

WP3 Tools and services

D3.5 First version of guidance on sustainability

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Document history

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Definitions and abbreviations

Partners of the NEURONET Consortium are referred to herein according to the following codes:

1. **SYNAPSE**: Synapse Research Management Partners SL
2. **NICE**: National Institute for Health and Care Excellence
3. **AE**: Alzheimer Europe
4. **JANSSEN**: Janssen Pharmaceutica NV
5. **LILLY**: Eli Lilly and Company Limited
6. **ROCHE**: F. Hoffman – La Roche AG
7. **TAKEDA**: Takeda Development Centre Europe LTD (*terminated partner*)
8. **SARD**: Sanofi-Aventis Recherche & Développement
9. **PUK**: Parkinson's Disease Society of the United Kingdom LBG
10. **TAKEDA AG**: Takeda Pharmaceuticals International AG

Grant Agreement: The agreement signed between the beneficiaries and the IMI JU for the undertaking of the NEURONET project.

Project: The sum of all activities carried out in the framework of the Grant Agreement.

Work plan: Schedule of tasks, deliverables, efforts, dates and responsibilities corresponding to the work to be carried out, as specified in Annex I to the Grant Agreement.

Consortium: The NEURONET Consortium, comprising the above-mentioned legal entities.

Consortium Agreement: Agreement concluded amongst NEURONET participants for the implementation of the Grant Agreement. Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.

IMI: Innovative Medicines Initiative

ND: Neurodegeneration Disorders

WP: Work Package

Publishable summary

NEURONET WP3 Tools and Services will develop specific tools and services to support IMI ND projects on key areas where unmet needs are detected. These will compile state-of-the-art knowledge and best practice across IMI projects and other initiatives worldwide so that projects can be more efficient, save time and resources.

In this report we compile knowledge and information derived from the NEURONET Working Group on Sustainability about the sustainability models used in or applicable to IMI neurodegeneration projects, as well as general lessons learned, as a resource for current and future projects to improve the chances of successful sustainability decisions through the IMI neurodegeneration portfolio.

1 Definition of sustainability and exploitation

Sustainability in the context of NEURONET refers to the maintenance and further development of outputs or deliverables ('assets') from IMI-funded research programmes beyond the duration of the funding when it is conceived that this would benefit one or more stakeholders, e.g. EU citizens, public health agencies, industry, academic researchers, regulatory agencies, etc. 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. It is worth noting that sustainability may not concern all the parts of a project. A project can be considered sustained if all or some of its outcomes (or parts of these) continue to be developed after the end of the funded project duration. Since almost inevitably maintenance and/or development of assets implies a cost, sustainability is often understood as capacity to generate income consistently in the long term by devising products and/or services associated to such assets, that can at least cover the corresponding costs.

Exploitation is associated with the use of the project's results at different levels, both during and after the implementation of the project. Exploitation is very much related to dissemination (which essentially brings visibility to the project) to involve all relevant stakeholders and convince them to adopt or use the main results, products and tools of a project. Exploitation is therefore closely associated with the sustainability of the project after its conclusion, since exploitation activities facilitate that the outputs of the project are used or maintained beyond the funding period. This also ensures the survival of the learnings and work.

2 General considerations

Sustainability is a challenging undertaking for most research projects. In fact, during the preparation of NEURONET's proposal, nine IMI neurodegeneration projects were asked to list the project areas in which they would appreciate support, and sustainability was ranked as a high interest top priority.

Furthermore, issues around sustainability and exploitation of project results have been raised at every meeting of the Scientific Coordination Board (SCB) to date, thus evidencing the need for the support and ideas that NEURONET aims to provide.

A key issue for project survival and sustainability often centers around access to diverse, long-term sources of continued economic funding, especially if the project is not able to generate steady revenues as a consequence of its activities, and considering that current funding mechanisms do not foresee that project budgets can be topped-up during the project lifetime; funding ends after the defined time period of the grant, and only occasionally extensions involving extra resourcing can be applied for.

Sustainability is a complex topic involving a huge variety of considerations. Of special note, different asset types (such as preclinical tools, clinical datasets, etc.) may require completely different viability roadmaps. Each asset type involves different considerations that would need the input of different kinds of experts along the way. This report is thus intended to help delineate those variables and best practices for creating a tailored and actualized sustainability plan.

In the next sections of this report we compile recommendations and best practices for sustainability planning as a resource for current and future IMI projects to improve the chances of successful sustainability decisions. It compiles the output of discussions of the NEURONET Working Group on Sustainability (virtual meetings held on 12-Mar-20, 16-Apr-20 and 18-May-20, where sustainability strategies of the projects EPAD, DPUK, EMIF-AD, EQIPD and AETIONOMY were presented and discussed), and is only intended as a first version of a living document, which will be enriched and refined as NEURONET progresses.

2.1.1 The notion of “value”

Many collaborative projects assume that what they develop has value. This has special relevance in IMI because calls for proposals are defined around industry needs. However, the struggle to make results sustainable proves that this assumption of inherent “value” must be continuously revised, challenged and confirmed. Arguably, the two basic questions that have to be made repeatedly in projects in relation with any potentially sustainable asset or result are: “For whom has this value?” and “Is there anyone willing to pay for the appropriate delivery of such value?” (note that the payer and the recipient of the products/services don’t have to necessarily coincide). Ability to respond to those basic questions and to adapt the project accordingly so that they can be answered is probably key for any sustainability strategy. Importantly, the answer to those and other critical questions evolves with time. Stakeholders that would seem a “natural fit” at some point may change their priorities and no longer be ready to sustain outputs; and, conversely, new opportunities may arise. This is why sustainability assumptions need to be continuously revised.

2.1.2 Internal vs. external emphasis

Collaborative projects are implemented through consortia, typically formed by 5 to 50 different institutions, many of them being responsible for results, totally or partially. Crafting a sustainability plan that is agreeable by all partners in a consortium, and that is compliant with the basic legal and IPR provisions in the Grant and Consortium Agreements is not a trivial task. When faced with this challenge, even if sustainability work is started early on, many projects may be tempted to focus their energy on getting internal alignment. This means that potential external stakeholders may be contacted later in the project lifetime. Sometimes, decisive interactions are only seriously tackled when the project is about to end. This may be reinforced by the simple fact that results are more definite and complete towards the end of the project. However, if the project depends on such external stakeholders for its future sustainability, then it may be wise to start sounding them out as soon as possible, and even let them influence to the extent possible the project’s strategic approach and its evolution.

2.1.3 Sustainability of the project vs. sustainability of assets

Due to their integrated nature, projects may also understand sustainability as a holistic concept that should provide a long-term solution for all of the project components, and with participation of all consortium partners. However, projects are complex constructs, and complexity seldom bodes well with clear value propositions or business models – leaner models may yield better sustainability prospects. Simplification and clarity may be an advantage. Additionally, not all project components or results have the same value or chances to be sustained. Similarly, not all partners are interested or prepared to participate in sustainability activities, especially if it involves risk, and not all partners are actual owners of one or more results. Some partners are typically better positioned to take one specific output further. In that context, trying to come up with a global sustainability plan may prove to be an impossibly daunting task, which can lead to overly complicated schemes and distort the actual sustainability

potential for specific assets. It may be a better strategy to honestly appraise and select the assets with the most potential, and devise a specific sustainability plan for them.

3 Best practices for sustainability planning

3.1 Create an exploitation and sustainability plan

Increasingly, funding agencies request that all projects develop a sustainability strategy and deliver a sustainability plan, often through a specific clause or obligation embedded in the Grant Agreement, thereby becoming a contractual obligation. Although it is hard to anticipate sustainability plans and answering how results will be sustained in the long-term at project inception, sustainability planning of technical resources, expert personnel and funding should be part of the project design (e.g. a separate work package will often be foreseen with specific deliverables and milestones pertaining to sustainability) (Lima and Bekeredjian-Ding, 2018).

The purpose of the exploitation and sustainability roadmap is to create an independent and sustainable plan for the assets and platforms created beyond the scope of the initial project. Additionally, this will help configure a space for intellectual property rights, legal and infrastructure coordination and associated business workflows to enable the continued progress of the project. The sustainability measures will depend on the expected outcome of the project and can sometimes be pre-defined by IMI in the topic description or the call text.

When developing a sustainability plan, the approach can be either top-down or bottom-up. A top-down approach is good to set the direction at a global level and requires agreement at the political level, while a bottom-up approach is usually better to agree on the details (e.g. what are the key variables or requirements in terms of data standards) and obtain engagement, however, there is a risk that the personal and/or professional interests' of those involved might prevail and making decisions can sometimes be chaotic. Each approach has its pros and cons, and it is difficult to ascertain which of the two will yield the best results – it wholly depends on the project, the consortium and the asset(s) in question.

The Exploitation and Sustainability plan is an official document reflecting the vision of project partners of the project results, potential and impact. It complements the dissemination plan and sets the targets, indicators and milestones for ensuring the project results' life after the completion of project. It will also specify the guidelines for exploitation and transfer of project results outside the original project network and duration.

Not all the project results and assets have the same value and therefore may not be equally considered in the project's sustainability plans. Rather than thinking about a project as a whole, the consortium may want to shift the focus and decide to break down its assets and results into smaller parts that can be independently taken forward. One example of this strategy is the five component model developed by EPAD, where each component's plan was independent of the other from a governance and finances perspective. The five components were developed from the key assets of the EPAD project, that were either linked to specific objectives of the project or developed organically (e.g. the "EPADista" community).

The Exploitation and Sustainability plan is not a static document and may evolve over the project cycle. This could be for example due to unexpected scientific results or other changes in the strategic landscape. In this sense, many projects have found that a measurement plan with six

month checkpoints is useful to evaluate the project goals. The plan should re-evaluate the list of outcomes and deliverables from the original project, and redistribution of resources and activities to maximize the ultimate value of the project.

Naturally, the selection of assets worth sustaining is vital and should result from careful analysis. This means that every deliverable should be analysed in regard to its sustainability value. Following with the EPAD example, some components that had been critical for EPAD as a project, such as for example the work on ethical considerations of biomarker disclosure, were in the end not included in the project's sustainability plans.

Another option would be for projects to follow a phased-approach to sustainability, i.e. considering that not all project results will arrive at their maturity state at the same time. Consortia could start devising (and even implementing) sustainability plans for specific project results as soon as these are delivered or become available, so that the 'project' and 'sustainability' activities run in parallel instead of sequentially.

3.2 Create an interdisciplinary sustainability advisory group

It may be convenient to create an interdisciplinary *sustainability advisory group* composed of different profiles who are leaders in various disciplines including industry, academic projects, business development, information technology, clinical, scientific, legal, etc. Having experts from different backgrounds and an appropriate, balanced membership in the group is of paramount importance for the success of the sustainability strategy (Lima and Bekeredjian-Ding, 2018). Consortia often have insufficient legal and business development knowledge (most consortium members are scientists or academics) and this can represent an important challenge for their sustainability strategies.

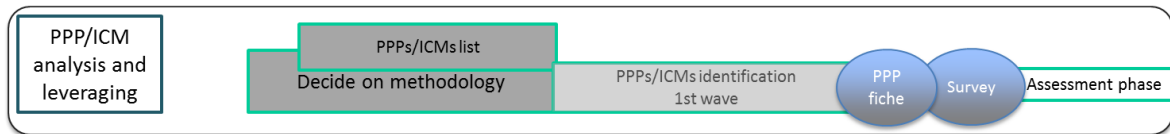
Hiring external advisors may be considered, however, their fees are usually prohibitive. Moreover, to be able to pay for external expert advice, projects should have a dedicated budget for sustainability planning activities, which is often overlooked at the planning stage. The EQIPD team also mentioned that neither IMI nor EFPIA provide by default dedicated sustainability advice to projects, and experts from pharma industry are usually only allowed to advise on matters of interest to their company, so finding resources that offer guidance on sustainability can really be a challenge.

A sustainability advisory group can work closely together with the Executive or Steering Committee and Work Package leads to coordinate oversight of issues pertaining to engagement terms, intellectual property (IP), data use, regulatory strategy, sustainability models and other business matters. If needed, the sustainability advisory group can be expanded into separate Task Forces, each with a specific remit and dedicated membership at crucial times to facilitate progress.

3.3 Identify and assess similar Public-Private Partnerships (PPPs)

A study of PPPs entails a careful analysis of existing models and other relevant innovative collaboration models (ICMs) that operate in the healthcare space and are relevant to the project. This involves the study of joint ownership, organizational models, codes of conduct, policies and workflows that can be leveraged. Special attention must be devoted to sister initiatives that can represent useful paradigms and potentially opportunities for a partnership (e.g. identify already existing infrastructures, funding opportunities, etc.). In addition to such companion initiatives, the study can also examine other life sciences models focusing on open innovation and include a critical assessment of their benefits and limitations.

Please see below a diagram that shows a potential template for executing this process:



A detailed review of many different PPPs and their key characteristics can serve both as examples and also as a benchmarking analysis that may provide insight into a business and sustainability plan.

Example: *EPAD D7.2 Analysis of existing public private partnerships.*

3.4 Analyse your stakeholders

Once the sustainability assets have been defined, the stakeholders who benefit from the assets need to be identified (Lima and Bekeredjian-Ding, 2018). As a cornerstone of further business planning work, a stakeholder analysis employs feedback from work package leads and also identify other relevant stakeholder groups affecting (and affected by) sustainability, and profile them according to the key business variables and workflows foreseen.

Of special relevance, the stakeholder analysis may focus on understanding the needs and interests of subjects as stakeholders and will dovetail with efforts undertaken in the framework of e.g. dissemination and ethics. The stakeholder analysis can employ regular interaction with all stakeholder groups, enabling initial mapping out of their interests and incentives. Additionally, this task may employ the learnings derived from PPP benchmarking, and can help identify key challenges among the groups for consensus in sustainability planning.

Examples: *EPAD D7.3 Stakeholder analysis.*

3.5 Develop value propositions

In order to maintain and attract diverse revenue sources for continued funding of promising assets, it is critical to develop the key value propositions. This may include an analysis of a social or economic problem that the project is addressing in a specific healthcare area.

Suggested components include:

- Statement of project mission/goal
- Problem statement for project
- Project solution to specified problem
- Required budget for sustainability
- Financial impact including cost/benefit analysis
- Business development outreach plan
- Communication strategy including a marketing campaign for profile enhancement during project

When developing value propositions, it is important to keep in mind that what potential funders might see as the true value of a project deliverable or asset might be different from what the consortium initially thought or planned (internal consensus vs. external buy-in). Different stakeholders can have different perspectives on what brings value, and this is very relevant for IMI projects, which are always formed by extended complex consortia with multiple, sometimes maybe even opposing, views and interests (Aartsen et al., 2018; Lima and Bekeredjian-Ding,

2018). Some 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. EPAD for example implemented an excellent, very involved process in order to get internal consensus, however the preferences of external stakeholders were only discovered later on to lack alignment with the results produced. The Quality Management System developed by EQIPD gained interest from potential funders yet they required a PoC to demonstrate its utility, which had not been conducted.

The development of a stakeholder engagement plan when building the consortium (e.g. through regular interaction, or by creating advisory boards), with adequate monitoring against sustainability scenarios may preserve stakeholder alignment. A continuing sounding out of potential funders and/or customers could be a must in order to successfully implement any sustainability strategy. In general, the more niched a project is, the more difficult will it be to repurpose its results or make them attractive to a range of potential funders.

Once value propositions are complete, the sustainability advisory group may want to begin outreach to potential funding parties with the support of the project leadership.

Examples: [EPAD value proposition presentation.](#)

3.6 Create a data sustainability process

A significant aspect of the value created in IMI projects is the data that is generated through collection, experimentation and other novel methods among the consortium members. During the project period, data can often be stored within the participating organizations. However, after the IMI funding period, there is an opportunity for it to get disconnected and lost unless specific plans for the custody and preservation for the data are created and embedded in the project strategy.

Examples of data storage, management and preservation are discussed below.

- **EPAD** utilizes an outside vendor Aridhia Informatics, Ltd. to store and centralize the data for the Longitudinal Cohort Study. Additionally, this data has been made available to the public for research purposes through a portal (WizeHive) that allows submission of requests for data access on the basis of research proposals, evaluation of such proposals, approval and streamlining of access.
- **EQIPD** will most likely utilize a University of Edinburgh-based database with a link to the CAMARADES database at no additional cost.
- **EMIF** has built an integrated, efficient Information framework for consistent re-use and exploitation of available patient-level data to support novel research. The catalogue is available for public use through Bioinformatics, UA.
- **AETIONOMY** provides data sustainability through the knowledge base transfer to the ELIXIR-LU node. Data access needs approval by the AETIONOMY Data Access Committee. Maintenance of the database is provided by a consortium partner.

3.7 Work on your sustainability model and business plan

The final step in sustainability planning can be led by an appointed task force and is to create a detailed business plan and model that will serve as a flexible template for the sustainability of selected assets. This is a culmination of all the preparatory steps described above. The creation of the model is an iterative process, and will, of course, be subject to change during the project lifetime (Aartsen et al., 2018; Lima and Bekerredjian-Ding, 2018). It may include drafting,

interviews and feedback from the Executive/Steering Committee and corresponding results owners and/or Work Package leads. The sustainability advisory group or sustainability work package is typically a convening and organizing support resource for the consortium, not a decision making one. Some of the key components of the plan are discussed below:

Mission statement. A summary of the aligned goals and objectives of the project, and how this relates to the asset. At this point, the original project goals may change towards the sustainability phase. It will be important to clearly state how the project is evolving, and how it is still aligned with the mission.

Value proposition. Restatement of the value proposition and problem statement that the asset addresses in healthcare/life sciences. It is critical that this be in alignment with the mission.

Project solution. As the project moves from sustainability planning to building, the project solution will likely evolve to better address the problem than during the planning phase. A summary of how the asset addresses a specific problem, as well as a plan to continue to address the ongoing issue are an important part of this section.

Operational structure. During the IMI project phase, projects establish many procedures for decision making and workflows. These often include an executive committee and a council derived from work package leadership. During the post IMI funding phase, the organizational structure may evolve to dissolve work packages and change the form of leadership. This section thus describes the plan for governance, decision-making and workflows for efficient continuation of the specific asset, potentially (but not necessarily) including creation of a new entity which may be a consortium, for-profit organization or other institution. Note that each asset may require a completely different form of organisation to efficiently exploit it. It is recommended that this section be reviewed with all of the relevant institutional leadership to ensure alignment with future activities.

Legal structure. Following the IMI funding phase, legal activities such as contract negotiation, IP filings and patent protection will need to be conducted. This will be in harmony with the operational structure, but roles and responsibilities may need to be specifically highlighted for the protection of value in the sustainability period.

Budget. The budget outlines the financial needs for sustainability of the asset in the post IMI period. Given the complexity of this task, it often involves an advisory committee and/or financial task force. These groups may conduct a comprehensive process to develop a cost proposal utilizing financial experts from industry partners and input from across work package leadership. This section of the business plan summarizes the budgeting process and details additional items that need to be analyzed for infrastructure maintenance.

Data/IT. Where relevant, it will be critical to define the steps around data handling and stewardship and come to agreement with the key stakeholders in the consortium. Aspects such as FAIRness of data (findability, accessibility, interoperability and re-usability) might be critical for the asset's future. Alternatives in terms of operational infrastructure and how this affects the delivery of value need to be carefully analysed.

Business development. Business development planning for revenue is often an important part of the project from the beginning. It is important to develop a strong relationship network to

achieve financial stability and mission awareness. The core aspects of an active business development discipline include:

- Biopharmaceutical industry engagement (with focus on active players involved in the project)
- Alliances with sister initiatives
- Possible integration of assets into pre-existing (EU or national) infrastructures
- Relevant grant opportunities sourced from national leadership
- Fundraising initiatives

Fundraising Initiatives. To build and de-risk the project, building an endowment through targeted fundraising is often the foundation of the long-term business development strategy. Target organizations can include nonprofit groups, philanthropies and for-profit institutions. Mechanisms for funding may include straight donations, capital investment, grants or hybrid schemes. Over time, project governance may probably need to review requirements of potential investors alongside the established project foundation.

Risks and challenges. A successful project will be able to identify its risks, challenges and competitive landscape. This section of the business plan may attempt to identify the key factors that may hinder the progress and mission achievement of the project in the post IMI phase. This is not meant to be a comprehensive analysis. Instead, it is meant to highlight the variables that should be evaluated with each strategic review cycle.

Examples: [EPAD D7.6 Business Plan.](#)

[EMIF D15.7 Final Business plan.](#)

4 Virtual Incubator for IMI Projects (VIP)

As previously mentioned, IMI and other funding agencies are increasingly requesting consortia to plan and advance sustainability activities as much as possible during the project life, however, by definition, the vast majority of projects are research and development activities, for which risk and uncertainty are inherent characteristics. In this context, an innovative idea proposed by NEURONET to be considered in the future development of the European research programme (Horizon Europe) is the creation of a Virtual Incubator for IMI Projects (VIP) to help projects bridge the gap towards sustainability in a consistent manner. A similar idea had been previously discussed by Aartsen et al. in 2018, while other authors recommended establishing sustainability actions, next to the well-established ‘research and innovation’ and ‘coordination and support’ actions in IMI (Lima and Bekeredjian-Ding, 2018). H2020 includes a quite comprehensive programme for new business and start-up support (e.g. EIC), however these are generic in nature and lack adaptation to the particular characteristics of the IMI projects and, especially, the neurodegeneration portfolio. The existence of such incubator could be a perfect complement to the current sustainability plans developed by each project, which could go beyond the mere ‘declaration of intentions’ to actually serve for an initial appraisal. Admittedly, not all projects should be able to benefit from the incubator, and some assessment and filtering may be necessary to be able to focus incubator resources where the potential benefit is highest. For further details about the Virtual Incubator for IMI Projects please refer to NEURONET deliverable D1.2. *Integrated programme analysis.*

5 Conclusion

This first NEURONET deliverable on lessons for sustainability planning is meant to just be a first broad compilation of experiences acquired from past experience and discussed through the corresponding Working Group, where a few projects have been presented so far, typically those that have finished or are close to completion already. It is not intended to provide a full, comprehensive view on all aspects related to sustainability of IMI ND projects.

According to the lessons learned so far, sustainability planning has three major components listed in the diagram below with corresponding activities.

Planning	Building	Implementing
<ul style="list-style-type: none"> • Draft exploitation and sustainability draft plan • Form interdisciplinary sustainability advisory group • Identify and assess similar PPPs • Analyse stakeholders 	<ul style="list-style-type: none"> • Develop value propositions for selected assets and priority stakeholders • Business development plan • Explore fundraising initiatives • Draft business and sustainability plan for selected assets 	<ul style="list-style-type: none"> • Implement findings from business plan • Create new organizational, governance, IP, legal workflows necessary to deliver value associated to selected assets • Iterate and review

Deliverable D3.10 *Final version of guidance on sustainability*, to be submitted in month 30, will expand on all those aspects to serve as inspiring document for current and new projects, including additional, practical insights, examples and tools that can be leveraged.

6 References

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