

## Patient engagement strategy workshop summary

Improved patient involvement and input along the value chain of pharmaceutical R&D, regulatory process and drug approval as well as post-marketing surveillance have recently been identified as top priorities by the WHO, EMA and the pharmaceutical industry. Initial attempts are being made across the globe to develop productive interactions with patients; however the appropriate framework has yet to be well defined. IMI, as a neutral platform with the ability to bring together many public and private stakeholders, is ideally positioned to significantly contribute to this effort.

IMI has already undertaken significant efforts to include patients' perspectives in its activities and to facilitate patient participation in IMI projects. IMI is also investing in several projects that aim to bring patients closer to the centre of the medicines lifecycle. With a significant number of projects underway and ongoing discussions on the portfolio of future projects, now is an ideal time to further optimise IMI's efforts to become more patient-centric and to define the scope and boundaries of future activities in this field.

Therefore, on April 28<sup>th</sup> 2016 IMI has organised Patient Engagement Strategy Workshop, during which a number of experienced stakeholders shared their experience to help IMI identify:

- appropriate levels and mechanisms of involvement of patients in IMI and its projects;
- strategy for optimising and coordinating patient engagement practice in different projects and turning the patient-centric goals of the IMI Strategic Research Agenda into reality;
- possible future research projects for IMI on enabling patient involvement in the medicines lifecycle, including collaboration opportunities with similar and complementary initiatives in various countries and regions.

During the workshop it was very much emphasised that patient involvement is critical and should be encouraged, facilitated and imbedded in IMI at all levels. It was also pointed out that IMI needs a robust IMI patient engagement strategy to ensure that patient engagement is universally understood, recognised and effectively upheld where appropriate.

In terms of achieving meaningful patient involvement in IMI projects discussions focused on ways to optimise and stimulate patient engagement, identification of the necessary tools/resources as well as pointing out existing gaps. It was concluded that in order to stimulate better patient engagement, throughout the medicines life cycle, its benefits need to be demonstrated possibly via the use of metrics. Best practices and failures need to be shared to enable broad alignment and learning. It was also emphasised that an adequate and universal framework for patient engagement is needed to operationalise and facilitate patient engagement.

The following aspects of the potential scope of patient engagement were identified:

- improving understanding of the disease and its impact on patients;
- providing patient experience of living with the disease and the current state of care;
- providing patient preferences of treatment and patient relevant outcome measures;
- contribution to the design of clinical trials (choice of statistical methods and eligibility criteria);
- discussing measurement methods, their relevance and real life practice;
- discussing selection of sites and patient recruitment plan;
- contribution to Patient Informed Consent and information tools about the study;
- collection of Patient Reported Outcomes;

- contribution to interpretation of results;
- communication to the wider patient community and society.

Further outcome of the discussions pointed to ways of ensuring meaningful and successful patient engagement in research projects. The following recommendations were made:

1. For topic writers:

- consider patient engagement and the role for patients at the idea generation and topic writing stage.

2. For IMI:

- communicate on patient engagement needs and opportunities at call launch;
- identify most effective channels of communicating the call to patient and other relevant organisations;
- communicate on best practices of patient engagement in IMI projects;
- facilitate patient engagement in consortia.

3. For consortia building:

- be mindful on the need to properly budget for patient involvement, adequate to the anticipated tasks;
- plan early and include patients from the onset (at or before proposal preparation stage);
- use good practices from ongoing projects to engage patients; for example ensure structured approach for efficient input, exchanges and feedback;
- plan for concrete support to patient engagement and mediation role;
- ensure management of potential conflict of interest in a transparent, realistic, proportionate and adaptive way.

Another important point was the discussion around different levels of patient involvement at IMI. A lot has been achieved in terms of the participation of patients in IMI projects and on-going research on methodologies for patient engagement at various stages of medicines development. However, a couple important gaps were identified. Namely; patient input into IMI governance as well as lack of efforts to coordinate, share and align best practices and collaboration both within the IMI programme and with other initiatives. To this end it was recommended that IMI puts in place an advisory committee which would be primarily composed of patients but possibly also included other relevant stakeholders. This body would provide a patient view on the overall strategy, input into IMI's research priorities, consultation of call topics, etc. In addition it might be appropriate to also create a public private advisory or steering group that would work on patient engagement coordination activities and facilitation.

Lastly, ideas on future topics for IMI projects were put forward including:

- Development of an infrastructure/solution for the European/international landscape to operationalise patient engagement.
- Training on the content and processes of medicines development (building on EUPATI) including patient groups not previously covered (pediatrics, geriatric and elderly).
- Addressing gaps of patient centricity to achieve alignment amongst stakeholders on the nature and value of patient engagement at different points of the medicines lifecycle and its implementation. This would include development of standard processes, collecting comprehensive information and guidance.
- Development of evidence based metrics of patient engagement, testing at scale and validation of engagement practices, reflecting continued learnings.
- Addressing real and perceived conflicts of interest (in internal compliance rules, in regulation, in legislation).

- Improving health literacy of the general public.
- Research on the societal impact of innovative medicines on healthcare systems.
- Effective process for patient engagement in outcomes research, use of big data in the medicines pathways, patient access and healthcare systems ability to pick up medicines innovation (access).
- Piloting a global solution, co-funding patient involvement in ICH, partnerships with countries, patient group involvement.
- Sustainability of developed tools, resources and skills to ensure continuity and progress.