Patient Perspectives (enhancing patient voice) in the Medicines Life Cycle

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20.12.2016 • IMI webinar

Opportunities and challenges

- Many initiatives focus on patient perspectives in medicines lifecycle.
- Progress, however, remains too slow and engagement inconsistent :
  - No clear alignment amongst stakeholders on the nature and value of patient engagement at different points of the medicines lifecycle.
  - Lack of broadly accepted tools, processes, guidance and capabilities amongst stakeholders, result in the use of anecdotal and/or fragmented information.
  - Perceived or real differences in conflict of interest rules amongst stakeholders block progress

Objectives of the full project

Effective integration of patient perspectives - in qualitative and quantitative terms - in the medicines lifecycle*

- **Further alignment of stakeholders** on the nature and value of patient engagement at different points during the medicines lifecycle
- **Provide a blueprint and tools (including capability)** that will ensure and enhance patient engagement in the decision making process
- **Develop rules of engagement** to ensure each stakeholder's perspective is considered

** from discovery to patient access and beyond for medicines, vaccines, diagnostics, etc.*

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Expected impact

- More meaningful, systematic and effective patient engagement in medicines life cycle

- Involvement of those under-represented today or who may not normally participate in critical decision-making, including patients not affiliated to patient groups or vulnerable populations such as children, elderly or minorities, etc.

- Improved and more sustainable innovation and meaningful outcomes for all stakeholders

Deliverables – important remarks

- The intent of the project is to accelerate and upscale patient engagement in an effective and applied manner taking into account current experience (not to “bureaucratise” it)

- The project design is pragmatic and will build on tools and methods that will be available at the time of start and fill in gaps where needed.

- The call topic text is not proscriptive: The applicants will identify the main gaps from their perspective and propose solutions to address them.

Deliverables - other considerations

- Applicant consortia are invited to select a maximum of 3 stages in or aspects of the lifecycle, so as to allow for focus and depth – with as a result generalised approach which can serve medicine development in a variety of disease-areas

- The call topic text lists deliverables that address gaps identified by industry and those suggested in the public consultations. It does not exclude other deliverables and does not impose how these shall be achieved.

Key deliverables of the full project

- **Blueprint** for inclusion of patient perspectives **aligned across key stakeholders** (who, when, what, how) for specific lifecycle stages
- **A set of metrics** (quantitative & qualitative) to evaluate the impact of patient engagement practices
- **Application of blueprint criteria and metrics to existing frameworks and tools**, to identify good patient engagement practices
- **Recommendations on capabilities and rules of engagement** for both researchers/sponsors (industry and academia; i.e. those generating the data) and patients
- **Communication of above outputs** (via plan with milestones, and execution thereof) to all stakeholders groups in a transparent and timely manner
- **Sustainability**: keep the project deliverables up-to-date over time

The need for public-private collaboration

- There should be no discussion about patient involvement without patients.
- Interaction between patients and industry requires a formal and neutral framework to ensure maximum transparency and buy-in by all stakeholders while avoiding conflicts of interest.
- Patient engagement is relevant at all stages of a medicines' lifecycle and has an impact on all processes that deliver data for and via authorities.
- Academic and industry research and healthcare delivery are closely interconnected and thus needs similar tools, processes and guidance to engage with patients. This requires alignment of and input from all those stakeholders.
- Current and new patient engagement processes should require selection criteria that all stakeholders support, as well as independent scientific evaluation and value evaluation by patients.

Pre-competitive nature

- The project is fully pre-competitive and is in principle not intended to generate IP or exclusive rights tools.
- All outputs (tools and methodologies) will be made available in the public domain for all stakeholders.
- For the long-term sustainability, ownership of tools and methodologies by public partners should be considered (e.g. link to European infrastructures, healthcare systems, etc.).

Suggested architecture of the project

- There is **no imposed architecture** – the final architecture will be defined and agreed by the public private consortium.

- The following **should be considered**:
  - Collaboration framework that takes account of industry and public partners expertise and contributions
  - Effective and simple architecture against the proposed deliverables
  - Link to relevant national, European (as well as non-European) initiative, in order to incorporate past achievements, available data and lessons learnt where possible, thus avoiding unnecessary overlap and duplication of efforts

Expected contributions of the applicants (1)

- **Patient/healthcare consumers experience is paramount to the success of the project.** The consortium will have representation from or be able to bring in all types of patient expertise, including from under-represented groups and non-umbrella groups.

- **Academic community** would bring their engagement experience, tools and practices, as well as support development and testing of qualitative and quantitative metrics.

- **Healthcare stakeholders** (regulators, HTA bodies, payers, healthcare professionals etc) will set expectations and bring their experience related to resources and rules of engagement.

Expected contributions of the applicants (2)

- **The consortium is expected to address the following:**
  - a strategy on the translation of the relevant project outputs into regulatory, clinical and healthcare practice
  - a plan for interactions with Regulatory Agencies/health technology assessment bodies with relevant milestones
  - administrative project management

- The size of the consortium shall be **proportionate to the budget available (4,5 mln EUR)** and activities planned

- Resources allocated should be **aligned with the strategy** – including e.g. testing/piloting implementation, outreach and engagement with broader stakeholder community

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Industry (in-kind) contributions

Human resources/expertise

- Chief Medical Officers, Medical Affairs, Scientific Affairs,
- Patient Officers, Patient Groups relations, etc.
- Preclinical and Clinical development
- Outcomes research
- Regulatory, HTA, market access and post-marketing
- Data and Knowledge Management
- Project management
- Communication
- Legal & compliance

Other (including outsourcing)

- Companies R&D processes to test tools and metrics and share experience
- Web-based and social media tools
- Translation services, and other services as appropriate
- Meeting/workshop infrastructures

Industry Consortuim

Leads:

What's in it for you?

- **All**: patient-stakeholder engagement at key decision points throughout the medicines life cycle can drive better innovation and efficiency and quality of processes.
- **Patient representatives**
  - build standard and sustainable capacities for your organization consistent with stakeholder needs and processes
  - clarity on rules of engagement amongst stakeholders
  - greater opportunity for their voice to be heard and engaged
- **Academia and Healthcare systems stakeholders and providers**
  - The consortium provides a ready incubator to share learnings and develop and grow sustainable research approaches and metrics to build on and complement other initiatives in the EU

Questions?

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