

IMI Scientific Committee Recommendation Sustainability solutions are important criteria determining project quality and output in IMI

Introduction and problem statement

The Innovative Medicines Initiative (IMI) was conceived and created 10 years ago to respond to the urgent needs of improving the drug development process by overcoming existing bottlenecks. It is a unique model for public private partnership (PPP) funding of common research interests in health within the EU. Many important assets have been generated by the projects, ranging from substance libraries and catalogues for drug targets to iPSC repositories from healthy and diseased subjects and methodologies for capturing real world data.

Due to the very broad orientation of the IMI programme, IMI projects differ strongly in their scopes and project organisation and management. Most IMI projects are designed to deliver results that can significantly impact the health system in the EU. If they succeed specific project assets may require sustainability measures that enable the scientific community to build on the results obtained. However, without a strategy to keep these assets available beyond the project timelines continued use and access to the results can be strongly compromised. This challenges the IMI concept of delivering output that permanently improves drug development in the EU. Nevertheless, independently of the project focus and structure, sustainability after project termination is often in question and - possibly due to the nature of the PPP - it seems especially challenging.

There are many reasons for why this problem is hard to tackle: generally, high investments are made, but due to the project-based structure of the IMI programme, the project budgets cannot be topped-up during the project lifetime and funding ends after a defined time period. Furthermore, some assets were not initially foreseen and, thus, sustainability was not planned, while other assets may turn out to have value for some but not all original stakeholders or the stakeholder making use of the asset may even be a third, uninvolved party. Lastly, following the principles of freedom of science and the Horizon 2020 rules it is considered as unacceptable to impose the use of certain infrastructure in a particular project, or to impose certain solutions to expert project participants.

Therefore, seeking sustainability solutions seems a worthwhile undertaking, because sustainability can make the overall high investments in IMI more efficient and effective, and can bring more value for the health care system, which can contribute to broader acceptance of the past investments in society. On this background, the IMI Scientific Committee has decided to examine sustainability requirements in IMI projects and highlight the value of sustainability planning with this document.

Definition of sustainability

Sustainability refers to the maintenance of outputs or deliverables from IMI-funded research programmes beyond the duration of the funding when it is conceived that this would benefit the EU public health and/or industry. Due to the diverse nature of the projects sustainability requirements need to be identified for each project individually. This requires qualified rating of sustainability as well as an oversight mechanism.

Overall, several major project assets can be distinguished that require preservation but different types of sustainability measures such as:

1. Sustainability measures for technical infrastructure*

- Research infrastructure-type services and
- Biorepositories

*A prominent example for a research infrastructure founded in IMI1 is the High Throughput Screening (HTS) screening platform from the European Lead Factory (ELF). It exemplifies that maintenance of technical infrastructures is bound to both equipment and expertise of personnel. Furthermore, accessibility of all types of biorepositories implies that they are preserved in conjunction with the clinical and laboratory data from the associated patient cohorts (see below under 2.). In IMI1 an exemplary biobank was created in the U-BIOPREP project.

2. Sustainability measures requiring digital solutions**

- Digital tools such as software and in silico devices (apps, etc.)
- Databases and data sets
- Education and training materials
- Protocols, guidelines and recommendations

** Examples for illustrating the value of sustainability are the EU-AIMS autism database and the European Medical Information Framework (EMIF) database on Alzheimers' disease cohorts, both created under IMI1. It should be noted that digital sustainability solutions involves data integration and compliance with data protection laws and ethics approval conditions, which requires anticipatory action. Furthermore, digital systems require long-term curation, e.g. in some cases updated content and in all cases maintenance of software applications to guarantee long-term accessibility.

3. Sustainability measures for collaborative networks***

- e.g. clinical or laboratory networks

*** Notably, the unique consortia formed between public and private sectors can have own scientific value and it may sometimes be relevant to continue the collaboration but this needs to be actively pursued by the partners. Furthermore, networks such as clinical trial networks will only be sustainable if they succeed in establishing efficient management and communication plans and if they can look back upon a visible track record with high quality performance. The networks founded under COMBACTE-NET in IMI1 are examples for investments entailing sustainability measures.

Importantly, sustainability requirements need to be distinguished from other difficulties that inhibit or limit the application of project results or developments, i.e. hurdles in regulatory policies or uncertainties in regards to reimbursement of medicinal products or services. If these obstacles are relevant and insuperable, sustainability measures may even be rated as superfluous.

Sustainability rating

Identifying the project-specific sustainability requirements and the time frame required for sustainability is vital and should result from analysis performed by the different experts involved. This includes:

- Call and topic writers from Strategic Governing Groups (SGG) (industry perspective)

- Applicant consortia (academic/SME perspective)
- Evaluation panel and experts serving as reviewers
- IMI office, EFPIA and European Commission staff responsible for approval of call topics and programme implementation

Once the sustainability assets have been defined, the stakeholders who benefit from the assets need to be identified and the assets need to be rated in regards to:

- possible sustainability solutions and type of measures required
- public health relevance and forecasted impact on the EU health system
- benefit for industry and/or other stakeholders

The sustainability measures depend on the expected outcome of the project and should ideally be defined in the topic description and the call text. They might, of course, be subject to change during the project lifetime. If the project or programme is expected to be wound down after the IMI funding term this should be explicitly stated in the proposal.

A roadmap for sustainability should be described for every project by the applicant consortium and must be re-evaluated during the project lifetime. Every deliverable should be analysed in regards to its sustainability value. A separate work package might be foreseen with specific deliverables and milestones pertaining to the sustainability issues. This might facilitate monitoring of progress of the measures taken that enable sustainability of the assets identified as requiring sustainability.

Most importantly, there is a need to take on the responsibility for sustainability after termination of the funding. At the start of project the consortium partners and their legal entities need to accept their share in responsibilities for implementation and continuation of sustainability measures and infrastructures. Thus, the actual stakeholders who benefit from the project output need to be identified early on. If sustainability is sought after by industry partners, the companies involved might need to develop concepts or tools on how to guarantee sustainability of the qualified assets.

Sustainability landscape mapping

Regular evaluation of IMI projects is necessary to account for changes in sustainability requirements during project lifetime. Specific audits should have the scope of identifying:

- (newly arising) project-specific sustainability assets
- possible integration of these assets into preexisting (EU or national) infrastructures
- established commercial and non-profit or not-for-profit organisations that due to their portfolio may be fit to manage long-term sustainability measures

Indeed, when a sustainable asset is identified and becomes a project goal the consortium should perform a landscape mapping to identify already existing infrastructures as well as potential funding opportunities (i.e. research institutes, foundations, public bodies, investors) that could later on be used to leverage sustainability. Support could in particular be provided by European research infrastructures, including those identified in the ESFRI roadmap or in specific cases by the ESFRI Forum itself.

Sustainability funding and resources

For each project sustainability measures and the necessary resources, such as expert personnel, equipment and budget, need to be defined early on, e.g. in the call topic, the proposal and the grant agreement. Sustainability funding could become a *go* or a *no go* criterion from the onset, if sustainability is identified as relevant such as with a new research infrastructure to be developed by the project.

The funding options might need to be diversified depending on the nature of the sustainability measure, and the costs that will become necessary in the future might need to be foreseen early on e.g. the minimum funding required for sustaining the asset of interest. This might include combining public and private funding of different (additional) sources (e.g. regional, national, EU, etc.) or creating new commercial or non-profit organizations by applying cost recovery or fee-for-service models. In the founding phase of such an organization support could also be provided by the European Investment Bank.

Overall, these arguments reflect the need for development and establishment of business models that allow continuity after termination of IMI project funding.

Legal mechanisms affecting sustainability

Depending on the type of sustainability measures required it may be necessary to analyse the legal framework to avoid that legal requirements impede the establishment of a sustainability solution. Ideally, legal hurdles should be identified early on, which would allow to seek for legal solutions in cases where a relevant negative impact is expected but the sustainability value is rated as high. This could, however, imply that specific project goals would need to be adjusted or even that a *no go* decision could be taken at the very start of the project. Furthermore, the IMI2 Governing Board should be aware of its responsibility to justify a *go* decision for a project and/or funding of topic in the absence of an applicable sustainability plan albeit sustainability would actually be needed.

Guidance on the IMI and Horizon 2020 legal framework should be provided to project consortia by the IMI office and the European Commission staff. If general legal obstacles are identified as a hindrance for sustainability measures early implementation of legal changes that enable sustainability measures may represent a solution. However, this emphasises the importance of anticipatory thinking when drafting the legal frameworks for complex research programmes such as IMI, which should include taking possible sustainability and business models into account.

Lastly, in the current framework a legal basis for enforcing realisation of sustainability measures after the termination of the project is inexistent. However, a legal means to justify this demand and its implementation is considered necessary.

Sustainability oversight

Sustainability oversight needs to include the control of sustainability measures started within the duration of the project but also has to extend to the period after official termination of the project. This should also include a sunset clause to wind down the sustainability mechanisms after the indicated time frames. As explained above, this also involves very clear definition of responsibilities for continuation after the funding period. At present it also requires resources at the IMI office or, eventually, a dedicated unit in the relevant European framework programme.

Changes ahead

The Scientific Committee has committed to supporting the development of sustainability concepts that could apply to different categories of IMI project output. It has identified several action items required for the implementation of an IMI-specific sustainability concept.

Recommended Change

- Whenever the final goal of a project is the creation of a research infrastructure or different asset that is intended to be maintained beyond the lifetime of a project, sustainability planning of technical resources, expert personnel and funding should be part of the project design, deliverables and evaluation criteria.
- Where applicable, exchange with regulators and payers should be sought at an early stage. This can avoid uncertainties in the forecasting of the applicability of the business models proposed for continuation of development and subsequent licensing and market access of IMI project assets.
- Offset funding mechanisms should be developed for cases where an asset that was not planned nor considered to possess sustainability value turns out to be worthwhile maintaining during a project (i.e. midterm review).

Requirements for application of sustainability concepts

- **Provision of information and guidance** to topic writers, applicants, reviewers and stakeholders on:
 - identification of sustainability needs and assets
 - drafting of sustainability plans
 - existing sustainability measures and infrastructures
 - support programs from the European Investment Bank
- **Improved templates** for call text, proposals and evaluation with concrete criteria on sustainability assets and sustainability planning
- **Revision of the current IMI legal framework** to:
 - enable/facilitate sustainability, in particular if data integration or funding solutions are at hand but cannot be effectuated for legal reasons
 - provide a legal basis for enforcement of the realisation of sustainability measures after project termination.
- **Commitment to using existing EU and national infrastructures** (wheel and spokes model), with potential participation as main beneficiaries in the project consortia
 - If new technical infrastructures are created there should be an early evaluation of the utility of the envisaged infrastructure as service platform in IMI or EU funded projects
- It is further recommended that the future development of the European research programme (Horizon Europe) conveys the significance of sustainability measures through **establishment of sustainability actions**, next to the well-established `research and innovation` and `coordination and support` actions. This type of action could serve as bridge financing to allow consolidation and/or expansion needed for the newly developed research infrastructures to achieve competitiveness, similarly to the ESFRI infrastructure support programme.
- **Dedicated IMI actions**
 - identification of third party stakeholders that benefit from the assets

- raising awareness of stakeholders through dissemination of results generated in IMI projects and their possible applications
- communication of accessibility of outputs to potential stakeholders
- raising awareness for sustainability requirements in stakeholders who could draw benefit from the assets
- in very restricted cases, dedicated IMI calls could provide the necessary financial support for establishment of long-term sustainability. This type of action needs to be well justified and could be considered when a project result is found to require sustainability, which was not predictable earlier on, and, if, at the same time, continuation means deviation from the initial work plan and top-up funding would be required.

On behalf of the Scientific Committee

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