

IMI2 JU Scientific Committee recommendations regarding public private partnership funding – what makes a topic ultimately suitable for this kind of funding model?

Getting the balance right between public and commercial interests in the IMI public-private funding scheme has been a topic of discussion within the IMI2 JU Scientific Committee, the IMI2 JU Programme Office, the European Commission and other institutions for some time. If there is no potential for commercial benefit, then for-profit organisations are unlikely to want to contribute. Likewise, for the benefit of citizens and for the optimal use of taxpayers' money to be spent in this funding structure there needs to be an obvious public health benefit of the supported research projects and programmes.

Arguably, whilst the potential for commercial benefit is accepted as a prerequisite for funding, precisely because of this prerequisite, the public health benefit needs to be at least as obvious in a public-private partnership (PPP) funding scheme as in non-commercial funding. Additionally, it needs to be clear why public funding is required and why for example a private-private partnership would be less desirable, why carrying out the research by one company alone would not happen, and why the involvement of academia is crucial. This approach is aligned with the European Partnerships criteria identified under Horizon Europe.

It is recommended therefore that the rationale for choosing the topic for a PPP is clearly articulated, justified, and the rationale detailed in the preparation phase of the topic selection, development, and in the drafting of the topic descriptions. Specific recommendations for public-private partnership funding are given below:

Recommendation 1: it is recommended that the public health benefit is identified as *at least one* deliverable in the Topic Description and described in the Proposals/Projects as *at least one* Objective, Deliverable and Impact (with sustainability, as required).

Recommendation 2: the Topic Description and the Proposals/Projects need to state clearly

- *why* public funding is required;
- *why* a private funding only is less desirable,
- *why* carrying out the research by one company alone or many companies would not happen without the involvement of other stakeholders (e.g academia, patients organisations, small and medium sized enterprises, regulatory agencies etc.) and
- *why* synergy is expected from industry and other stakeholders joining forces in this particular area of medicines innovation.

Recommendation 3: given that for innovative medicines, regulatory acceptance is foreseen for marketing authorisation, early dialogue with regulators is considered useful. It is therefore recommended that the regulatory interaction is specifically included as a deliverable.

Recommendation 4: it is recommended to develop a mechanism to systematically enable the IMI office to contribute lessons learned to benefit future PPPs to be selected, including topic selection and considerations regarding funding, regulatory, impact, and sustainability aspects, both in preparation of and during IMI projects.

Recommendation 5: in line with the nature of innovative medicine development and to help therefore with enabling a holistic approach, it is recommended to develop structures to open IMI2 JU to include devices, wearables, digital tools, and so on.

Recommendation 6: it is recommended to consider including public health institutions (for example, General Data Protection Regulation, the Environmental Protection Agency) to help raise awareness of the practicalities involved in accommodating the anticipated innovation, clinical practice considerations, and to help ensure the innovation can be accommodated in the various health care settings where they need to be implemented.

Recommendation 7: finally, it could be considered to have a workshop with experts, patient representatives and other stakeholders as relevant before each call topic, to help shaping the scope of the topic proposals to help enhance public health impact.

On behalf of the Scientific Committee

Isabelle Bekeredjian-Ding, Chair

Dolores Cahill, Vice Chair