and Citizens, an open-source of a document management system: https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp

5.6 Human Resources

In 2012, IMI finally reached the authorised ceiling of 36 staff members, of which 29 temporary agents and 7 contract agents. The total headcount will remain identical in 2013 and 2014, despite an overall increase in workload as illustrated in the graph below in relation to number of projects managed by IMI JU.



5.6.1 Staff activities mapping

The organisation chart indicates that 12 staff members are assigned to the Science pillar, 3 to the Communications pillar, 16 to the Administration and Finance Pillar and 5 to the Office of the Executive Director.

The following table provides a detailed picture on types of activities to which these resources are allocated:

A. Direct support to IMI core business

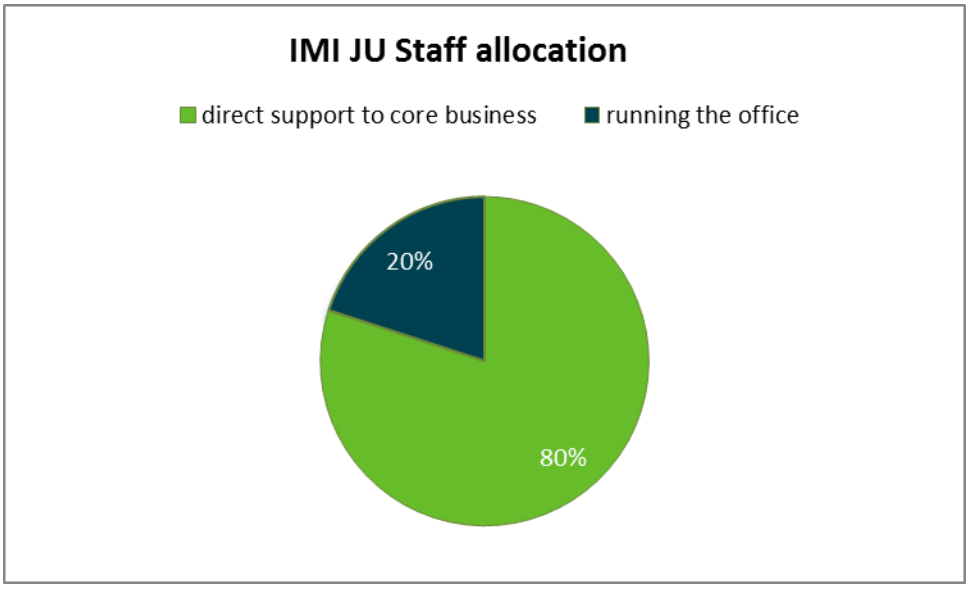
Categories	Activity type	Staff input	Total resources estimate (FTE[9])
Call preparation and evaluation	Call preparation and evaluation (Interaction with topic writers, experts, independent observers, organisation and running of evaluations, Governing Board decisions)	Scientific officers, legal officers, assistants	6
Project management	Project management, scientific and financial reporting monitoring and analysis, liaison with consortia	Each project managed jointly by scientific officer and finance officer. Legal officers. Assistants for workshops and interim review meetings. IMI management and accountant for authorising and executing payments.	11
IMI operating framework and systems	Various activities including ENSO, non/EU in kind, simplification exercise, training and guidance on financial rules, IP, development and upgrade of IT SOFIA tool, ex-post audit	Scientific, finance, legal and IT staff, internal auditor	6
Promotion of IMI	Networking, data extraction and analysis for KPIs, IMI promotional material, IMI visibility in scientific journals, international scientific cooperation, advocacy in relation to H2020	Communications staff, science staff, IMI management, policy and legal manager	6
		Total:	29

[9] Full Time Equivalent

B. Running the Executive Office

Categories	Activity type	Staff input	Total resources estimate (FTE[10])
Finance	Budget planning and monitoring, Finance running costs (salaries, missions, building and office costs) internal IT systems	Finance officers and assistants, IT manager, accountant, authorising officer	2.5
Staff management and HR	Recruitment, staff performance appraisal, staff policies	HR staff, IMI management	2.5
Procurement and contracts, horizontal legal issues	Purchase of goods and services, data protection, access to documents	Finance and procurement officer, legal officer	1
Internal and external controls	Relations with European Court of Auditors, IAS, monitoring of internal control standards, risk assessment	Internal auditor, internal control coordinator, accountant, IMI management	1
		Total:	7

IMI JU Staff allocation per broad activity areas can be presented as follows:



5.6.2 Recruitments

One of the immediate activities for HR will be to fill two positions that will become vacant at the end of 2012, Communications and Events Manager AD8 and IT Manager AD8. As a general principle, when a position has become vacant the Executive Office's needs are being reviewed based on business priorities, taking into account activities, profile as well as grade.

The sustained level of activity in Communications supports the hiring of Communication and events officer at AD7 level.

As regards IT, IMI JU no longer needs a second manager at AD8 level. IT development has progressed well in 2012 and the outstanding development tasks set out in section 5.5 may be handled by one manager, with a significant portion of the work being outsourced. It is therefore

[10] Full Time Equivalent

proposed to assign the post to the Finance section at AD5 junior level to support the following activities:

- Grant management process, for handling the financial reporting of participants and beneficiaries. Reinforcement of the team is essential given the fast growing workload in terms of number of projects managed by IMI. This is also intended to maintain a certain balance with increase of the population of scientific officers, as the scientific and financial officer *duo* constitutes the backbone of IMI JU support to project management.

- Ex-post audits of beneficiaries and EFPIA companies, also a fast growing activity in line with the strategy adopted by the Board. Unlike other Joint Undertakings, IMI JU has not been able to earmark a full time staff to this activity, yet it manages by far the largest number of audits. The assignment would also include development of guidance and training to beneficiaries in order to reduce the error rate.

5.6.3 Better organisational efficiency through Staff performance assessment

Staff performance assessment started in 2012 and the setting of personal objectives will continue in 2013, enabling to identify:

- how best to use available skills and competencies;
- work contracts to be renewed (7 of which will end in 2013).

In addition, best use of competencies and resource allocation will continue to be assessed regularly so as to ensure optimal staff motivation as well as enhanced organisational efficiency. This will build on significant progress achieved in reaching a good level of maturity of the organisation, with most workflows and processes being set up, teams and individuals responsibilities and tasks clarified and the availability of a series of IT tools such as electronic document management or leave management tool.

5.6.4 A smooth and continuing adaptation of the Staff Policy Framework

In 2012, the Human Resources section has deployed another set of implementing rules (i.e. the Staff Committee) and reviewed and simplified some policies (i.e. public transport scheme). In 2013, it will bring this work further in close consultation with the Staff Committee established in 2012 and also concentrate on ensuring the smooth implementation of the new EU Staff Regulation as it enters into force, in principle in Q1 2013.

5.6.5 A work environment oriented towards a greater Staff retention

IMI is faced with an inherent risk of high turnover which can be explained by short term contracts offered by a time limited organisation. IMI's turnover points to the importance of stabilising IMI workforce, which is critical in view of the steep increase in workload foreseen in the years to come. In this context, IMI JU will have to reinforce a stimulating and motivating work environment, notably through a staff learning and development policy to be implemented from Q4 2012. As regards professional development, a range of actions will be undertaken to keep up staff motivation and develop staff skills through various actions that include trainings and coaching. This will also contribute to reinforce a corporate culture based on the key values of

efficiency, effectiveness and flexibility. Finally, IMI intends to develop a promotion scheme for contract agents in order to better reflect the level of responsibility amongst the staff.

5.6.6 Inter-JU cooperation

IMI continues to explore and encourage all flexible arrangements, including close collaboration with other Joint Undertakings, and mechanisms of pooling expertise for specific time-bound tasks.

5.7 Procurement and Contracts

5.7.1 Procurement

In order to reach its objectives and adequately support its operations and infrastructures, IMI JU will allocate funds to procure the necessary services and supplies. In the past years, IMI has simplified the tender and contract management by establishing a number of multi-annual framework contracts for goods and services, having as much recourse as possible to inter-institutional tenders. Most framework contracts will be running beyond 2013, a year during which few new tenders should be launched.

The table below list the tenders planned for 2013 and sets out the procedure to be used, the estimated expenditure as well as the estimated schedule for publication. Only tenders with a value exceeding EUR 130,000, which is the statutory limit for publication of the tender in the S series of the Official Journal, are listed here.

The single most important tender in 2013 is the renewal of the framework contract for IT infrastructure and support services. Firstly, IMI intends to increase the budget ceiling of the current contract (Lot 1) under Article 126, in order to ensure that a basic level of services can be procured until the end date of the contract in November 2014. This possibility was explicitly foreseen in the terms of reference of the tender for the current framework contract.

A new tender will in the meantime be launched in 2013 in order to have the new contract ready for signature for the end-date of the current one. As with the current contract, to achieve best value and administrative efficiency, IMI will tender jointly with four other JUs[11]. As the server infrastructure is in place, the new framework contract will essentially cover maintenance, IT support and possibly renewal of hardware in the longer term.

As regards communication, IMI will postpone until 2013 the tender procedures initially planned for 2012 to establish framework contracts in audio-visual services and event organisation. In 2012, IMI has relied on the Commission's framework contracts for event organisation, but intends to conclude its own to achieve shorter procedural delays for individual contracts.

[11] ARTEMIS JU, Clean Sky JU, ENIAC JU and FCH JU

5.7.2 Contracts to be tendered in 2013

Title indicative	Expenditure indicative	Type of procedure	Timetable indicative
Managed IT infrastructure services			
• IT infrastructure and hardware including management and maintenance services • IT support	App. EUR 500,000/year for the entire contract, of which IMI's share app.30% Maximum 4 years' contract duration*	Open procedure Framework contract with a single provider	Launch Q3-Q4 2013 Contract to commence in Q4 2014
Events agency			
• Organisation of Stakeholder Forum and other events	App. EUR 500,000/ year from 2014 onwards Maximum 4 years' contract duration*	Open procedure Framework contract with a single provider	Q2-Q3 2013
Audio visual services			
• Video recording of IMI info sessions and Stakeholder Forum sessions • Professional photography for IMI website and other publications	App. EUR 50,000/ year from 2014 onwards Maximum 4 years' contract duration*	Open procedure Framework contract with a single provider	Q2-Q3 2013

*Framework contracts do not carry any obligation to spend. Annual expenditure estimates are preliminary and indicative.

5.8 Data protection and access to documents

5.8.1 Data protection

In 2013, IMI JU will continue to ensure that personal data are protected and that Regulation (EC) No 45/2011 is complied with. Key actions for 2013 will include:

- Raising awareness with the IMI JU Staff: the IMI Data Protection Officer will invest time in informing the staff in particular in relation to the implementation of the accountability principle and to the follow-up of the thematic guidelines issued by the European Data Protection Supervisor;
- Defining procedures internally for handling notifications related to standard administrative procedures or to processing operations already in operation;
- Follow-up the on-going developments on the EU legal framework for data protection, alongside a continuous analysis of the impact of technological developments on personal data protection, especially those connected to the Internet.

5.8.2 Access to documents

IMI will also continue to address requests for access to IMI documents according to Regulation (EC) No 1049/2001, in a spirit of openness and transparency in order to bring its activities and output closer to the public.

The objectives of actions in this field are the following:

- Stimulating the public interaction on key issues and on the future of IMI;
- Improving public awareness of IMI activities and processes;
- Strengthening public confidence in IMI by giving the opportunity to the public to monitor its work.

In this context, and as part of its communication strategy, IMI will continue to use various information and communication tools and means such as social networks, webinars, info-days, dedicated workshops, regular website updates and the IMI info-desk.

5.9 Internal Control Environment

5.9.1 Internal Audit Control

The key function of the Internal Audit Capability (IAC) of IMI JU is to help management accomplish the goals and objectives of the Joint Undertaking by bringing a systematic and disciplined approach to the evaluation and review of the regularity, reliability, efficiency and effectiveness of the organisation's risk management, internal control and governance systems and processes.

In 2013, both the IAC and the Internal Audit Service (IAS) of the European Commission will continue to implement the coordinated multi-annual audit strategy for 2012-2014. These activities will collectively include the provision of independent, objective assurance as well as consulting engagements on various aspects of IMI JU's processes and activities.

5.9.2 Internal Control and Risk management

IMI JU's internal control framework and risk management process provide the basis for ascertaining that sufficiently robust measures are in place to ensure overall compliance with rules and procedures, sound financial management as well as effective governance and management supervision of the JU.

With this regard, in 2013, the internal control function will contribute to the achievement of IMI JU objectives and priorities through:

- Definition, coordination and follow up within the JU of the annual action plan for the implementation of the 16 internal control standards (ICS);
- Maintaining a systematic risk management process in the annual planning and performing an annual risk assessment exercise;
- Identification and prioritisation of the ICS that need to be improved taking also in consideration the recommendations resulting from external audits;
- On-going self-assessment and reporting on IMI JU's formal compliance with the internal control standards and requirements and on the effectiveness of the ICS put in place.

The following ICS will be therefore prioritised for the year 2013:

ICS 2 – Ethical and organisational value: with particular attention to the avoidance of conflict of interest across IMI JU activities;

ICS 8 – Processes and procedures: in particular monitoring the implementation and compliance with IMI JU policies and procedures, assessing the level of awareness among staff and evaluating any possible divergence;

ICS 11 – Document management: ensuring that the newly designed platforms are used and effectively put in practice;

ICS 13 – Accounting and financial reporting: with particular attention to the budgetary process, the underlying systems supporting the accounting function and the validation of claims submitted by project participants (including ex-ante and ex-post procedures).