Initial outcomes of a consultation on Big Data for Better Outcomes:
a proposal for a new programme in IMI2

About this paper

In May 2015, as part of preparations for an IMI2 programme on Big Data for Better Outcomes, EFPIA (the European Federation of Pharmaceutical Industries and Associations) and IMI (the Innovative Medicines Initiative) launched a consultation on a concept paper on the subject.

Stakeholders were invited to provide feedback in writing or in person at a dedicated session at the IMI Stakeholder Forum in Brussels on 15 June.

This paper summarises the comments received and sets out EFPIA's initial response to them.
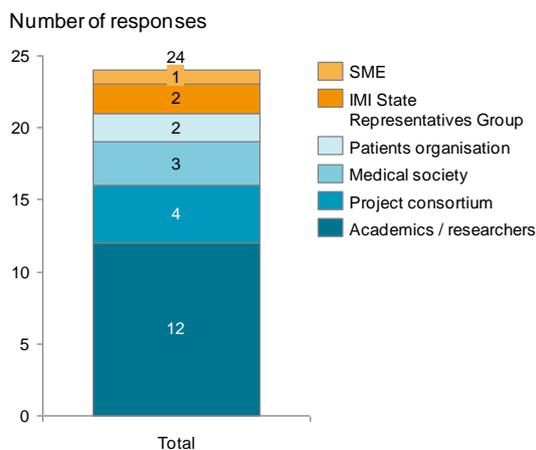
About the consultation

The initial consultation paper is available online. Specifically, stakeholders were asked to assess:

- Are the objectives and scope relevant and clear?
- What therapeutic areas (or types of products) would benefit most from such an approach?
- What questions related to measuring health outcomes would benefit most from a multi-stakeholder collaboration in IMI?
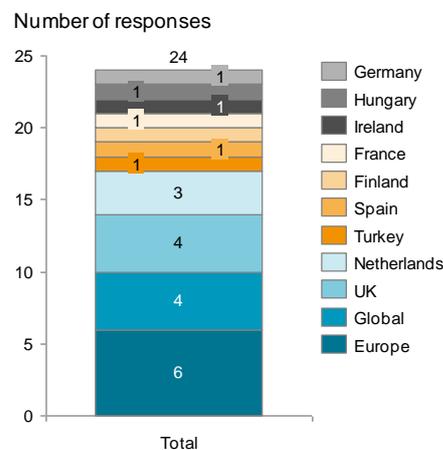- Whose participation and what contribution would be key for success?

Who took part in the consultation?

Around 100 people attended the **Stakeholder Forum session**, which can be watched on IMI's YouTube Channel. In total, 24 **written responses** were sent in by e-mail; the graphs below give the breakdown of the sources of this feedback by stakeholder type and country/region.

Feedback received by type of stakeholder

Number of responses

Value	Category
1	SME
2	IMI State Representatives Group
2	Patients organisation
3	Medical society
4	Project consortium
12	Academics / researchers

Total

Feedback received by geography

Number of responses

Value	Category
1	Germany
1	Hungary
1	Ireland
1	France
	Finland
1	Spain
1	Turkey
3	Netherlands
4	UK
4	Global
6	Europe

Total

The most frequent questions and suggestions, and EFPIA's response to them, are summarised below:

Scope and objectives of this **public-health driven programme** have been considered **relevant and clear** and many organizations have shown **interest to join** current or future proposals within the programme.

→ Consultation pointed at multiple aspects already reflected in the proposals, such as public-health focus, the need to address **multiple healthcare solutions** and the 4 key **enablers**, and **collaboration** with ongoing initiatives that address outcomes definition and measurement.

Multiple therapeutic areas have been suggested, including cardiovascular diseases, oncology, rare diseases, multiple sclerosis, dementias and age-related cognitive disorders, human infertility, medication during pregnancy, respiratory diseases, spinal cord injury, stroke, and infectious diseases. An approach addressing chronic disease in the elderly, including comorbidites, vs. specific diseases has also been proposed. **Personalized care**, including upcoming **innovative treatments**, should be considered for those diseases.

→ Interest on these areas will be shared with EFPIA members and partners in research so that it is considered for additional projects. Any disease area or patient population which is considered relevant can be proposed as a topic within the programme.

→ Projects will cover different types of products across the care delivery value chain, including prevention, screening, therapy, etc.

→**Diseases with high economic burden** are being addressed: e.g. Alzheimer's disease, cardiovascular diseases, cancer.

Need for sustainability of the programme results has been highlighted, not only in terms of the governance framework for data access but also of results such as the implementation and measurement of defined sets of relevant outcomes per disease.

→ As recommended, the programme infrastructure will be **rooted in existing infrastructure** and **build on other data projects** such as EMIF, EHR4CR or ETRIKS as well as disease-specific projects to work on a common governance framework for sustainable data sharing in Europe.

→ **Data companies** are being actively reached out to collaborate with EFPIA members as part of the industry consortium on the projects - all companies interested.

Projects within the programme should address challenges in **data privacy, data interoperability and comparability**, including differences in data capture and data quality. **Coordination and training** on data capture, access and use has been mentioned as relevant to address these challenges and enable achieving better health outcomes through big data.

→ **Data privacy** is addressed in a number of initiatives with which the programme shall connect (e.g. through the Coordination and Support Action).

→ **Data quality** will be one of the key drivers considered in all projects both during mapping of existing sources and for generation of new data.

→ **Data interoperability**, **data ownership** challenges, and development of **new capabilities/skills** are planned to be addressed in a dedicated research programme on Distributed Data Network.

There is also consensus on the relevance of **active involvement of patients** and following a **patient-centric approach**, including holistic and personalised management of patient health, analysis of patient pathways, the use of wearables and digital health to improve care, etc.

→ **Patients** are key stakeholders in the programme and expected to be **active partners** in the **shaping of all projects** in order to **reflect their needs** and in the projects **execution**. Relevance of their participation will be made explicit in the call text for all projects and particular attention will be paid to

promoting the calls within this stakeholders group. We count on everyone receiving communications on the programme to translate the information to the right stakeholders.

Multiple partners, beyond patients and patient organizations, should be involved for the programme to be successful: healthcare providers, physicians, regulatory bodies, HTAs, payers, academia, scientific groups, registries, organizations with access to long-term follow-up data in real-life situations, experts in managing governance and patient rights, data and bioinformatics ethicists, experts in data analysis (clinical, epidemiological, health economic), key opinion leaders, data collection software companies, etc.

→ The need for collaboration of multiple partners will be addressed explicitly in the call text for each project.

Finally, a **central coordination function** should ensure consistency in definition of outcomes across therapeutic areas, provide methodology support, share learnings across projects and ensure consistency and high quality of resulting outcomes sets.

→ This will be the role of the **Coordination and Support Action**.

Next steps

EFPIA, in collaboration with IMI, will continue to develop the programme in the coming months. The first topics under this new programme will come under **new IMI Calls for proposals** scheduled for launch in **autumn 2015**.

To get the **latest information** on the launch of new topics under the programme:

- Visit the **Future Topics page** of the IMI website
- Follow IMI on Twitter: **@IMI_JU**

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