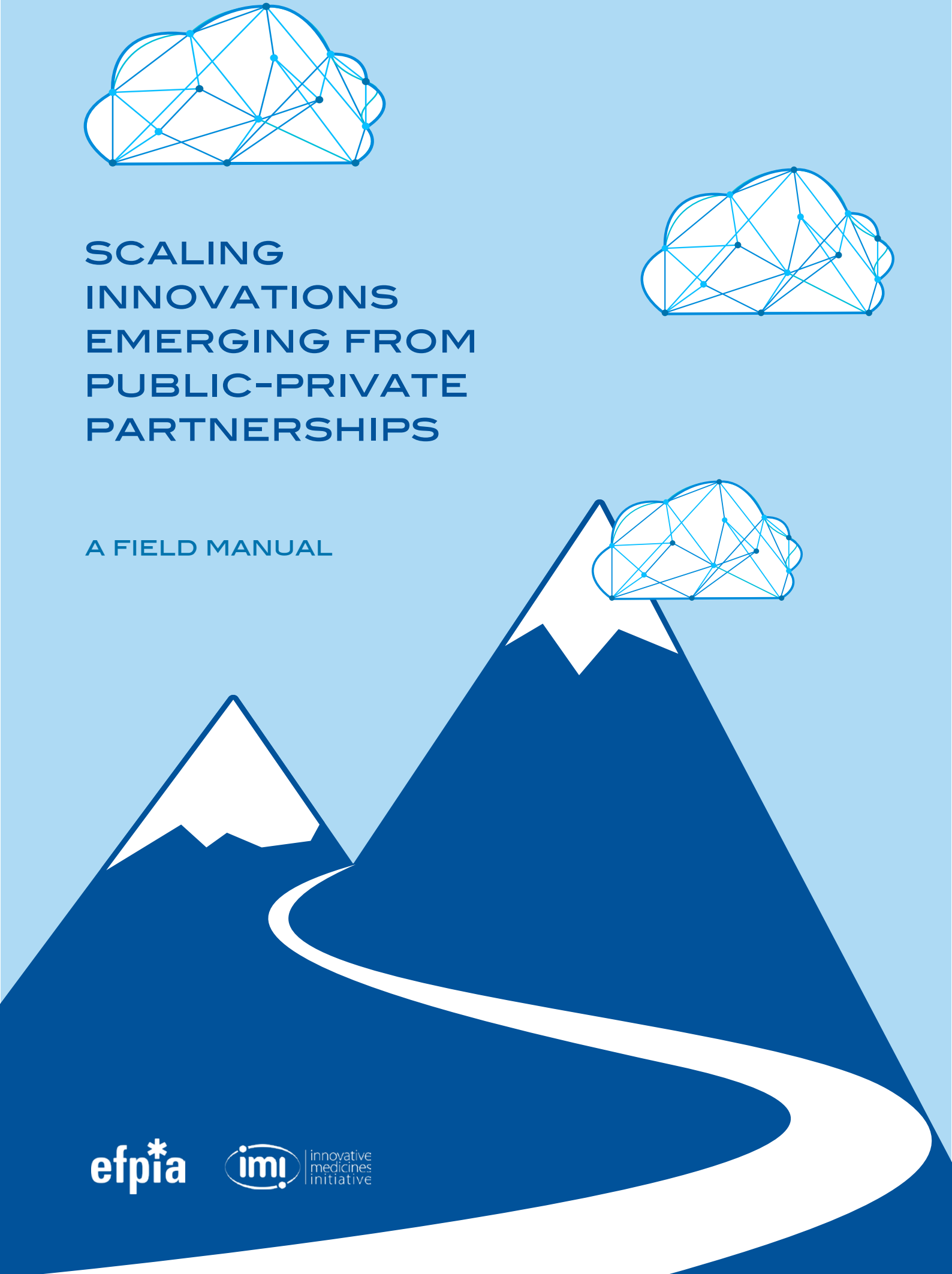
SCALING INNOVATIONS EMERGING FROM PUBLIC-PRIVATE PARTNERSHIPS

A FIELD MANUAL



efpia

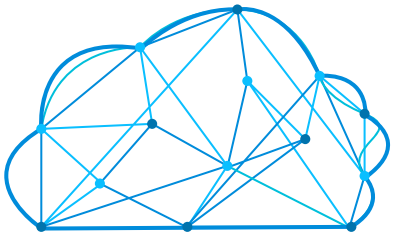
imi innovative medicines initiative

CHARTING A COURSE TO SCALE

IMI's public-private partnership (PPP) model has resulted in powerful fit-for-purpose solutions, or assets, with the potential to transform the healthcare industry and improve patient outcomes on a global scale.

As PPPs plan for scale in a multi-stakeholder environment they must consider a wide variety of factors well beyond a standard startup or commercial product. The following field manual provides high-level, actionable guidance - combining leading models from both the public and private sectors[1] - to help PPPs systematically and strategically chart their scale-up pathway. It is best applied early in a project's life cycle, and encourages an agile approach that adapts to the shifting healthcare landscape.

As with any journey, one must first clarify where they are headed, broadly scan for opportunities and obstacles, and have an actionable plan to navigate the terrain ahead. This approach is described in further detail on the following pages with a specific emphasis on components that are not typically considered in traditional business planning processes. Examples from other IMI projects are also included to provide context and share learnings.



SCALE-UP VISION

Develop an aspirational summary of what ultimate success could look like if the asset is taken to scale and what value it would provide to stakeholders.

Define Success
What is the desired impact? And who will benefit from the value creation or impact?

Define value and target market
What is the unique value proposition of the asset at scale? What is the target market? What problems are being solved?

Define Aspiration
What is the scale aspiration of the project? Scale definitions are unique to each project.

LANDSCAPE SCAN

In order to bridge from vision to pathway, the scale-up vision must be pressure-tested to see if it is fit-for-purpose and remains valid within a multi-stakeholder environment. A top-line assessment is applied at three distinct levels - consortium, members, and ecosystem - to uncover what may be encountered and needed along the scale-up pathway.

Drivers
Identify independent forces that can push the scaling-up forward.

Opportunities
Identify circumstances that, if leveraged, could help the asset go to scale.

Challenges
Identify circumstances that, if left unmanaged, could pose a threat to the asset's scale.

Capabilities
Identify the skills and expertise needed to take the asset to scale.

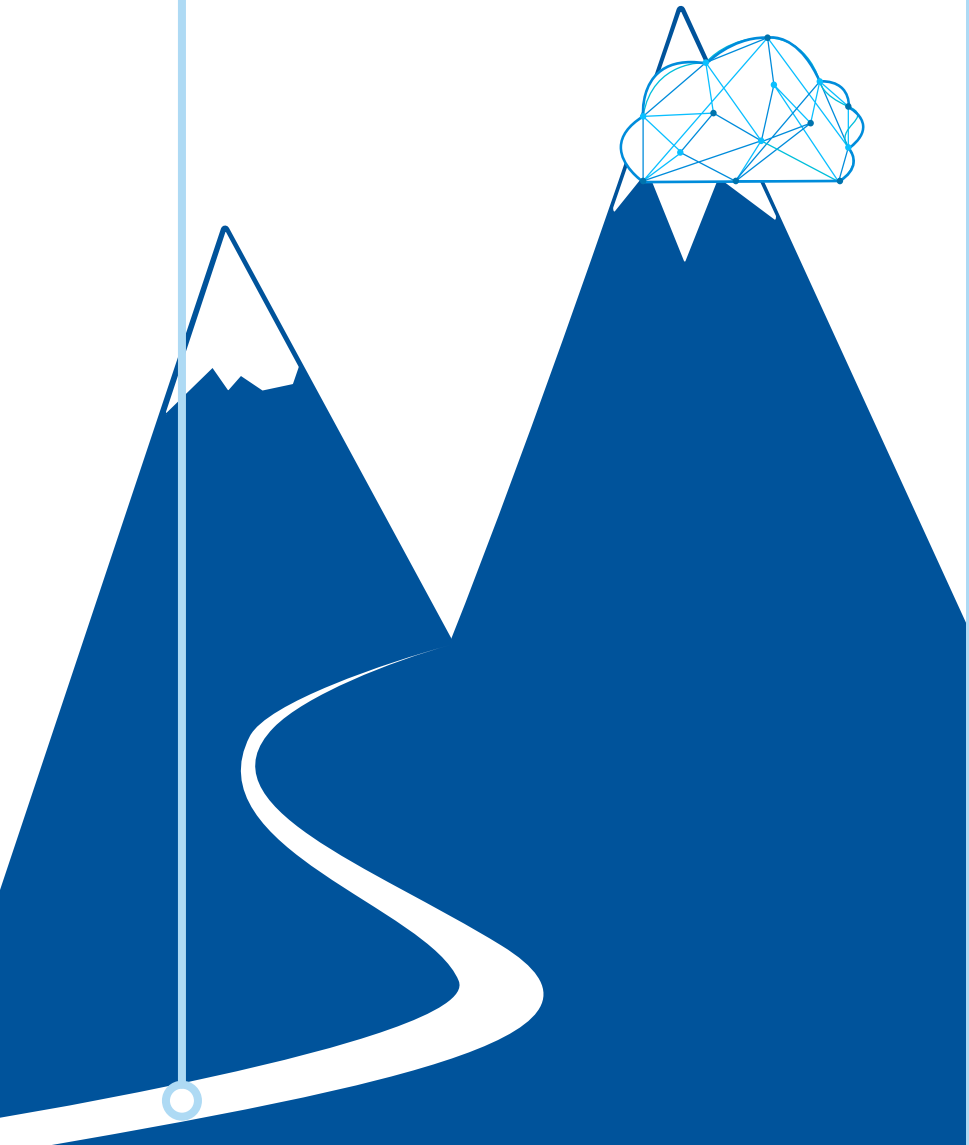
SCALE-UP PATHWAY

The scale-up vision can now be refined to reflect the findings of the landscape scan and to ensure the greatest likelihood of success. The scale-up pathway builds upon the vision and the landscape scan to determine:

Ownership
What level of ownership is required to achieve the aspiration and impact?

Structure
What is the ideal structure and funding model to achieve the aspiration and impact?

Mechanisms
What strategies and capabilities are needed to take the asset to scale, and by whom?



efpia

imi innovative medicines initiative

PRE-SCALE CHECKLIST

- [ ] Have you defined what **success** could look beyond the life of the IMI grant?
- [ ] Have you considered the **ultimate impact** the innovation could achieve?
- [ ] Do you have a clear, concise, and compelling **value proposition**?
- [ ] Have you identified **target markets** who will use your innovation to achieve the impact?
- [ ] Do you have a clearly **defined asset** that can be scaled up?
- [ ] Have you articulated your **aspiration of scale**?
- [ ] Do you have a clear **scale-up vision** ready to be tested through a landscape scan?
- [ ] Have you carried out a **landscape scan** at three levels: consortium, members, and ecosystem?
- [ ] Have you considered **applicability across various regions in countries** with differing socio-economic potential?
- [ ] Have you identified your **drivers of scale**?
- [ ] Have you identified your strategic **opportunities**?
- [ ] Have you identified **challenges** that could pose a threat to scale-up?
- [ ] Have you identified missing **capabilities** - the skills and expertise needed to take the asset to scale?
- [ ] Have you considered how you might **collaborate and or integrate** with other IMI/IHI/EFPIA funded projects at a similar or more advanced stage of scale?
- [ ] Have you determined the level of **ownership** require to achieve the aspiration and impact?
- [ ] Have you determined the ideal **structure and funding model** to achieve the aspiration and impact?
- [ ] Do you have **mechanisms** to fill gaps and source the required capabilities?
- [ ] Do you have an **agile process** to reflect often, track progress, pivot as needed, and continue to evolve as the landscape shifts?
- [ ] Have you consolidated your findings into an **actionable and agile scale-up pathway?**

SCALE-UP VISION

Develop an aspirational summary of what success could look like if the asset is taken to scale and what value it would provide to stakeholders. The scale up vision needs to be concrete enough to be pressure-tested via the landscape scan, but not too narrow as to prevent big picture thinking. Think beyond the life of the grant and don't limit based on political or financial constraints at this point. Figure 1 on the following page will help the team map the scale-up vision. The canvas in Annex 2 can be used to capture outcomes of the discussion.

DEFINE SUCCESS

What is the desired value creation or impact over the long-term, and what is the ambition in terms of impact?

Each IMI project will have a different definition of success. In fact, there will likely be disparity on the project leadership team as to what success should look like. This is normal and the dynamics explored through out are inherent in any collaboration.

The following questions can help the leadership team explore and come up with a common aspiration. Remember to focus on the outcomes and impact, not necessarily the scale of success which will be dealt with in the next section.

Questions to consider

- What is the impact vision? In 5 years? In 10 years?
- What is the ultimate impact that could be achieved given:
  - User demand (target stakeholder/industry member, customer/patient, etc.)?
  - The nature of the innovation?
- What is the time horizon needed to achieve desired vision?
- What are the core values and purpose?

DEFINE VALUE AND MARKET

The value proposition at scale will differ from the value proposition of the original IMI project in terms of its scope and impact. Aim to articulate the value proposition in two sentences. Additionally, the target markets will vary depending on the impact the asset is aiming to achieve.

Questions to consider

- What are the core elements of the value proposition at scale?
- For whom does it create value? How does it create value?
- What are the target markets and how can they be reached?
- Consider the following key areas:
  - Patient-impact
  - Economic and social impact
  - Digital transformation of industry
  - Clinical trials
  - Market access
  - Build trust/increase brand confidence
  - Linkages and synergies created (sectors, entities), i.e. regulatory
  - Knowledge creation
  - Operational efficiency

DEFINE SCALE

What is the scale aspiration of the project? Scale is a ubiquitous term especially in the innovation space. Oftentimes it is understood as the aspiration of a business to grow as much as possible. In practice, scale must be defined for each project or business and will look different for each one.

First, begin by clearly defining the core asset (see figure 1). Is it a platform, a product, or knowledge? The project may have one or more assets. For instance, a platform may also have a proprietary product that accompanies it or it may create knowledge that can later be leveraged. If more than one asset, consider carefully they synergies between each and how they could mutually reinforce one another.

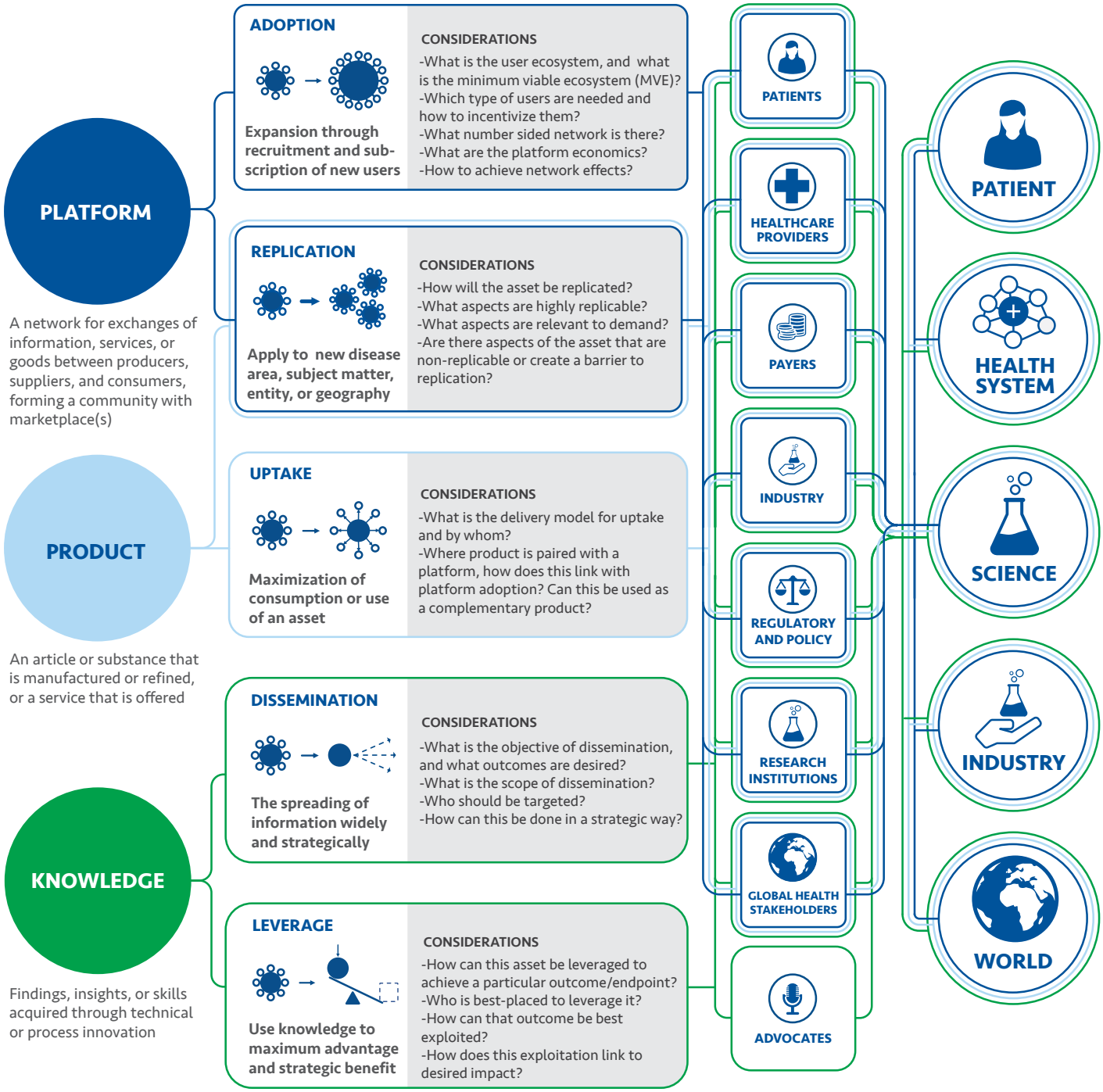
Once the asset(s) has been defined, it is time to define the scale aspiration. For platforms, does scale mean adoption or replication? For products, does scale mean replication or uptake? For knowledge, does scale mean dissemination or leverage?

LEARNINGS FROM OTHER IMI PROJECTS

PLATFORM:
EHDEN uses a federated data network to apply standardized analytics, resulting in powerful real world health research in a fraction of the time. EHDEN's data network, collaboration on research methodologies and open science collaboration all operate through a platform model.

PLATFORM & PRODUCT:
RADAR-CNS provides a wearable technology product to capture biosignatures that can be measured remotely to predict relapse or deterioration. It is used with the RADAR-BASE platform which analyzes aggregate data resulting in insights to improve patient outcomes for multiple-sclerosis, epilepsy and depression.

FIGURE 1:



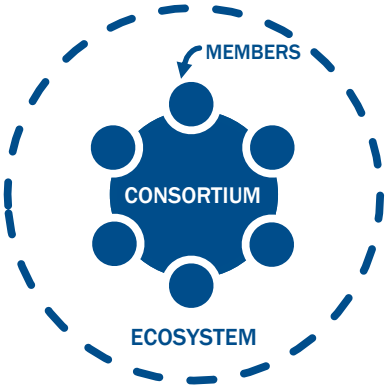
KNOWLEDGE:
Mobilise-D aims to establish digital mobility data as a measure in clinical trials. MOBILISE-D is developing a comprehensive system to analyze people's gait based on digital technologies, including sensors worn on the body. The project focuses on conditions which often affect mobility and is working with regulators to leverage this knowledge.

IMPACT:
Pharmaledger has clear outcomes for each of its use cases in clinical trials, supply chain, and health data. For instance, they aim to reduce the length of clinical trial recruitment time by 25% and save an estimated €10 billion a year in counterfeit medicines.

LANDSCAPE SCAN

In order to bridge from vision to pathway, the scale-up vision must now be pressure-tested to see if it is fit-for-purpose and remains valid within a multi-stakeholder environment. This landscape scan has been adapted from leading public and private sector frameworks[1] and aims to inform the unique scale-up pathway faced by IMI assets. It is a top-line assessment of significant factors along an asset's growth trajectory. The aim is not a detailed analysis at this point, especially since scaling is an iterative process. The scan is applied at three distinct levels - consortium, members, and ecosystem - that may be run simultaneously.

For each level, the primary objective is to identify Drivers, Opportunities, Challenges, and Capabilities (DOCCs) that may impact the trajectory. Once DOCCs are identified, they will inform the scale-up pathway, and further analysis may be needed to inform bespoke strategies for each. Outcomes can be captured in the table in Annex 1.



DRIVERS

Independent forces that can push the scaling up process forward.

For example, champions often drive the scaling up process by unlocking pathways and connections otherwise difficult to access. Other drivers could include pandemics, pressure from outside actors, and more.

OPPORTUNITIES

Circumstances that, if leveraged, could help the asset go to scale.

For example, other IMI projects that are complimentary and looking to partner, a new funding call from a government or foundation, or policy co-creation opportunities.

CHALLENGES

Circumstances that, if left unmanaged, could pose a threat to scale-up.

For example, there may be an internal budget discontinuation anticipated or a potential shift in market dynamics that could impede growth.

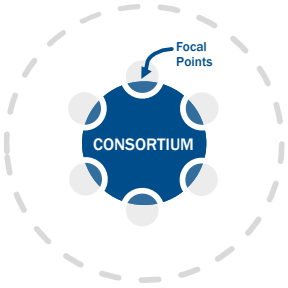
CAPABILITIES

The skills and expertise needed to take the asset to scale.

The skills needed for initial proof of concept are not the same needed for scale(e.g. business development, government relations). These capabilities may be identified within members or potential partners.

CONSORTIUM SCAN

The consortium scan is applied with an internal lens, focused on the focal points, structures, and processes. As in most consortia, staff, structures and processes may be borrowed or inherited from member organizations. The member scan will dig deeper into the member organizations.



Focus on the team that runs the day-to-day operations. Does the consortium have the resources and expertise required to take the asset to scale? What challenges and opportunities lie ahead? How does sustainability feature?

More specifically:

- **Sustainability:** What is the status of sustainability planning and execution, and is this work properly resourced?
- **Governance:** What governance requirements are in place from the IMI grant agreement? How will these need to be updated or changed for post-project exploitation?
- **Legal & IP:** What legal requirements are in place from the IMI grant agreement? How will these need to be adapted for post-project exploitation? What is the optimal balance of open source and proprietary IP for scaling innovation?
- **Budget:** the costs of the innovation at scale need to be anticipated in terms of financial space
- **Skills & Expertise:** Involvement of entrepreneurial experts and those with the right expertise at the right time
- **IT Infrastructure:** inadequacies in technology architecture which hinder collaborative innovation or make it difficult to manage complex integrations of services with products

LEARNINGS FROM OTHER IMI PROJECTS

DRIVERS

The COVID-19 pandemic has acted as a driver of scale. For example, in March 2020, EHDEN reviewed over 10,000 publications in only five days, and the outcomes were incorporated into EMA guidance within just three weeks. EHDEN is now part of the EMA's COVID-19 response strategy. EHDEN's federated, fast observational research was able to impact patient health at a critical moment.

OPPORTUNITIES

By proactively scanning for opportunities, Pharmaledger identified the potential to collaborate with another IMI project, Gravitate Health. They joined forces on the electronic product information leaflet (ePI), and are co-creating with the EMA to support emerging regulation.

MEMBERS SCAN

The consortium scan is applied with an internal lens, focused on the individual member organizations. This scan is often overlooked but is invaluable when trying to understand the future involvement of members and the resources they can bring to the scale-up process.

This scan acknowledges the focal points and their home organization supervisors can sometimes face internal realities that may limit their ability advance the consortium's interests at all times. Better understanding internal alignment can help the team discover opportunities and challenges that may lie ahead, and potentially identify nascent resources to be utilized as in-kind expertise.

More specifically:

- **Executive Alignment:** alignment between top and middle management on the definition of the innovation's value, and on the right ways to leverage talent, assets and ecosystems to create the same
- **Strategic Linkages:** scaling linked to relevant strategies/ departments to ensure uptake (therapeutic area, business development pipeline, innovation, incubators, operations, etc.)
- **Comparative Advantage & Business Impact:** Does the organization have a comparative advantage, or are they well-placed, to use the innovation at scale? Do they wish to play a key role in the scale-up? How will it affect the core business?
- **Budget:** Is there a dedicated budget and resource plan in place to support the consortium's efforts over the long term?
- **Skills & Expertise:** Ensure skills required to scale-up. Involvement of entrepreneurial people and those with specific expertise at the right time
- **Culture & Incentives:** a culture which nourishes innovation and risk-taking, and supports the design and development of new products and platforms.
- **IT Infrastructure:** inadequacies in technology architecture which hinder collaborative innovation or make it hard to manage complex integrations of services with products

ECOSYSTEM SCAN

The ecosystem scan is applied to the broader environment surrounding the consortium and the many external factors that may impact the asset's trajectory. This is especially important when taking a public-private innovation to scale in a multi-stakeholder environment. A public-private ecosystem is complex with many different perspectives to keep in mind, but it also offers a vast pool of resources that more traditional approaches do not have access to. Importantly, the external ecosystem will evolve regularly, so finding a way to regularly scan or account for changes over time is needed.

More specifically:

- **Funding:** Financial resources may need to be identified and mobilized to support the scaled-up intervention
- **Regulatory:** What regulatory requirements are needed to ensure scale? What existing regulations need to be accounted for? Is there regulatory space that needs to be defined in order to secure the innovation's viability? Are there opportunities for co-creation? How can regulatory be engaged early in the process?
- **Market Dynamics:** What trends in the market create opportunities or threats for the innovation? Have all relevant market data and metrics been considered? What other innovations are in the market that can affect bringing this innovation to scale? What innovations are in other markets that can be learned from? What is the timeline and lifespan of this innovation? How can the longevity of this innovation be ensured so that it can be updated or upgraded over time to remain competitive?
- **Policy & Political:** Important stakeholders, both those in support of and those against the intervention, need to be attended to through outreach and suitable safeguards to ensure political support for a scaled-up intervention. Does the EU policy environment support this type of innovation? Are there resources that can accelerate or ensure scale?
- **Partner Ecosystem:** Consensus building and engagement of key partners, including identifying common goals and potential synergies. What opportunities and synergies, and obstacles and barriers exist among the current IMI project consortium stakeholders and beyond? Are there complementary IMI projects to consider for collaboration? Is there awareness of the full stakeholder ecosystem and how it can be leveraged?

CHALLENGES

Mobilise-D recognized the potential challenge but critical importance of receiving regulatory approval for their innovation. To mitigate this challenge, they engaged with regulators early and in the first year of the project received a letter of support from the European Medicines Agency.

CAPABILITIES

RADAR-CNS realized early on that there was a need for greater understanding of the patient perspective. They brought in this capability by establishing a Patient Advisory Group to provide feedback and expert opinions on project design and implementation.

SCALE-UP PATHWAY

CHARTING THE PATH

Following the landscape scan, the scale-up vision should be refined as needed and the Drivers, Opportunities, Challenges, and Capabilities clearly articulated.

A viable scale-up pathway can now be mapped. Figure 2 provides step by step questions in the header and potential answers in the columns below. The color-coded lines are based on the type of asset and can be used to navigate the options along the pathway.

More specifically, ownership, structure and mechanisms can now be considered. Ownership concerns who will own the asset including decision-making, whereas structure refers to the type of entity which is best fit. The mechanisms are the various strategies needed to take the asset to scale.

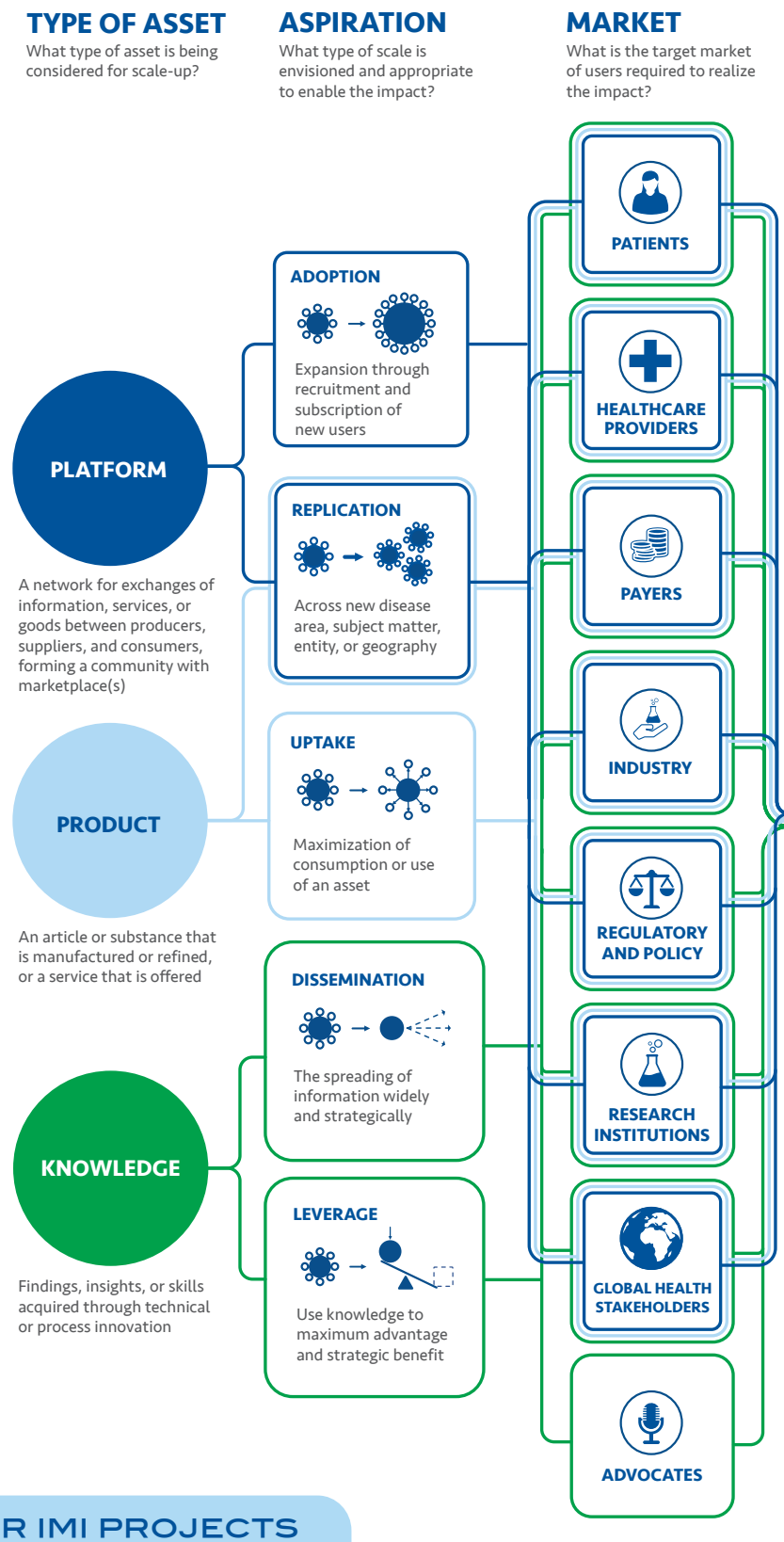
The canvas in Annex 2 can be used to consolidate the outcomes of this exercise.

CLOSING THOUGHTS

Scaling innovation is iterative, especially in a multi-stakeholder ecosystem. Staying one step ahead will require dedicated resources to ensure sustainability remains front and center and that the team is able to react to an ever changing environment.

By planning for scale, IMI project teams can ensure the lasting impact of their innovation. Boldly charting a course early in a project's life cycle will enable them to realize their vision, transform healthcare, and dramatically improve the lives of patients in Europe and the world.

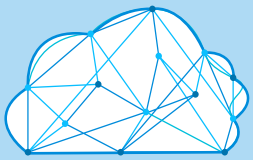
FIGURE 2:



LEARNINGS FROM OTHER IMI PROJECTS

OWNERSHIP
Pharmaledger is exploring the concept of decentralized ownership where no one organization or individual owns the platform but a broad set of users can benefit. Such a model requires blockchain to ensure immutability, transparency and federated ownership.

STRUCTURE
EHDEN is planning for sustainability by establishing the EHDEN Institute as a foundation with visionary thought leadership, research programs, and network studies.



LANDSCAPE SCAN

Top-line assessment applied at three distinct levels - consortium, members, and ecosystem. What will be encountered and needed along the scale-up pathway?

OWNERSHIP

What level of ownership is required to achieve the aspiration and impact?

STRUCTURE

What is the ideal structure and funding model to achieve the aspiration and impact?

MECHANISMS

What strategies and capabilities are needed to fill gaps identified through landscape scan, and determine how to source capabilities.

IMPACT VISION

What impact is envisioned and for whom?

DRIVERS

Independent forces that can push the scaling up forward.

What strategies are needed to fully leverage these resources? (e.g. mobilization strategy to fully activate asset evangelists)

OPPORTUNITIES

Circumstances that, if leveraged, could help the asset go to scale.

What strategies are needed to capture opportunities?(e.g. funding, government affairs, public relations, regulatory co-creation)

CHALLENGES

Circumstances that, if left unmanaged, could pose a threat.

What strategies are needed to mitigate challenges? (e.g. internal resourcing, culture and change, infrastructure, market dynamics)

CAPABILITIES

The skills and expertise needed to take the asset to scale.

The expertise needed for proof of concept is typically not the same needed for scale-up (e.g. business development, government relations)

CENTRALIZED OWNERSHIP

Establish a new legal entity with mandate to scale asset

MERGED OWNERSHIP

Join another IMI or other asset's scale pathway through merger

DECENTRALIZED OWNERSHIP

No one owns the asset but everyone potentially benefits

SHARED OWNERSHIP

Original or new consortium with similar levels of ownership

EXIT FROM OWNERSHIP

Ownership is not viable and sustainable exit strategy required

FOR PROFIT

Standard business model operating with the main goal of generating profits

FOUNDATION OR NON-PROFIT

Organization with the primary goal of serving a public or social good, typically donor-funded

SOCIAL BUSINESS OR B-CORP

Business that has specific social objectives, profits fund social programs

DAO

Blockchain enabled for transparent, decentralized control by all members

PUBLIC-PRIVATE PARTNERSHIP

Formal cooperative arrangement between public and private sector to achieve common goal

COALITION

Informal, temporary alliance for combined action towards a common goal

ACQUISITION

Ownership transferred or consolidated within other entity

HAND-OFF

Free transfer of asset to another entity for continued use or stewardship

LICENSING OUT

Licensing rights to parties to drive commercialization and generate financial payback

OPEN LICENSING

License to allow others to freely use IP, replicate and enhance the asset

AGILE BESPOKE STRATEGIES

Strategic approaches to address Drivers, Opportunities, and Challenges

SELECTIVE OUTSOURCING

Select functions are acquired externally (partners, contractors)

SYNERGIES

Informal agreements with other asset owners to share expertise and leverage learnings

IN-KIND EXPERTISE

Utilize untapped member staff expertise and value as in-kind

PATIENT

HEALTH SYSTEM

SCIENCE

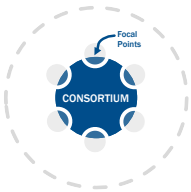
INDUSTRY

WORLD

MECHANISMS

Radar-CNS is targeting health system uptake for their solution which can improve the quality of life for patients and transform their patient journey. They have identified HTAs as a critical component of health system uptake, and are employing a strategic approach to their research agenda to fulfill HTA requirements.

ANNEX 1:
LANDSCAPE SCAN TEMPLATE



DRIVERS			
OPPORTUNITIES			
CHALLENGES			
CAPABILITIES			

ANNEX 2:
SCALE-UP PATHWAY CANVAS

IMPACT VISION

What impact is envisioned and for whom?

TYPE OF ASSET

What type of asset is being considered for scale-up?

ASPIRATION

What type of scale is envisioned and appropriate to enable the impact?

MARKET

What is the target market of users required to realize the impact?

OWNERSHIP

What level of ownership is required to achieve the aspiration and impact?

STRUCTURE

What is the ideal structure and funding model to achieve the aspiration and impact?

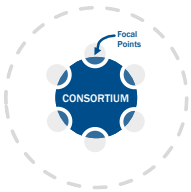
MECHANISMS

What strategies and capabilities are needed to fill gaps identified through landscape scan, and determine how to source capabilities.

Gaps identified through landscape scan	**Strategies and capabilities** required to address gaps	**Responsible** person who owns this stategy

ANNEX 3: EXAMPLE LANDSCAPE SCAN

PLEASE NOTE: This is an illustrative example and not based on an actual project.



DRIVERS	The project has a strong existing value proposition	Executive champion in Company X with a personal commitment to advancing cancer treatment	EU Policy environment is strongly encouraging digital and AI solutions
OPPORTUNITIES	Opportunity to collaborate with other IMI project using big data to inform patient decisions around their own cancer care as well as better understanding the caregiver experience	Several consortium members have indicated commitment to uptake asset within their organizations	Opportunity to deploy the platform across various regions in countries with different socio-economic potential
CHALLENGES	Lack of visibility on emerging and rapidly shifting market trends	Lack of long-term budget visibility in central budgets of partner organizations Challenges in executive alignment in terms of understanding and value of the project to the business	Financing requirements for COVID pandemic response is leading to scarcity in other areas of healthcare
CAPABILITIES	Lack of business development skills within the consortium. The team is not well-placed to grow the project beyond the current grant	Strong AI unit discovered within member organization	Transferable elements of AI solutions from applications outside of healthcare

ANNEX 4:
EXAMPLE SCALE-UP PATHWAY CANVAS

PLEASE NOTE: This is an illustrative example and not based on an actual project.

IMPACT VISION

What impact is envisioned and for whom?

Healthcare providers across Europe are fully empowered - via a novel AI-enabled decision-support platform - to make optimized treatment recommendations to patients with solid tumors.

TYPE OF ASSET

What type of asset is being considered for scale-up?

Platform

ASPIRATION

What type of scale is envisioned and appropriate to enable the impact?

Replication to additional treatment areas

MARKET

What is the target market of users required to realize the impact?

Primarily Healthcare providers

OWNERSHIP

What level of ownership is required to achieve the aspiration and impact?

Centralized

STRUCTURE

What is the ideal structure and funding model to achieve the aspiration and impact?

Social Business

MECHANISMS

What strategies and capabilities are needed to fill gaps identified through landscape scan, and determine how to source capabilities.

Gaps identified through landscape scan	**Strategies and capabilities** required to address gaps	**Responsible** person who owns this stategy
Executive engagement and alignment	Executive engagement strategy to leverage exec champion and EFPIA to build broad support across partner organizations' leadership teams.	WP6 lead with support from Company X chief of staff
Opportunity to leverage EU digital policy environment	Commission consultancy to examine policy environment and advise on alignment and potential areas for co-creation	WP5 lead with support from consultant and Company Y Government Affairs team
Opportunity to collaborate with other IMI project	Engage other IMI project team to formally explore collaboration - Set retreat for next quarter	WP4 lead with support from Company Z BD team
Anticipated deployment challenges in countries w/dif socio-economic potential	Engage with national and regional partners to agree on equitable deployment approach and to ensure infrastructure is in place for eventual uptake	Project lead
Lack of visibility on emerging market trends	Outsource periodic market analysis (annually) for updated market demand insights	WP3 lead
Financing for scale-up	Develop Resource Mobilization / Fundraising strategy	WP6 lead in close collaboration with Company Z BD and Company Y Government Affairs teams
Lack of business development capabilities amongst consortium	Activate BD colleagues in partner companies, and identify dedicated resource for scale-up	Project lead
Strong AI unit within industry member organization	Value potential in-kind contribution and approach leadership to access capabilities	WP2 lead
Transferable elements of AI solutions from applications outside of health	Identify potential synergies with AI firm active outside of healthcare	WP4 lead

NOTES

[1]SOURCES AND ADDITIONAL RESOURCES

The following documents have informed this field manual and are recommended as additional resources:

Pathways to Scale, A guide for early-stage global health innovators on business models and partnership approaches to scale-up; USAID Center for Accelerating Innovation and Impact
https://www.usaid.gov/cii/pathways-scale

Larry Cooley and Johannes F. Linn (2014), *Taking Innovations to Scale: Methods, Applications and Lessons*, Results for Development Institute, downloaded from https://www.msiworldwide.com/what-we-do/our-services/education/scaling on November 23, 2020

Global Health Innovation Guidebook; Stanford University
http://www.gsb. stanford.edu/sites/gsb/ files/files-fpp/28721/ globalhealth innovationguidebook_2. pdf

David Abood, Aidan Quilligan, Raghav Narsalay, Aarohi Sen (2019), *Rethink, Reinvent, Realize. How to successfully scale digital innovation to drive growth*, Accenture downloaded from: https://www.Accenture.com/_acnmedia/Thought-Leadership-Assets/PDF/Accenture-IXO-HannoverMesse-report.pdf November 23, 2020