Innovative Medicines Initiative

Innovative Medicines Initiative
Annual Implementation Plan
2013

ANNUAL SCIENTIFIC PRIORITIES FOR 2013

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

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

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

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

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

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

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

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

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

1.1 Pharmacogenetics and Taxonomy of Human Disease

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

This would include for example:

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

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

1.2 Infectious Diseases

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

This would include for example:

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

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

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

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

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

Projects under consideration for 2013 would include for example:

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

1.4 Coping with Regulatory and Legal Hurdles

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

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

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

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

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

This would include for example:

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

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

1.5 Knowledge Management

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

This would include for example:

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

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

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

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

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