

IHI MASTERCLASS: SCALING INNOVATIONS EMERGING FROM PUBLIC-PRIVATE PARTNERSHIPS



AGENDA

- 15:00 Welcome - Niklas Blomberg, IHI
- 15:10 Introducing the Field Manual - *Lisa Leenhouts-Martin, The Forward Group*
- 15:30 Case Study 1: EHDEN project: approach, challenges & scale/impact outcomes - *Patrick Ryan, Johnson & Johnson*
- 15:45 Case Study 2: Mobilise-D: approach, challenges & scale/impact outcomes - *Tilo Hache, Novartis*
- 16:00 Panel discussion: The Reality of Taking PPP Assets to Scale - Moderated by *Matthias Mullenborn, Novo Nordisk*
- 16:20 Closing remarks
- 16:30 End

INTRODUCING THE FIELD MANUAL

FIELD MANUAL

RESOURCING IMI PROJECTS WITH SCALE AND UPTAKE BLUEPRINT



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.

PPP plan for scale in a multi-stakeholder environment they must make a wide variety of actions 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, tally team for opportunities and obstacles, and have an actionable plan to navigate the terrain ahead. This approach is refined in further detail on the following pages with a specific focus on components that are not typically considered in external 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 - consumers, 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 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 aspirational goals?
- ☐ Do you have a clear scale-up plan ready to be tested through a landscape scan?
- ☐ Have you carried out a landscape scan across consumers, members, ecosystem?
- ☐ Have you identified your drivers?
- ☐ Have you identified your strategic opportunities?
- ☐ Have you identified challenges it could pose a threat to scale-up?
- ☐ Have you identified missing capabilities and expertise needed to take the asset to scale?
- ☐ Have you considered how you can collaborate and/or integrate with other IMI/MS/EPHA-funded projects similar or more advanced stages?
- ☐ Have you determined the level of ownership required to achieve the aspiration and impact?
- ☐ Have you determined the ideal structure and funding model to achieve its aspiration and impact?
- ☐ Do you have mechanisms to fill a source the required capabilities?
- ☐ Do you have an agile process to 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?

Pragmatic process and checklist to Inform robust sustainability planning and execution

SCALE-UP PATHWAY

FIGURE 2: TYPE OF ASSET
What type of asset is being considered for scale up?

ASPIRATION
What type of scale is being considered for the impact?

MARKET
What is the target market of your innovation to realize the impact?

LANDSCAPE SCAN
What are the external forces that can push the scaling up forward? What are the external forces that could pose a threat to the asset's scale?

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?

IMPACT VISION
What impact is envisioned and for whom?

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.

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

MECHANISMS
Radix CIG 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 IMIs as a critical component of health system uptake, and are employing a strategic approach to their research agenda to ensure 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

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

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Define value and target market

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Define Aspiration

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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

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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?





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?



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

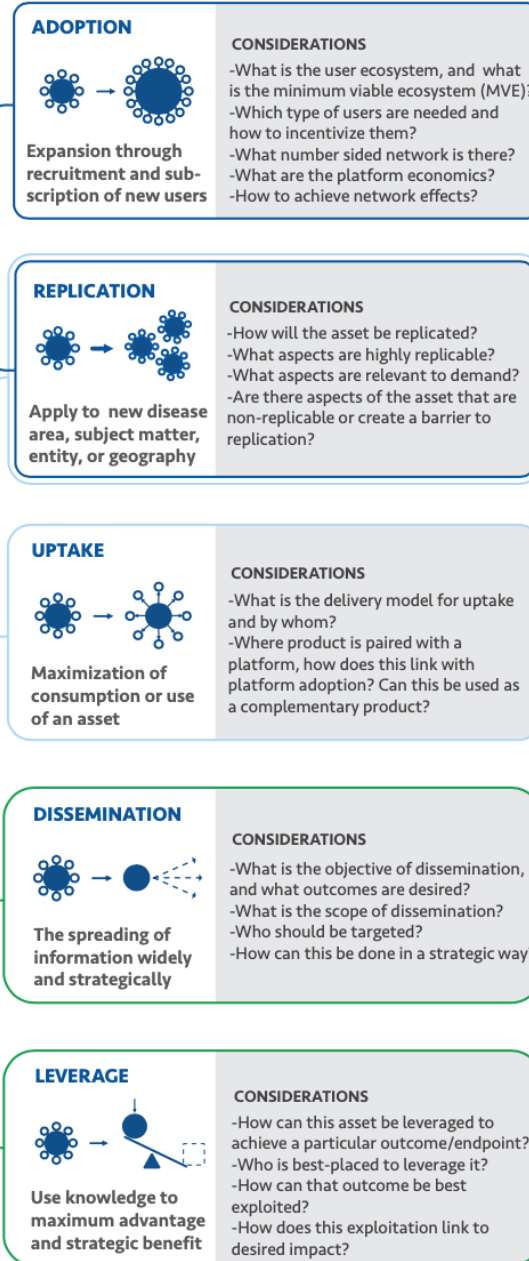


KNOWLEDGE

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

ASPIRATION

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



MARKET

What is the target market required to realize the impact?



IMPACT VISION

What impact is envisioned and for whom?





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.



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?

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

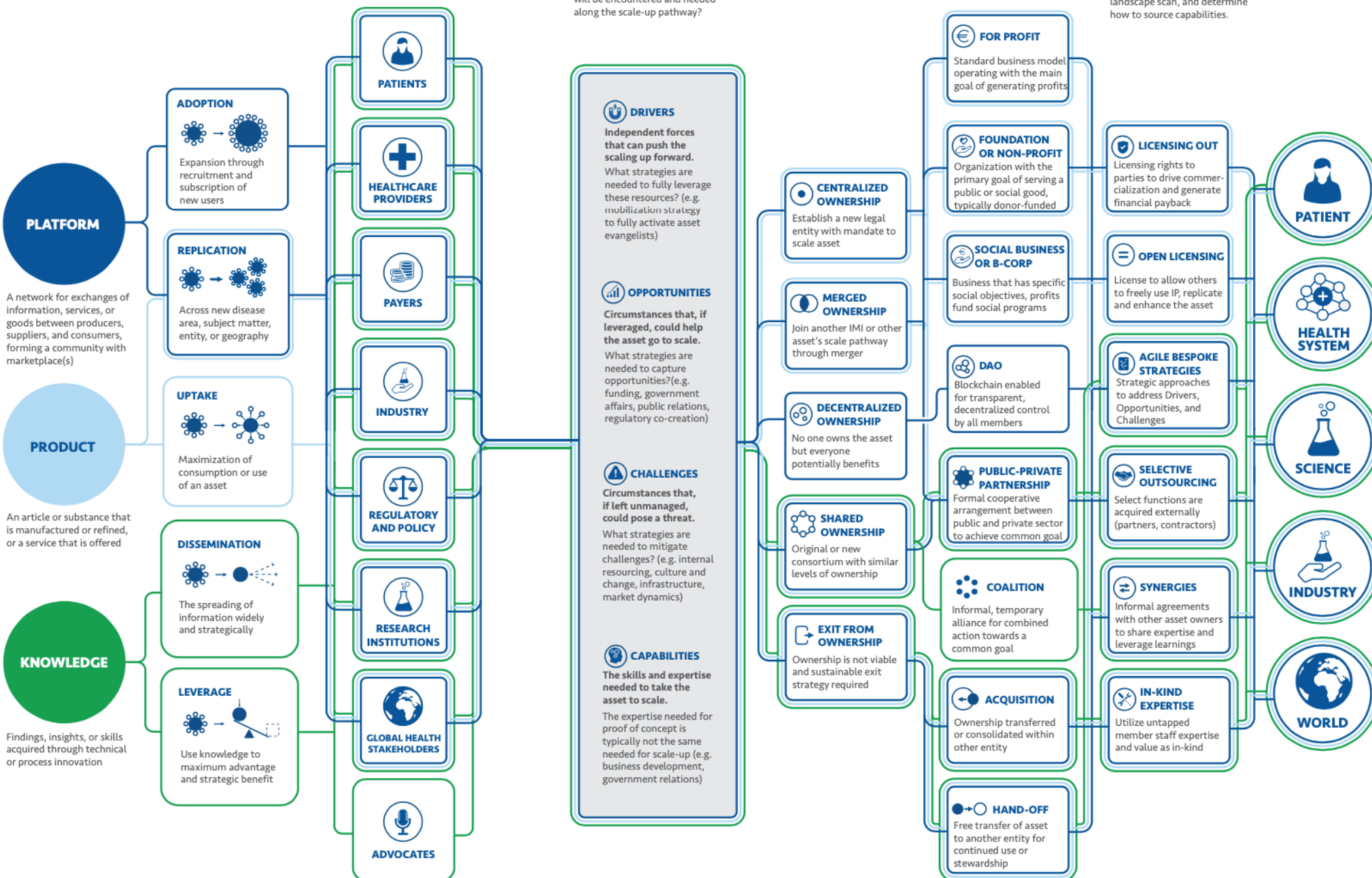
What strategies and capabilities are needed to fill gaps identified through landscape scan, and determine how to source capabilities.

IMPACT VISION

What impact is envisioned and for whom?

scale-up pathway

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Scale and uptake 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?

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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.

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DISCUSSION

CASE STUDY 1



EHDEN

EUROPEAN HEALTH DATA & EVIDENCE NETWORK

Scaling Innovations in Real-World Data and Evidence: Lessons from the EHDEN project

Patrick Ryan, PhD

**Vice President, Observational Health Data Analytics,
Johnson & Johnson**





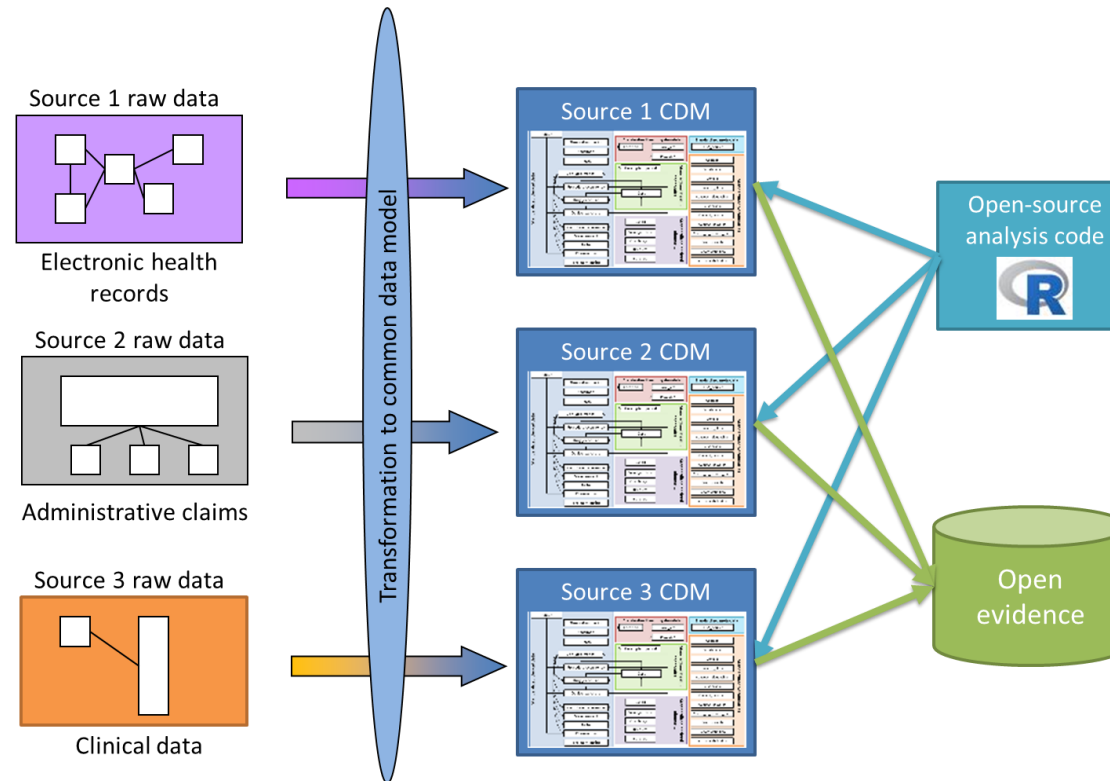
EHDEN: VISION AND MISSION

Vision

The European Health Data & Evidence Network (EHDEN) aspires to be the trusted observational research ecosystem to enable better health decisions, outcomes and care

Mission

Our mission is to provide a new paradigm for the discovery and analysis of health data in Europe, by building a large-scale, federated network of data sources standardised to a common data model





EHDEN PROJECT BASICS

Mission: to provide a new paradigm for the discovery and analysis of health data in Europe, by building a large-scale, federated network of data sources standardised to a common data model



Start date: 1 Nov 2018
End date: 30 Oct 2024
Duration: 72 months



25 partners



~€30 million

Universities, public bodies and research organisations



Academic coordinator



Small & Mid-sized companies



Other organisations



EFPIA & Associated partners

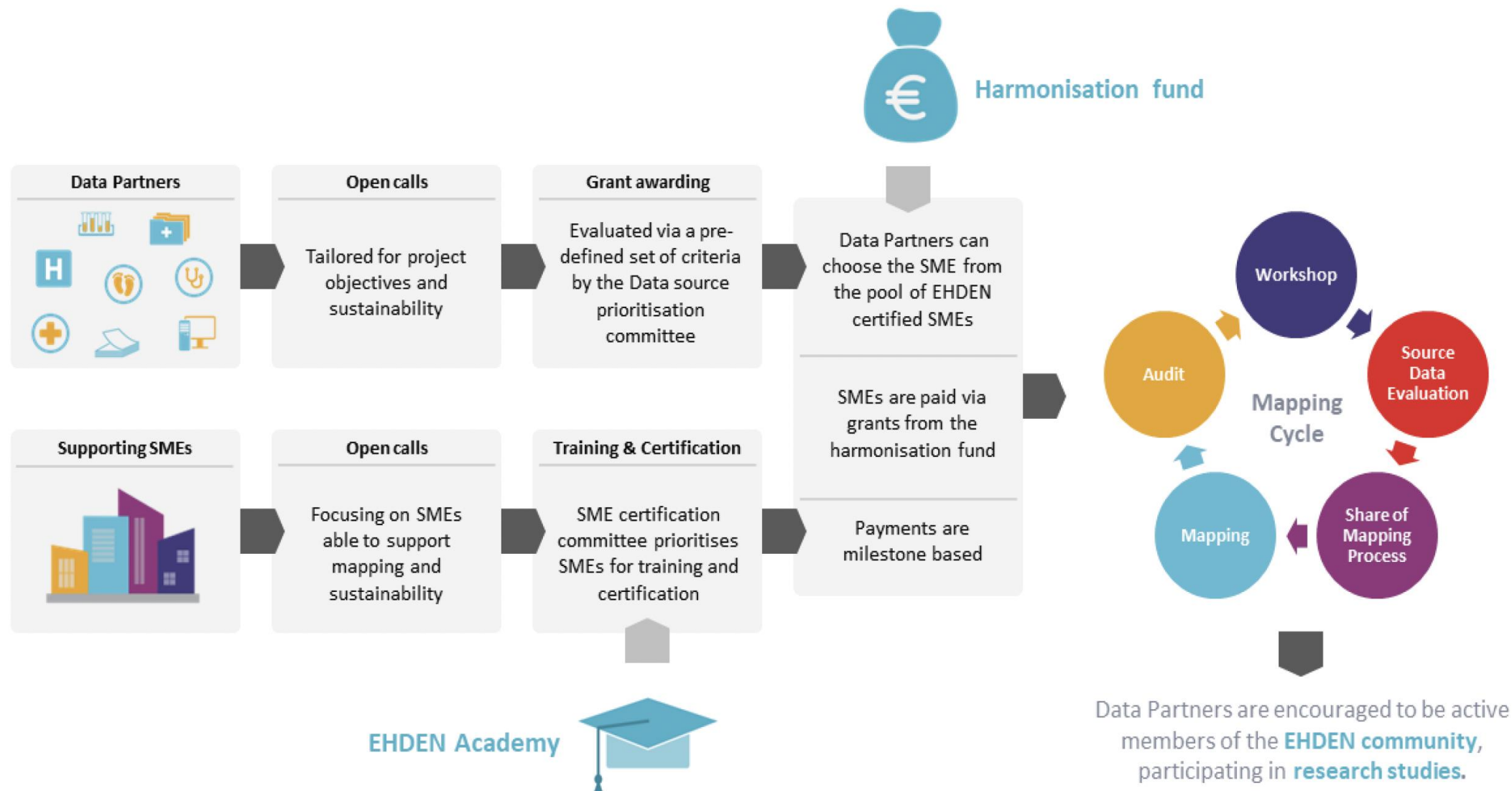


EFPIA Lead





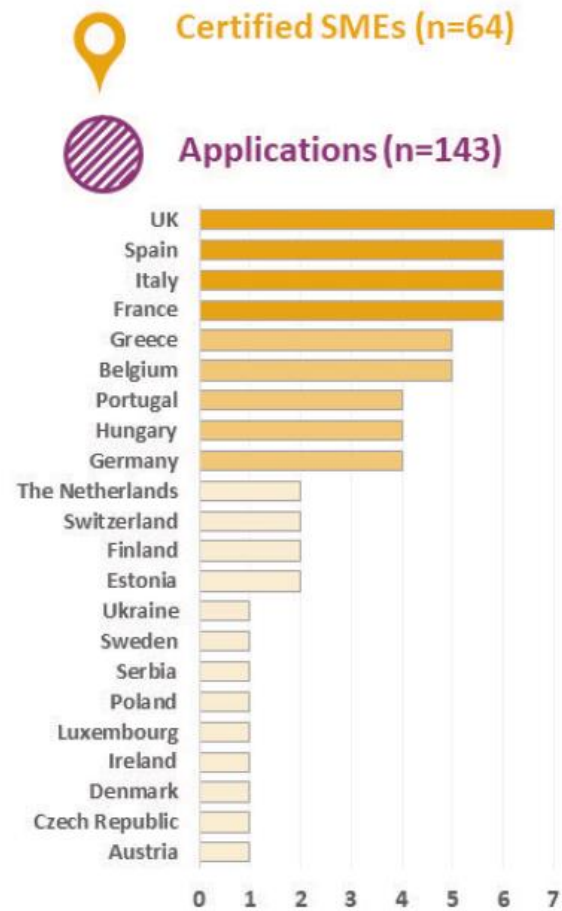
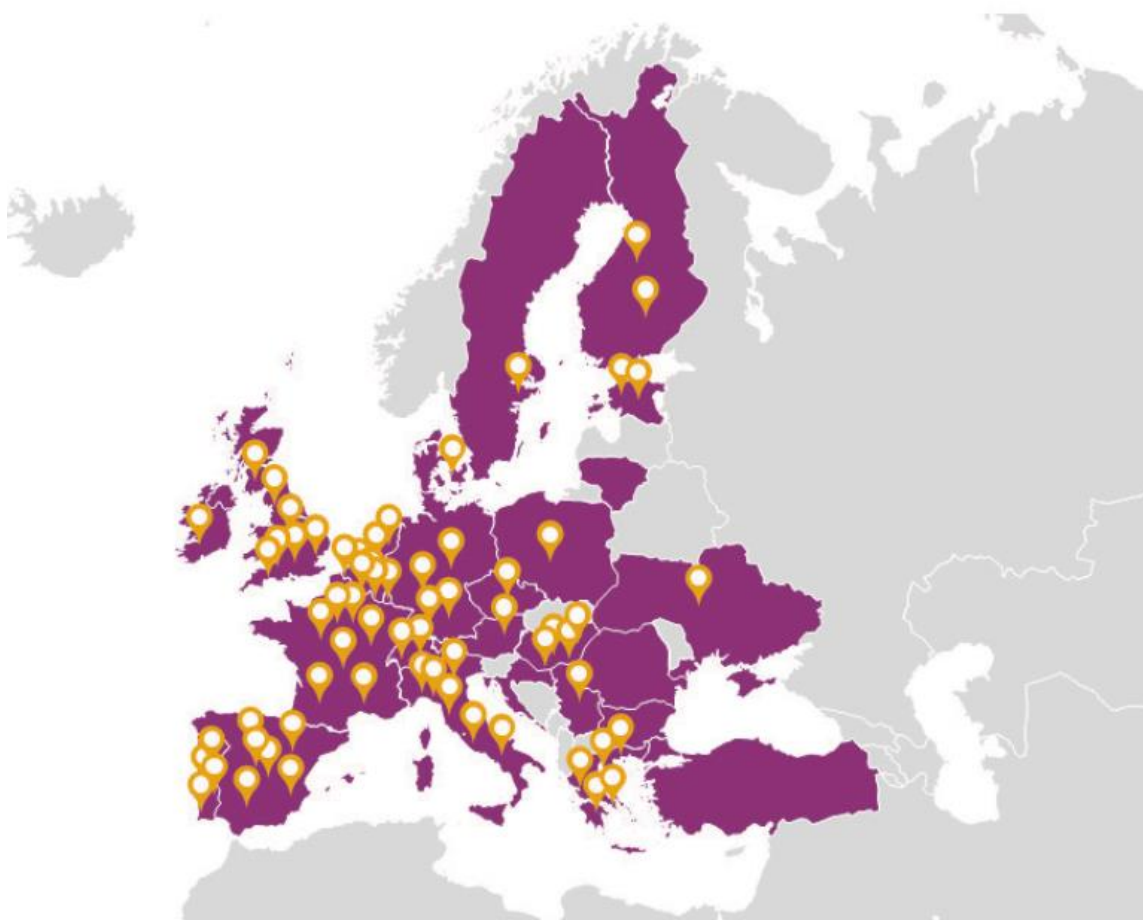
OUR COMMUNITY: OPEN CALL PROCESS





OUR COMMUNITY: SMEs

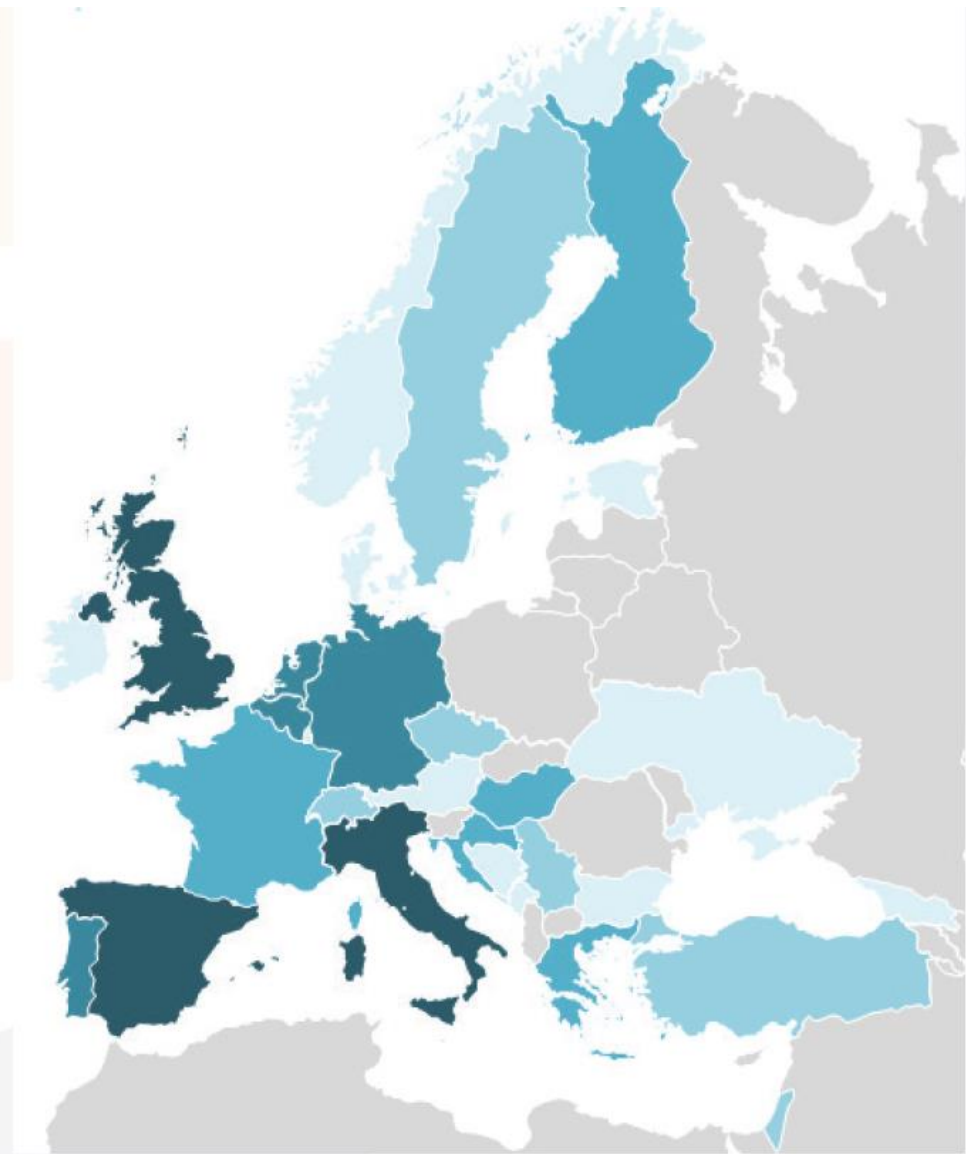
A total of **64 SMEs** from **22 countries** completed Certification and received the seal to help Data Partners map their data to the OMOP CDM and install the necessary tools.



Europe map representing the countries with EHDEN-Certified SMEs.



1 Common Data Model





Learning for Anyone, Anywhere

On-demand training and development programmes developed by the OHDSI and EHDEN community.



Tool Ecosystem

Learn to use our latest tools for observational research in your organisation



Meet Like-minded People

Share and develop your ideas with an interdisciplinary group of learners



Join the Journey

Prepare to participate in worldwide research initiatives across the OHDSI community



Connect with Experts

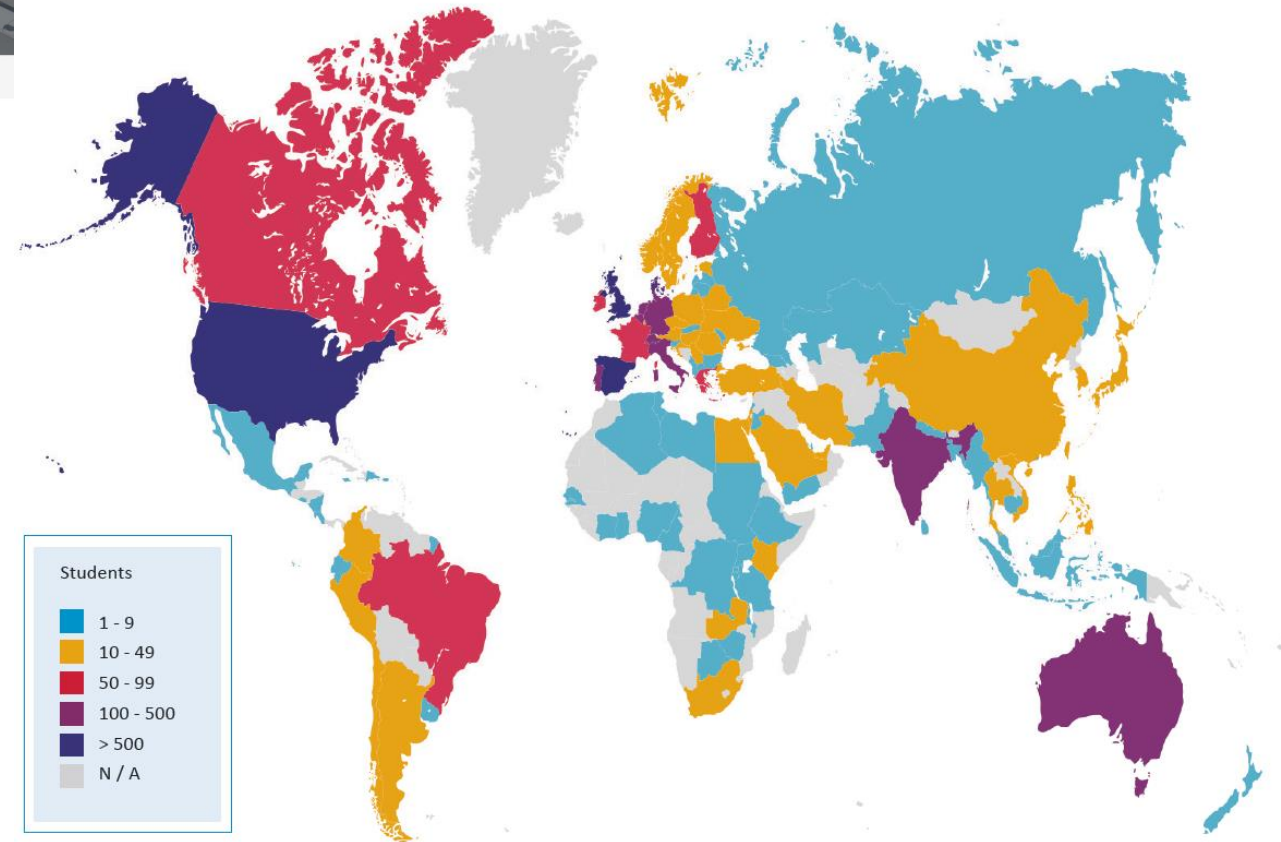
Learn from internationally acknowledged expert trainers and educators

EHDEN Academy

24 courses

>5,200 active learners

108 countries





THE PROJECT MAY BE FINISHED, BUT OUR STORY IS STILL BEING WRITTEN...



EHDEN

EUROPEAN HEALTH DATA & EVIDENCE NETWORK





RECOGNIZING EHDEN'S IMPACT TO EUROPEAN COMPETITIVENESS

The future — — of European competitiveness



THE FUTURE OF EUROPEAN COMPETITIVENESS — PART B | SECTION 1 | CHAPTER 9

1. Maximise the impact of the European Health Data Space (EHDS).

“Leverage existing health data for regulatory, policy and clinical decision-making by stepping up the standardisation of pre-existing ‘legacy’ health data. In the run-up to the full application of the EHDS Regulation, it will be necessary to continue and increase efforts to standardise existing data sources to a common data model building on the work initiated by the European Health Data Evidence Network (EHDEN), set to end by October 2024. The initiative can be set up as a new public-private partnership, aiming to work in full alignment (forward compatibility) with the EHDS. Through this work, standardised health data will be leveraged to generate evidence for regulatory, policy and clinical decision-making.”



OUR FUTURE, NOW A REALITY

[About](#) ▾[Network](#) ▾[Training](#) ▾[Research](#)[Careers](#)[Contact](#)[The EHDEN Project](#) ▾[We are hiring!](#)

We operationalise a large federated network of
OMOP-standardised data sources to generate
reliable Real-World Evidence in Europe

106 **128** **291** M **26**



Data partners



Data sources

People
covered

Countries

[Visit the EHDEN portal](#)[Learn in the EHDEN Academy](#)[The EHDEN project](#)

Our pillars

The activities we carry out within the following areas define who we are

Community

We maintain a network of over 100 data partners mapped to the OMOP CDM, as well as training resources for the community

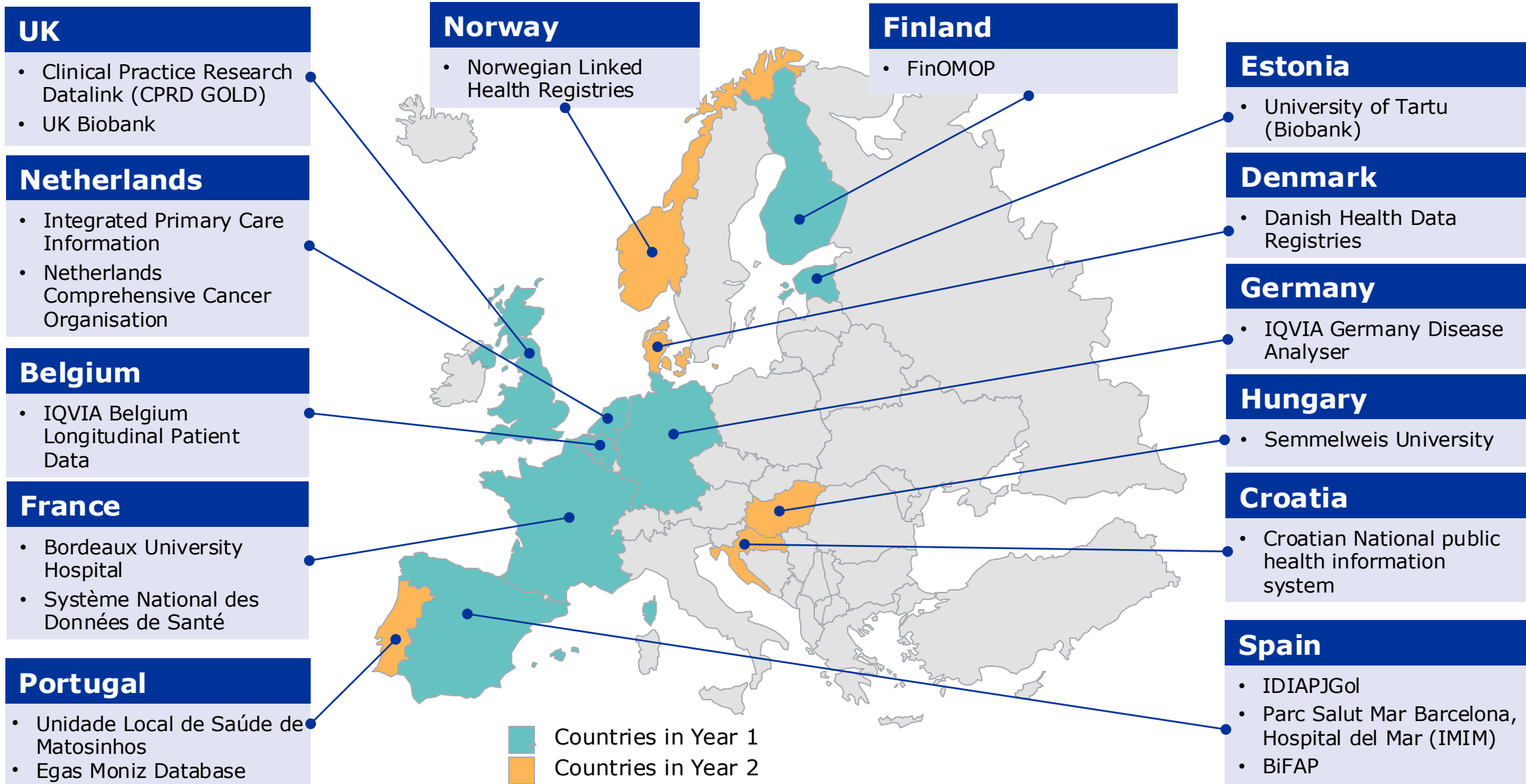
[Meet the network](#)

Research

We engage in studies and research projects and provide advisory services for RWE in healthcare

[Discover our research](#)

The DARWIN EU® Data Network



The data network will contain 40 data sources by year 4 (10 per year)

Local Networks.
Large Impact.



LEGEND

-  National Node
-  OMOP Adopting Country

Home / National Nodes

[NATIONAL NODES]

OHDSI Europe National Nodes

The OHDSI Europe National Nodes form a distributed network of national coordination hubs that bring together local expertise to drive the adoption, implementation, and long-term sustainability of the OMOP CDM and the wider OHDSI community across Europe. Operating within the OHDSI Europe Chapter, and in close collaboration with the EHDEN Foundation, the National Nodes connect stakeholders within their countries to address local priorities, while coordinating with the European coordinating center to support trustworthy, reusable health data.

National Nodes play a unique role: they understand local data, local stakeholders, local coding systems, and local policy environments — transforming these insights into valuable contributions that strengthen the European research ecosystem and global OHDSI community as a whole.

<https://www.ohdsi-europe.org/national-nodes>



EUROPEAN PROJECTS USING OMOP COMMON DATA MODEL



... with
more to
come!



FIGURE 2:

TYPE OF ASSET

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MECHANISMS

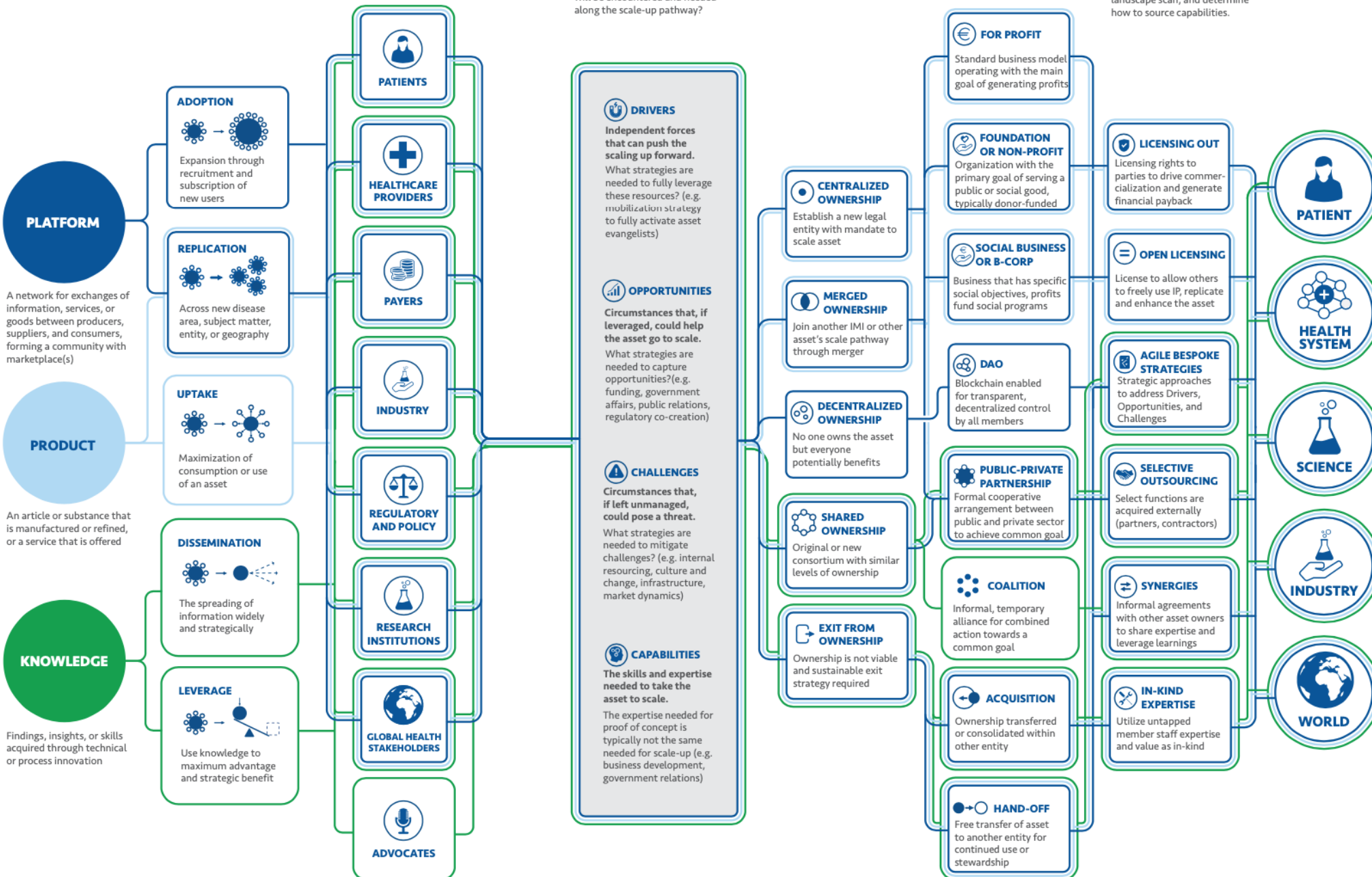
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IMPACT VISION

What impact is envisioned and for whom?

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.





JOIN THE JOURNEY!

<https://www.ehden.eu/>

<https://www.ohdsi.org/join-the-journey/>

Looking forward to collaborating with all of you!

Email me: ryan@ohdsi.org

CASE STUDY 2

Scaling Innovations Emerging from PPPs **IMI2 Mobilise-D (<http://mobilise-d.eu>)**

Masterclass IHI Field Manual (03-Jun-2026)

Tilo Hache, Novartis

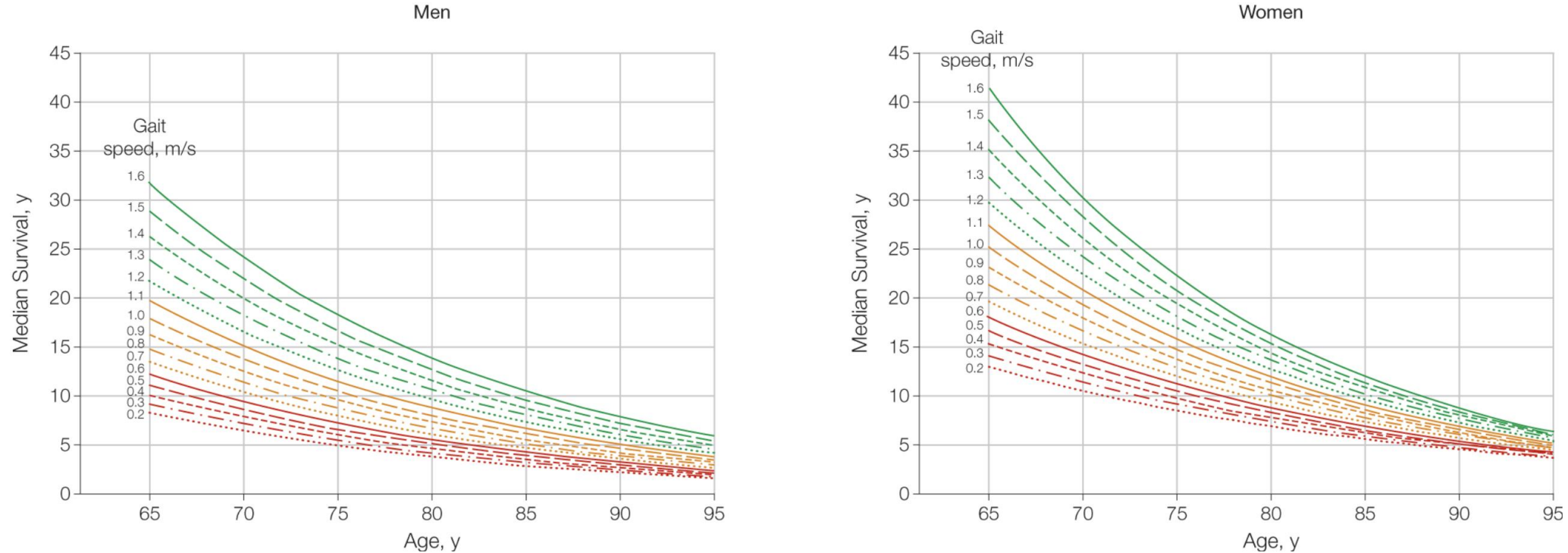
This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 820820. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

www.imi.europa.eu

This presentation reflects the author's view and neither IMI nor the European Union, EFPIA, or any Associated Partners are responsible for any use that may be made of the information contained herein.



Scientific Background: Predicted Median Life Expectancy by Age and Gait Speed*

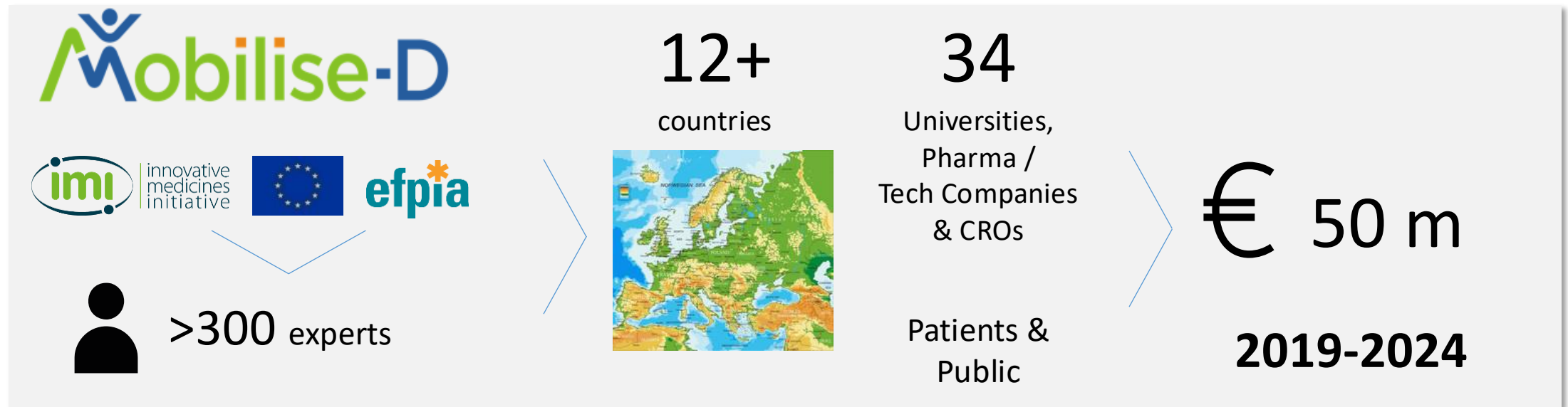


*Studenski S et al., Gait speed and survival in older adults. JAMA. 2011 Jan 5;305(1):50-8. doi: 10.1001/jama.2010.1923. PMID: 21205966; PMCID: PMC3080184.

Challenges for broader adoption:

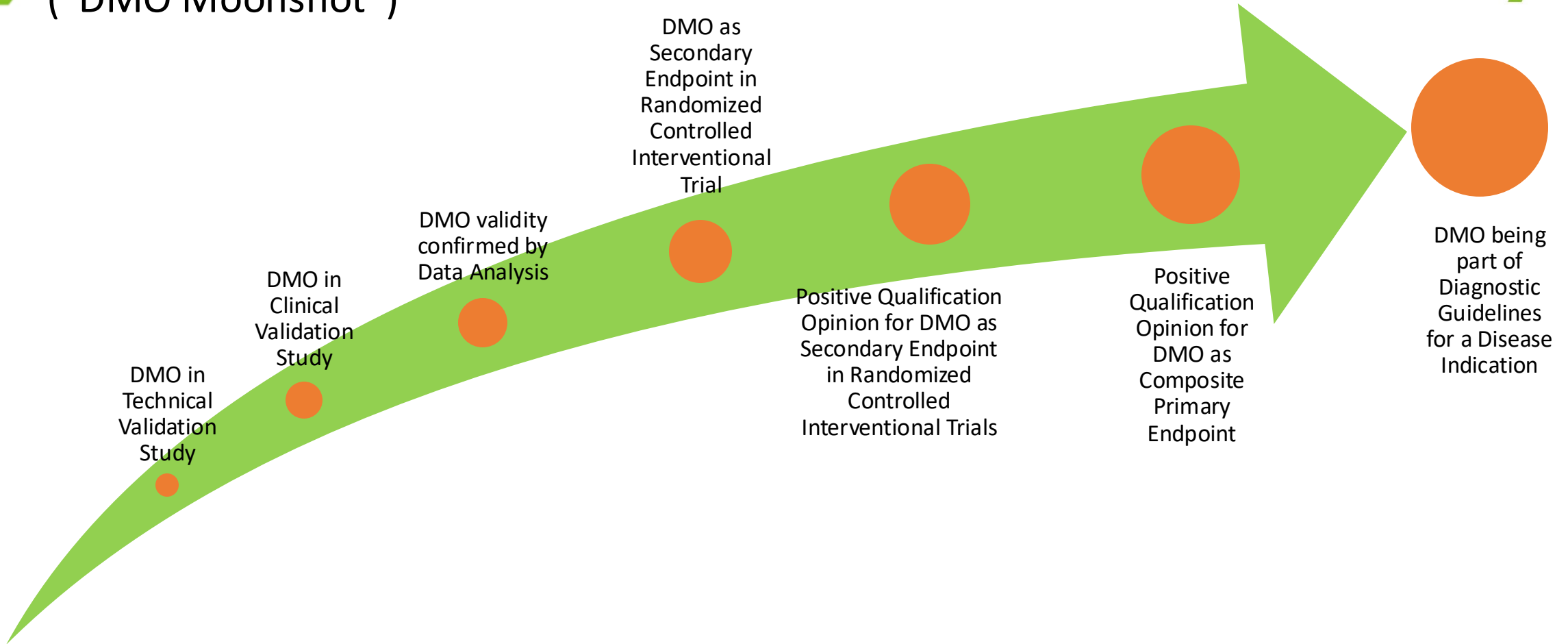
- **In-Clinic Assessments only** (cumbersome to patients, variable, point-in-time assessment)
- **Limited correlation to specific disease progression / state** (accepted regulatory endpoint)
- **Agnosticism** (device, indication, sponsor interests)

MOBILISE-D: Connecting digital mobility assessment to clinical outcomes for regulatory and clinical endorsement



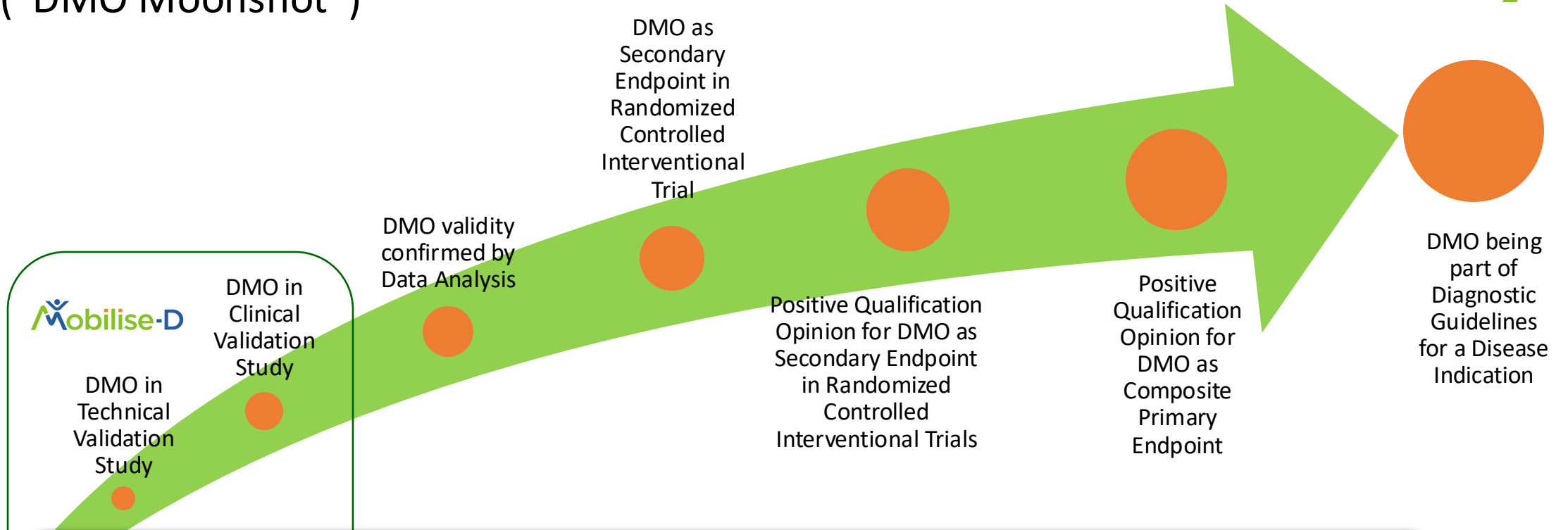


Mobilise-D Scale-Up Vision for Digital Mobility Outcome ("DMO Moonshot")



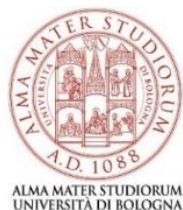


Mobilise-D Scale-Up Vision for Digital Mobility Outcome (“DMO Moonshot”)



- Finished two studies with ~2500 patients in COPD, MS, PD, PFF (+CHF in Technical Validation Study).
- Data standardization for wearable data + sensor qualification (<https://doi.org/10.1038/s41597-023-01930-9>)
- Publications: >120 peer-reviewed publications, 11+ public webinars held, dissemination on relevant conferences
- Two EMA letters of support for qualification advice. Held pre-LOI (Letter of Intent) meeting with FDA.
- Results publicly shared for research use: Data from both studies, algorithm, data processing pipeline

"Mobilise-D" Consortium Partners



Robert-Bosch-Krankenhaus



“SUSTAIN Mobilise-D” Consortium Partners

+2 Years:
July 2024
– June 2026



Universitätsklinikum
Erlangen



Finalize Data
Curation & Analysis

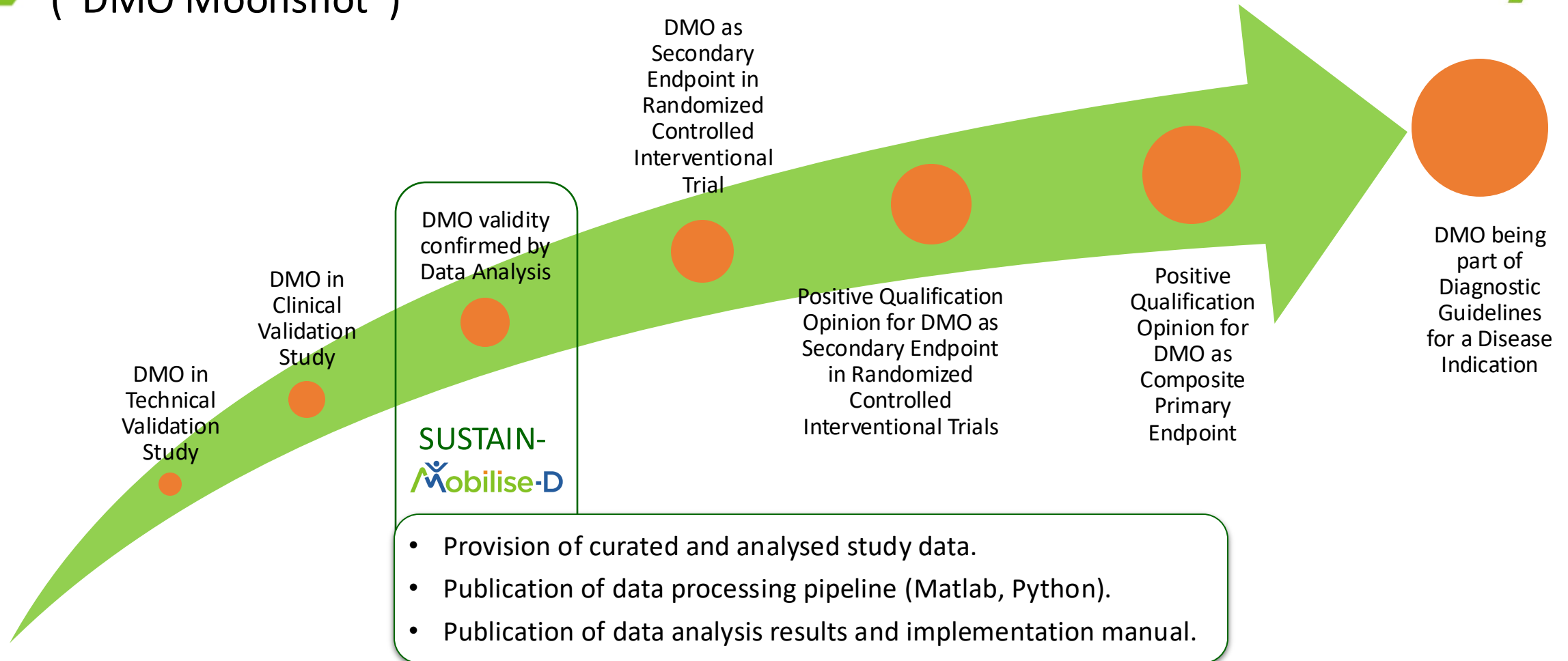


CLARIO.





Mobilise-D Scale-Up Vision for Digital Mobility Outcome ("DMO Moonshot")





Patients / Healthcare

- Includes patient feedback from start
- Patient convenience (at-home monitoring) = better compliance, more holistic
- Enables informed clinician / patient conversations



Academia

- Public Datasets
- Open-access code
- Broad involvement in European research community
- Modular research approach enables expansion (devices, diseases)



Industry

- Independent scientific validation
- Plug-and-Play: Implementation Manual
- Algorithms available on four commercially available devices
- Device-agnostic data enables modular expansion (devices, diseases)



Enablers

- “Settled”, flexible and open academia team
- Very capable and interested CROs
- “Putting into each others’ shoes”
- (Clinical trial) data is a honeypot!
- Tech readiness for Pharma trials
- Early and intense health authority interactions (led by academia)
- Understand business drivers & models (CROs, Tech companies, EFPIA)

Challengers

- Pandemic & “no cost extension”
- “Romantic” initial sustainability ideas
- Project Duration ⇔
 1. strategy & personnel changes in EFPIA companies,
 2. lifecycle of electronic (wearables)
- Different goal posts: Academia / EFPIA (Publication vs. HA approval)
- Risk-averse EFPIA Drug Trial Teams
- Changing regulatory landscape



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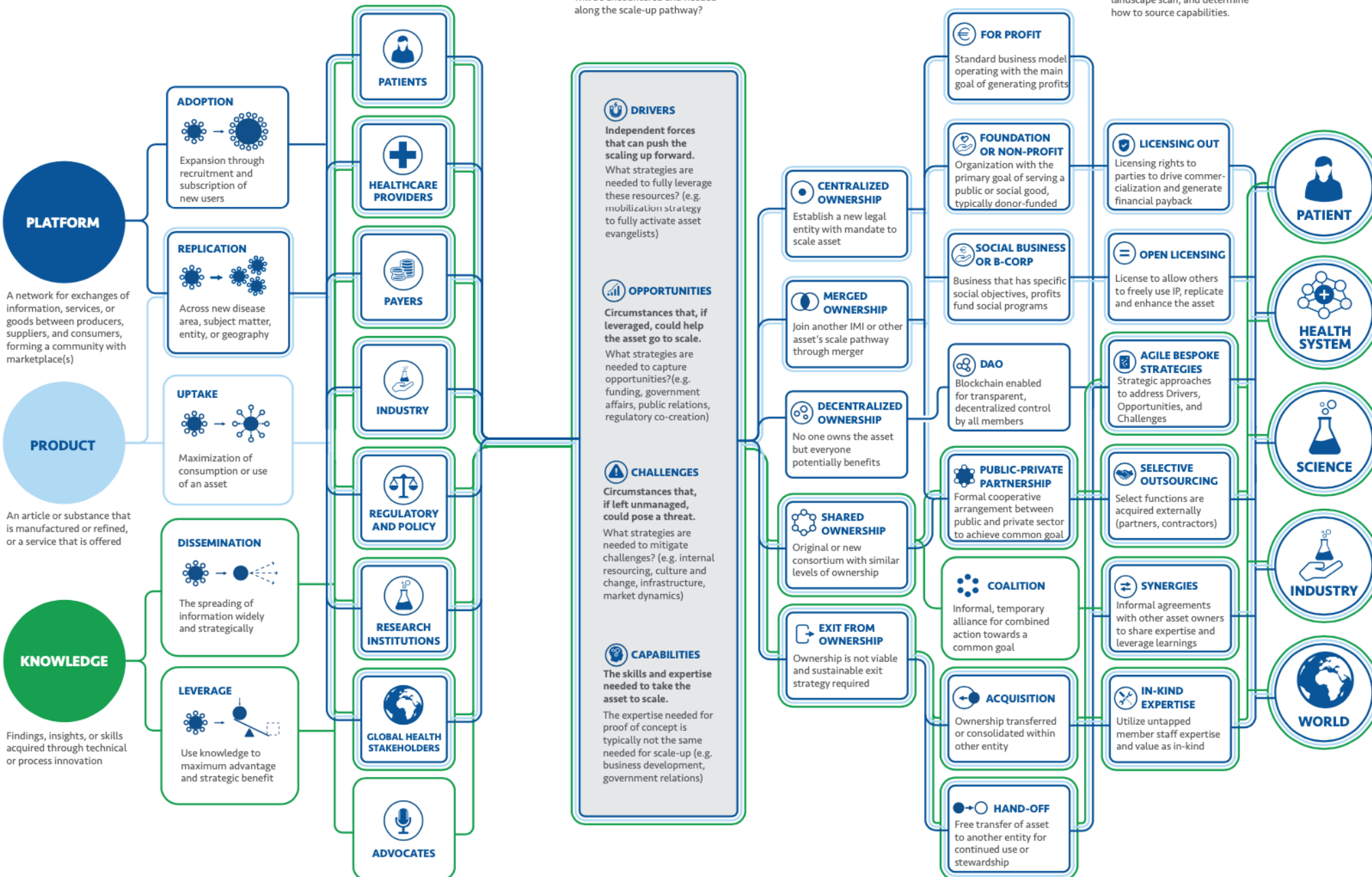
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Q&A PANEL DISCUSSION: THE REALITY OF TAKING PPP ASSETS TO SCALE

CLOSING REMARKS