

## **IMI2 821513 – NEURONET**

Efficiently Networking European Neurodegeneration Research

## **WP3 Tools and Services**

# D3.10 Final version of sustainability guidance

Lead contributor	Carlos Díaz (01-SYNAPSE)
Other contributors	Nina Coll (01-SYNAPSE)
	Lewis Killin (01-SYNAPSE)
	Aneleen Stinckens (04-Janssen)
	Lennert Steukers (04-Janssen)
	Paul Peeters (04-Janssen)
	John Gallacher (U. of Oxford)
	Martin Hofmann-Apitius (Fraunhofer)
	Frank Tennigkeit (UCB)
	Lisa Leenhouts-Martin (The Forward Group)
	Nicolas Creff (EFPIA)

## **Document History**

Version	Date	Description
V0.1	16/05/22	First draft
V0.2	22/08/22	Comments
V1.0	10/11/2022	Final draft











# Contents

D	efin	ition	ıs anı	d abbreviations	. 3		
Αl	ostr	act.			. 4		
1	I	ntro	duct	ion	. 4		
	1.1	•	Gen	eral considerations	. 5		
	1	1.1.1	=	The notion of "value"	. 5		
	1	1.1.2	<u>.</u>	Internal vs. external emphasis	. 5		
	1	1.1.3	;	Sustainability of the project vs. sustainability of assets	. 6		
	1	1.1.4	ļ	Project mindset vs. start-up mindset	. 6		
	1	1.1.5	;	Business planning knowledge	. 6		
	1	1.1.6	<b>;</b>	Communication	. 6		
2	E	Best	prac	tices for sustainability planning	. 7		
	2.1	•	Crea	te an exploitation and sustainability plan	. 7		
	2.2		Crea	ite an interdisciplinary sustainability advisory group	. 8		
	2.3		Iden	tify and assess similar Public-Private Partnerships (PPPs)	. 9		
	2.4		Anal	yse your stakeholders	. 9		
	2.5	,	Deve	elop value propositions	. 9		
	2.6	•	Crea	ite a data sustainability process	10		
	2.7	,	Wor	k on your sustainability model and business plan	11		
	2	2.7.1	-	Mission statement	11		
	2	2.7.2	<u>.</u>	Value proposition.	11		
	2	2.7.3	3	Project solution.	11		
	2	2.7.4	ļ	Operational structure	11		
	2	2.7.5	;	Legal structure.	11		
	2	2.7.6	<b>;</b>	Budget	11		
	2	2.7.7	,	Data/IT	12		
	2	2.7.8	3	Business development.	12		
	2	2.7.9	)	Fundraising Initiatives.	12		
	2	2.7.1	.0	Risks and challenges.	12		
3	١	√irtu	al In	cubator for IMI Projects (VIP)	13		
4	(	Conclusion					
5	F	Refe	rence	es	15		









## 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**: Neurodegenerative Disorders

WP: Work Package

SCB: Scientific Coordination Board











## **Abstract**

NEURONET WP3 Tools and Services will develop specific tools and services to support IMI ND projects on key areas where unmet needs are detected, such as sustainability planning.

The Sustainability WG looks at exploitation activities and sustainability models (spanning business design, modelling, financial estimates, IP issues, organisational models, legal solutions, etc.) that can help projects with long-term sustainability.

In this report we will include the best practices and lessons learnt in terms of sustainability, as well as some additional resources and ideas that can be very useful for IMI neurodegeneration projects to improve the chances of successful sustainability decisions.

## 1 Introduction

The IMI project portfolio represents an unprecedented wealth of public-private partnerships carrying out research and development activities on biomedical sciences, with -great potential impact on patients, industry, health professionals, governmental agencies, and many other stakeholders. Anchored on industry needs, and therefore extremely pragmatic in nature, IMI projects typically take 1 to 2 years to conceive and design, and 3 to 6 years to implement. More than 100 projects have been funded under both IMI-1 and IMI-2 programmes to date, with hundreds of institutions and thousands of researchers involved, both in the EU and beyond, representing a large variety of stakeholder groups.

Despite this -great success in terms of research collaboration and innovation across multiple stakeholders, the ultimate impact of most IMI projects on society depends on the capacity of each project Consortium to guarantee uptake of its results and ensure continuity of the necessary activities to fully leverage the value of its assets. These, generically labelled as "sustainability" activities, are challenging for several reasons, including, among many other factors:

- Consortia are not legal entities themselves (and must therefore respect autonomy of their participants).
- Sustainability activities after the project period do not fall under the Grant Agreement
  and therefore require a *de novo* commitment from interested parties beyond the
  original commitment, subject however to ownership, access rights and other legal
  conditions imposed by the Grant Agreement and that survive the project phase.
- The long period (typically 7 years) between conception and conclusion of implementation, which sometimes occurs alongside quite radical changes in the scientific, business and institutional contexts.
- A lack of incentive for consortia to objectively appraise the true value of their generated assets.
- Misalignment within institutions between the principal investigators and decisionmakers in terms of long-term commitment.
- A general lack of knowledge and experience within consortia about business planning, assessment and set up, which hampers an appropriate analysis of value of assets and of the ways in which these could be sustained and expanded.
- Excessive focus on intra-Consortium reflection and consensus, but not necessarily on buy-in or uptake by external potential funders or customers.
- Timeliness is key to benefit from **windows of opportunity**. This may require initiating sustainable operations of certain assets well before the end of the project phase.











As a consequence, 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 centres 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 variety of considerations, as mentioned above. 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.

## 1.1 General considerations

## 1.1.1 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, hence "value-by-design" is often assumed. 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.

#### 1.1.2 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 simply due to the management of time and resource. Sometimes, decisive interactions with external stakeholders











that are expected to provide key revenue 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 that it is possible) the project's strategic approach and its evolution.

#### 1.1.3 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 might be 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. This sometimes can be approached from the perspective of defining a "minimum viable product" or a "minimum sellable product".

#### 1.1.4 Project mindset vs. start-up mindset

Moving away from the traditional and sometimes restrictive - 'project mindset' to approaching the development of a project proposal and then its implementation with a 'start-up mindset' could contribute to achieving a more successful sustainability strategy with faster deliverables and, perhaps, lasting impact of the projects' innovation. The start-up mindset is by definition more flexible and agile, and it involves the development of value propositions, the continuous research of opportunities (including funding) and being highly adaptable to the needs and challenges of a constantly evolving field. The idea of running a project like a business is also discussed in episode #5 of the Voice of EHDEN podcast, focused on the sustainability of the EHDEN mission <sup>1</sup>.

#### 1.1.5 Business planning knowledge

Sustainability planning and implementation requires knowledge on business planning, and it cannot be assumed that this skillset is present in scientific teams. Therefore, including partners with valuable business skills and entrepreneurial motivations is highly recommended to avoid important gaps in the areas of expertise of the consortium. This would facilitate the mutual and fair exchange of benefits between academics and the private sector.

#### 1.1.6 Communication

Another aspect to be considered is communication. Open communication across stakeholders and actors involved in projects is crucial for managing expectations, for better alignment and for transparency. This will affect not only the scientific output of the project but also its sustainability.

For example, sometimes conversations between partners or stakeholder groups lack definition and may not be completely open. The can happen in particular within the pre-competitive space,











where conversations are, usually by necessity, guarded or lacking complete detail, which can hinder collaboration and innovation. In this regard, the Pistoia Alliance <sup>2</sup> was mentioned within the WG as a resource to drive collaboration and empower organizations to work together by providing a legal framework to enable straightforward and secure pre-competitive collaboration.

Lastly, fluid communication between IMI research projects would also enable the exchange of learnings and experiences, and hopefully avoid the repetition that results from working in isolation (suppression of silos).

# 2 Best practices for sustainability planning

## 2.1 Create an exploitation and sustainability plan

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.

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).<sup>3</sup>

The purpose of the exploitation and sustainability roadmap is to create an independent and sustainable plan for the project assets and platforms 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/IHI 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 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) involved

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 (www.ep-ad.org), where each component's sustainability 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 should 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, as their value was essentially deemed to be circumscribed to the project context.

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.

## 2.2 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 (especially if they are external to the Consortium, to maximise objectivity) from different backgrounds and an appropriate, balanced membership in the group is of paramount importance for the success of the sustainability strategy<sup>3</sup>. As already mentioned, and from experience, consortia often have insufficient legal and business development 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 o 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.











## 2.3 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.

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: <u>EPAD D7.2 Analysis of existing public private partnerships.</u>

Example: NEURONET D1.6 Map of relevant initiatives and gap analysis v2

## 2.4 Analyse your stakeholders

Once the sustainability assets have been defined, the stakeholders who benefit from the assets need to be identified <sup>3</sup>. As a cornerstone of further business planning work, such a stakeholder analysis can benefit from the substantial collective knowledge existing in any consortium through its members. The analysis should not only identify relevant stakeholder groups affecting (and affected by) sustainability, but also 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.

## 2.5 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, key benefits
- 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 <sup>3, 4</sup>. Some assets may have value for some but not all original stakeholders, or the stakeholder making use of the asset may even be a third, uninvolved party (e.g., a group outside of the consortia). EPAD, for example, implemented a process - to achieve internal consensus, however the preferences of external stakeholders were later discover to be lacking alignment with internally agreed measures. 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, stakeholders or customers could be a must in order to successfully implement any sustainability strategy. In general, the more -niche 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 to outreach to potential funding parties with the support of the project leadership.

Examples: <u>EPAD value proposition presentation.</u>

## 2.6 Create a data sustainability process

A significant aspect of the value created in IMI projects is the data that are 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.
- ROADMAP uses the Dementias Platform UK Data Portal for managing access and analysis of >50 research cohort datasets.
- **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.











## 2.7 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 <sup>3, 4</sup>. 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, organizing, and supporting resource for the consortium, not a decision making one. Some of the key components of the plan are discussed below:

#### 2.7.1 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.

## 2.7.2 Value proposition.

Here, it is important to outline a value proposition and problem statement, which explains what the asset addresses in the field of healthcare/life sciences. It is critical that this be in alignment with the mission.

#### 2.7.3 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.

#### 2.7.4 Operational structure.

During the IMI project phase, decision-making and workflow processes are put in place. 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 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.

#### 2.7.5 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.

#### 2.7.6 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 analysed for infrastructure maintenance. The experience gained during the project can inform the cost structure and estimates to provide a sound basis (although of course projects typically run at cost, and in the sustainability phase commercial rates can apply). Typically, revenue estimates are more shaky, however these should be grounded as much as possible on stakeholder analysis.

#### 2.7.7 Data/IT.

Where relevant, it will be critical to define the steps around data handling and stewardship (e.g., GDPR) 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.

#### 2.7.8 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 may 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 international and/or national leadership
- Fundraising initiatives

#### 2.7.9 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 non-profit 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.

## 2.7.10 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 influence, positively or negatively, 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: <u>EPAD D7.6 Business Plan.</u>

EMIF D15.7 Final Business plan.

Additional guidance on sustainability planning and implementation can be found in the *Field Manual on Scaling Innovations emerging from Public-Private Partnerships* <sup>5</sup>, a guidance tool sponsored by EFPIA, and endorsed by both EFPIA and IMI.











# 3 Virtual Incubator for IMI Projects (VIP)

As explained throughout this deliverable, most consortia struggle to come up with credible plans for sustainability, and the most practical solutions tend to recurrently fall into two basic options: instigate a follow-up, publicly funded project, or have consortium industry partners fund directly any follow-up activities. Both solutions are generally difficult and sub-optimal and may ultimately fail to actually deliver value or maximise uptake by the appropriate stakeholders.

In an attempt to ameliorate the problem, funding agencies are increasingly requesting consortia to advance sustainability activities as much as possible during the project life. This is useful in terms of creating "sustainability-aware" projects already from the initial stages. However, the problems remain since, by definition, the vast majority of these projects are research and development activities, for which risk and uncertainty are inherent characteristics. Generally, results are yet to be obtained or produced years before any basic appraisal can take place, such as what is of value, how it will be delivered, or why such delivery will be better than any alternatives or competition.. The danger is that any sustainability deliverables are only theoretical and not grounded on real potential for success in the market.

Despite current efforts, the return on investment of IMI projects in terms of impact on society, better products and solutions that ultimately help citizens get access to better healthcare needs to be consolidated.

In this context, a Virtual Incubator for IMI/IHI Projects (VIP) has been proposed by NEURONET to help projects bridge the gap towards sustainability in a consistent manner. Business incubators have been widespread over the last decades in Europe and elsewhere into the thousands, as a way to support new and start-up companies in their critical initial stages in order to maximise their chances for successfully enter the market, grow and develop until they're ready to fly on their own. Incubators are typically developed by local and national authorities, and more recently as well by big corporations as part of open innovation programmes. In essence, incubators try to compensate for the archetypical lack of resources of start-up companies in areas such as office space, fundraising, access to loans and guarantees, logistics, computing and internet facilities, mentoring, business knowledge, marketing assistance, networking, technology appraisal, etc.

Obviously not all of these are needed or applicable to IMI projects, but on many aspects they do resemble start-up companies when they try to make the shift from a 'project mindset' to a 'sustainability mindset'. They need to select their most valuable assets, consider ownership of those (thereby maybe not extending sustainability efforts necessarily to the whole Consortium), prioritise business logic over scientific-political considerations, honestly assess their competitive advantage, obtain sound financial projections well beyond the "wishing well", devise the most appropriate organisational structure for value delivery, etc.

A VIP could act as neutral party to:

- Objectively assess the assets resulting from each project and their true chances of succeeding in the market, including technology maturity appraisal.
- Support projects with expert knowledge on business planning and development, marketing, financial projections, project management, legal and IP issues, organisation, etc.
- Offer **mentoring** and assistance services to continuously support the initial steps of the transition until full sustainability is reached.











- Training of project teams on key aspects related to sustainability and business development.
- If needed, help projects with **fundraising** by facilitating channels to the appropriate sources (venture capital, business angels, charities, philanthropy, national and international grants, etc.).
- Offer networking possibilities and economies of scale thanks to a wider perspective that includes many projects.

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 incubators resources where the potential benefit is highest. Resulting from such initial assessment, successful project teams should commit to a clear plan of action and key performance indicators that would act as kill-points at regular intervals to evaluate the impact of the VIP, the maturity level reached and renewal of incubator support. It is estimated that the incubator support may range from a minimum of one year to a maximum of four years, and it could start already during the project phase, so that transition into sustainability is accelerated if a good basis and sound business case is present already.

The VIP team should consist of experts in the above-mentioned areas, preferably with knowledge on EU projects and particularly complex private-public partnerships, and governance should include a variety of stakeholders, including funding agencies and potential investors.

An idea similar to the VIP was discussed by Aartsen et al. in a publication entitled "Getting Digital Assets from Public—Private Partnership Research Projects through "The Valley of Death" and Making Them Sustainable"<sup>4</sup>, while other authors recommended establishing sustainability actions, next to the well-established 'research and innovation' and 'coordination and support' actions in IMI <sup>3</sup>. More recently, the idea of the VIP has been discussed at several meetings on sustainability led by different initiatives and organisations (e.g., BD4BO programme, EFPIA office, the NEURONET CSA itself)as a low-hanging fruit or tangible, pragmatic next step forward.

# 4 Conclusion

The final version of NEURONET's deliverable on guidance on sustainability provides a compilation of high level recommendations, best practices and lessons learnt acquired from past experience and discussed through the corresponding Working Group. These encompass all components of the sustainability process: Planning, Building and Implementation.

Planning	Building	Implementing
<ul> <li>Draft exploitation and sustainability draft plan</li> <li>Form interdisciplinary sustainability advisory group</li> <li>Keep a very open mind at what assets can be</li> <li>Identify and assess similar PPPs</li> <li>Analyse stakeholders</li> </ul>	<ul> <li>Develop value propositions for selected assets and priority stakeholders</li> <li>Business development plan</li> <li>Explore fundraising initiatives</li> <li>Draft business and sustainability plan for selected assets</li> </ul>	<ul> <li>Implement findings from business plan</li> <li>Create new organizational, governance, IP, legal workflows necessary to deliver value associated to selected assets</li> <li>Iterate and review</li> </ul>









We also include above an extended description of the Virtual Incubator for IMI/IHI Projects (VIP), an idea that had been mentioned (but not developed) in the first version of the deliverable.

We hope that this deliverable will become a helpful guidance document for current and future projects; that will encourage them to make appropriate choices for creating an adequate pathway for sustainability, while being aware of the common challenges and obstacles faced in the context of a multi-stakeholder private-public partnership.

The fact that there is an ongoing conversation (not only within the NEURONET WG on sustainability, but also within the IMI/IHI project framework) and that several groups are increasingly devoting time to discuss and think about the sustainability of private-public partnerships already signifies a change, and demonstrates that all stakeholders are becoming increasingly aware of the relevance of the topic and the challenges it entails.

## 5 References

- 2. The Pistoia Alliance. <a href="https://www.pistoiaalliance.org/">https://www.pistoiaalliance.org/</a>
- 3. Lima, B. da S. and Bekeredjian-Ding, I. (2018, June 20). IMI Scientific Committee Recommendation Sustainability solutions are important criteria determining project quality and output in IMI. <a href="https://www.imi.europa.eu/sites/default/files/uploads/documents/About-">https://www.imi.europa.eu/sites/default/files/uploads/documents/About-</a>
  - https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/Governance/sc/SC Sustainability June2018.pdf
- 4. Aartsen W., Peeters P., Wagers S., and Williams-Jones B. (2018) Getting Digital Assets from Public–Private Partnership Research Projects through "The Valley of Death," and Making Them Sustainable. Front. Med. 5:65. doi: 10.3389/fmed.2018.00065
- 5. Leenhouts-Martin, L. Field Manual on Scaling Innovations emerging from Public-Private Partnerships (2021).
  - https://www.imi.europa.eu/sites/default/files/events/2021/20211026 Masterclass/Scaling%20PPP%20Innovation%20Field%20Manual.pdf







