SCALING INNOVATIONS EMERGING FROM PUBLIC-PRIVATE PARTNERSHIPS

A FIELD MANUAL
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 sectors⁴ 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.

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.

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.

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?

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?
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 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.
**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.
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 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.

**CONSORTIUM SCAN**

**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 scaling (e.g. business development, government relations). These capabilities may be identified within members or potential partners.

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

**MEMBERS**

**ECOSYSTEM**

**CONSORTIUM**

**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.
MEMBER ORGANIZATIONS

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.

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:
• 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

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.
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.

LEARNINGS FROM OTHER IMI PROJECTS

OWNERSHIP

Pharmalegger 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.

FIGURE 2: 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?

PLATFORM

A network for exchanges of information, services, or goods between producers, suppliers, and consumers, forming a community with marketplace(s)

PRODUCT

An article or substance that is manufactured or refined, or a service that is offered

KNOWLEDGE

Findings, insights, or skills acquired through technical or process innovation

ADOPTION

Expansion through recruitment and subscription of new users

REPLICATION

Across new disease area, subject matter, entity, or geography

UPTAKE

Maximization of consumption or use of an asset

DISSEMINATION

The spreading of information widely and strategically

LEVERAGE

Use knowledge to maximum advantage and strategic benefit

PATIENTS

HEALTHCARE PROVIDERS

PAYERS

INDUSTRY

REGULATORY AND POLICY

RESEARCH INSTITUTIONS

GLOBAL HEALTH STAKEHOLDERS

ADVOCATES
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 profit

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

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

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

LICENSEING OUT
Licensing rights to parties to drive commercialization and generate financial payback

AGILE BESPOKE STRATEGIES
Strategic approaches to address Drivers, Opportunities, and Challenges

Selective Outsourcing
Select functions that are acquired externally (partners, contractors)

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

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

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 3: Example Landscape Scan

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

<table>
<thead>
<tr>
<th>Drivers</th>
<th>Opportunities</th>
<th>Challenges</th>
<th>Capabilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>The project has a strong existing value proposition</td>
<td>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</td>
<td>Lack of visibility on emerging and rapidly shifting market trends</td>
<td>Lack of business development skills within the consortium. The team is not well-placed to grow the project beyond the current grant</td>
</tr>
<tr>
<td>Executive champion in Company X with a personal commitment to advancing cancer treatment</td>
<td>Several consortium members have indicated commitment to uptake asset within their organizations</td>
<td>Lack of long-term budget visibility in central budgets of partner organizations</td>
<td>Strong AI unit discovered within member organization</td>
</tr>
<tr>
<td>EU Policy environment is strongly encouraging digital and AI solutions</td>
<td>Opportunity to deploy the platform across various regions in countries with different socio-economic potential</td>
<td>Challenges in executive alignment in terms of understanding and value of the project to the business</td>
<td>Transferable elements of AI solutions from applications outside of healthcare</td>
</tr>
<tr>
<td>Financing requirements for COVID pandemic response is leading to scarcity in other areas of healthcare</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 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.

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