Innovative Medicines Initiative

The Innovative Medicines Initiative (IMI)
Annual Implementation Plan
2012

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1. Foreword

The Innovative Medicines Initiative Joint Undertaking (IMI JU) was established in 2008 as a public private partnership between the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA) with the mission to support the drug development process in Europe through projects that focus on research & development and education & training. The first three Calls for Proposals resulted in 30 projects launched between 2009 and 2011. The fourth Call for Proposal was published in July 2011 and further Calls for new projects are foreseen during 2012. The topics for these Calls will be derived from the IMI Scientific Agenda which was revised in 2011. A number of important achievements have already been reported by IMI consortia, creating new opportunities for ongoing and new projects, demonstrating the added value of IMI JU in the context of the EC framework programme.

Major efforts will be made to streamline and simplify procedures and processes related to IMI JU operational activities in order to tailor them to IMI needs, taking advantage of new IT tools and platforms. The performance of IMI JU as a whole will be monitored using Key Performance Indicators (KPIs) which were defined in 2011 and will be further developed in 2012. Communication and external activities will be increased through the development and use of new tools for IMI "ambassadors" and "multipliers" and by focusing on key messages targeting key IMI stakeholders.

2. Implementing R&D and Education & Training Projects

2.1 Activities related to Calls and Projects

2.1.1 Monitoring and supporting execution of on-going (1st and 2nd Call) Projects

IMI JU will continue supporting and monitoring the implementation of the twenty three projects under way (scientific, financial and administrative aspects).

A key objective will be the implementation of the modified model Grant Agreement and new rules related to methods of calculation of indirect costs and for the reporting of in-kind contribution by EFPIA companies. The Executive Office will continue to provide support and advice to the consortia, including on the preparation of amendments to Grant Agreements. The new IMI financial guidelines and new templates for administrative, financial and scientific reporting tailored to the requirements of IMI JU will be communicated by the Executive Office to the consortia.

The Executive Office will implement interim reviews of the projects, with the assistance of independent external experts and the IMI Scientific Committee. These reviews will be based on the periodic reports submitted by the consortia. It is expected to receive in 2012 23 scientific reports and corresponding financial statements. In addition of these 23 reports, EFPIA companies will send 25 missing financial statement from the previous years. The total estimated IMI contribution is € 34.7 million and the total estimated in kind contribution is € 44 million on 2012 budget and € 41 million on previous years. They aim at evaluating the status of the projects according to foreseen milestones and deliverables and to advise the consortia accordingly. In addition, ex-post audits of the projects will continue to be conducted.

“Cross project” meetings will be organized to identify synergies and avoid duplication between projects with common objectives or focusing on closely related fields.

Finally, feedback from participants and stakeholders on the implementation of the projects will enable the Executive Office to implement communication activities

and to ensure the appropriate follow up of the discussions regarding Intellectual Property (IP) related matters and simplification.

2.1.2 LAUNCH OF 3RD CALL PROJECTS

The Third Call for Proposals, launched on 22 October 2010 for an IMI contribution of € 111.816 million, matched by the EFPIA in-kind contribution of €68.884 million, led to seven full project proposals for which negotiation finished in Q4 2011.

The signature of the Grant Agreements will be concluded as from Q4 2011 and corresponding pre-financing payments executed subject to finalisation of relevant Project Agreements. The key objectives for 2012 are to sign other Grant Agreements of the selected proposals and to follow up on scientific, financial and administrative aspects of the projects.

2.1.3 EVALUATION OF 4TH CALL FOR PROPOSALS

The Executive Office launched the Fourth Call for Proposals on 18 July 2011. The Call includes seven topics addressing the strategic areas[1] foreseen in the revised Scientific Research Agenda adopted in July 2011. IMI JU will support evaluation, selection and negotiations of proposals with the successful consortia. The signature of the Grant Agreements and the payments of pre-financing are expected to be concluded by Q3 2012.

The EFPIA in-kind contribution to the Fourth Call for Proposals is of about € 93.6 million. Subject to an increased EFPIA in-kind contribution, the IMI contribution may reach up to € 105 million.

2.1.4 PREPARATION AND LAUNCH OF NEXT CALLS FOR PROPOSALS

The scientific priorities are based on the Scientific Research Agenda and are set out in Annex 8.1.

Simplification and streamlining of processes from “idea generation” to conclusion of the Grant Agreements should result in shortening current timelines and maximising efficiency for project teams. In the preparation of the Call topics, special attention will be given towards eliciting the necessary input from opinion

[1] *Patients, Diseases Drug Efficacy, Knowledge Management, Strategies in R&D, Development in Regulatory Framework, Tools and Techniques, Sciences Communication.*

leaders within the academic community. For this purpose, appropriate consultations will be organized in collaboration with the Scientific Committee and the States Representatives Group in the form of workshops or webinars. These consultations are the prerequisites to finalise planned topics. The European Medicines Agency and the US Food and Drug Administration will be involved in these consultations.

Proposals will be evaluated on the basis of the following criteria: scientific and/or technological excellence; consistency with Call topic; excellence of partnership; excellence of project implementation plan; potential impact of project results and ethical issues.

The major changes in the Call process to be implemented in 2012 include:

- Several Calls will be launched each year with at least three Calls foreseen in 2012. The timing of the launches will be defined;

- More precise information on project proposals will be requested from Applicants at stage 1 to streamline the evaluation process at Stage 2;

- Consortium partners will be asked to prepare the Full Project Proposal and the Project Agreement in parallel in order to reduce the time between Stage 2 evaluation and the signature of the Grant Agreement.

The total budget for the next Calls for Proposals for new projects foreseen for 2012 includes a maximum financial contribution from the EC to the IMI JU of €347.4 million and a matching EFPIA in-kind contribution.

In addition, following the request of the IMI Governing Board, a Call for research will be implemented as from Q1 2012 in the areas where the specific topics have to be further defined in line with the priorities identified/defined by IMI JU and recent scientific developments. Several cut-off-dates will be set up until end of October 2013. A budget of €5.4 million matching additional EFPIA in-kind contribution will be earmarked in 2012 (see Annex 8.3) and equally distributed over the different cut-off-dates. Relevant and simplified Call documents will be published.

2.1.5 KNOWLEDGE MANAGEMENT

The Knowledge Management Workgroup targets to collect and share information among the ongoing IMI projects with respect to the Knowledge Management challenges in each of these projects. Knowledge Management is broadly defined as topics pertaining to e-collaboration, digital asset management (documents, data, and images) and Biobanking. For the purpose of digital asset management one needs to ensure 1) availability of descriptive metadata, 2) description of the quality of the digital assets, 3) use of standards to ensure both technical and semantic interoperability of the digital assets. The requirements for digital asset management ensure that digital assets can be preserved and re-used under appropriate governance that will be defined in 2012. This is relevant both within and between projects and for future projects. Furthermore it is key to ensure best practices in terms of digital asset management.

In 2012, the following activities of the Knowledge Management Workgroup are planned:

- Maintain the monthly teleconferences/webinar and two face-to-face meetings on relevant topics to knowledge management;
- Renew the Clinical Data Interchange Standards Consortium (CDISC) membership;
- Organise the CDISC overview course for IMI JU beneficiaries to further facilitate the adoption of data standards;
- Ensure implementation of data standards in new IMI projects and define a mitigation strategy for ongoing projects;
- Given a successful rollout of the e-collaboration platform for one project, roll-out among new projects and define a mitigation strategy for ongoing projects;
- Investigate potential collaborations, potentially leading to Memorandum of Understanding and memberships with organizations that can provide assistance on generation of descriptive metadata, and description of the quality of data in order to facilitate adoption of best practises in terms of digital asset management.

2.2 Simplification of processes

In 2011, the EFPIA in conjunction with the EC and IMI JU called up for a review of the administrative processes with the aim to simplify and optimise them wherever possible. Two main areas have been identified where the focus of the simplification exercise should concentrate upon: “Call Process and project life cycle” and “Review and Documents”. To progress with the work in these areas, teams composed of members from IMI JU, the Industry Liaison Group (ILG) from EFPIA and the EC have been formed and a separate dedicated online collaborative platform has been developed. In parallel, upon request of the Governing Board, the IMI JU carried out a benchmarking exercise with other funding initiatives to feed the simplification exercise.

The work initiated in these areas will continue in Q1 2012, notably in relation to:

- the optimisation of the process and timelines from “idea generation” to conclusion of Grant Agreement to allow the launch of several calls per year as already presented in section 2.1.4;
- the simplification of documents/forms and elaboration of guidance for coordinators and project teams, in particular for the project application (with its administrative forms), the monitoring of the project through the periodic report and interim review.

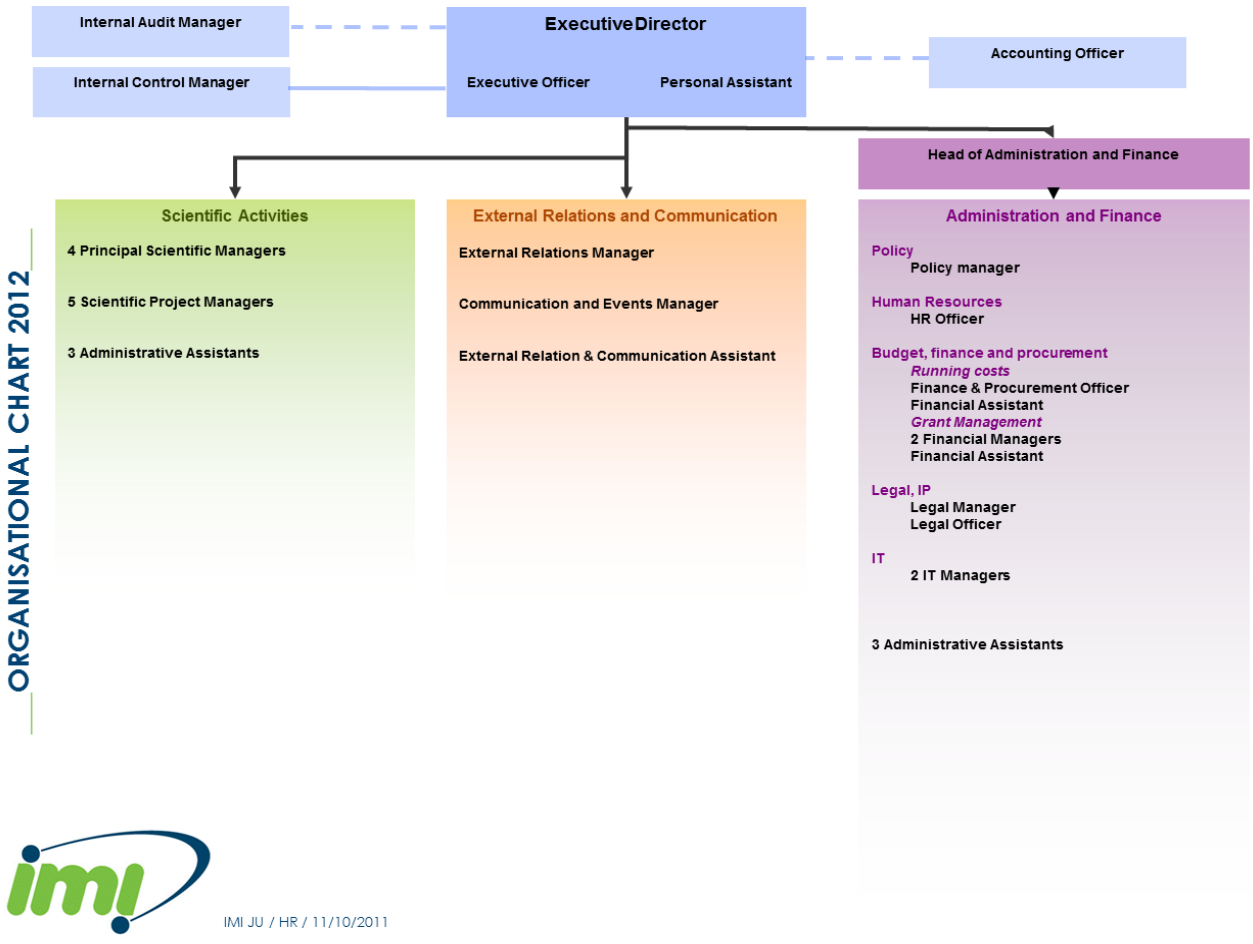
The objective is to implement the simplified procedures and documents in the Call 5 process as well as in the ongoing projects wherever appropriate and to conclude this simplification exercise by the end of Q1 2012 at the latest.

3. Maximising the Efficiency and Effectiveness of the Executive Office

The year 2012 will be marked by the consolidation of the organisation of the Executive Office with the aim of optimizing internal processes and workflows. This will represent a priority task for the new Head of Administration and Finance who took up duties in Q4 2011.

3.1 Staff implementation

As agreed by the Founding members in 2011, the IMI JU Executive Office will be organized according to the following chart:



In order to implement the revised Scientific Research Agenda approved by the Board in 2011; to cope with the additional workload related to the increase in the number of calls to be launched each year; the increased number of projects to be monitored; and the measurement of IMI JU KPIs, the organization of the Scientific team will be reviewed according to the following principles:

The 4 Principal Scientific Managers (AD11) will focus their activities on:

- Mobilization of public partners/ facilitating public consortia creation for EFPIA companies;
- Finalization of Call topics in conjunction with EFPIA and the EC;
- Evaluation of proposals;
- Support to project negotiations;
- Monitoring of and amendments to projects;
- Establishing synergies between IMI projects and of IMI projects with other projects funded via other sources;
- Relations with Scientific Committee, C-DISC, Critical Path and JDRF.

With the Principal Scientific Managers, the 2 Scientific Project Managers (AD9) will contribute to the management of calls and projects. They will also be specifically in charge of the following cross-cutting activities:

- Submission and reporting processes;
- Call coordination;
- Organisation of consultation processes (i.e. workshops) in preparation of the Calls for proposals;
- Relations with regulatory agencies and SME organizations.

Three additional Scientific Project Managers are foreseen to be recruited in 2012 in line with the establishment plan approved by the Board, preferably at a more junior level. These additional resources will be assigned to cope with the growth of the scientific workload in line with the Calls schedules (interim review for Call 1, agreements negotiations for Call 4, stage 1 evaluation for Call 5, preparation for Call 6). They will also be assigned to cross-cutting activities such as setting-up data-bases and measurement of Performance Indicators for Projects.

In parallel, the work of the administrative assistants will be organized in pools in order to provide flexibility and optimize allocation of tasks between them.

3.2 IT

3.2.1 IT Infrastructure

In Q1 2012 IMI staff will migrate to a new hardware setup following the change in Q3 2011 to Windows 7, Outlook 2010 and Office 2010 and to a more mobile working environment in IMI offices.

3.2.2 IMI Submission platform

The IMI Submission platform was developed by EFPIA and donated to IMI JU. The migrated version of the submission tool will be available in Q1 2012 for 4th Call – stage 2 submission. The tool will be further developed to be ready for 5th Call stages 1 and 2 submissions, on the basis of user requirements agreed and prioritised by the Simplification task force. The submission tool will be completed with a reporting component as from Q1 2012 so as to improve the financial and administrative management of on-going grant agreements as well as facilitate processing, analysing and reporting of call statistics.

3.2.3 MATURING OF THE FORMAL IT ENVIRONMENT

In 2012 the IT environment will be supported by a more comprehensive IT policy framework and the implementation of best practices. The IT environment will also be improved with the transition to an ITIL based service management and a digital inventory.

3.2.4 Collaboration Environments

In 2012 IMI JU will continue to develop online collaboration environments to facilitate the interactions of the Executive Office dedicated with the Industry Liaison Group of EFPIA and the IMI Governance Bodies and to ease the preparation of IMI annual reporting documents.

3.2.5 Human Resources Applications

Some parts of the functional HR requests may be covered by the *Internal IMI Environment* but certain HR related tasks will require a dedicated E-HR tool to streamline HR procedures and processes.

3.2.6 PLATFORM CONSOLIDATION

In addition to the IMI Submission platform, two parallel IT platforms are currently in use: the IMI Website and the platform for the other environments. As IMI is standardizing new developments the goal is to upgrade the older environments to this new platform. This change will also harmonize efforts in areas such as tendering; licensing; required technical expertise; Support (Service Level Agreements); hosting; visual identity; inter-environment content promotion and workflows; and, training.

In 2012 IMI JU will continue to develop online collaboration environments to facilitate the interactions of the Executive Office dedicated with the Industry Liaison Group of EFPIA and the IMI Governance Bodies. The SRG platform was made available in October 2011. The Scientific Committee platform will be made available at the end of December. A dedicated platform for the Governing Board will be gradually set up by Q1 2012.

3.2.7 EC FP8 Platform (SEP & SyGMa)

The European Commission has started the process of building a toolset for "Horizon 2020" in 2011. The European Commission intents to also allow the Joint Technology Initiatives (such as IMI) to use the platform for submission of proposals (SEP); proposal selection & negotiation (SEP); Grant Agreements & amendments (SyGMa); and monitoring (SyGMa).

This will require an assessment by IMI JU on the feasibility and cost of using this toolset.

3.2.8 Scientific Project Environment - Knowledge Management

The Scientific Project Environment is the online environment for building up and sharing knowledge amongst IMI Scientific projects. Project content will be structured, indexed and searchable. It will also enable cross-project functionality such as cross project search, expert database and monitoring dashboards.

3.2.9 Internal Environments

Particular attention will be paid to strengthening the efficiency of the internal processes. IMI IT will also assume the role of *process analyst* to digitalize current paper flows and to simplify, where appropriate, those aspects which require automation.

3.3 Financial operations

The Executive Office will forecast the IMI's annual revenue and expenditure and prepare, implement and control the budget. In this context, IMI will reinforce its budget plan system, in particular for multiannual operations and rigorous budget execution. It will also ensure proper accounting and financial management and reporting.

3.3.1 Financial Grant Management

In 2012, IMI will manage 30 projects (fifteen projects from the First Call, eight projects from the Second Call and seven projects from the Third Call). Grant agreements of the additional seven projects resulting from the Fourth Call are planned to be signed and negotiations for the Fifth Call are envisaged to start during the third quarter of 2012.

In 2012 EFPIA companies will continue reporting their actual in-kind contribution as part of the respective periodic reports.

The Executive Office will also continue with the implementation of the ex-post audit strategy. In 2012, the audits will cover cost claims received from beneficiaries as well as the reported in-kind contributions of EFPIA companies. In parallel, the results of the first ex-post audits launched at the end of 2011 will be followed up during 2012.

A more structured and simplified Manual of Financial Procedures will also be introduced in 2012.

3.3.2 Budget

The table below provides an overview of the budget:

Commitment appropriations:

Running costs:	€9.400.000
*Operational costs:	€362,922,547

*) The amount of commitment appropriations for operational costs is provisional as the final figure depends on the total carried-over amount from previous year.

Payment appropriations:

Running costs:	€9.400.000
**Operational costs:	€111,885,963

** The payment appropriation will depend on the EC´s voted budget for 2012 and final amount of carried-over payment appropriation

Running Costs:

- Title 1: All costs linked to staff, employment and recruitment costs, cost of travel (missions), training and social measures (€ 4.5 million).

- Title 2: Running costs of the IMI JU office such; office equipment, IT and telecommunications, housing, communication and events, the evaluation process, formal meetings, and expenditures in connection with research activities (workshops, meetings and events targeting the IMI projects) (€4.9 million).

Grant management:

- Title 3: The available commitment appropriation for Calls in 2012 is budgeted at € 362.9 million in 2012 including:
    - 2012 commitment appropriation 307.3 million €
    - unused appropriations for Call 3 and 4 of € 52.5 million;
    - transfer from running costs appropriation of EC contribution € 1.8 million; and,
    - cancelled appropriation from closed contracts in 2009/2010 of € 1.3 million.

In financial year 2012 IMI JU foresees payments for projects of Call 1, 2, 3, 4 and possibly for some projects of Call 5 in amount of € 111.9 million. The carried-over payment appropriation (€ 18.8 million) will be used in 2012 after full consumption of the 2012 budget (€ 93 million).

IMI JU's preliminary draft budget plan for 2012 was adopted with a budget of €113.5 million for payment appropriation. This budget suffered a reduction of €13.5 million (payment appropriation) as proposed by the budgetary authority and further reduction following approval of the EU budget of additional €7 million. In addition, IMI JU plans to consume the carried over payment appropriations from years 2009, 2010 and 2011 in accordance with the IMI JU Financial Rules.

Procurement

In order to reach its objectives IMI JU will allocate funds to procure the necessary services and supplies for the support of its operational activities. The tenders planned for 2012 are mainly in the field of communication activities and IT to support the core activities. The tender and contract management will be simplified through the use of multi-annual framework contracts.

The table below list the main tenders planned for 2012 and sets out the procedure to be used in each case, the estimated expenditure as well as the estimated schedule for publication.

As regards IT, no major new tenders will be carried out. A framework contract concluded in 2010 accommodates the general needs of all JUs to function at the offices in White Atrium as regards infrastructure and software. These framework contracts will be used to cover IMI's needs in 2012, essentially consisting of operational IT costs such as IT support and some new software development to improve IMI's working platforms (Project Submission Tool; platforms for States Representatives Group and Scientific Committee; internal tools for the Executive Office such as human resources management tool).

As regards communication, IMI intends to tender for a number of framework contracts to cater for recurring needs in the coming years, with the biggest share of the expected expenditure going towards event organisation.

Contracts to be tendered in 2012			
Subject (Indicative Title)	**Indicative IMI JU expenditure**	**Procedure**	**Indicative timetable**
PR - Media relations - Media monitoring - IMI messages and Communication Strategy - Stakeholder Surveys - Communication training to IMI staff	App. EUR 50,000/year in 2012 and 2013. Maximum 4 years' contract duration*.	Open procedure – framework contract with a single provider	Q1 - 2012
Events agency - Organisation of Stakeholder Forum and other events	App. EUR 500,000/ year in 2012 and 2013. Maximum 4 years' contract duration*.	Open procedure – framework contract with a single provider	Q1 - 2012
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 in 2012 and 2013. Maximum 4 years' contract duration*.	Open procedure – framework contract with a single provider	Q1 – 2012

*contracts do not carry any obligation to spend. Annual expenditure estimates are made for the period until the end of 2013 only in line with the duration of the current funding scheme under Framework Programme 7.

3.4 Data Protection

In 2012, IMI JU will continue to ensure that personal data are protected and that Regulation (EC) No 45/2001 is complied with. The actions foreseen for 2012 will include addressing prior checking notifications; implementing the Guidelines for specific areas; and following-up the IMI register of data processing operations. The IMI JU will also act on the recommendations of the European Data Protection Supervisor.

3.5 Internal Audit and Control

3.5.1 INTERNAL AUDIT

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.

During 2012, the activities of the IAC function will be in line with the coordinated multi-annual audit strategy for 2012-2014 that was agreed with the Internal Audit Service (IAS) of the European Commission in Q3 2011 and approved by the Governing Board. These will include the provision of independent, objective assurance and consulting activity on various aspects of IMI JU's processes and activities as well as acting as the internal and external focal point on audit matters.

3.5.2 INTERNAL CONTROL & RISK MANAGEMENT

Internal Control encompasses those internal systems and processes intended to provide reasonable assurance regarding the achievement of IMI JU´s objectives and compliance with applicable provisions, in particular the IMI Financial Rules. The main operational and financial processes and procedures will also be adequately documented.

At IMI JU the internal control and risk management are seen as a strategic component for reaching key objectives and improving the effective and efficient management of activities. To this end a systematic risk management process is integrated in the IMI JU's annual planning according to ICS No 6.

In preparation for the AIP 2012, the annual risk assessment exercise was performed in June-July 2011. The exercise identified two critical cross-cutting risks for which the Joint Undertaking is particularly exposed: (1) The risk that the Executive Office may be unable to react effectively to emerging expectations; (2) Legal, organisational and resources constraints of the Executive Office.

The Executive Office is taking a number of actions and measures to mitigate and manage these risks. In this context, the main internal control activities planned for 2012 include:

- Developing an effective document management system, carrying out appropriate controls and assisting financial services on the implementation of the Ex-post audit strategy;

- Follow-up of the risks emerging from the annual risk assessment exercise performed with particular emphasis to the standards regarding operational structure and to information and communication.

The follow-up will be conducted mainly by means of on-the-spot checks on a sample of files in selected processes as well as interviews with the concerned staff.

4. Monitoring IMI JU Performance

In the two years since the Executive Office became autonomous, IMI has made significant progress in many areas. 2012 will mark a significant increase of activities as well as further strengthening and consolidation of internal structures, operations and processes. The main focus will 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 following twelve Key Performance Indicators (KPIs) 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. These KPIs and other supporting metrics will be used to measure, track and report progress during 2012, both on an annual basis as part of the AIP and Annual Activity Report and regular basis through periodic scoreboards.

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 effectiveness and impact of IMI JU's activities. In this context a collaborative research project will also be carried out in 2012 through an agreement with Cambridge University (Department of Chemical Engineering and biotechnology). All these initiatives are particularly relevant in the context of Horizon 2020, in preparation of which the added value of public private partnerships in the pre-competitive space should be demonstrated. In addition, these may also be relevant in the framework of an independent peer review requested by the Governing Board, aimed at better assessing the long term impact of IMI JU's actions.

No.	KPI	
Reinforce Pharma R&D in Europe by addressing bottlenecks and gaps in drug research		**Target 2012**
1	The extent to which IMI JU projects cover the value chain of drug development.	Qualitative Assessment in 2012
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 in 2012
4	Bibliometric indicator: Citation scores of project publications	Quantitative and qualitative assessment in 2012
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 in 2012
7	Impact on societal and healthcare challenges	Collect in 2012 preliminary indications on the impact on society and healthcare from launched projects

No.	KPI	
Maximise the Efficiency and Effectiveness of the Executive Office		**Target for 2012 (to be reviewed by the Board as necessary)**
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	Average Time to Recruit (TTR) Percentage of filled positions	≤ 60 days 100 %
12	Annual budget execution rate	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 ≥ 80%

5. Relations with Governance Bodies

The IMI JU provides support to the activities of the governance bodies and working groups.

5.1 Support to Governing Board

The Governing Board is the governance body which has the overall responsibility for the operations of the IMI JU and oversees the implementation of its activities.

The Governing Board will meet at least two times during 2012, namely in Q1, and Q4, and will hold teleconferences for information purposes in months when no meeting is scheduled.

5.2 Support to Scientific Committee

The Scientific Committee as an advisory body to the Governing Board of the IMI JU conducts its activities in close liaison and with the support of the IMI JU Executive Office.

The Scientific Committee will meet at least twice during the year 2012.

5.3 Members States Representatives Group

The IMI States Representatives Group (SRG), will be consulted on the Call process and will receive the evaluation outputs. The Executive Office will provide the secretarial, administrative and organizational support for the meetings and will maintain the SRG platform. At least two meetings of the SRG are foreseen for 2012.

5.4. Stakeholders Forum

Through a one-day event, IMI aims to engage key stakeholders in discussions about the activities of IMI. The 2012 Stakeholder Forum will offer IMI the opportunity to present achievements and success stories from on-going IMI projects and to preview upcoming Calls.

The 2012 meeting is scheduled to take place in Q2.

6. Relations with External Institutions

These activities cover co-operation and coordination at European and international levels in the areas that can best contribute to fulfil the objectives of the IMI JU.

The collaboration and interaction is being tailored according to the impact that these activities may have in promoting research on the biopharmaceutical sector in Europe.

During 2012, IMI JU will assess the benefits drawn from the Memoranda of Understanding, which have been concluded in 2010/2011 with the Critical Path Institute, the Juvenile Diabetes Research Foundation and the Clinical Data Interchange Standards Consortium (C-DISC). Regarding the collaboration with Critical Path, IMI JU will explore the benefit of strengthening the collaboration between the SAFE-T and PSTC consortia regarding clinical biomarkers of drug safety, a field in which links with the Biomarkers Consortium from the Foundation of the National Institutes of Health might also be established.

Upon the invitation of the International Alliance for Biological Standardization (IABS), IMI JU will explore possible collaboration with this non-profit organization, which aims at facilitating communication among those who develop, produce and regulate biological products for human and animal health.

Likewise, IMI JU will explore possible collaboration with the Bill & Melinda Gates Foundation which is proposing to partner with IMI JU to foster industry-biotech-academia partnerships to harness development of new vaccines.

IMI JU will continue to work with its founding partners and external organisations 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, particularly a resource on its website dedicated to SMEs. The IMI Executive Office will host and attend meetings specifically aimed at and involving the SME sector, in particular, it will host a workshop focusing on SMEs in Brussels, Q1 2012. 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 fulfilment of IMI JU objectives.

Memoranda of Understanding are foreseen to be concluded between IMI JU and relevant SME-representation organisations to establish a framework for collaboration, 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.

Relevant organisations include, but not exclusively, European Biopharmaceutical Enterprises, Europabio, European Biotechnology Network and Steinbeis-Europa-Zentrum.

7. Communication and External Relations Activities

7.1 Strategy

IMI Communication actions will be in line with the Communication strategy that was presented to the IMI Governing Board in 2011, and with the objectives defined therein. Key Communication initiatives will include promoting the IMI Calls for proposals as well as IMI achievements and successes.

In order to maximise the effect of the Communication efforts, the IMI Executive Office will increasingly rely on **multipliers and ambassadors**:

- local multipliers in the Member States, such as National Contact Points for Health (NCPs) and members of the States Representatives Group (SRG) → reaching out to potential applicants;
- EFPIA and the European Commission
  → reaching out to policy makers and decision makers inside EFPIA companies;
- IMI project coordinators and participants;
  → communicating the success of IMI to various audiences.

7.2 Objectives & Actions

7.2.1 OBJECTIVE 1: Attract the best talents in Europe for partnering with EFPIA in IMI projects

TARGET GROUPS:	**Potential applicants:** academics, SMEs, patients' organisations, regulatory agencies
MESSAGE:	Benefits of participation in IMI projects.
ACTIONS:	**Call promotion:** - **Open Info session** around Call launch; - **Open Webinar** per Call topic around Call launch; - **NCPs and SRG members: local info sessions** in Member States, info material provided by IMI office; - **Campaign on internet and social media**; - IMI staff participation at **external events**.
	IMI visibility at key events, e.g. - DIA Euromeeting, Copenhagen, 26-28 March 2012; - ESOF, Dublin, 11-15 July 2012 (IMI session foreseen); - BIO International Convention, Boston, 18-21 June 2012 - Additional events according to topics selected for 2012 Calls.

7.2.2 OBJECTIVE 2: Mobilise decision makers by demonstrating the added value of IMI for drug development in Europe

TARGET GROUPS:	**Decision makers** in the area of research policy, in industry and in public institutions
MESSAGE:	**Success** of on-going projects.
ACTIONS:	**Publish in high-level journals** (Nature Reviews Drug Discovery, Nature Biotechnology …).
	High-level media coverage (Financial Times, European Voice, Biocentury …), through: - **press releases;** - building **media relations.**
	Targeted events, e.g. - European Parliament event on anti-microbial resistance under consideration; - participation to Annual EFPIA meeting; - participation to events organized by the EC; - participation to events organized by EMA and/or FDA.

7.2.3 OBJECTIVE 3: Support to project coordinators

TARGET GROUPS:	**Project coordinators**
ACTIONS:	Provide **communication guidance** about: - project website; - events; - publications.
	Maximise use of web based **collaboration platform** (implemented by IT) for information exchange with project coordinators.
	Provide **communication guidelines** and helpful **material** to projects coordinators/participants.

7.2.4 OBJECTIVE 4: Maximise efficiency and effectiveness of IMI communication efforts

ACTIONS:	Engage other IMI staff, including Scientific Managers, in communication activities.
	Maximise use of **internal collaboration platform** (implemented by IT) for internal information flow.
	Provide **communication material** (brochures, posters …) to IMI staff for use at conferences.
	Build and activate network of IMI 'multipliers' (NCPs, SRG members, EFPIA/ILG …): - provide **information packages;** - encourage and engage via **networking opportunities, webinars** etc.
	Conclude **contracts** for PR and other communication-related services such as printing, design, events etc.

8. Annexes

8.1 Annual Scientific Priorities 2012

The scientific priorities for 2012 are based on the Scientific Research Agenda, which has been revised in 2011 following consultation of the IMI States Representatives Group and of the IMI Scientific Committee.

These priorities include the ones already established in the 2008 Scientific Research Agenda as well as new ones identified in the revised Agenda.

8.1.1 Established research priorities present in the initial agenda

In close interaction with Regulatory Authorities, the development of:

- tools, methods and techniques for drug development and innovation or disease prevention;
- knowledge management approaches;
- expertise in biomedical R&D knowledge.

in the following areas:

- safety sciences;
- cancer;
- infectious diseases;
- metabolic and cardiovascular diseases;
- inflammatory disorders;
- neuropsychiatric and brain disorders.

8.1.2. New key research areas detailed in the updated agenda

- New taxonomy of human diseases and phamacogenetics;
- Rare diseases and stratified therapies;
- Systems approaches in drug research;
- Beyond high throughput screening – pharmacological interactions at the molecular level;
- Active pharmaceutical ingredients technology;
- Advanced formulations;

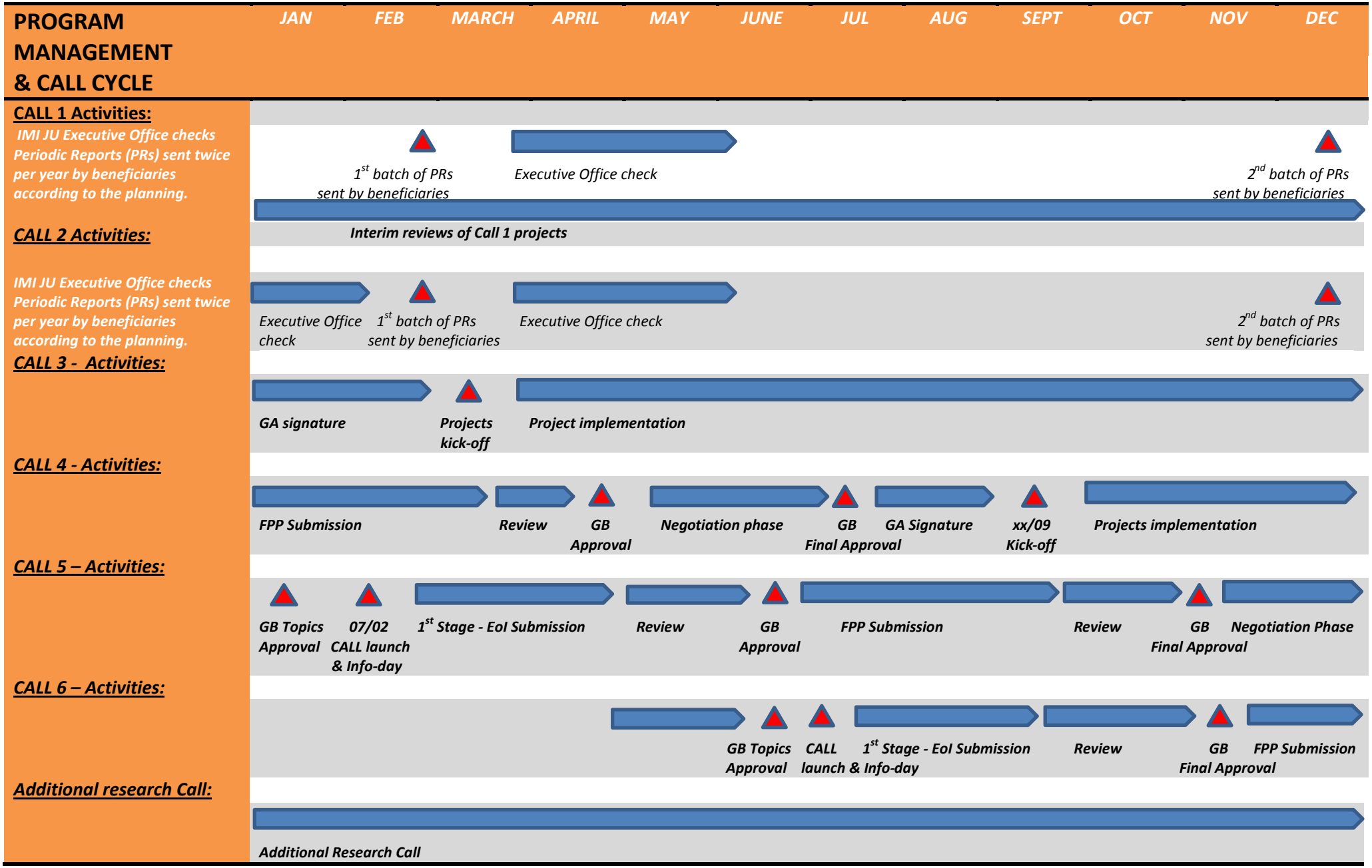
- Stem cells for drug development and toxicity screening;
- Integration of imaging techniques into drug research.

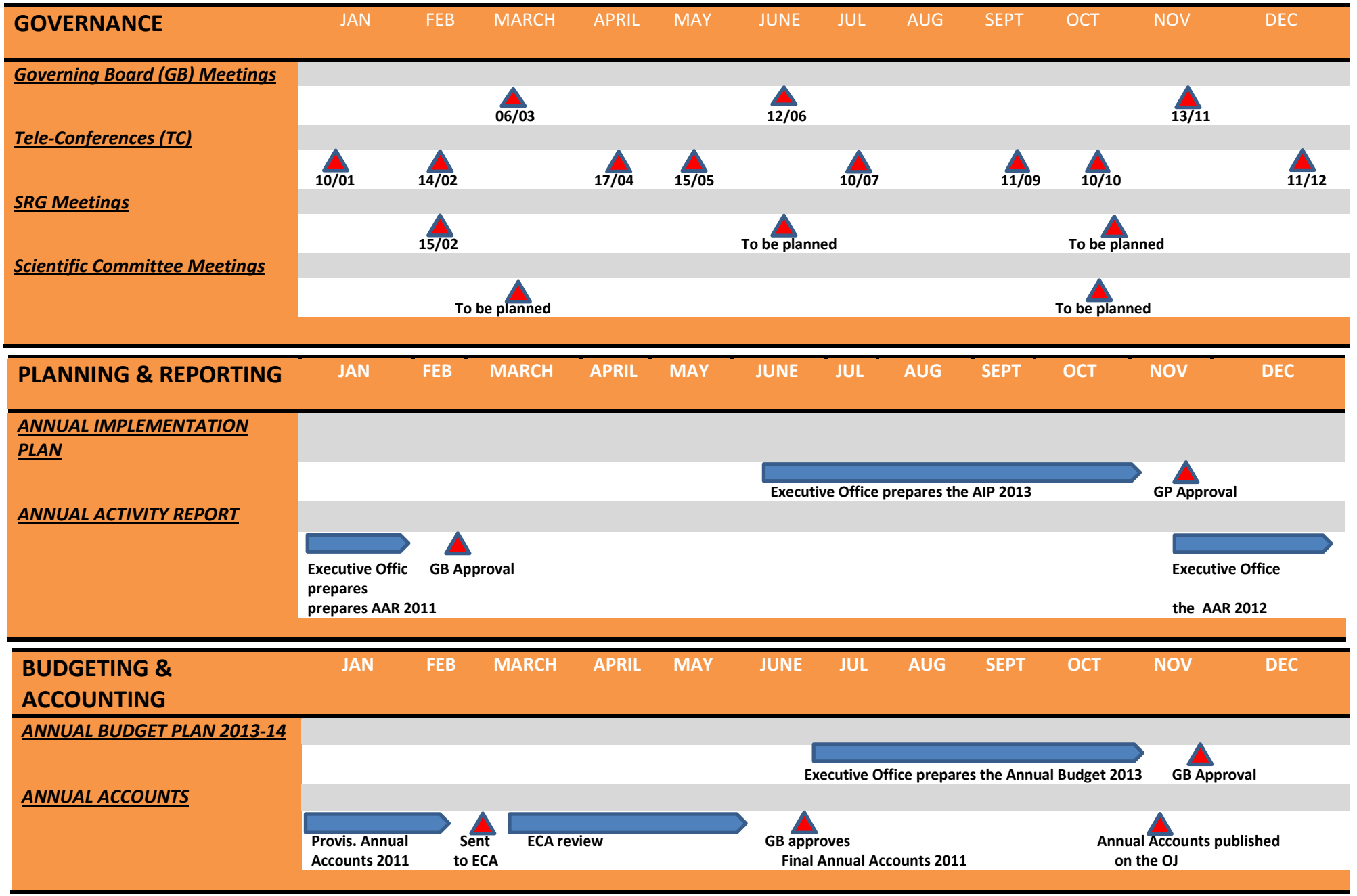
As mentioned in the revised SRA, IMI will focus on defining strategic themes, as research clusters focused on 'game-changing' ideas and areas where the maximum number of companies can join forces. ‘Think big’ initiatives are to be developed which strategically integrate many different aspects of science and technological investigation. Under these, future projects will be defined that will change the landscape in which pharmaceutical industry, academic institutions and healthcare operate. It is anticipated that such “Think big” projects will be launched during 2012, such as projects focusing on anti-microbial resistance, on combination therapy development, and on innovative approaches for the identification of new lead compounds in drug development.

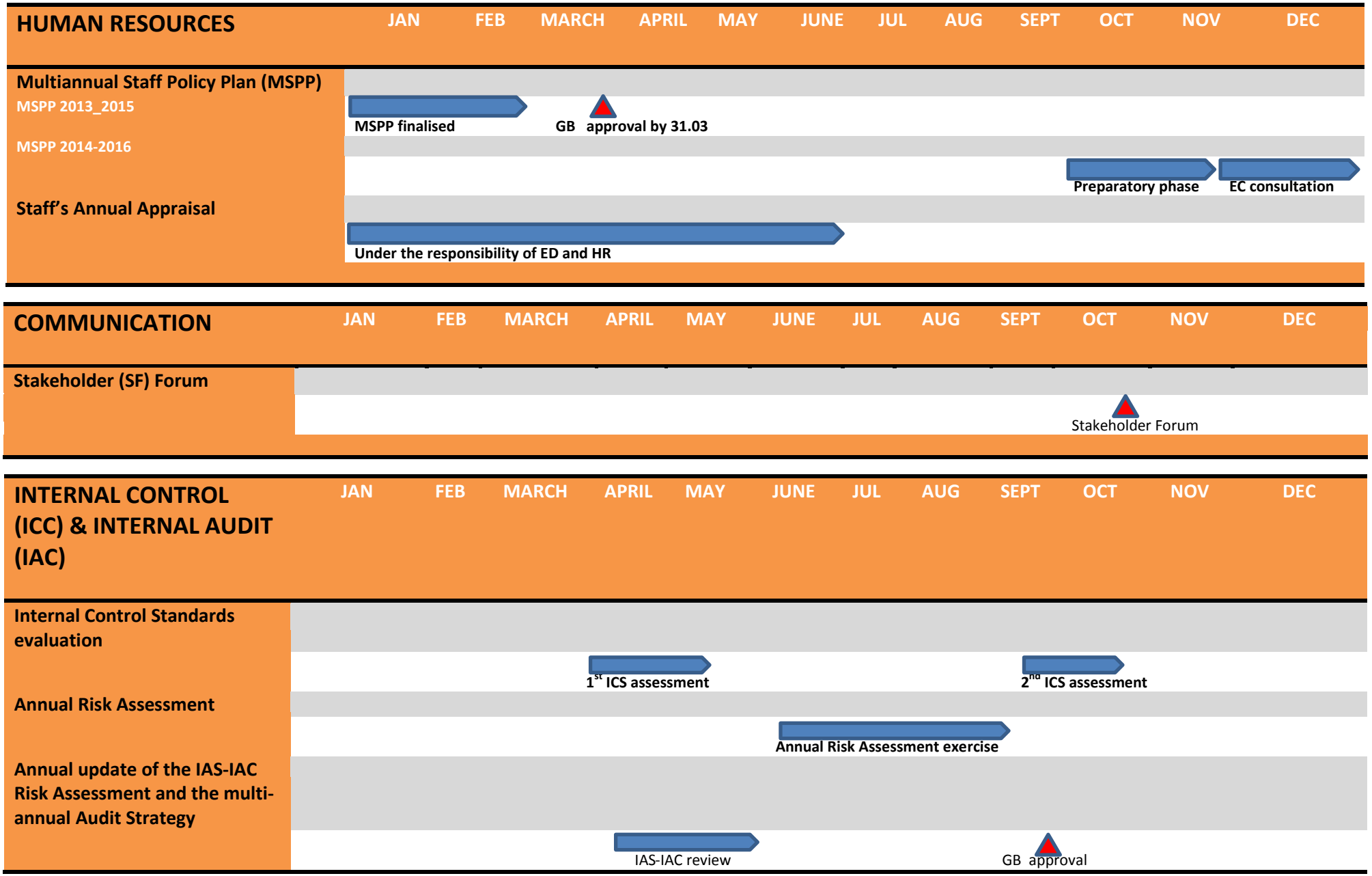
As for previous Calls, the evaluation and selection processes will be based on the following key principles: scientific excellence, transparency, fairness and impartiality, confidentiality, efficiency, speed and attention to ethical considerations.

Proposals will be evaluated on the basis of the following criteria: scientific and/or technological excellence; consistency with Call topic; excellence of partnership; excellence of project implementation plan; potential impact of project results and ethical issues.

8.2 Overview of Timelines for Key Corporate Activities




GOVERNANCE
JAN
FEB
MARCH
APRIL
MAY
JUNE
JUL
AUG
SEPT
OCT
NOV
DEC
Governing Board (GB) Meetings
06/03
12/06
13/11
Tele-Conferences (TC)
10/01
14/02
17/04
15/05
10/07
11/09
10/10
11/12
SRG Meetings
15/02
To be planned
To be planned
Scientific Committee Meetings
To be planned
To be planned
PLANNING & REPORTING
ANNUAL IMPLEMENTATION PLAN
Executive Office prepares the AIP 2013
GP Approval
ANNUAL ACTIVITY REPORT
Executive Offic prepares prepares AAR 2011
GB Approval
Executive Office
the AAR 2012
BUDGETING & ACCOUNTING
ANNUAL BUDGET PLAN 2013-14
Executive Office prepares the Annual Budget 2013
GB Approval
ANNUAL ACCOUNTS
Provis. Annual Accounts 2011
Sent to ECA
ECA review
GB approves Final Annual Accounts 2011
Annual Accounts published on the OJ


HUMAN RESOURCES
JAN
FEB
MARCH
APRIL
MAY
JUNE
JUL
AUG
SEPT
OCT
NOV
DEC
Multiannual Staff Policy Plan (MSPP)
MSPP 2013_2015
MSPP finalised
GB approval by 31.03
MSPP 2014-2016
Preparatory phase
EC consultation
Staff's Annual Appraisal
Under the responsibility of ED and HR
COMMUNICATION
JAN
FEB
MARCH
APRIL
MAY
JUNE
JUL
AUG
SEPT
OCT
NOV
DEC
Stakeholder (SF) Forum
Stakeholder Forum
INTERNAL CONTROL (ICC) & INTERNAL AUDIT (IAC)
JAN
FEB
MARCH
APRIL
MAY
JUNE
JUL
AUG
SEPT
OCT
NOV
DEC
Internal Control Standards evaluation
1st ICS assessment
2nd ICS assessment
Annual Risk Assessment
Annual Risk Assessment exercise
Annual update of the IAS-IAC Risk Assessment and the multi-annual Audit Strategy
IAS-IAC review
GB approval