



Innovative Medicines Initiative

Innovative Medicines Initiative Annual Implementation Plan 2014



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FOREWORD

The Innovative Medicines Initiative Joint Undertaking (IMI JU) is now established 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.

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.

In order to address these challenges under the currently applicable legal framework, a continued effort will be made over the next few years as reflected in the European Commission proposal to extend the IMI JU under Horizon 2020, with a potential increase in funding. The timing of Council adoption of a new Regulation is unknown at this time of writing. It is clear, however, that a continuation of IMI JU will have an impact on the activities described in this document, which would have to be revised to reflect the new features of IMI JU. In preparation for this eventuality, IMI JU will be preparing for a smooth transition into the future.

In 2014, IMI JU will continue to manage its portfolio of 46 projects and will carry out the evaluation and kick-off of projects resulting from Calls for proposals launched in the second half of 2013. As running projects are progressing and maturing, specific efforts will be dedicated to document and monitor progress, notably through key performance indicators, and best exploit outputs. In parallel, IMI JU's communication activities will be further expanded by conducting outreach campaigns targeting different audiences. Furthermore, IMI JU will continue to ensure the delivery of high-quality work according to strict ethical standards, administrative and financial processes which will be continuously reviewed and adapted as needed.

IMI JU will also start implementing recommendations arising from the second interim evaluation, and most notably the following:

- A more articulate communication strategy with clear and measurable goals and objectives, addressing both the key stakeholders and a wider audience;
- Expanding the key performance indicators (KPI) framework to better demonstrate IMI impacts and socio-economic benefits;
- Further enhancing the efficiency of the Executive Office.

With an enthusiastic team fully committed to fulfil our ambitious mission, I am confident that 2014 will set the stage for a successful future!

Michel Goldman
Executive Director

1 MANAGEMENT OF CALLS AND PROJECTS

1.1 Activities related to Proposals Evaluation and Grant Negotiation

Key activities in 2014 will comprise the evaluation of Expressions of Interest and/or Full Project Proposals submitted for the topics of Calls 9, 10 and 11, launched in Q4 2013. Furthermore, proposals submitted to the third ENSO Call will be evaluated.

Timelines for completion of the evaluation process and of negotiation will be kept as lean as possible with the aim of completing signature of the Grant Agreements for Calls 9 projects by Q2 2014, for Call 10 projects by Q3 2014 and for Call 11 projects by Q4 2014.

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

1.2 Activities to support and monitor on-going projects

46 on-going and currently in preparation projects generated from Calls 1-8 will be running at different stages of their life cycle in 2014. IMI JU will continue to provide support and advice to the consortia, including on amendments to Grant Agreements. In addition, 4 new projects from Calls 9, 1 from Call 10, should start in 2014, as well as 8 projects from Call 11.

An overview of the project support and monitoring activities for 2014 is provided in the table below (status of projects as forecasted for 1st January 2014).

IMI Calls	Number of IMI projects						
	on-going	starting in 2014	1 st year	Interim/ scientific reviews	post-interim review phase	final year	submitting annual reports & financial statements
1	15				15	12 ¹	15
2	8			2 ²	7	1	8
3	7			7			7
4	7			1 ³			7
5	1						1
6	2						2
7	2		2				2
8	4*		4	1			4*
9		4					
10		1					
11		8					

Figure 1

¹ Based on a justified demand one project U-BIOPRED has been granted a 1 year extension to finalise the activities.

² The project DDMORE will undergo a supplementary scientific review upon request of the interim reviewers.

³ The project EMIF will undergo a 1st year scientific review.

*Of the 5 topics in Call 8, ND4BB 1C (the "Innovative Trial Design & Clinical Development" subtopic) will become part of the Call 6 COMBACTE project.

12 out of 15 of the projects generated from **Call 1** will complete the final year of activities in 2014 and 8 will submit their final activity reports.

The 8 projects generated from **Call 2** will enter their fourth year of activities. For one of these projects, OpenPHACTS, a budget neutral 6 months extension of the project period was granted in 2013 and thus 2014 will be the final year of activities, with also submission of the final activity report. Quick-Concept, the latest starting project from Call 2, will undergo an interim review. The project DDMORE will undergo a supplementary scientific review upon request of the interim reviewers.

The 7 projects generated from **Call 3** will enter their third year of activities in 2014, with all of them due for their interim review.

6 out of 7 **Call 4** projects will enter their third year of activities in the Q4 2014.

The Project EMIF from Call 4 will enter its second year of activities and it will be due for its first year scientific review as recommended by the expert panel during the Call 4 Stage 2 evaluation.

The **Call 5** European Lead Factory project and the first two projects part of the New Drugs for Bad Bugs (ND4BB) platform launched in **Call 6** will all enter their second year of activities, while the projects generated from **Calls 7 to 11** will all be in their first year of activities.

A key task will be to continue maximising efficiency, facilitating, optimising, and monitoring the implementation of all these projects and seeking feedback for continuous improvement to IMI JU operations. To this end, further workshops to provide guidance on the financial and administrative aspects of the projects to the EFPIA coordinators and to beneficiaries will continue in 2014.

Furthermore, **interactions between projects** and sharing of lessons learnt will be promoted by organising joint and cross-projects meetings and/or using various other channels (e.g. the IMI Group on LinkedIn).

Activities are expected in particular in the following areas:

- Diabetes Research: further collaboration and data sharing will be facilitated by the memorandum of understanding and specific agreements signed in 2013 between SUMMIT, IMIDIA and DIRECT projects.
- Neuroscience: activities will be organized to facilitate links between the Call 1 projects and those generated from later calls (e.g. EMIF-AD and AETIONOMY).
- Knowledge Management (KM): a cross projects meeting between KM projects will be organized. Activities will be developed to foster implementation and development of standards for clinical data (CDISC and CFAST) as well as non-clinical data. Furthermore, 2014 should mark the finalisation of a Code for use of health data in collaborative scientific research projects developed collaboratively across projects, in particular the KM projects.
- Antimicrobial resistance: activities are planned to boost integration of projects under the ND4BB programme. To this effect, dedicated meetings will be organised in 2014 for ND4BB projects and, more widely, for other initiatives active in the fight against antimicrobial resistance.
- Stem Cells and iPS Cells Research and Banking: IMI JU will facilitate in 2014 a networking event with ongoing European funded stem cell initiatives including STEMBANCC from Call 4, EU AIMS Call 3, MIP-DILI Call 3, and EBISC Call 8, for which the ultimate goal is the establishment of a European Induced Pluripotent Stem Cell Bank. Such event will aim at facilitating the interaction between the different consortia, explore new ways of collaboration and ultimately maximise European added value in health research in this area.

1.3 Monitoring and analysis of projects' outputs

Key Performance Indicators

Twelve strategic Key Performance Indicators (KPIs) were previously identified as critical for providing both internal and external stakeholders with a clear and consistent view of the IMI projects' performance and achievement of strategic objectives. (Figure 2) These KPIs and other supporting metrics will be used to measure, track and report progress during 2014, both on an annual basis as part of the Annual Activity Report and on regular basis through periodic scoreboards. Such KPI framework will be reviewed in 2014 to reflect the evolution and needs of IMI, with the assistance of external consultancy, notably on the basis of recommendations arising from the second interim evaluation of IMI which called for, alongside the existing KPIs, aggregated KPIs to be developed and measured in order to quantitatively demonstrate the IMI impacts and socio-economic benefits.

IMI will therefore expand the current set of KPIs along the following lines:

1. Socio-economic impact
 - a. Impact on the healthcare system
 - Impact on regulatory framework
 - Impact on policy
 - b. Cross-sector collaboration and its impact on the *modus operandi*
2. Macro-economic impact
 - a. Return on investment beyond monetary terms
 - b. Impact on EU economy
 - Job creation and sustaining
 - Spin-off creation and buy outs
 - Impact on small business survival and performance
 - Level of R&D investment in EU
 - c. Impact on biopharma in EU
 - Sharing the investment
 - De-risking of investment in difficult areas or basic research
 - Impact on cross-company collaboration
 - Impact on business model
 - Impact on rate of translation
3. Added value of participation in IMI project
 - a. Increased access to research networks
 - b. Access by academia and SME to industry tools, know-how and facilities
 - c. Expansion of the collaboration outside IMI consortia
 - d. Added value of the multi-stakeholder set up (patient, regulators, payers etc. at the table)

A combination of internal management information systems, external databases, periodic reports on the projects, independent evaluations and, if necessary, commissioned studies and surveys will be used to measure the progress and identify significant achievements of IMI projects.

In order to continuously and effectively monitor IMI projects and the overall program there is a need to develop an online platform that would allow for customisable, real-time analytics on all project outputs beyond publications; such as progress reports, data repositories, SOPs, standards, templates. Due to the high demand for customisation IMI Executive Office will have to resource to external collaboration on this matter to best design such a monitoring tool and explore the feasibility of interlinks with any existing systems.

In 2014 the collaboration with Thomson Reuters will continue to allow the analysis of the IMI project outputs in terms of publications and collaboration among IMI researchers.

No.	KPI	
Reinforce Pharma R&D in Europe by addressing bottlenecks and gaps in drug research		Target 2014
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: <ul style="list-style-type: none"> – 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	<ul style="list-style-type: none"> – 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
8	Average Time to Pay (TTP)	<ul style="list-style-type: none"> – Pre-financing payments: ≤15 days – Interim payments to beneficiaries: ≤90 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	<u>Running costs:</u> 100% commitment and payment appropriations <u>Operational costs:</u> <ul style="list-style-type: none"> – commitment appropriations as close as possible to 100% but ≥95% – payment appropriations as close as possible to 100% but ≥95%

Figure 2

Exploitation of results

In 2013, a pilot study analysis of project results was undertaken by KU Leuven on a small selection of IMI projects with a focus on IP and business opportunities. The results offered a basis for designing means to optimise the exploitation of IP and value generated in a number of selected IMI projects.

In 2014, the analysis will extend to other areas of focus not necessarily directly linked to IP and commercial exploitation but key to ensure that the impact of IMI projects can be maximised and that the results are sustainable; can be considered in the development of new medicines; and may impact decision making. To that end, IMI launched a tender for an Exploitation of results platform in August 2013. Activities to build the platform are expected to start late 2013 and last initially 9 months. The platform should help maximise the translation of project outputs into standard of care (new practices and processes leading to improved healthcare), by bringing together all key and representative stakeholders, including the clinical community (e.g. clinicians, physicians, nurses, pharmacists), and patients in a discussion forum ('Think tank').

Such a multi-stakeholder Exploitation of Results Forum should be responsible for the following:

- Analyse IMI project outputs;
- Address legal, ethical, institutional opportunities and limitations for uptake of such outputs in the current regulatory/legal/institutional framework;
- Define the uptake route and workable processes and formulate recommendations to be implemented by the relevant stakeholders/organisations to support delivering improved treatment options to society.

Intellectual Property

IMI JU will continue providing information, training 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 IMI JU will:

- continue regular communication in order to further improve knowledge and understanding of IMI IP Policy to all 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;
- provide support during the grant agreement negotiations to ensure compliance with the IMI IP Policy and right balance between the participants while maintaining tight timelines;
- participate in events organised at European level on IP management and best practices.

In addition, IMI JU will explore ways to implement recommendations of the KUL study in terms of project sustainability (data management), transparency of exploitable assets and further strengthening SME participation/interests.

1.4 Stakeholders' engagement and external collaborations

Patients

Based on the Governing Board's strategy to improve patient involvement at IMI, discussed at the October 2013 meeting, the IMI JU will invest in improving the patients and lay community understanding of what IMI delivers and how it might impact their lives by developing a patient-dedicated section on IMI's website, translating outputs from IMI projects into lay language, including patient sessions in IMI stakeholder forum and organising dedicated patient meetings. This also follows on from the June 2013 pilot patient group meeting, with two Patient Focus Meetings to be held in 2014: one session on diabetes, as requested by the Juvenile Diabetes Research Foundation (JDRF), and the second one around overall challenges facing patients regardless of the disease they are suffering from.

Efforts will also be made to improve the way IMI draws on the patients' expertise by involving patients into defining and executing IMI projects. This has already been implemented in Calls 9-11 by including sections dedicated to patient involvement in call topic texts for relevant projects. In addition, patient input will be sought more systematically in scientific challenge workshops as well as where appropriate in evaluation process. This way patients involvement at all levels will be ensured.

Finally, IMI aims to provide a forum for discussion and interaction between patients and other stakeholders, in particular scientists, to help collaboratively determine the best way to actively involve patients in research. This will be done via workshops where best practices would be exchanged between IMI projects as well as other initiatives.

Regulators

The strengthening of the relations with regulatory agencies including EMA, FDA and PDMA will continue in 2014 to ensure that IMI projects benefit from the Regulators' input. As IMI projects start delivering tangible results, engagement with Regulators is important to facilitate their translation into the regulatory practice, with the aim to enhance the efficiency of the development and the registration of medicinal products. IMI will therefore continue raising awareness of the IMI projects to liaise early with the Regulators in the context of qualification advice/opinions procedures.

In addition, joint meetings and teleconferences will be organised in conjunction with EFPIA and the European Commission to further discuss the impact the IMI projects in the regulatory environment.

Experiences and lesson learnt will continue to be shared with other initiatives (e.g. C-Path, NIH) to better explore synergies.

Small and Medium Size Enterprises

Based on past activities IMI JU has been successful in encouraging SME participation in IMI Calls. As of the end of September 2013, 15.4% of the successful applicants to IMI were SMEs. Furthermore, SMEs that have successfully applied have been allocated 22.5% of the IMI budget for the projects launched. To build on this success, IMI JU will continue to work with its founding members and other stakeholders 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 and its website.

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.

To provide further support to SMEs, IMI will increase its efforts in communicating information on sources of funding available within IMI projects but also more widely within European Institutions and bodies, both public and private. It is envisaged that a series of networking events will be held to discuss business funding opportunities for SMEs with life science venture capitalists, representatives from EFPIA investment units and representatives of the European Commission.

CDISC

The collaboration with the Clinical Data Interchange Standards Consortium (CDISC) will continue in 2014 for the benefit of IMI JU beneficiaries, in particular with the training activities by CDISC offered to partners of IMI consortia. In order to further facilitate implementation of data standards, in-depth trainings on CDISC standards (CDASH⁴, SDTM⁵, ADAM⁶, SEND⁷) and any other applicable, as well as a consultancy session will be organized for the projects. The standards developed in the context of IMI projects will continue to be discussed in the context of CDISC standards. The latter will be enhanced with taking part in the Scientific Advisory Committee of the Coalition for Accelerating Standards and Therapies (CAFAST), a joint partnership between CDISC and Critical Path Institute created to accelerate clinical research and medical product development by developing and maintaining data standards, tools, and methods for conducting research in therapeutic areas that are important to public health.

C-PATH Institute

The fruitful collaboration of 2013 with C-Path Institute will continue in 2014, notably with a second joint IMI & C-Path meeting scheduled in Q4 of 2014. The objective remains to foster synergy in areas of common interest such as modeling and simulation, and to maintain collaborations between specific projects and research areas as follows:

- SAFE-T and PSTC for pre-clinical safety;
- IMI Portfolio of Alzheimer's Projects and CAMD;
- PreDICT-TB and CPTR for tuberculosis research.

IMI and C-Path Institute will work together for synergies and alignment and avoiding duplication of efforts in these programs and to collaborate/advise in the data standard space to ensure that the respective data sets are remapped in a consistent fashion to enable leveraging the data in both databases.

Furthermore, collaboration in the area of anti-microbial resistance will start in 2014.

FNIH Biomarker Consortium

Collaboration will be enhanced, in particular between EU-AIMS project and FNIH Biomarkers Consortium's Autism Initiative to align initiatives in particular for biobanking and clinical research aspects.

⁴ Clinical Data Acquisition Standards Harmonization

⁵ Study Data Tabulation Model

⁶ Analysis Data Model

⁷ Standard for Exchange of Nonclinical Data

2 COMMUNICATION AND EVENTS

2.1 IMI Communication strategy

The IMI Communication and External Relations Strategy for 2014 will focus on the following objectives:

- Raise awareness levels and perception of IMI among all target groups.
- Increase engagement of patients in IMI's activities.
- Support the European Commission and EFPIA on activities relating to IMI 2.

Raising awareness and perception of IMI among all target groups

In recent years, IMI has enjoyed increased positive visibility in key general and specialist media and at a wide range of events in Europe and worldwide. In 2014, the IMI External Relations team will build on this by working to raise awareness and perception of IMI among the following key target groups:

- Academic researchers – convince them of the excellence and applicability of research coming out of IMI projects;
- Industry – convince them that IMI is a forum that allows them to share risks and move forwards, especially in the most challenging disease areas;
- Small and medium-sized enterprises (SMEs) – convince them that IMI provides opportunities to not only receive funding, but to work with networks of the leading experts in their area;
- Patient groups – engage them in IMI's activities, and inform them that IMI is speeding up the development of better, safer drugs;
- Regulatory authorities – engage them in IMI's activities, so that the novel tools developed by IMI projects can be formally validated as rapidly as possible;
- Policy makers and opinion leaders – convince them that a public-private partnership is an essential component of the health research and innovation landscape, delivering results that would not be possible through other programmes;
- General public – inform them that IMI is speeding up the development of better, safer medicines, including for conditions that affect a large proportion of the population.

Actions in support of this goal will include:

- Maintaining contacts with projects to gather success stories that support IMI's key messages;
- Promoting project successes via various channels;
- Maintaining contacts with editors of major media outlets, including scientific journals (e.g. Nature, Science), economic outlets (e.g. Financial Times) and EU media (e.g. European Files);
- Press releases, media interviews, inviting media to IMI events.

IMI will employ the following channels in support of this goal:

- Events (both IMI and external);
- Website;
- Newsletter;
- Social media (LinkedIn, Twitter);
- Multipliers (IMI Executive Office staff, IMI founding members, SRG, NCPs, relevant umbrella groups / associations, IMI projects, organisations partnered by IMI, e.g. through a Memorandum of Understanding);
- Media (regional and national, if relevant);
- Direct mailings;
- Publications;
- Direct contacts with opinion leaders.

The Executive Office will also remain alert to issues that could damage IMI's reputation, and respond accordingly, for example by preparing briefings or sets of questions and answers.

Increase engagement of patients in IMI's activities

It is increasingly recognised that patients and carers have an important role to play in research. Throughout 2013, the Executive Office made significant efforts to reach out to patients and explore ways of boosting their involvement in IMI projects. This initiative was warmly welcomed by patients and projects alike, and will continue in 2014.

Significantly, patient engagement will form the focus of the 2014 Stakeholder Forum. IMI will also develop additional communications materials designed specifically for patients.

Other key target groups

In 2014, the External Relations team will continue to support efforts led by the Scientific team to reach out to other key target groups, in particular SMEs and regulators.

2.2 Key messages

Key messages for all target groups and supporting material were developed in 2013 – these will be updated throughout 2014 and made available to multipliers.

Top level messages

- IMI accelerates the development of new therapies for major yet unmet public health needs and diseases where treatments are lacking.
- IMI develops better tools to ensure the safety of existing and future medicines.
- By providing a unique neutral platform for a continuous dialogue with patients, regulators, academia and industry, IMI contributes to making the EU a world leader in cross-sector collaborative healthcare research.
- IMI contributes to a European pharmaceutical sector creating jobs in Europe.

Messages for the pharmaceutical industry

- IMI is an attractive instrument to implement collaborative programmes involving industrial and non-industrial partners.
- IMI provides incentives for drug innovation in particularly challenging / high risk areas.
- IMI delivers tools and instruments to improve pharmaceutical R&D.
- IMI shapes a new image of the pharmaceutical industry.
- IMI trains a new generation of industrial scientists and regulators as well as current professionals.

Messages for academic researchers

- IMI offers unique opportunities to translate breakthrough discoveries into clinically useful tools and products through open innovation networks.
- IMI projects are generating scientifically excellent results.
- IMI is creating new training schemes designed to address specific unmet needs identified by affected individuals/carers.
- IMI has a flexible intellectual property (IP) policy that brings many benefits

Messages for SMEs

- IMI supports small and medium-sized enterprises engaged in drug development and innovation.
- IMI has a flexible intellectual property (IP) policy that brings many benefits

Messages for patients and their families

- IMI projects are focused on patients' interests.

Messages for policymakers

- IMI implements EU policies.
- IMI contributes to improving European citizens' quality of life.
- IMI creates/maintains jobs and contributes to the competitiveness of the pharmaceutical sector in Europe.
- IMI has a flexible intellectual property (IP) policy that brings many benefits
- IMI projects are generating scientifically excellent results

Messages for regulators

- IMI is developing tools to facilitate (innovative) drug approval by regulatory authorities.
- Through IMI, regulators can have direct contact with collaborative consortia as opposed to individual research groups or institutes.

Messages for general public

- IMI is developing new treatments for diseases where there is a high, unmet societal need.
- IMI is contributing to improved medicine and vaccine safety.
- IMI creates/maintains jobs and contributes to the competitiveness of the pharmaceutical sector in Europe.

2.3 Key events planned in 2014

Event	Date - Place	Target audience	Objective
DIA Euomeeting (tbc)	25-27 March Vienna, Austria	Researchers, industry	Raise awareness of IMI
IMI Stakeholder Forum	May / June (tbc) Brussels, Belgium	Policy makers, researchers, patients	Raise awareness of IMI Increase patient engagement
Greek presidency event (tbc)	1 st half of year Greece	Policy makers, researchers, patients	Raise awareness of IMI
Italian presidency event (tbc)	2 nd half of year Italy	Policy makers, researchers, patients	Raise awareness of IMI

Figure 3

3 MANAGEMENT OF THE EXECUTIVE OFFICE

Building on 2013 achievements, a key strategic action for 2014 will be to further consolidate IMI JU's Executive Office as a strong and creative organisation, notably in preparation for the transition to the future IMI2.

3.1 Support to Governance bodies

The IMI JU will continue to provide support in 2014 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 2014, in addition to monthly teleconferences between the Chair, Vice-Chair and IMI office senior management.

The Scientific Committee is an advisory body to the Governing Board. It will meet at least twice in 2014 with a partially renewed membership.

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 2014.

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. In addition, these bodies will be increasingly called upon advising on how best to exploit IMI projects outputs, enhance cross-projects' collaboration as well as explore synergies with similar or complementary activities at national level.

The collaborative platforms for supporting the Governing Board, the Scientific Committee and the States Representatives Group will be maintained and updated both from a content and operations point of view. In addition, communication on IMI achievements will continue to be available through QlikView, a specific tool that generates statistics and data.

3.2 Budget and Finance

Draft Budget Plan 2014

The forecast put forward in the preliminary annual budget plan for 2014 approved by the Governing Board in December 2012, as part of the Annual Implementation Plan for 2013, has been re-evaluated based on past expenditure patterns and following review of current and foreseeable needs. It should be highlighted that the projection is for the time being exclusively based on continuation of IMI1 under the currently applicable legal framework, on the understanding that it would be revised should IMI 2 come into existence.

A table overview of the 2014 draft budget is set out in Annex I to this report together with the staff establishment plan. It is without prejudice to the outcome of the procedure with the Budgetary Authority (European Parliament, Council), which is expected to be known in December 2013.

Commitment appropriations (in EUR)	
Running costs	7,900,000
*Operational costs	0

Figure 4

*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 set at the beginning of 2014 based on the Governing Board decision.

Payment appropriations (in EUR)	
Running costs	7,900,000
Operational costs	161,187,993

Figure 5

Budget for running costs (in EUR)	
Title 1 – costs related to IMI staff	
Salaries, missions, training and recruitment costs	4,541,000
Title 2 – running costs of the IMI JU office	
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).	3,359,000

Figure 6

The overall budget forecast for **running costs** in 2014 remains identical to the Preliminary draft budget 2014, with a total amount of EUR 7.9 million. Without affecting the total envelope, some technical adaptations have been made based on an analysis of 2013 expenditure.

As regards **operational expenditure**, whilst no commitment appropriation is foreseen, the level of payment appropriation is being reduced from EUR 198,000,000 to 161,187,993 taking into account reduction of budgets for Calls 6 and 8 compared to the original plan and extension of duration of a few projects resulting into postponement of final payments to 2015. This new amount will enable IMI JU to cover all projects interim and final payments due in 2014 and pre-financings for Calls 9, 10 and 11. The bank interest is not budgeted at this stage. The amount of bank interest yielded in 2014 will be entered in the budget 2015.

Preliminary Draft Budget 2015

The preliminary annual budget plan for 2015, together with the staff establishment plan, is set out in Annex II.

In a nutshell, the driving elements are the following:

- A total of EUR 126,000,000 in payment appropriations is planned to cover payments of cost claims of Calls 1 to 10.
- A further reduction of running costs is foreseen, with total appropriations of EUR 7,500,000, i.e. a reduction of EUR 400,000 from 2014 level. The reduction will affect activities expected to scale down under IMI1, mostly costs related to experts and evaluations.

Financial Management

During 2014, 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 that is under regular revision. 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.

3.3 Human Resources

Together with well-defined workflows and processes, human resources management is at the heart of IMI's Executive Office organisational efficiency, namely through:

- Adequate recruitments and staff performance assessment;
- A balanced workload allocation and clear teams coordination;
- Learning and development opportunities;
- A clear organisational culture and open communication;
- Inter-JU cooperation.

2014 Staffing level

In 2014, 9 work contracts will end with a possible renewal up to 31/12/2017 (end of the organisation's life). The renewal of a work contract is based on both the business need (is the position still needed and for how long?) and the staff assessment (did the staff member satisfyingly reached his/her yearly assigned objectives?). The objectives assigned to staff members in 2014 will mirror the objectives set up in the respective AIP 2014's chapters.

Since 2012, IMI has reached the authorised ceiling of 36 staff members, of which 29 temporary agents and 7 contract agents. The total headcount remained identical in 2013 and shall remain identical in 2014, despite a growing workload.

A balanced workload allocation and clear team's coordination

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 [*])
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

Figure 7

*Full Time Equivalent

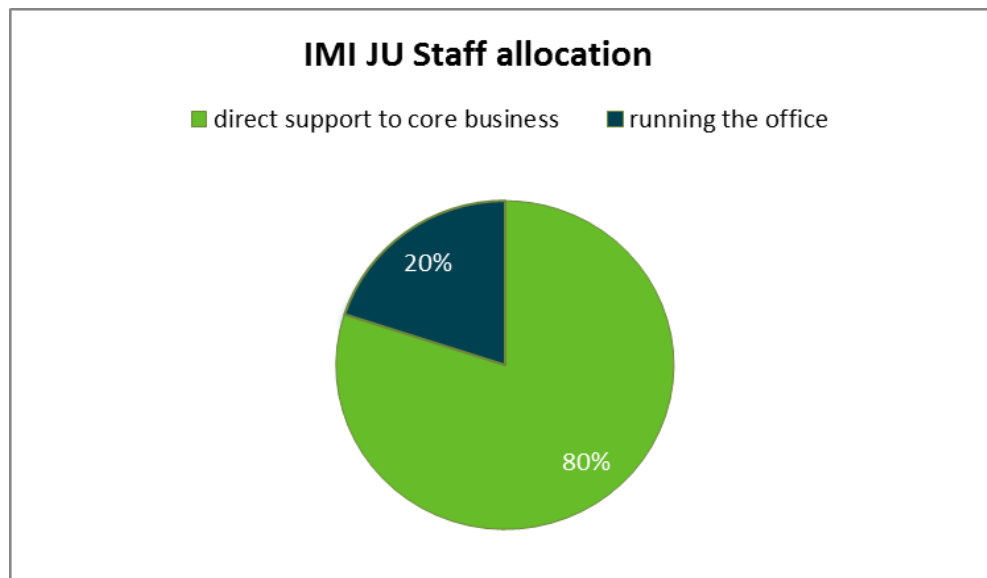
B. Running the Executive Office

Categories	Activity type	Staff input	Total resources estimate (FTE*)
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 (portions of the Executive Director, Head of Administration and Finance and 1 HR Manager, 1 HR Assistant)	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

Figure 8

*Full Time Equivalent

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

**Figure 9**

This organisation is fully aligned with IMI's missions and should allow the Executive Office to manage its increasing workload.

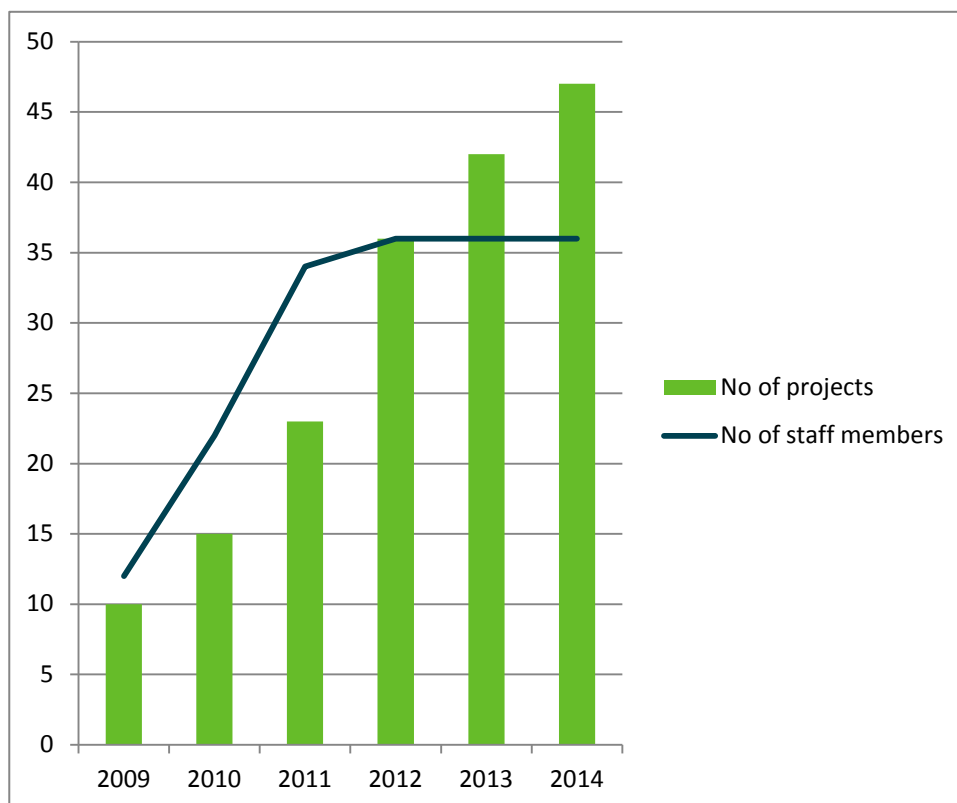


Figure 10

Learning and professional development opportunities for better efficiency and staff retention

The IMI JU's organisational efficiency is also the result of a rational learning and development policy. This policy relies on internal as well as external trainings in order to keep staff members up-to-date mainly on:

- IT skills on tools such as Word, Excel, MS Project or ABAC, the European Commission's financial IT tool, and on any IT tool developed by IMI;
- Scientific knowledge (Drug Development cycle, Medicines regulations or more specific topics linked to research area);
- Legal context: IP recent case law, financial regulations, audit rules, staff regulations, etc.;
- Communication: communication strategy, social media, public speaking, languages, etc.

All training actions are oriented towards greater flexibility and reactivity of staff (ability to back-up an absent colleague, good understanding of the work context, etc.).

IMI is faced with an inherent risk of high turnover which can be explained by short term contracts offered by a time-limited organisation and an uncertain future. This risk points to the importance of stabilising IMI's workforce, which is critical in view of the increase in workload foreseen in 2014. The problem of staff retention is critical for an organisation of this size and will remain a key challenge for HR in 2014. This requires maintaining a stimulating and motivating work environment.

A new staff regulation in 2014 but still the same internal culture and open internal communication

In 2014, one of IMI's HR objectives will be to implement the new Staff Regulation of the EU's civil service due to enter into force in January 2014. Proposed changes include an increase of working time to 40 hours weekly and a reduction of some leave entitlements. The Governing Board will accordingly adopt IMI's implementing rules in line with the EU new Staff Regulations.

IMI JU will ensure a smooth transition for staff. It will first have to identify:

- Implementing rules from the European Commission to be adopted by analogy by IMI's Governing Board;
- Implementing rules to be redrafted before adoption by IMI's Governing Board in order to take into account the specificities of a Joint Undertaking. Most of the time, the size of the Executive Office explains the need to adapt the text.

If, 9 months after the European Commission has issued an Implementing rule, no action is taken from IMI's side (adoption by analogy, redrafting or opt-out), this Implementing Rule will automatically apply to IMI. In order to be able to implement a rule quicker, and in order to benefit from the input from its Staff Committee, IMI JU will limit this adoption by default to texts:

- that only brings small and/or technical changes;
- that cannot be amended (e.g. rules on pensions etc.);
- that don't require to be quickly implemented.

Since its autonomy IMI's Executive Office has developed its own identity and work culture. This work culture is based on an open internal communication, ensuring that all staff members do share the same understanding of IMI's overall objectives and priorities. A consistent service-oriented culture has progressively arisen among staff members while maintaining compliance with the EU legal and regulatory framework and the highest ethical as well as integrity principles and rules.

Further efficiency and savings through inter-JU cooperation

In 2013, IMI continued to explore and encourage all flexible arrangements, including close collaboration with other Joint Undertakings, and mechanisms of pooling expertise for specific time-bound tasks. In 2014, IMI is willing to go further notably through common calls for tender, common recruitment procedures (setting-up of common reserve lists for administrative positions), common approach on Implementing rules, etc.

3.4 Information and Communication Technology

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 and activities planned in 2014.

IMI Core Business	
SOFIA (Submission OF Information Application)	<ul style="list-style-type: none"> – Electronic Signature (Q2) – Monitoring system for EFPIA In-Kind Contribution cap (Q1) – Ex-post Audit (Q2) – Interim Reviews (Q3) – Enhancements for Experts management (Q3)
ICT Internal Support	
DORA (Document Repository Application)	<ul style="list-style-type: none"> – Process flow for invoices approval (Q3)
ISA (Information System for Absences)	<ul style="list-style-type: none"> – Adapt for new staff regulations (Q1)
eMA (electronic Missions Application)	<ul style="list-style-type: none"> – New platform for managing the missions requests and expenses claims (Q2)
IMI Intranet	<ul style="list-style-type: none"> – Maintenance (continuous improvements)
ICT Tenders	
File, email and Print Servers plus support services	<ul style="list-style-type: none"> – Current FWC finishing in Q4 2014. New joint tender.
sTesta	<ul style="list-style-type: none"> – Current EC FWC renewed till next year. For 2014 a different supplier already selected by the European Commission.
Internet	<ul style="list-style-type: none"> – Current FWC finishing in Q4 2014. New joint tender.
Software development	<ul style="list-style-type: none"> – Current FWC finishing in Q4 2014. New tender.
Other IMI Business tools	
Support to Governance Bodies (GB, SC, SRG)	<ul style="list-style-type: none"> – Maintenance (continuous improvements)
PST (Partner Search Tool)	
Events Registration Tool (IMI and JTIs platforms)	
IMI website	

Figure 11

Support to IMI Core Business

The management of current IMI Calls and Projects plus related processes is done electronically via an integrated IT System: SOFIA (Submission of Information Application) and QlikView - a statistics and KPI monitoring module, with a variety of tailor-made dashboards, enabling the analysis of scientific and financial data in SOFIA.

Due to the increased workload derived also from the Calls launched in 2013 it is of vital importance to achieve completeness of SOFIA. Therefore 2014 developments will be as follow:

- Electronic Signature (Q2)

The financial statements and adjustments are already submitted to IMI electronically but still is required the printing step for blue print signature. In view of a paperless grant management in IMI it will be developed the electronic signature for the electronic-only transmission of financial statements (Form C) and adjustments.

- Monitoring system for EFPIA In-Kind Contribution cap (Q1)

We will implement a monitoring system to allow easy verification that EFPIA non-EU In-Kind contributions remain within the caps defined by Special Clauses 13A and 13B.

- Ex-post Audit (Q2)

In 2014 it is envisaged to finalise the development of this module to support the ex-post audit sampling, implementation, analysis and follow-up.

- Interim Reviews (Q3)

EoI, FPP and ENSO evaluations are already managed via SOFIA. For 2014 it is envisaged to integrate in SOFIA the management of the Project Interim Reviews also, increasing efficiency and facilitating the capture of the output from project activities.

- Enhancements for Experts management (Q3)

In view of a paperless Call management it is envisaged to have in SOFIA the electronic-only administration of Experts including the appointment management.

Support to other IMI Business Tools

IMI has well established collaborative platforms to provide support to the Governance Bodies, namely GB, SC and SRG. In 2014 such platforms will have continuous improvements whenever needed.

Regarding the Partner Search Tool (PST) in 2014 it is envisaged to enhance further its usability for coordinators and partners to team up.

The events registration tool has been extended to also help the management of events shared by other Joint Undertakings. Continuous improvements for the IMI events registration tool are envisaged to be implemented during 2014, such as a pre-event networking module and a workshop module.

ICT Tenders

2014 will be a demanding year concerning IT tenders as all Framework Contracts will be finishing. This also implies several planning and coordination of possible systems' handovers, should contracts be awarded to new operators.

ICT Internal Support

Further efficiency gains in the operations of the Office will be sought through improvements of IT systems. Key actions will include:

- Improvements to common file and email servers with other Joint Undertakings.
- Further development of DORA (DOcument Repository Application), the IMI JU's electronic document management system enabling full electronic processing, storage and fast retrieval of all official IMI documents, to manage the process flow for invoices approval.
- ISA (Information System for Absences) will be adapted to the new EU Staff Regulations.
- A new platform will be developed: eMA (electronic Missions Application) to manage the complete missions work flow, from the request up to expenses claim.

Following a request from other Joint Undertakings located in the same premises, in order to best exploit synergies towards enhanced efficiency and cost-effectiveness, IMI will make available its internal HR and other administrative IT applications for their own use.

In addition, staff portable laptops and printers shall be upgraded for the majority as they turn 3 years of usage.

3.5 Procurement and contracts

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 order to make tender and contract management as effective and cost-efficient as possible, IMI makes use as much as possible of multi-annual framework contracts and inter-institutional tenders. All essential framework contracts IMI is using will be running beyond 2014 with the exception of the IT and telephony services framework contracts mentioned below.

The most important contracts to be concluded in 2014⁸ are the renewals of the framework contracts for IT support services; telephony infrastructure and support services; and software development. The call for tenders will be launched in Q1. IMI is tendering for the contracts in a single tender jointly with four other Joint Undertakings located in the same building and sharing the same ICT infrastructure⁹.

As regards communication, in Q3 2013 IMI has expressed its interest to join a tender procedure carried out by European Commission's DG RTD for a framework contract for events' organisation. Therefore IMI has reversed its plan to launch its own procedure for a similar contract. For public relations consultancy, IMI intends to conclude a specific contract in 2014 under the framework contract of DG RTD.

On the operational side, IMI has in 2013 concluded a contract for consultancy services to establish a platform to study the optimisation of exploitation of IMI's project results. This contract is likely to be renewed in 2014, a possibility foreseen in the original tender.

3.6 Data protection and access to documents

Data protection

In 2014, IMI JU will continue to ensure that personal data are protected and that Regulation (EC) No 45/2011 is complied with. Key actions for 2014 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 new thematic guidelines issued by the European Data Protection Supervisor;
- Finalising procedures internally for handling notifications related to standard administrative procedures or addressing new processing operations;
- Follow-up on developments and implementation of the revised 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.

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 will continue, as a means to strengthen public confidence in IMI by giving the opportunity to the public to monitor its work. In addition, this will bring additional benefits such as:

- a. Improving public awareness of IMI activities and processes;
- b. Stimulating the interaction on key issues and on the future of IMI.

⁸ I.e. tenders for contracts with a value exceeding €130,000, which is the statutory limit for publication of the tender in the S series of the Official Journal. In addition, IMI uses negotiated procedures for low-value contracts below this statutory threshold.

⁹ ARTEMIS JU, Clean Sky JU, ENIAC JU and FCH JU.

4 INTERNAL CONTROL AND AUDIT ENVIRONMENT

IMI JU has in place an integrated management system of governance structures, internal controls and risk management procedures to plan and implement its strategic and operational goals and objectives. In addition, the organisation relies on a combination of internal and external audits, ex-post audits, performance measurement tools, continuous improvement initiatives and independent expert reviews to monitor and ensure that IMI JU remains efficient, effective and compliant with all relevant regulations, rules and procedures. The existing internal control and audit set-up and arrangements take into account the nature and objectives of the public-private partnership as well as its size and organisational needs.

IMI JU will continue to build on the experience and lessons learned from the past four years as well as respond and adapt to new challenges and developments. It will implement and enhance its established internal control measures, ensuring in the process that all critical risks are appropriately mitigated; key priorities are achieved; legal and regulatory requirements are complied with; and stakeholders' expectations are met. The annual risk assessment exercise carried out by the Executive Office in the second semester of 2013 signalled the need to take specific measures in 2014 to adequately manage the risks resulting from the envisaged transitional change to reflect Horizon 2020 objectives, obligations and *modus operandi*, as well as to mitigate the risk that IMI JU may continue to detect an average 'error rate' that is higher than the 2% threshold set for the programme.

More specifically, throughout 2014, management will pro-actively assess and ascertain the robustness of internal controls and ensure overall compliance with rules and procedures. This will be achieved mainly through the:

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

The following ICSs will be therefore prioritised for the year 2014:

ICS 3,¹⁰ ICS 7¹¹ and ICS 10¹²

Particular attention will be given to the impact of new challenges and developments on the organisation structure as well as on staff allocation and business continuity. This is crucial in order to ensure that the structure and resources in IMI JU continue to meet evolving organisational objectives and needs.

ICS 5

Objective and Performance Indicators: Management will ensure that annual goals and objectives as well as key performance indicators are updated to reflect changing strategic priorities.

ICS 8

Processes and procedures: Management will take measures to safeguard the integrity and maturity of IMI JU's internal control system as the organisation evolves to respond to new challenges and developments.

¹⁰ Staff allocation and flexibility

¹¹ Operational structure

¹² Business continuity

Ex-Post Audits of beneficiaries and EFPIA companies

Throughout 2014, the Executive Office will carry on with the implementation of the Ex-post Audit Strategy adopted in 2010 to ensure the legality and regularity of the operational expenditure. This strategy complements ex-ante controls embedded in IMI JU's management processes and includes the correction of any amounts found to have been paid in excess. Errors of a systematic nature will also continue to be extended to cover unaudited financial statements ('Forms C') of the same participants.

Representative and, if necessary, risk-based audits of beneficiaries will be launched during the year to cover new cost claims received and validated by IMI JU since the last audited period. In parallel, independent reviews of submitted certificates of in-kind methodology as well as audits of accepted declarations of in-kind contributions by EFPIA companies will also be continued and followed-up.

Internal and External Audit

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

In parallel, during the year, the European Court of Auditors will audit and report on the reliability of IMI JU's 2013 Annual Accounts as well as the legality and regularity of the underlying transactions.

Anti-fraud strategy

In 2014, IMI JU will prepare and implement a comprehensive anti-fraud strategy in line with the European Commission Anti-Fraud Strategy (COM(2011)376) applicable to its services and also extended to agencies and other EU bodies.

Anti-fraud measures are part of sound financial management required under the EU Financial Regulation. In essence, the anti-fraud strategy will outline specific objectives and pro-active actions for fraud protection and detection within the existing internal control system with the aim of further protecting IMI JU's financial interests, its compliance with ethical values and the protection of the JU's reputation. The strategy will cover the following features:

- preventive measures against fraud, corruption and any other illegal activities;
- carrying out effective checks;
- recovering amounts wrongly paid and
- imposing effective, proportionate and dissuasive administrative and financial penalties where appropriate.