

IMI MASTERCLASS: SCALING INNOVATIONS EMERGING FROM PUBLIC-PRIVATE PARTNERSHIPS



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AGENDA

- 14:00 **Welcome**
Magda Chlebus, EFPIA
Colm Carroll, IMI
- 14:10 **Introducing the Field Manual**
Lisa Leenhouts-Martin, The Forward Group
- 14:35 **Case Study**
Lisa Leenhouts-Martin, The Forward Group
- 15:00 **Q&A Panel Discussion:
The Reality of Taking PPP Assets to Scale**
Magda Chlebus, EFPIA
Colm Carroll, IMI
Nigel Hughes, Janssen
Kai Langel, Janssen
Lisa Leenhouts-Martin, The Forward Group
- 15:20 **Closing Remarks**
Colm Carroll, IMI

INTRODUCING THE FIELD MANUAL

FIELD MANUAL

RESOURCING IMI PROJECTS WITH SCALE AND UPTAKE BLUEPRINT

SCALING INNOVATIONS EMERGING FROM PUBLIC-PRIVATE PARTNERSHIPS

A FIELD MANUAL

efpia **imi**

SCALING INNOVATIONS EMERGING FROM PUBLIC-PRIVATE PARTNERSHIPS

A FIELD MANUAL

efpia **imi**

CHARTING A COURSE TO SCALE

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

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

with any journey, one must first clarify where they are headed, why scan for opportunities and obstacles, and have an honorable plan to navigate the terrain ahead. This approach is critical to further detail on the following pages with a specific focus on components that are not typically considered in official 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 created?

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 – context, 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?

PRE-SCALE CHECKLIST

- Have you defined what success could look beyond the life of the 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?
- Do you have a clear scale-up plan ready to be tested through a landscape scan?
- Have you identified your drivers?
- Have you identified your strategic opportunities?
- Have you identified challenges that could pose a threat to scale-up?
- Have you identified missing capabilities and expertise needed to take the asset to scale?
- Have you determined the level of ownership required to achieve the aspiration and impact?
- Have you determined the ideal and funding model to achieve the aspiration and impact?
- Do you have mechanisms to fit the source the required capabilities?
- Do you have an agile process to define, track progress, pivot as needed, and continue to evolve as the landscape shifts?
- Have you communicated your field plan to an actionable and agile scale-up pathway?

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 on 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.

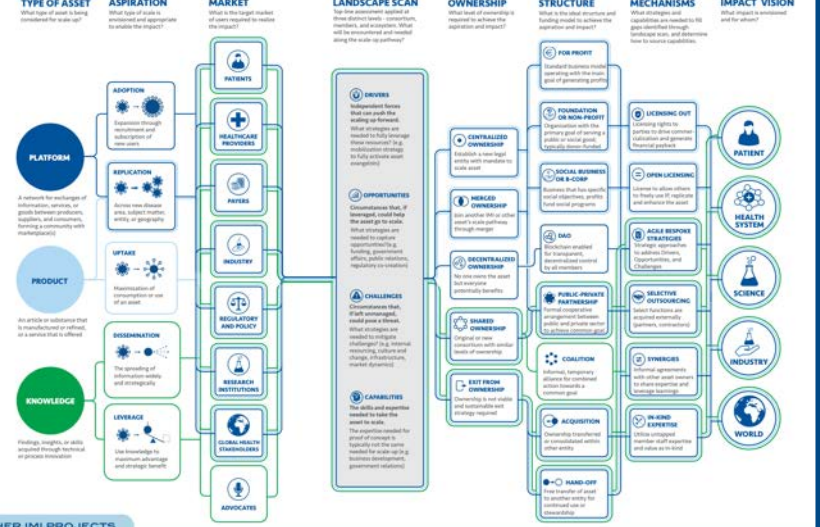
More specifically, ownership, structure and mechanisms can now be considered. Ownership concerns who will own the asset including decision-making, whereas structure refers to the type of entity which is best fit. The mechanisms are the various strategies needed to take the asset to scale.

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: SCALE-UP PATHWAY



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

MECHANISMS Radar-CMS is planning health system uptake for their solution which can improve the quality of life for patients and improve their patient journey. They have identified IMIs as a critical component of health system uptake, and are employing a strategic approach to their research agenda to build IMI requirements.

Accessible field manual format to encourage broad use

Actionable public-private framework to define what scale means for each project, and to assess and anticipate internal and external opportunities and challenges

CHARTING A COURSE TO SCALE

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.



SCALE-UP VISION

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LANDSCAPE SCAN

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SCALE-UP PATHWAY

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Ownership

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



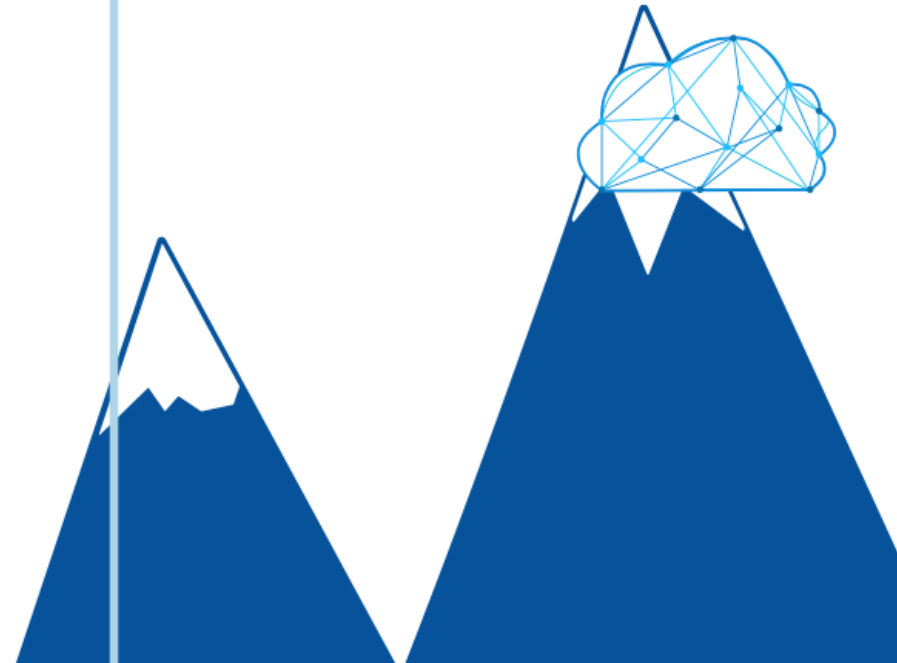
Structure

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?



Q:

What can be an asset?

- a. A new biomarker
- b. A new method to assess value
- c. A clinical trial network
- d. A database
- e. **All of the above**



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.

TYPE OF ASSET

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



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



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



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

ASPIRATION

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

ADOPTION

Expansion through recruitment and subscription of new users

CONSIDERATIONS

- What is the user ecosystem, and what is the minimum viable ecosystem (MVE)?
- Which type of users are needed and how to incentivize them?
- What number sided network is there?
- What are the platform economics?
- How to achieve network effects?

REPLICATION

Apply to new disease area, subject matter, entity, or geography

CONSIDERATIONS

- How will the asset be replicated?
- What aspects are highly replicable?
- What aspects are relevant to demand?
- Are there aspects of the asset that are non-replicable or create a barrier to replication?

UPTAKE

Maximization of consumption or use of an asset

CONSIDERATIONS

- What is the delivery model for uptake and by whom?
- Where product is paired with a platform, how does this link with platform adoption? Can this be used as a complementary product?

DISSEMINATION

The spreading of information widely and strategically

CONSIDERATIONS

- What is the objective of dissemination, and what outcomes are desired?
- What is the scope of dissemination?
- Who should be targeted?
- How can this be done in a strategic way?

LEVERAGE

Use knowledge to maximum advantage and strategic benefit

CONSIDERATIONS

- How can this asset be leveraged to achieve a particular outcome/endpoint?
- Who is best-placed to leverage it?
- How can that outcome be best exploited?
- How does this exploitation link to desired impact?

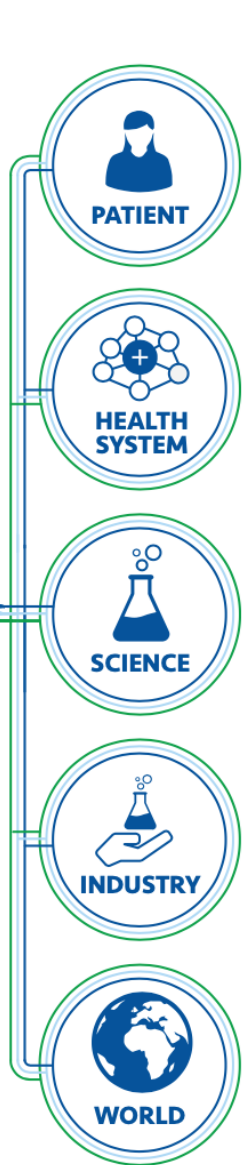
MARKET

What is the target market required to realize the impact?



IMPACT VISION

What impact is envisioned and for whom?



Q:

When speaking about scaling an asset, what is uptake?

- a. Expansion through recruitment and subscription of new users
- b. Application to a new disease area, subject matter, entity, or geography
- c. **Maximization of consumption or use of an asset**
- d. The spreading of information widely and strategically



LANDSCAPE SCAN

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.



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.

Q:

Joining forces with another IMI project to go to scale is an example of a

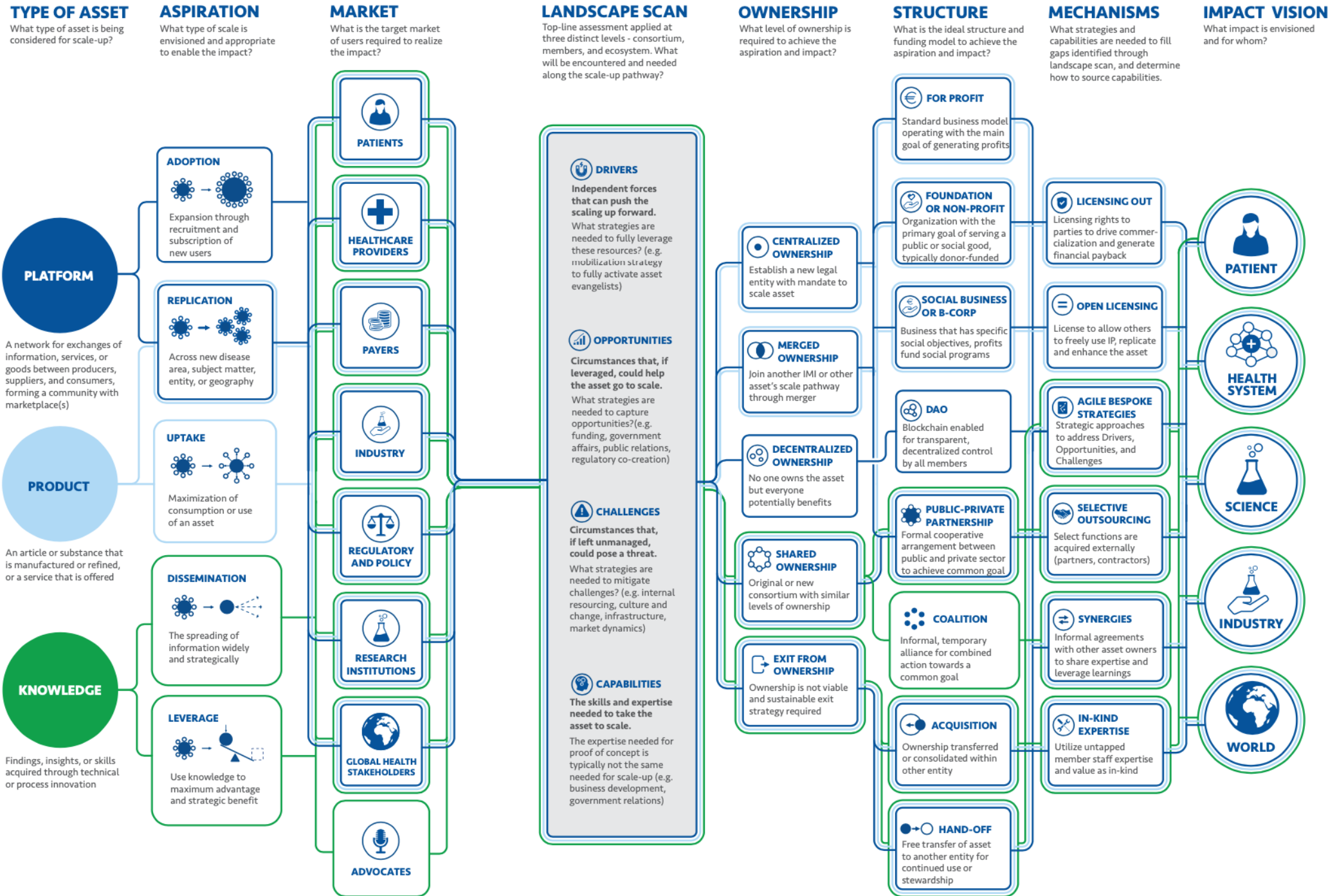
- a. Driver
- b. Opportunity**
- c. Challenge
- d. Capability



scale-up pathway

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.

FIGURE 2:



Q:

Which type of assets are best suited for a for-profit or B corporation?

- a. Product
- b. Platform
- c. Knowledge
- d. a & b**
- e. b & c

Q:

What do you see as the greatest challenge to scaling your asset?

- a. Governance & Ownership
- b. Financing
- c. Legal & IP
- d. Strategy development
- e. **All of the above**

DISCUSSION

CASE STUDY



RADAR-CNS

WEARABLES TO HELP PREDICT AND PREVENT RELAPSE

ABOUT

A collaborative research programme exploring the potential of wearable devices to help prevent and treat depression, multiple sclerosis, and epilepsy.

VALUE PROPOSITION

RADAR-CNS aims to improve people's quality of life and change how conditions are managed and treated. Data from mobile devices can give a full picture of a person's condition at a level of detail which was previously impossible. This offers the potential to detect changes in behavior, sleep, or mood before the individual themselves is aware of it, helping them to predict – or even avoid – a relapse.

- MS: gain understanding of disability, disease course and patient journey
- Epilepsy: track, predict and prevent seizures
- Depression: predict and preempt relapse

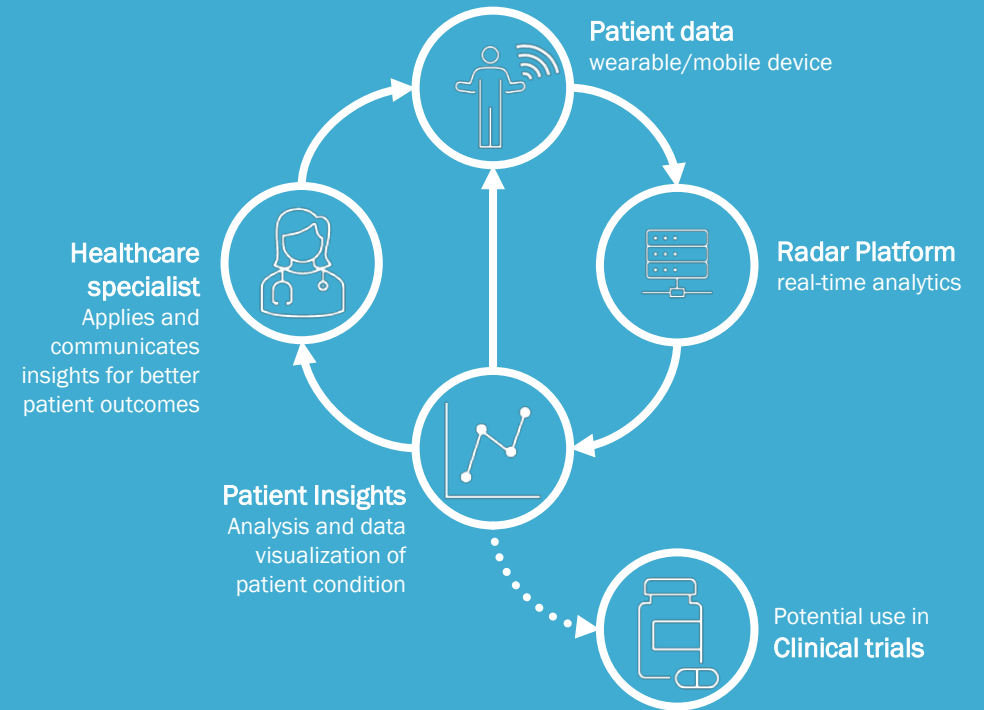
KEY FACTS

22
PARTNERS
EU, UK, US

€26
MILLION
BUDGET

2016-2020
PROJECT
DURATION

HOW IT WORKS



RADAR-CNS

THE ASPIRATION AT SCALE

WHY IT MATTERS

The future:
Predict relapses,
before they happen.



PATIENT

New model for patient empowerment and enhanced patient experience

Accelerated patient-centered care, better quality of life and outcomes

Improved outcomes for epilepsy, depression and MS

Physician and patient understanding of trajectory yields enhanced care

Prevents hospitalizations and burden on healthcare/clinical system



INDUSTRY

Accelerated time market due to smarter, faster clinical trials

Digital technology creates new business models for growth: open-source, open-data, flexible, scalable, data-driven, data privacy

Aligned to outcome-based care



SCIENCE

Powerful tool for clinical insights

Biomarker data for clinical trials

Establish new standard of care

ID new inter-related predictive factors for disease management

New guidance on use of predictive biomarkers for disease



WORLD

Scaled across geographies

Scaled to other diseases: cardiac, stroke, etc.

Q:

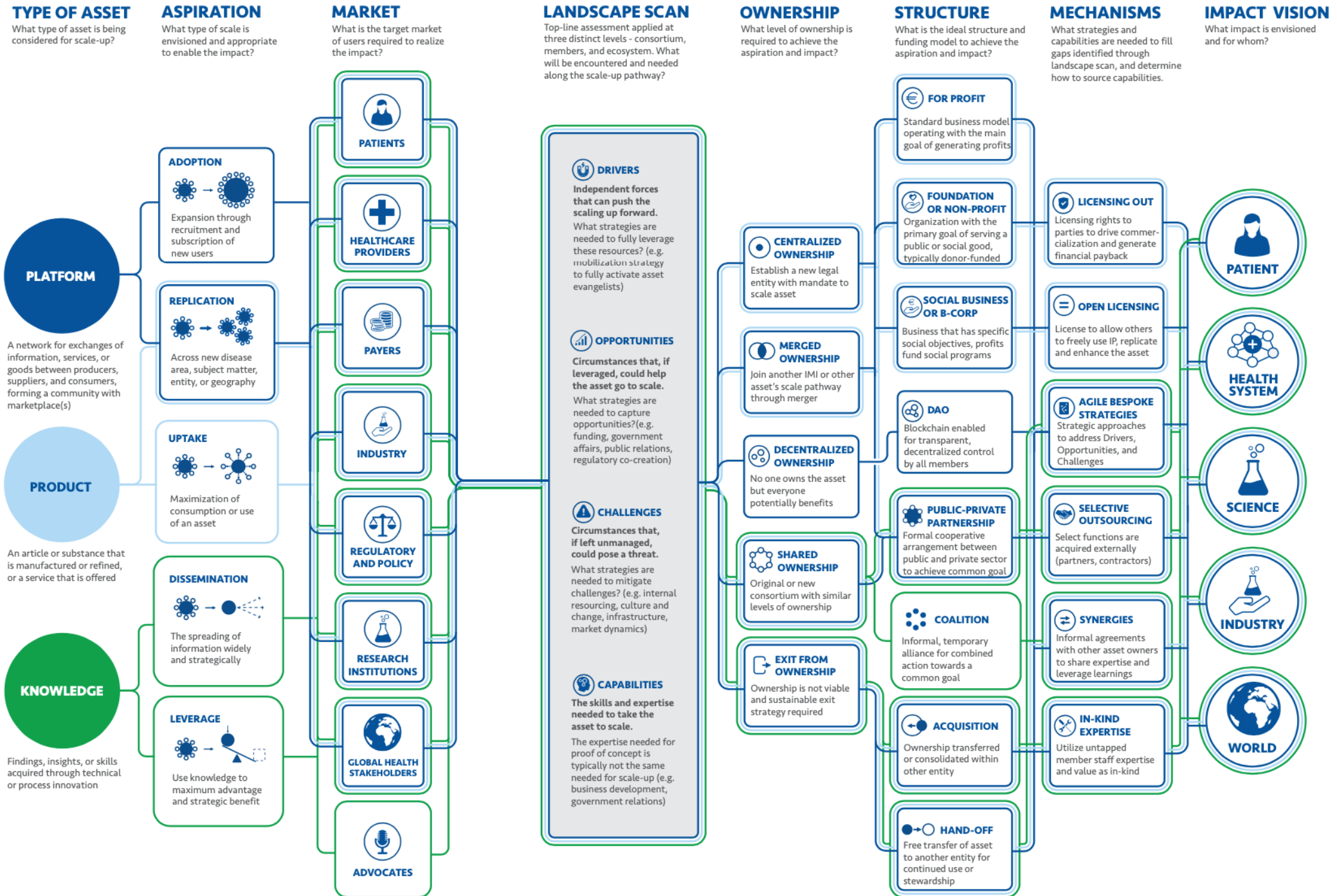
Radar is a:

- a. Product
- b. Platform**
- c. Knowledge



scale-up pathway

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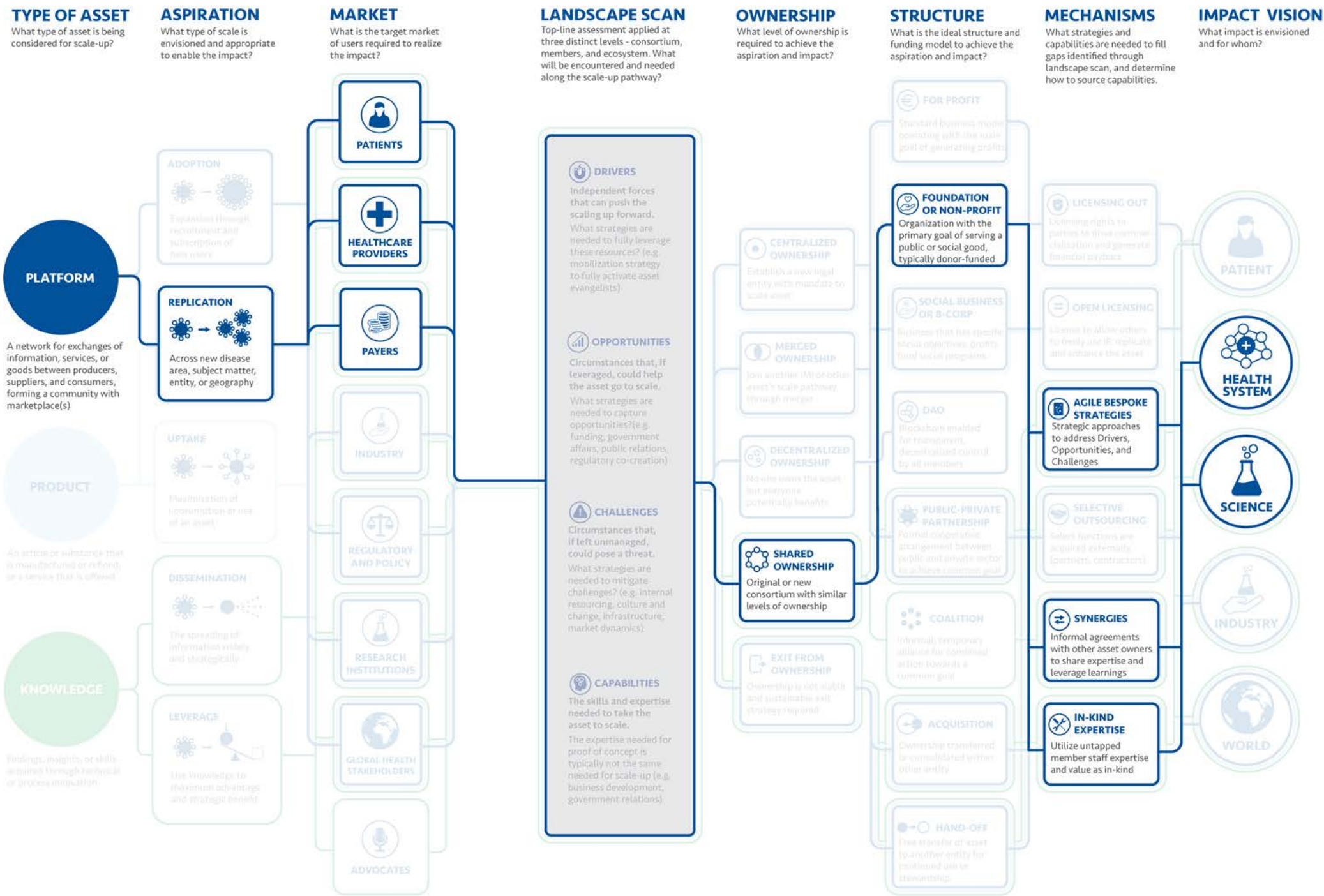
Q:

Radar is best suited for:

- a. Adoption
- b. Replication**
- c. Uptake
- d. Dissemination
- e. Leverage



scale-up pathway



radar-base: scale and uptake canvas

IMPACT VISION

What impact is envisioned and for whom?

RADAR-BASE established as a niche platform of choice for researchers requiring customizable real-world evidence. The platform enables large scale studies and accelerates health research.

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 across different disease areas in niche markets

MARKET

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

Sponsors/PIs of large research studies:

Medium Term:
Clinical researchers who are doing real world cohort studies in clinical settings with thousands of people

Long Term:
Eventually, public health studies and citizen science studies with hundreds of thousands or millions of participants

OWNERSHIP

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

Hybrid model of ownership, with both focused leadership/platform management and broad engagement of community of researchers.

STRUCTURE

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

Foundation. Sustainability through revenue generation. Catalytic transition funding required in the interim.

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 (to leverage Drivers, Opportunities, Challenges & Capabilities)	Strategies and capabilities required to address gaps	Responsible person who owns this strategy
Articulate & define USP and target niche to address pressures in Healthcare system	Market research on target niche and further develop value proposition	WP Lead and consultant
Business model expertise: how to sustain revenue stream with pragmatic plan	Develop business plan	WP Lead and in-kind BD expert from partner A
Fundraising for short term until transition to sustainable revenues	Explore donor funding options	External fundraising consultant in collaboration with Project Leads
Leverage RADAR data streams, algorithms, data base, in addition to managing RADAR-base.	Create additional asset development plan	WP Lead
Ensure robust community uptake	Identify incentives for community growth	WP and in-kind community expert
Consider other potential opportunities for RADAR-base	Develop BD approach	WP lead and in-kind expert from Partner A
IP: Datasets are not open source and IP issues need to be considered in handover to foundation	Develop legal and IP framework	In-kind legal expert from Partner B

Q:

When is the best time to start planning for scale?

- a. Before the grant application is submitted to IMI/IHI
- b. Once the project funding is approved
- c. Halfway through the project
- d. After the project is finished

Q&A PANEL DISCUSSION:
THE REALITY OF TAKING PPP ASSETS TO SCALE

CLOSING REMARKS



Horizon Results Platform ●●

A public platform that hosts and promotes **research results** thereby **widening exploitation opportunities**. It helps to bridge the gap between research results and **generating value for economy and society**. You can create your own page to showcase your results, find collaboration opportunities and get inspired by the results of others!

<https://europa.eu/!XP94Yp>



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Training in Innovation Management
Business services
Examining options for exploitation
Access to non-EU funding

MORE INFORMATION

<https://www.imi.europa.eu/resources-projects/exploitation-project-results>

- Field Manual
- Webinar recording & slides
- Links to EC resources