

DOP

PEER₂SCALE - HEALTH



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I. Abstract

The overall objective of the Peer2Scale-Health project is the mutual learning of existing support services, the testing of them, and the delivery of optimized support tools to young health SMEs and start-ups to prepare them to the scale-up process. In the following, the term "SME" is mainly used and includes start-ups.

As a consortium, our intention was to investigate the most suitable tools and mechanisms to support SMEs in their scale-up process. We did this through the Twinning+ methodology, which encouraged us to look both at our current actions but also at the unmet needs encountered by the SMEs we are accompanying in their scale-up pathway.

The present Design Options Paper (DOP) explains the applied methodology, summarizes the results during this peer learning action, and provides need-orientated, practical recommendations to health innovation agencies, cluster management organisations, and their ecosystems on how to support SMEs. In the following, the term "cluster" is used to include cluster management organisations, other innovation agencies and intermediaries, and related institutions.

This DOP is also an invitation to clusters and their ecosystems to conduct peer learning actions for the optimization of regional activities.

The target groups of this document are: cluster and health innovation intermediaries, health-related project teams, entrepreneurs-to-be, start-ups, and SMEs, but also innovation intermediaries from other sectors, European & national regional authorities, funding and financing bodies and organisations running health entrepreneurship programmes.

II. Introduction

A. The Peer2Scale-Health project and its main objectives

Peer2Scale-Health is a 12-month peer learning action conducted by four regional health innovation agencies acting as cluster management organisations and providing specific innovation support services to their regional health network, in particular to SMEs. The consortium is composed of Eurasanté (Hauts-de-France), the lead partner, BioM (Bavaria), Biocat (Catalonia) and lifetech.brussels (Brussels).

Within the Horizon 2020 programme, Peer2Scale-Health is funded as an INNOSUP project to enable peer learning of innovation agencies for enhancing the innovation capacity of European SMEs.

Through the adopted Twinning+ methodology, the project is about mutual learning based on the consortium's best practices, and about the design of a "best model" for a cluster innovation programme that raises entrepreneurship skills in health SMEs at the time they go through the critical scale-up process. The project addresses a triple demand coming from i) SMEs facing specificities of the health industry sector (long time-to-market, specific financial needs, complex regulations, etc.), ii) clusters promoting their health ecosystems, and iii) the European Union furthering the competitiveness of the life sciences sector. This DOP wants to provide a guidance, to engage more clusters in a peer learning action, and to be the basis for a follow-up initiative to further implement the co-designed activities for the benefit of European SMEs.

The first two months of the project were dedicated to the collection and assessment of information about those professional SME support programmes and tools that are currently provided by the project partners, and about the frameworks each partner operates in.

The subsequent eight months were spent organising joint thematic workshops and peer-review actions to learn how to optimize current support tools. Three workshops were organised at three different partner locations, providing a double benefit:

- Attract people and interact with the local ecosystems of each partner region, and thus with relevant stakeholders (SMEs, funding networks and investors, entrepreneurs, business coaches, etc.).
- Communicate about the project in the community to ease dissemination and future exploitation of results, and to prepare the ground for the future implementation of new support services at a larger scale.

The first step was to assess to what extent a supporting environment has an impact on the SMEs in their different

development phases. In a second step, the consortium collected feedbacks and expectations on the Peer2Scale-Health initiative, and measured the SME satisfaction level during the implementation of the project. The survey we designed during the second step, for example, was focused on SMEs' main needs and hurdles, in which they reported on the type of support tools they found most beneficial, and which support tools they are missing. The final part of the project was dedicated to creating this DOP.

B. Innovation support services for health SMEs in Europe: facts, figures, and preliminary observations

Innovation translated from research is the root from which successful SMEs grow, especially in the health industry. The success of such companies can be measured in improvements in the care provided to patients, but also in employment numbers. This benefits both, the health of humans and the economy, with a high growth being correlated with a higher employment rate^[1].

Regardless of the sector, entrepreneurship can be difficult. 90%^[2] of start-ups fail (most of them in 3-5 years following their creation) for different reasons, including products or services not fitting the market needs, or misallocation of financial resources.

Health SMEs are also confronted to these realities, but have specific obstacles to overcome, including complex healthcare regulations, long time-to-market, higher than average operating costs, and financial needs.

According to the Cambridge business dictionary, a business incubator is "an organisation that helps people to start new companies, especially ones involved with advanced technology"^[3] while a business accelerator is an organisation helping "new companies to grow quickly or become successful"^[4]. In practice, these denominations are often not clearly distinguishable.

Subsector	Average time-to-market
Biotech and highly regulated medtech and digital health	5-10 years
Lowly regulated medtech and digital health	2-3 years

Table 1 : Average time-to-market in healthcare per subsector

The services a cluster provides can be of crucial value to their SMEs. The goal for a cluster is to work together with the SMEs in order to overcome the barriers on the path towards success and growth. This is achieved by offering demand-driven support to address those skills and resources required by an SME in its individual growth stage.

Young businesses have different levels of maturity, different available sets of skills and resources, and different needs depending on their subsector (biotech, medtech, digital health). Hence, it is almost impossible to imagine a single set of services leading all these different businesses to success. It is therefore not reasonable to offer a 100% standardized support programme for every SME. It is rather recommended to analyse the current state of a business, discover its strengths and weaknesses, and build a customized programme around it. To achieve this goal, clusters often already offer a range of services gathered in one or several programmes, often called "incubation" or "acceleration".

THE EUROPEAN HEALTH BUSINESS
INCUBATION AND ACCELERATION
LANDSCAPE

The European Cluster Collaboration Platform^[5] (ECCP) provides a map of the leading cluster organisations in Europe. By using the appropriate filters, we can estimate the number of healthcare-oriented structures to more than 135.

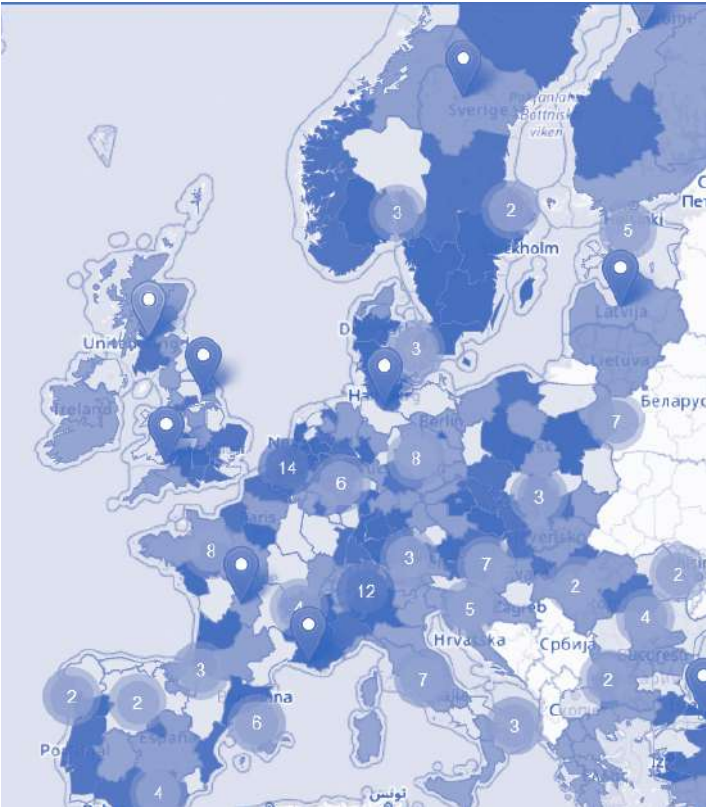


Figure 1 : Leading healthcare-oriented cluster organisations in Europe, provided by the ECCP (2020)

This document does not have the pretention to provide an exhaustive list of health clusters, incubation and acceleration programmes in Europe, but rather show the potential impact that our research results could have on clusters across Europe. There are examples of successful innovation clusters in the geographical areas shown in the map.

The table below shows the filters used for the estimations^[6].

Filter	Number of cluster organisations
Biological sciences	135
Sub-Filters	Number of cluster organisations
Medicine, Human Health	67
Biology, Biotechnology	37
Genome Research	11
Micro and Nanotechnology related to Biological Sciences	5
E-Health	50

Table 2 : Filters and sub-filters used to estimate the number of European Clusters on the ECCP map

The examples below are featured in sifted.eu^[7] (relayed by the European Commission^[8]) and labiotech.eu^[9] lists of leading European health incubators and accelerators in 2019. Also other sources provide inspiring instances of successful healthcare-oriented innovation clusters and programmes.

A complementary insight is given in the section V.b.ii (page 15) of this document, with the description of the programmes provided by the consortium partners. Notice that there are also virtual incubation concepts (such as BioM's inQlab).

The programmes mentioned above are focused on the region where the cluster is based, which is the case for most innovation programmes. With EIT Health, there is a unique initiative operating at European-wide level:



ACCELERACE

ACCELERACE ACCELERATOR, DENMARK:

Description:

Founded in 2008, Accelerace is a leading business accelerator located in Denmark. Biotech, Medtech and Digital Health are amongst its expertise fields with industry specific teams. Through its acceleration programmes, Accelerace offers its expertise and experience to operate the transition from start-ups to scale-ups. This is achieved through Business trainings by serial entrepreneurs, support for the access to the Danish health market, intensive business workshop sessions and an access to a network of leading investors, investor programmes. Accelerace has funds to invest directly in start-ups.

Selection and Application process:

Applications are open at specific times during the year, start-ups can also send unsolicited applications outside these periods via the Accelerace website.

Note: Accelerace emphasizes the importance of experience and mentoring. It gives access to the **NOME Network (Nordic Mentor Network for Entrepreneurship)**, which is an elite mentoring programme dedicated to health and life science start-ups.

Results: 88% start-up survival rate for 10 years.



ACCELERATE@BABRAHAM, UNITED KINGDOM:

Description:

Launched by the Babraham Bioscience Technologies in 2018, the Accelerate@Babraham initiative provides support to ambitious life sciences venture through two programmes. The **startup@babraham** programme includes £10k non-dilutive funding, access to shared free lab and office space, mentoring from industrials in the campus (i.e. AstraZeneca & Eli Lilly), exposure to financial partners and the participation to a 5-months bio-entrepreneurial programme.

The **scaleup@babraham** programme takes the form of 5 days of training sessions on the topic of human resources (building a team), finance, business development, communication, and pitch. It is also a privileged occasion for networking.

Selection and Application process:

The **startup@babraham** programme is designed for pre-seed projects and companies below £500k investment. Five candidates are selected for this programme through a competition with a rigorous application process.

The **scaleup@babraham** training sessions is a paying programme (£1500 for 5 days) for seed to pre-series A companies (from £500k to £3m investment).

Note: The Babraham Research Campus has been very successful in supporting biotech companies from pre-seed to seed and on to IPO.



HEALTH2B HEALTHTECH ACCELERATOR, SWEDEN:

Description:

Operating at SmiLe Incubator, Health2B is a lean start-up accelerator located at the Medicon Village in Lund in proximity of the Swedish health ecosystem. Health2B offers an intensive 2-month global acceleration programme, including on-site and online coaching sessions as well as networking opportunities. These meetings are organized with industry leaders, well-known entrepreneurs and specialists in various fields (such as communication and marketing, design, branding, social media, public relations, sales, patents, regulatory issues, lawyers, economists, packaging, etc.), who can help with specific business questions.

Selection and Application process:

This programme is dedicated to medtech and digital health start-ups. Candidates can apply at specific times during the year, up to ten companies are accepted simultaneously. Special attention is paid to the team carrying the project during the selection.

Note: Health2B highlights its use of the Lean forward with the LUNA meaningful learning loop (Learning, Understanding, Navigating, Assuming). This tool aims to create learning organisations in start-ups.



EIT HEALTH, EUROPE:

Description:

Created by the European Institute of Innovation and Technology (EIT) in 2015, EIT Health's mission is to foster health innovation by bringing together experts in business, research and education. Conversely to most innovation programmes, EIT Health is active at European-wide level thanks to six regional hubs disseminated across borders. This European presence is implemented by a partnership strategy with more than 150 partners across the territory, including regional health clusters.

Services:

EIT Health targets projects in the ideas-stage with the **Wild Card Programme**, with the aim to **create two companies per year** with **up to 2 million €** investment for each. Alongside with the investment, a **24-month long** support is provided including training, mentoring & coaching from world-class experts, and proactive networking to create a solid business plan and build a venture.

EIT Health has also **20 "Acceleration programmes"**. The goal is to work with entrepreneurs, start-ups and SMEs to shorten the time-to-market for life-changing products and services. Programmes treat numerous topics (regulation in medtech, healthcare systems, digital healthcare solutions, funding, internationalization, and more) and have different formats (12-month long programmes, 5-week long intensive bootcamps, training sessions, competitions). The notions of growth and scale-up are central in these programmes. The amounts invested in projects are programme dependent.

Selection and Application process:

For the **Wild Card Programme**, candidates must apply to an annual call for projects. Applications are then reviewed and selected giving the opportunity to participate in an intensive week-long training. Candidates will then pitch their ideas and the two chosen projects benefit from the programme.

The **Acceleration programmes** are also accessible through dedicated calls for projects, made available on a dedicated online platform.

Impact:

-162 innovation projects supported; 55 products launched to market; 3.2 million € investment attracted through the **Wild Card programme**.

-740 start-ups supported; 22 products and services brought to market, and 205 million € attracted through the **Acceleration programmes**.

Note: EIT Health connects partners and hubs to offer programmes in multiple countries in Europe.

III. The challenge: giving the right support for an efficient scaling-up

Preliminary observations show the **high potential impact** that clusters can have through their services on SMEs to address their scale-up phase. However, they also show that there is **room for improvement** to bring demand-driven entrepreneurship skills to the next level.

The following key-questions will guide this DOP to **identify challenges** faced by the innovation ecosystem (especially by health SMEs, clusters, policy makers) to raise entrepreneurship skills and to **design options for clusters** to build or adapt their measures and tools.

- What are the **main barriers for SMEs to unlock their potential** in the scale-up phase (especially with regards to internationalisation, cross-sector markets, product range expansion, commercialization model)?

- Which **are the features for a cluster to adapt or develop in its current or future innovation support measures?**
- Which options explored in this DOP could be implemented **at the level of a single innovation ecosystem**, and what options can be **addressed jointly** by several clusters?

Before we address the above questions, the following chapter tries to clarify the term of a scale-up company, and explains the approach taken to design support measures and to disseminate them.

A. Approach to address the challenge: Twinning+ methodology – mutual learning of best practices

The Horizon 2020 topic "Peer learning of innovation agencies" (in this DOP, such agencies, cluster management organisations and other innovation facilitators are included in the term "cluster") provides incentives to national and regional clusters to engage in peer learning on topics relevant for the design and delivery of innovation support programmes for SMEs^[10].

Although the European Commission has supported mutual policy learning and exchange of good practices in several programmes, traditional methodologies for learning among clusters did not lead to the expected results, e.g. the traditional Twinning methodology, where the roles of "teacher" and "student" is clearly separated.

As a result, the "INNO-Partnering Forum" (IPF, 2009-2012) made some significant contributions to tackling this issue. In a collaborative exercise, the IPF developed the Twinning+ methodology, which combines elements of traditional peer reviews and the twinning method in small learning groups of equally interested agencies. This mechanism is not limited to transferring good practices among clusters, but it creates an opportunity to commonly design a best-practice innovation support programme in order to improve the implementation of the optimized practices identified. The outcomes of the joint work under the IPF scheme are later translated into a DOP, which serves as a guide and useful tool that compiles the

different options to address the identified challenges. However, the first experiences with DOPs uncovered that it is not so simple to just identify a good practice and then transfer it, mainly because of the different contexts that the participating entities may face. Thus, as the guidance document provided by the European Commission on this methodology states, a successful Twinning+ project should involve the right partners and experts at European level, addressing those support needs identified by SMEs, and implementing cooperative methods to create long-term partnerships and services.^[11]

During the design of the concept and methodology of the Peer2Scale-Health project and, in particular, during the writing of the DOP, these aspects were carefully taken into account. The project consortium set up a cross-border framework to help Europe's clusters to identify and overcome the hurdles and pitfalls they find when supporting the acceleration and scale-up process of innovative SMEs in the healthcare sector. The present DOP provides guidelines for optimal innovation services and their implementation to other clusters.

B. Definition of a scale-up company

When assigning resources on a specific target group, it is necessary to aim for a clear definition, especially when the activity is meant to be compared and applied to other regions.

When researching on a definition for a scale-up company, it is mostly regarded as a development-stage business. All definitions refer to high-technology markets and have their main focus on growth in terms of market access, revenues, and number of employees. Scaling-up is defined here as an exponential economic growth. The OECD-Eurostat, as a commonly used definition, is defining scale-ups as the 'gazelles' or High Growth Firms: "All enterprises with average annualised growth greater than 20% per annum, over a three-year period should be considered as high-growth enterprises. Growth can be measured by the number of employees or by turnover"^[12]. In addition to a company growth of 20% in the last three years, Endeavor defines scale-ups as high-tech start-ups, and goes into

more detail on the number of employees, which "will increase from 10 to 17 employees in three years"^[13].

Franchini, the founder of ScaleIT, gives a more precise definition by identifying some key metrics: "1 million euros in turnover in the past 12 months or 1 million users per month (for online B2Cs); at least 20% of turnover from foreign clients; at least +10% growth month on month and +100% year on year."^[14]

As a consortium applying the Twinning+ methodology and based on experience, Peer2Scale-Health tentatively defined attributes associated with scale-up companies in healthcare. In the following table we oppose early-stage projects to scale-ups and distinguish subsectors with similar time-to-market.

	Biotech and highly regulated medtech and digital health	Lowly regulated medtech and digital health
Early-stage project	From the beginning of preclinical studies until their completion.	Before Proof-of-Concept to early commercialization phase.
Scale-up project	From the preparation of the clinical phases until their completion and the launch of the product.	Significant increase in sales volume (i.e doubling from 50,000 to 100,000 units sold) and internationalisation.

Table 3 : Characterisation of health early-stage and scale-up projects depending on the subsector

During the Peer2Scale-Health workshops, the consortium and the involved SMEs identified four main activities on which a significant company growth could be based:

- Entering new geographical markets (internationalization);
- entering adjacent markets, indications, or segments;
- adopting new commercial models, e.g. direct sales, using channel partners;
- going into a product expansion or diversification within the same customer segment, but developing new products.

Simplified, scaling-up is a distinct phase of significant company growth, no matter what size the company had before entering this process. But unlike a start-up company, a scale-up company has already validated its product on the market, has proven that it is economically sustainable, and has already achieved a considerable pulling power. Scale-ups already perfected their product-market fit, their assumptions are validated and their units are economically sustainable. Before seriously thinking about scaling-up, a company has successfully passed the seed-funding and mostly also the Series A round, although this external investment might be taken for opportunities to scale the product across different markets. The second

financing round is often accompanied by a step into the scale-up phase, and a market development through strategic cooperation with established companies.

In the scale-up phase it is important to focus on core business operation responsibilities and to set them less broad. This is inevitably accompanied by an increase in the number of expert employees and adds value to the economy. To monitor key figures, quotas and processes it is necessary to onboard new leaders with corporate management experience. In addition, to establish or adapt the onboarding process, it is essential to create additional structures to maintain quality control and complete projects on time.

Since the scale-up phase of a company is usually the fastest and most significant growth phase, it is obvious that it brings a number of challenges and requires a lot of support and advice. (cf. Section VI, page 22)

IV. The Peer2Scale-Health consortium

A. Description of project partners

I. EURASANTÉ



Eurasanté is successfully running a labelled incubation scheme since 1999, recently ranked amongst the top-15 of European biotech incubators according to LaBiotech. Significant positive results have been achieved since then: +170 projects supported, +100 companies created, 530 jobs created, 450 million € raised.

Moreover, Eurasanté has extensive experience in managing European-funded projects, being involved in 28 European projects over the past 15 years. Today, Eurasanté is partner or lead partner in 18 European projects (e.g. Interreg, H2020) and its European network is composed of over 100 partners coming from 17 countries.

FUNDING AND GOVERNANCE MODEL

Eurasanté established its Bio Incubator in 2000, approved by the French Ministry of Higher Education and Research. It supports various innovative biology, health, or nutrition projects, resulting from public and private research.

INNOVATION SUPPORT SERVICES EITHER DEDICATED TO EARLY-STAGE OR MORE MATURE SMES

Eurasanté is a development agency dedicated to technology transfer and business development in the life sciences sector, and it has an experience of 20 years in supporting the emergence, transfer, and valorisation of innovation in both academic and industrial worlds.

TEAM SIZES AND BACKGROUNDS

The incubation and acceleration teams are composed of 8 multi-disciplinary experts specialized in biotech, medtech, market access, business development and fundraising. In total, Eurasanté has over 100 employees in different services such as a support department with market study, legal, digital health experts, a European projects department and an events department.

ECOSYSTEMS: LOCAL ACTORS, EXISTING CAPACITIES, NETWORKS, STRENGTHS AND WEAKNESSES

Currently, the Eurasanté Bio-Incubator is supporting more than 60 companies (40% in medtech, 30% in biotech, 30% in digital health).

Eurasanté also organises four international healthcare-related partnering events that aim to increase and improve interactions between academia and industry: BioFIT (life sciences), MedFIT (medtech, diagnostics, digital health), NutrEvent (food, feed, nutrition, health) and AgeingFIT (healthy ageing).

Located in the Eurasanté Bio-Business Park, the Eurasanté Bio Incubator provides companies with a 2000m² state-of-the-art building, which houses laboratories, offices and shared facilities. Acting as a real driver of innovation, the Bio Incubator team works together with project initiators and entrepreneurs to help them at every stage of their project. All experts dedicated to the development in the incubator come from life sciences and health research sectors.

II. LIFETECH.BRUSSELS



FUNDING AND GOVERNANCE MODEL

The Brussels Business Support Agency (BBSA) is the economic development agency, under the regional authority of the Brussels Government. This public agency aims at providing information and support to Brussels-based entrepreneurs, projects and companies. Six regional clusters are hosted in the same organisation, one of these being dedicated to the HealthTech sector – lifetech.brussels. Since 2010, lifetech.brussels is the public enabler for innovation and entrepreneurship

for healthcare in the Brussels Capital Region in Belgium. With a main focus in HealthTech (digital health and medical technologies) since 2013, it aims for value-based medicine, patient empowerment, prevention, and continuity of care.

INNOVATION SUPPORT SERVICES EITHER DEDICATED TO EARLY-STAGE OR MORE MATURE SMES

Lifetech.brussels has three main missions:

- **Boost:** One of the major objectives of lifetech.brussels consists of stimulating innovation and entrepreneurship in the health sector. The cluster offers ad-hoc individual and collective support to innovative company and project members in order to allow them to well expand. It includes business and financial planning, third party financing, helping to build R&D projects, informing about intellectual property protection options, and also an acceleration programme dedicated to start-ups and scale-ups active in the medtech field.
- **Connect:** lifetech.brussels's actions envision the consolidation of the ecosystem by bringing closer together different industry stakeholders. lifetech.brussels organises seminars, thematic workshops, networking events (Health 2.0 Brussels, brokerage events with Enterprise Europe Network, etc.) and international missions (Medica, HIMSS, Medfit, etc.), and ensures that all opportunities and relevant information is transmitted via a platform and a newsletter, whilst promoting member activities.
- **Spotlight:** lifetech.brussels highlights the R&D activities and clinical competencies of the institutions of the Brussels Capital region. The cluster spreads a monthly newsletter amongst its members, and publishes background articles on relevant topics in the industry.

TEAM SIZES AND BACKGROUNDS

Run by a team of six people, it aims at supporting and facilitating the development of health and healthcare-related businesses. Team members have a business background and an accumulated experience of 30+ years of coaching and entrepreneurship in the healthcare sector (pharmaceuticals, biotechnology, medical devices and digital health).

ECOSYSTEMS: LOCAL ACTORS, EXISTING CAPACITIES, NETWORKS, STRENGTHS AND WEAKNESSES

Today, the cluster has 150+ active members among which are 90+ start-ups (60 digital health companies and 30+ medtech companies) but also support experts, research labs, federations etc.

III. BIOM BIOTECH CLUSTER DEVELOPMENT (BIOM)



FUNDING AND GOVERNANCE MODEL

BioM is a **leading German network organisation**, managing the biopharma region of Munich and the Bavarian Biotechnology Cluster. The non-profit cluster management is commissioned by the Bavarian Ministry of Economic Affairs.

INNOVATION SUPPORT SERVICES EITHER DEDICATED TO EARLY-STAGE OR MORE MATURE SMES

BioM manages a wide range of training sessions, events, and network meetings **"by experts for experts"**. The Gold Label awarded cluster management organisation provides comprehensive consulting and specialised coaching training as well as mentoring programmes especially for start-ups. For BioM's virtual incubation services, see **inQlab** (<https://www.bio-m.org/en/for-start-ups.html>). In total, BioM supported more than 200 start-up companies in 20 years.

TEAM SIZES AND BACKGROUNDS

The team of BioM consists of 18 staff members, managed by its Director Prof. Horst Domdey, a figure-head in the German biopharmacy sector. Coming from various research- and industry-related backgrounds, BioM staff continuously works on optimizing support schemes for entrepreneurs-to-be, start-ups, and SMEs. Three members of staff focus entirely on start-up support.

BAVARIA – THE PLACE FOR THE MEDICINE OF THE FUTURE

Bavaria holds 410 biopharma companies with 33,800 employees. The region's core competence is the development of innovative therapeutics & diagnostics, in particular for **virtual healthcare**. BioM connects the Bavarian biopharma sector with an extensive network of global business contacts and offers comprehensive information for prospective business partners.

The **research landscape** in Bavaria offers fertile ground for innovation and progress. It is a world-class location that is home not only to research-based biotech and pharmaceutical companies but also to superb universities and colleges, and non-university research institutes in the life sciences sector. A large number of successful **spin-offs** have been cultivated by these institutions. The BioM network, its advisory services, and the BioM inQlab virtual incubator have

supported most of the start-ups across the entire health sector.

In the up-and-coming field of **digital medicine**, Bavaria has witnessed the emergence of around 50 start-ups in the space of just a few years. For this reason, and with special funding from the Bavarian Ministry of Economic Affairs, numerous business incubators have been established throughout Bavaria.

IV. BIOCAT



FUNDING AND GOVERNANCE MODEL

Biocat is the institution that brings together the life sciences and healthcare innovation community in Catalonia. It is a non-profit, private foundation created in 2006 at the behest of the Government of Catalonia. Through its actions, Biocat acts as a knowledge partner for the government to design policies and programmes that affect the sector and facilitates collaboration between the stakeholders in the BioRegion and a variety of entities in Catalonia and beyond. Biocat's mission is to maximize the economic and social impact of the life sciences and healthcare innovation of the BioRegion.

The Board of Trustees is the main government body of the Biocat Foundation and gathers a representation of the diverse institutions and organisations committed in fostering life sciences in Catalonia. Board members are designated by the Catalan Government and the Barcelona City Council, industry organisations like Farmaindustria, CataloniaBIO & HealthTech and Fenin Catalunya and several sectorial entities.

INNOVATION SUPPORT SERVICES EITHER DEDICATED TO EARLY-STAGE OR MORE MATURE SMES

Biocat's strategic priorities are to grow innovation & accelerate business, to develop talent and boost knowledge and to position the BioRegion internationally.

- Regarding **innovation and business acceleration**, Biocat provides the life sciences and healthtech companies and projects with tailored programmes at every stage of their growth, with special emphasis on knowledge and technology transfer, commercialization, team building, and access to capital, from start-up to scale-up.
 - Key activities and programmes within this pillar are: CRAASH Barcelona Bootcamp, The Investment Readiness Series, Open Innovation Forum, Here comes your Lead and Health and Bio Team dating.
- Providing innovative training and programmes that empower researchers and entrepreneurs with the mindset, skills and network to bring healthcare solutions to the market is the goal addressed on the **talent development and knowledge boost** strategic pillar.
 - Key activities and programmes within this pillar are: the postgraduate course Design Health Barcelona, MOEBIO Short Programmes, B-Debate and Keys to Entrepreneurship in Bio and Medtech.
- Biocat **positions the BioRegion internationally** by promoting and showcasing the BioRegion of Catalonia brand to make it globally renowned for its excellence in science and healthcare innovation, increasing the opportunities to attract investment and talent.
 - Key activities and programmes within this pillar are: BioRegion Report, Catalan Life Sciences Platform, Fairs and Missions and Strategic Partnerships.

TEAM SIZES AND BACKGROUNDS

Biocat has a workforce of 23 people including project managers, department directors, and trainees, among others. Specifically, the departments of Innovation and International Relationships, which are in charge of Peer2Scale-Health, have a total of 10 employees, mainly with scientific, business, and international relations backgrounds.

ECOSYSTEMS: LOCAL ACTORS, EXISTING CAPACITIES, NETWORKS, STRENGTHS AND WEAKNESSES

With a population of more than 7.5 million inhabitants and a territory comparable to that of European countries like Belgium or the Netherlands, Catalonia has the most dynamic life sciences ecosystem in Spain and one of the most active in Europe. Furthermore, Catalonia is the leading Spanish autonomous community in internal R&D spending in biotechnology, with an investment of 454.7 million € in 2015.

The BioRegion of Catalonia has more than 1,000 companies and 89 research organisations. Of the 1,445 companies in the BioRegion of Catalonia, the largest group is the 288 businesses in the biotechnology sector, 59 of which focus on new therapeutic and diagnostic tools, 130 on R&D services and 99 on applications in other fields (like veterinary, industrial

biotechnology, food, agriculture, and the environment).

Moreover, the BioRegion has 101 medical technology companies, 67 in the pharmaceutical sector and 167 offering healthtech products or services. 91% of the companies are SMEs, with microenterprises with fewer than 10 employees, making up half of all companies (49.8%).

Regarding its research organisations, the BioRegion gathers 40 research centers (32 CERCA), 18 university hospitals, 12 universities with healthcare and life sciences degrees, 3 large science facilities (ALBA synchrotron, Barcelona Supercomputing Center and Centre Nacional d'Anàlisi Genòmica), 2 technology centers and 14 science and technology parks working in healthcare and life sciences.

Moreover, Catalonia is the birthplace and headquarter of large companies like Almirall, Esteve, Ferrer, Grífols, Bioibèrica, Lacer, Reig Jofré, and Uriach. Global leaders in the sector are also present in Catalonia, including Amgen, Novartis, Sanofi, Roche, Bayer, B.Braun, Boehringer Ingelheim, Chiesi, Hartmann, Lundbeck, and Menarini.

B. Why this consortium?

I. STRENGTHS

Peer2Scale-Health brings together four experienced regional health innovation agencies. In their role as cluster development organisations they build a synergistic consortium with a great expertise and geographical relevance. The powerful consortium aims at a larger impact across the four participating countries, eventually leaving a technology acceleration footprint, provoking mimicking processes over the European Innovation Ecosystem, and hopefully influencing policy makers and funding & financing decision-makers regionally, nationally and EU-wide.

The consortium partners, namely Eurasanté, Biocat, BioM, and lifetech.brussels, are renowned and strong European innovation agencies and clusters, with a vast experience on providing support to health SMEs. They accelerate biomedical and medical devices innovation, complementing each other in their sub-sector expertise, international networks, and focusing on different stages of company start-up and growth. All of the partners support the formation and development of start-ups and SMEs through scouting, incubation, start-up support, and accelerating services as well as go-global initiatives. Partners mostly focus on supporting innovative (academic) life sciences start-up teams and more established innovative SMEs.

Prior to the beginning of this project, the four consortium members identified and expressed a need for cooperation in certain areas in order to optimise and enrich the support services they provide. Based on the fragmentation of the European healthcare ecosystems and other intrinsic features such as the strict regulation and the long time-to-market of innovative products and services, the Peer2Scale-Health consortium decided to embark on this peer learning initiative in order to foster the exchange of good practices among innovation agencies, as well as the design of a common innovation programme around the concept of supporting SMEs in their scale-up process.

The Peer2Scale-Health consortium has set up a cross-border alliance to advise Europe's cluster management organisations, innovation agencies, and other innovation facilitators on how to identify and overcome the hurdles and pitfalls they find when supporting the acceleration and scale-up process of innovative SMEs in the healthcare sector. The initiative aims to boost SME competitiveness through tailored actions of their network agencies, and by fostering the creation of sustainable and competitive products and services.

Moreover, the composition of the consortium offers a wide range of dissemination possibilities, given their presence and participation in a great variety of projects, initiatives, networks, and programmes across Europe, which will ease the dissemination of the DOP to other innovation

agencies, decision makers, and ecosystems.

II. ACTIONS TAKEN BY THE PROJECT PARTNERS TO BOOST SME DEVELOPMENT

This chapter provides a number of best practice programmes in the field of incubation and acceleration within the project consortium.

EURASANTÉ INCUBATION PROGRAMME



Open to start-ups based in the North of France (Hauts-de-France) or willing to relocate or develop a significant subsidiary in the region.

The Incubation Programme lasts 36 or 48 months on average from the lab to the Seed Round (or the PoC) and is focused on:

- a) R&D – Proof of Concept / Intellectual Property
- b) Business Development – Strategy / Business Model
- c) Market Access – Regulatory / Reimbursement / Clinical Research
- d) Finance – Business Plan / Fundraising
- e) HR – Founding Team

EURASANTÉ ACCELERATION PROGRAMME

Open to start-ups based in the north of France (Hauts-de-France) or willing to relocate or develop a significant subsidiary in the region. The programme is also opened to established SMEs with a specific innovation programme as well as foreign businesses that would like to reach the French market.

The Acceleration Programme lasts 18 months from the Seed Round to Series A and if focused on:

- a) Business Development – Strategy / Marketing & Sales / Market Research / International
- b) Market Access – Regulatory / Reimbursement / Clinical Research
- c) Finance – Fundraising
- d) HR – Talent Acquisition / Culture / Leadership

For both programmes, different actions are developed: One-to-One Coaching with a dedicated start-up manager who supports about 10 start-ups, networking events (workshops, trainings, etc.) and access to 14 partners (KPMG, Neomed Services, The MarkeTech Group, Bignon Lebray, etc.).

HIBSTER (HEALTH INNOVATION BOOTCAMP) BY EURASANTÉ



Eurasanté has created Hibster in 2016, in partnership with the communication agency Exaeco, Lille European Metropolis and the Hauts-de-France region.

Every year, Hibster's bootcamp gathers 120 voluntary students from various backgrounds (engineering, medicine biology, finance, marketing, commercial, economics and politics) and 12 life sciences companies proposing real business challenges and cases to students. They must be solved during a single innovation weekend (sprint of 48 hours).

Juries composed of regional life sciences' stakeholders evaluate the 24 projects solutions, and a jury rewards the most realistic and innovative solution. It sets the scene to further fruitful collaborations between students as future employees, life sciences companies, and the innovation agency.

MEDTECH ACCELERATOR® BY LIFETECH. BRUSSELS



Since 2016, the health cluster of the Brussels-Capital Region set up the MedTech Accelerator®, the first pre-seed acceleration programme specifically dedicated to early-stage entrepreneurs (TRL ≥ 3; TRL ≥ 3) developing (connected) medical devices in the Brussels capital Region. Since its creation, the programme contributed to boost 50+ projects and start-ups. This non-profit programme is financially supported by the ERDF.

This 4-month programme aims at:

- Boosting the development of deep tech innovative (connected) MedTech solutions through confronting and validating start-ups value proposition and business model with their target customer and thanks to actionable knowledge;
- Helping early-stage entrepreneurs identify gaps pertaining to the development of their solution and help them formulate clear objectives to reach in a timely fashion with the help of dedicated coaches;
- Developing awareness about the swift changing and intricate regulations pertaining to the MedTech sector thanks to the help of a pool of 120+ experts (medical device regulation, quality standards, clinical trials, data management, and others);

Ensuring an appropriate product-market fit and an optimization of the time-to-market of innovative medical devices could significantly help improve or even save lives, hence drastically diminish the burden of healthcare costs of our Social Security system.

BIOM-INQLAB

BioM-inQlab offers extensive and individual support to start-ups and young entrepreneurs in medical biotechnology and health technology:

- **Start-up Coaching** - get hands-on support
- **Mentor Circle** - inspired by experience
- **Pitch Doctor** - how to convince investors
- **BioEntrepreneur Bootcamp** - validate your business idea
- **BioEntrepreneur Lounge** - join the community
- **BioAngels** - find the right investor
- **m4 Award** - create the future of medicine
- **BioEntrepreneurship Summit** - connecting the ecosystem





BioM start-up Coaching – get hands-on support

BioM supports entrepreneurs in developing a business model, writing a business plan, finding the right non-dilutive grants, and financing options for their start-up. Based on its long-standing experience, BioM can build on an extensive network with industry players, investors and other relevant partners.

BioM Mentor Circle – inspired by experience

Since 2012, BioM interconnects experienced mentors with company founders and scientists, who are interested in commercialisation or start-up creation, in the field of medical biotechnology. The mentors are experienced bio entrepreneurs, industry executives or renowned scientists experienced in commercialisation. They contribute as sparring partners, support the founders with their expertise and share their valuable contacts. The knowledge of more than 60 mentors covers a broad range from patent law via pre-clinical and clinical development to regulatory issues. The BioM Mentor Circle enables a valuable exchange in an informal and confidential environment. The mentors' commitment is voluntary and honorary.

BioM Pitch Doctor – How to convince investors

Pitch Doctor is a training workshop to learn the techniques of creating a convincing pitch. The participants also have the opportunity to practice their pitching competence using different case studies. In addition, the team of BioM is available for teams or founders who would like to practice their pitch presentation in order to convince investors, grant juries or potential partners. They will get feedback on their business case, the quality of their slide deck and presentation style, as well as support in writing convincing business plans and grant applications.

BioM BioEntrepreneur Lounge – join the community

The BioEntrepreneur Lounge gives start-ups and young entrepreneurs a chance to participate in the active entrepreneurial scene and to build networks in the early phase of their spin-off. The Lounge is scheduled 2-3 times a year. The entrepreneurs may meet like-minded people and exchange ideas with other founders in an informal ambience. BioM organizes the event at different locations and invites speakers to discuss different topics of bio-entrepreneurship and financing. Founders, persons from start-up financing, coaches, and mentors will be heard.

BioM m⁴ Award – create the future of medicine

Since 2011, the Bavarian State Ministry of Economic Affairs supports the m⁴ Award, initiated by BioM. The pre-seed grant is aimed at academic research projects with spin-off potential in the field of biomedicine and health technology. Research teams at Bavarian universities and research institutions can apply for project funding of up to 500,000 € for two years with their start-up project. The funding will be used to finance the steps required to set up a spin-off and, ideally, to reach the start-up stage. The winning projects not only receive financial support, but also active support from BioM, from the responsible technology transfer organisations, and from other experts.

CRAASH BARCELONA BY BIOCAT



CRAASH Barcelona is organised by Biocat in collaboration with CIMIT - Boston (the most experienced health accelerator in the world), and part of the EIT Health Bootcamp Programme. It is a 12-week programme that helps European research teams launch successful device, diagnostic and e-/digital health innovations to improve health and patient care. Teams move research to market through mentoring from experts at CIMIT.

Specifically, CRAASH Barcelona looks for top-notch healthtech technology (diagnostic, devices, and e-/digital health - drug discovery and drug development not included), emerging from research centers, research institutes, and universities in the BioRegion of Catalonia and other European ecosystems. The programme supports research projects with a TRL 3-4 (proof of concept and proof of feasibility). Nevertheless, established companies can also apply if they are looking for an application in healthcare for their technology and/or searching and validating their business model.

In the 2020 edition, the selected teams will validate the problems and solutions for their products and how they fit the market in some of the best healthcare ecosystems in the USA (Boston) and Europe (Barcelona, and other European cities).

THE INVESTMENT READINESS SERIES BY BIOCAT

The main goal of the Investment Readiness Series is increasing deal flow of projects ready for investment in the BioRegion.

Additionally, Biocat wants to add value to research projects through one-to-one mentoring, make it easier for projects scouting for partners by concentrating top-notch research, and establish long-term relationship with TTOs, leveraging the impact of their work on an ecosystem level.

There are several thematic editions of 'The Investment Readiness Series' per year. In each edition, the best research projects – both from companies and researchers – will meet face to face with investors, business angels, and VCs, who are looking for excellent projects in life sciences. The editions can be local (aimed at Catalan projects and investors) or international (aimed at Catalan projects and international investors). Some of the previous editions are, at international level, The Investment Readiness Series – France Edition and UK Edition, and locally, The Investment Readiness Series – Medtech Edition and Therapeutics Edition.

OPEN INNOVATION FORUM BY BIOCAT

The Open Innovation Forum is a programme that allows companies to share their innovation challenges and get proposals from research groups and centres. Therefore, it is a great opportunity to meet the right collaborator to tackle innovation challenges.

The initiative is divided into five areas of knowledge (food, healthcare, medical technology, chemistry and materials). Any companies and stakeholders that are interested in participating can send proposals until the end of the year so, innovation challenges will be received all year long. In 2019, several events were held so that companies and problem-solvers can meet face-to-face. In particular, a total of 34 companies and 62 groups and research centers have participated, and more than 120 meetings have taken place in total. It is organized by Biocat with other Government agencies (ACCIÓ) and universities' TTOs (Universitat de Barcelona, Fundació Bosch i Gimpera, Universitat Autònoma de Barcelona, Parc de Recerca UAB, Universitat Pompeu Fabra, Universitat Politècnica de Catalunya, and IDIBELL).

HERE COMES YOUR LEAD: COLLABORATIVE AND RISK-SHARING MODELS FOR DRUG DISCOVERY BY BICOAT

Biocat is looking for projects of excellence in the early-stages of drug discovery in therapeutics (e.g. new targets or new hits identified) in the BioRegion of Catalonia that are interested in bringing these therapeutics into the following stages: target validation, hit to lead or lead optimization in order to accelerate their drug-discovery process.

Biocat is connecting these projects with national and international platforms, CROs and big pharma (the partners) to establish a research collaboration model with shared risk and profit. This way, Biocat is helping boost the flow of therapeutic molecules in advanced phases in the BioRegion of Catalonia.

HEALTH & BIO TEAM DATING BY BIOCAT



Biocat runs Health & Bio Team Dating events with BStartup of Banc Sabadell and CataloniaBio & HealthTech (SMEs association). This meeting brings together scientists and research groups working in the life sciences field with business people in order to create groups that can generate new business synergies and start-ups. The initiative aims to encourage and promote the transfer of technology and knowledge, while developing the bio-entrepreneurship ecosystem in Catalonia.

The previous editions hosted more than 500 meetings with over 180 projects and business professionals. 85% of participants have found strategic contacts and new business thanks to the initiative and some teams have succeeded in reaching several agreements.

III. CONCLUSION: COMPARATIVE TABLE WITH A SWOT ANALYSIS OF THE PROJECT CONSORTIUM

The below SWOT analysis focusing on the project consortium is a summary of the status quo, undertaken by the partners to identify the alliance's internal strengths and weaknesses, as well as its external opportunities and threats with regards to scale-up support for SMEs. This SWOT might reflect the situation faced by other life science ecosystems and clusters, and outlines the helpful and harmful aspects of a cluster's support concept for scale-ups. As all SWOTs, this overview helps an organisation – in this case the consortium – to steer and optimise its activities in order to achieve the best results in the future.

SWOT

	Helpful to achieving the objective	Harmful to achieving the objective
Internal origin (attributes of the consortium)	STRENGTHS <ul style="list-style-type: none"> • Strong, long-standing, and renowned innovation agencies with expertise i. to identify, ii. deliver demand-driven support for, and iii. generate the necessary framework conditions to further innovation processes in the field of P4 medicine (biomedical and medical devices innovation) • A large number of excellent actions, projects, and initiatives that are already implemented by the consortium partners and which are relevant to SME support • A good understanding of the scale-up needs for health SMEs • A strong visibility at a European level • Experienced in sharing knowledge and participating in European projects • Ongoing and successful peer learning to implement new and optimized SME support services • Established networks (regional, national, European, global) for the benefit of SMEs but also for strengthening the cluster consortium, also cross-sectoral • The rather small consortium can share experiences in small effective working groups involving interested agencies, organized around already established conferences and sector-specific events • High motivation of the consortium partners to share best practice and no feeling of direct competition • The consortium has wide marketing and dissemination channels 	WEAKNESSES <ul style="list-style-type: none"> • Due to long-time-to-market of SME innovations, few measurable short-term KPIs and rather long-term effects of cluster services • Existing innovation support services either dedicated to early-stage or more mature SMEs • Funding/governance structures • No fixed structure for the horizontal flow and update on information within the consortium • Limited time/financial resources for cluster management team to remain up to date with all relevant topics on a global scale; small team sizes; limited backgrounds (e.g. scientific vs. business vs. non-sectorial) • Support services provided by clusters are often short-lived due to time-limited funding budgets, not providing the necessary support for sustainable SME growth • Only little funding for the consortium to develop new / optimized support services, especially for demanding topics such as generating a European early stage VC fund • Due to longer cluster funding periods secured by far-in-advance written funding proposals, cluster support schemes cannot adjust quickly to changing SME demands, regulatory frameworks, and financing/funding environments • In contrast to start-ups, business development managers of established SMEs are often sceptical about cluster managers "intervening" with their work

External origin (attributes of the environment)	OPPORTUNITIES	THREATS
	<ul style="list-style-type: none"> • Significant preparation for and contribution to SME growth • Improvement of health entrepreneurship skills in SMEs • Regional, national and European industry growth & strength, and an increase in global competitiveness, attracting investments and talent • Closing the gap to follow-on after scouting, incubation, and start-up support • Improving connections between regional ecosystems and SMEs across Europe • Improving the quality of also other EU cluster managements through peer learning, and with the DOP increase their success when applying for EU/INNOSUP grants to support SME growth activities • Development of novel demand-driven support services for young SMEs in coming years, also multi-national support services tapping into each other's knowledge networks • Other innovation agencies adopt the consortium's methodology and/or results to transform their programmes to support innovation in SMEs • Establishment of clusters being the key-drivers of growth support for innovative life sciences SMEs and the contact points/KOLs for external requests in this field • Training of national and regional innovation agencies • Influence relevant regional, national and international policies for the benefit of SMEs • Follow-up funding for the consortium's activities through a successful future proposal within H2020/Horizon Europe or ESIF to support the formation of a long-term partnership • The consortium connects to new innovation providers, relevant networks, industry-sectors, KOLs, SME funding and financing bodies; potential collaborations, e.g. with EEN and CEBR new complementing consortium members • Stronger engagement of SMEs in cluster activities 	<ul style="list-style-type: none"> • Competition through numerous services by other innovation agencies • Despite support through clusters, no SME/regional growth due to strong global competition for funding and collaboration partners, lack of relevant knowledge, lack of talent • Very limited time and financial resources by SMEs to consider/take advantage of the support by clusters, thus few interest and engagement of SMEs in the consortium's activities • Decrease in cluster funding (regional, EU-programmes) or shifts in the priorities of the funding bodies • In comparison to e.g. TTOs, cluster management organisations are not seen as key drivers for innovation, but as generalists providing training and networking on a rather shallow level • Policy makers to not take on recommendations of clusters / no easy options for clusters to influence decisionmakers, e.g. future funding programmes of the European Commission • Methodologies cannot be copied easily due to very different cluster structures • Staff changes in consortium partner organisations might cause a decrease in commitment

C. Challenges for clusters providing scale-up support to SMEs

Clusters and cluster consortia, mostly depending on public funding or on generating income from industry face various challenges. With the great potential that clusters have to accelerate business success in their region, those challenges are eventually slowing down SME growth. The vision of this project consortium, shared and supported by the European Commission, is that clusters play a crucial role in facilitating and accelerating the scale-up process of SMEs. Moreover, cluster consortia can create beneficial synergies to strengthen the transfer of knowledge and the collaboration between life science ecosystems in Europe. The ultimate goal is to support sustainable growth for SMEs and to create a globally competitive European life science community.

In this chapter, we list challenges that clusters face when supporting SMEs to grow.

I. DIFFERENCES IN CLUSTER COMPOSITION AND GOVERNANCE

The structures of cluster membership and the target groups of cluster activities vary greatly, not only between European clusters but often also within a given cluster. Many life science clusters are funded to serve biopharma product and service companies, as well as medtech, health-IT, related nanotech, food or cosmetics companies – sometimes clusters are also expected to run incubators and technology parks in parallel. The big challenge is to fit your services to the various needs of your target groups, while facing severe budget and time restrictions, especially when you are a publicly funded cluster organisation.

Under the above circumstances, a cluster management needs to keep up to date with the current, real-life needs of their target groups. This also requires close contacts to the target groups as well as regular trainings for the cluster management itself in order to understand the ever-changing global developments and regulatory framework conditions in the health industry sector.

Each SME faces individual challenges, which are often very different to other companies even within the same growth phase, due to different funding conditions, management setups, regulatory specifics, or certain demands of the customer market. Thus, a company is best supported by individual, customized coaching. Cluster funds are restricted, and also it may be prohibited by regional funding regulations to provide individual support for companies, but rather fund general cluster services where more than one company benefits. Thus, cluster management organisations often struggle to provide such an exclusive coaching, especially when they serve a large number of members.

II. LACK OF FUNDING FOR CLUSTER MANAGEMENT ORGANISATIONS

Many European publicly funded cluster network organisations face the challenge that their funding is gradually reduced over time. Having to fill the financial gap with industry money, most clusters increasingly have to focus their activities on those target groups able and willing to pay for cluster activities – or move into tight membership schemes. This might reduce the focus and freedom of cluster services and activities to benefit those companies generating a profit and paying for the services, excluding e.g. young drug development companies or start-ups. In addition, when applying for grants or designing novel services, cluster management organisations have to provide staff-time up front without payment. With decreasing public funding and paying members demanding perhaps other services addressing more imminent rather than forward-planning SME problems, clusters might find it difficult to invest in future concepts and proposals with unsure return on investment.

There is no comprehensive overview of current funding schemes for cluster management organisations. Moreover, existing multi-regional funding schemes often contradict regional funding regulations. For example, when a cluster management organisation succeeds in receiving European grant money for SME support measures, they are – understandably and rightly – obliged to open up the programme to SMEs from all EU countries. However, if those measures are meant to be made sustainable beyond the project end, a major challenge lies in the restriction of regional cluster funding, that only local companies are eligible to receive cluster services. Thus, tools and networks established throughout the EU-funded project, might not be as effective anymore when continued by a cluster alone, e.g. because there is no such large pool of similar SMEs available in the region as it was the case EU-wide, or international partner organisations are missing the critical mass of relevant SMEs when restricting the interactions after the project end to companies in the cluster's region only.

The European Commission supports the cooperation of clusters in its strive to counteract market defragmentation. However, clusters vary greatly in the way they are financed, if they have memberships or not, in the complexity of their target groups and life science sub-sectors. Industry-financed "clusters", which are rather regional trade associations, are often not eligible to join such EU-funded cluster consortia – and their members might not agree to a third-party role – even if they would be valuable partners.

III. THE HEALTH INDUSTRY IS BY NATURE A GLOBAL BUSINESS WITH A WIDE RANGE OF DEMANDS

Different sectors have their customers in different geographical regions. While biopharmaceutical companies reach out to the USA, Japan and China, MedTech companies might also want to expand to South America or Saudi Arabia, and Health-IT companies might show interest in India. Moreover, SMEs in a given cluster vary in their business model, some wishing to receive support in selling their products and services directly to the end-user, others looking for appropriate distributors, and others again scouting for expert agents connecting them to potential R&D partners and investors. SMEs do not have the time and staff resources to create the appropriate knowledge and network base themselves, which is why this is an ideal added value that a cluster management organisation could provide. However, international network building takes a lot of time and effort, and a cluster organisation can hardly provide market entry support for such a variety of target markets in parallel.

IV. IDENTIFYING APPROPRIATE FUNDING AND FINANCING SOURCES FOR SMES

One of the major challenges for innovative life science SMEs is to secure funding. There is a severe lack of European funding instruments to support pre-seed and seed R&D projects. Moreover, existing multi-regional funding schemes often contradict regional funding regulations. In general, it is difficult for a cluster management organisation to provide guidance individualized to the need of an SME in its region, since there is no comprehensive overview of current funding schemes for cluster and ecosystem managers available.

When financing demands increase after the pre-seed and seed phase, hardly any funding schemes are available to promising young start-ups. In addition, in many regions, local (and even national) investors being prepared to put high investments into high-risk scale-ups, are rare. For clusters, it takes a long time of trust-building to act as an intermediate between individual and corporate VCs. Moreover, organizing B-2-B meetings for large corporations such as big pharma with pre-selected SMEs, takes a lot of effort and preparations with often little direct outcome.

V. BE A GENERALIST AS WELL AS AN EXPERT

While clusters are run by industry experts, those are mostly generalists. Moreover, due to a lack of funding, a cluster organisation usually is quite small and cannot employ a wide range of experts. It is a great challenge to stay updated on all those various sectors represented in a given cluster.

SMEs often state that they gain mostly from peers – managers of small companies, who already went through similar developments in the same industry sector and who enjoy passing on their experiences, dos and don'ts to younger SMEs.

In some cases, SMEs are not aware of potential scale-up opportunities, especially concerning new trends such as AI and machine learning, but also with regards to new and fast evolving economic developments, e.g. in China. Ideally, this is a field where a cluster management should early identify new potentials for their SMEs and coach them individually. However, this is mostly unrealistic given the time and staff constraints in European cluster management organisations.

D. Future outlook

This document intends to identify the main SMEs' needs related to acceleration of their business and projects, and the solutions that innovation agencies and cluster organisations can provide.

Despite having identified the challenges faced by clusters, both in governance and funding (intrinsically related to their acceleration programs), the limited scope of this DOP does not allow for the provision of solutions. Therefore, the consortium has preferred instead to concentrate on presenting recommendations to be included in acceleration programs to help SMEs in their scale-up processes.

Since the consortium is aware that the above mentioned challenges need further discussion, the partners intend

to spark a discussion with other clusters, innovation agencies and involved stakeholders. This could be the subject of a follow-up peer learning action, leading to the development of solutions that improve the organisation of European innovation ecosystems.

Please contact the project partners if you are interested in this topic, and share this document with any interested parties.

V. The SMEs

A. Lessons learned

I. MAIN FINDINGS FROM THE PEER2SCALE-HEALTH SURVEY

The main needs of start-ups and SMEs (in this DOP summarised in the term "SME") when following incubation and acceleration programmes were identified by means of a survey. A questionnaire was sent to more than 200 companies which have followed at least one programme offered by the partners, and 64 answers were collected. This chapter is a summary and analysis of the most important data collected in the four European regions involved in this project: North of France, Catalonia, Brussels region, and Bavaria. It is important to take into account this geographic aspect, as the individual ecosystem may bring SMEs in the healthcare sector different challenges as well as different solutions.

1. SURVEY SCOPE AND SAMPLES

As the Peer2Scale-Health consortium is specialised in the health and nutrition fields, the SMEs answering this questionnaire are working in the field of biotech (40%), medtech (31%), digital health (31%) and other fields (8%) related to these sectors. It is important to consider this variable when interpreting the answers. Time-to-market for example can differ greatly across the sectors.

Another variable is the type of programme that an SME answering the survey participated in. As shown in the graph below (Figure 2), nearly a third of the answers came from participants in Eurasanté's incubation programme. Although nearly 50% of the answers came from SMEs receiving Biocat's support, those were distributed in several different programmes. SMEs entering different programmes might have a diversity of challenges during their growth phase. The incubation programme inQlab run by BioM represents nine answers in this survey, and the programme Medtech Accelerator implemented by hub. Brussels represents seven answers.

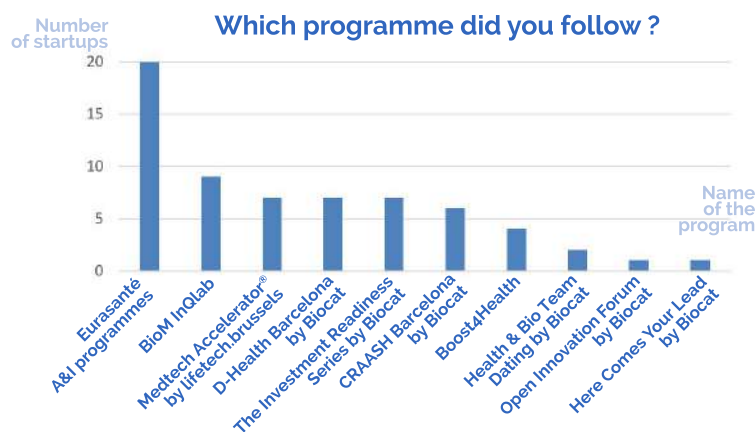


Figure 2. Programme joined by the SME (one answer per SME)

Most accelerators are seen as open innovation platforms supporting the entrepreneurs in launching or scaling their business, and connecting them to mentors, corporations, and investors. Their main objective is to help early-stage start-ups enter into a competitive, often global market. This definition, provided by the study "How to build a successful deep tech acceleration programme", is confirmed by research performed during Peer2Scale-Health (Figure 3). It showed that the main reason why SMEs enter an acceleration & incubation (A&I) programme is personalised coaching, followed by matchmaking with investors. The supporting and connecting roles are crucial, and the most important aspect for these companies. As a finding of this survey, a cluster should be able to provide a strong network and a good coaching expertise if it wants to attract SMEs to an A&I programme.

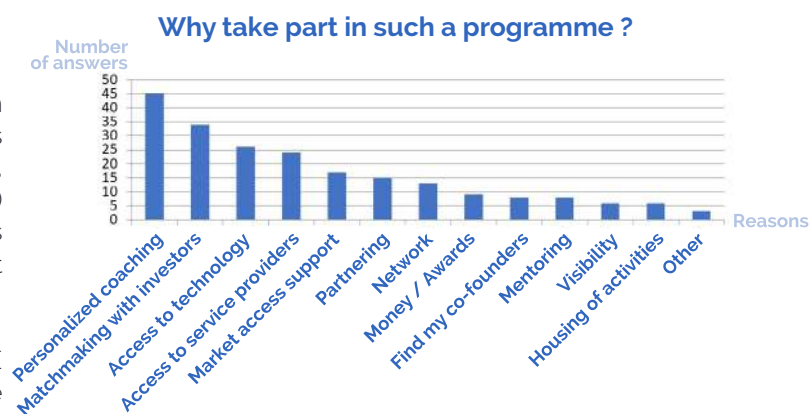


Figure 3. Reasons given by SMEs for joining an incubation/acceleration programme

Maintaining a good long-term relationship with a diverse network of experienced entrepreneurs and experts allows the clusters to address the needs of each SME in a tailored manner. A clear sector focus helps to further engage corporates and VCs in the acceleration programme.

Supporting the above recommendation, the graph below shows the most valued type of consulting offered by clusters to SMEs. The latter want to be connected to VCs and investors in order to get a viable financing plan, get personalised coaching on business development, and also personalised coaching on legal issues. Concerning legal issues, this type of consulting is valuable for many reasons. First, many CEOs and entrepreneurs do not have an in-depths expertise in this matter. Persons answering the survey were mostly scientists and business developers. Legal expertise needs to be delegated to some specialised advisor. Moreover, the regulatory and legal issues are crucial when you are developing a new

health company. This aspect is often experienced as a burden to many entrepreneurs who are naturally new to the field.

In recent years, the European Commission stated: The reduction of the administrative and regulatory burden is a top priority. A special focus on SMEs is necessary, since research indicates that SMEs are disproportionately affected by regulation. The regulatory and administrative costs (measured, for instance, per employee and compared to turnover) for smaller businesses can be up to ten times higher than for large companies^[15]. Several reasons are responsible for the disproportionate distribution of regulatory costs. First, a large part of regulation results in costs that are fixed or do not change much with the size of a business. Filling in a form takes a certain amount of time, no matter how large or small your company is. Second, larger businesses can afford to employ specialists easier and deal with regulatory obligations more efficiently. For larger businesses, investment in computerisation and rationalisation of regulatory obligations is often worthwhile because of the larger number of cases to be dealt with. This too results in higher efficiency. Third, in small enterprises the entrepreneur will often be responsible for taking care of the regulatory obligations. This means that the most valuable resource of the small business will be occupied with tasks that do not directly contribute to the business success of the enterprise. Thus, when entering an A&I programme, entrepreneurs are searching for external expertise to perform these tasks, so that they can focus on their business (Figure 4). An additional advice for clusters is therefore that in order to effectively personalise coaching and help for SMEs, it is valuable to employ or have access to a sector-specific legal and regulatory team.

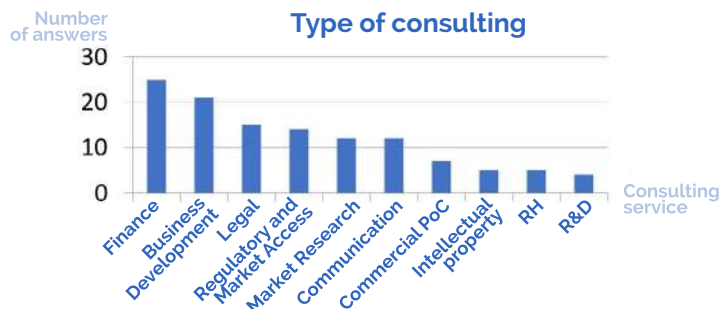


Figure 4. SMEs' most requested consulting services in incubation/acceleration programmes

The following graphs show the impact of a cluster support programme to help with the business projects of the participants, both on the TRL (Technology readiness Level) and on the CRL (Commercial Readiness Level). TRL^[16] and CRL^[17] scales are designed to assess a project's maturity (Figure 5). These consist in scales ranging from 1 to 9 for which each number is associated with the description of a development stage. The stage is related to the technology itself (TRL) or the company's position regarding commercial and market aspects (i.e. Market Alignment). The interpretation of these indicators can be diverse and is not fully objective. For instance, differences can be observed between the level announced by incubees and

accelerators regarding their project, and the assessment of the same project by innovation intermediaries. It is nonetheless a valuable tool used notably by grant funders when deciding on the projects they want to allocate their resources to.

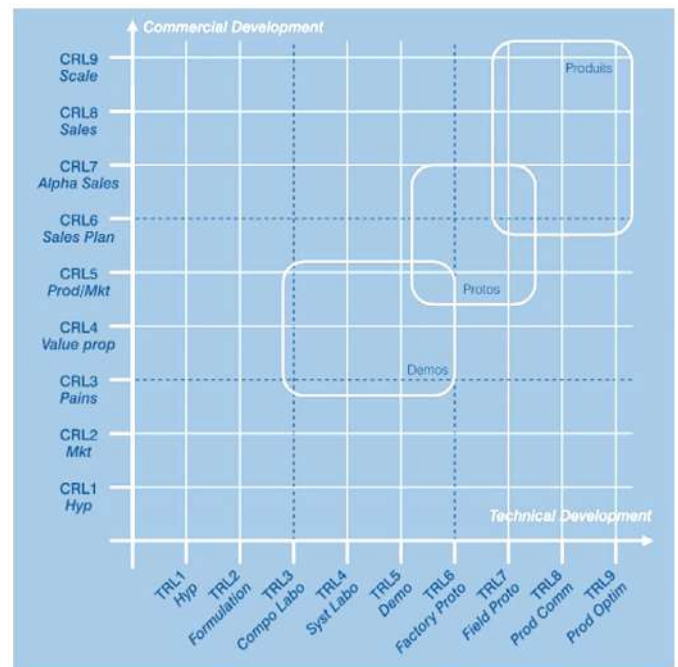


Figure 5. Maturity Matrix (MatMaX), a metrics designed as a work tool for the start-up entrepreneur or innovation project manager (Source: WSL http://www.wsl.be/matmax/home_d.php?lang=en).^[18]

Results show that the TRL at the beginning of a project is on average higher than the CRL. It needs to be highlighted that the information used for this study is how SMEs see themselves. It might not reflect an independently measured TRL and CRL of the company.

Concerning the TRL before they started the programme, the companies have an average TRL of 3.67. After they completed the programme, their average TRL rises to 5.28 (Figure 6).

SMEs enter the programme with an experimental proof of concept and finish it with a technology validated in a relevant environment. This depends on the programme, its duration, and the participation time in the programme.

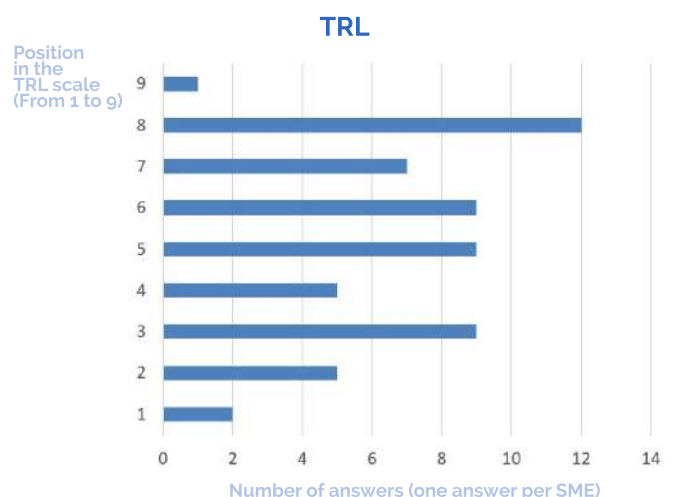


Figure 6. Technology Readiness Level of SMEs after the programme

Concerning the CRL, the average of the SMEs interrogated was 3. After they completed the different incubation and acceleration programmes, the CRL went up to an average of 5.13 (Figure 7). This shows the important role of the A&I programmes during the commercialisation part of the products.

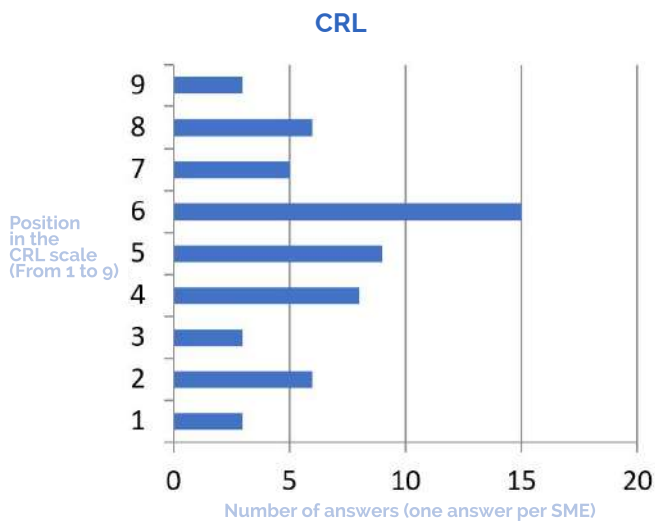


Figure 7. Commercial Readiness Level of SMEs after the programme

The above graph shows that entering an A&I programme helps companies and their products to move forward.

VC companies and business angels also appreciate the input of high-performance accelerators and incubators. Investors are interested in questions about a technology that A&Is can help to answer. Investors can count on the initial "market skimming" of the incubator to diminish screening time and costs, and then benefit from privileged access to many interesting and qualified targets. Pertinence of a given strategic positioning, credibility of objectives, or even the need for complementary team members – all these issues can be tackled by an accelerator.

The achieved data and findings of this project lead to a simple conclusion: acceleration programmes can be valuable to create more viable businesses and companies for the future of Europe.

It has been stated that SMEs might have "informal, unstructured, unsophisticated and weak HRM practices without any strategic element" (Dundon & Wilkinson, 2009; Orlitzky, 2007; Windolf, 1986). At the same time, it is also known that recruitment is part of a company's viability and success. SMEs are looking for the perfect candidate to fit the position they offer. In a qualitative research report published by the Department of Work and Pensions, UK, on recruitment decisions in SMEs, the factors considered as key elements include flexibility, competence, reliability, stability, proximity to work (location), attitude towards work, personality, and honesty (Davidson, 2011, p. 2-3). In the context of recruitment and selection, this range of eight factors is seen as vital, as it relates to the necessities and business requirements of the SMEs.

In the following graph, it can be seen that the options are divided equally (Figure 8). Some SMEs begin the A&I programme with a full team in place. Sometimes, the team is complete, but the project/company/business requires a CEO or business developer. When this is the case, the role of the incubator can be helpful, as it often has a network of experienced CEOs, which they can propose for the SMEs.

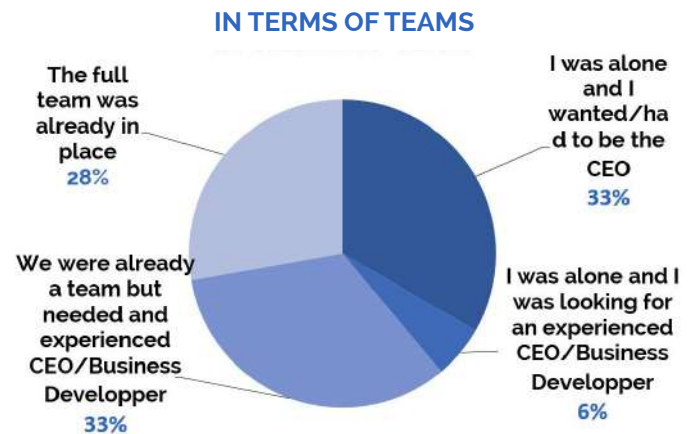


Figure 8. Composition of SMEs' teams before entry in an incubation/acceleration programme

Certain SMEs begin their business with only the project leader, who automatically takes over the role of the CEO, but the success of this approach depends strongly on the background of the project leader. Finally, a small part of project leaders were on their own and wanted to find an experienced CEO to co-create or lead the company jointly. In all these different situations, a good match is necessary.

Recruitment of both a partner and staff is key for an SME, but HRM is not an innate competence of an entrepreneur. He thus might prefer to join an A&I programme where such competences are conveyed. Another recommendation for clusters running an A&I programme is thus to organise HRM skill activities. As for mentors, investors and VCs, clusters can build up a network of experienced CEOs in different work areas, who they can connect to scientists.

The graph below reflects the above findings (Figure 9). Network, financing and business development (HR, management, prototyping, commercialisation) are the most sought-after features in an A&I programme. Clusters could focus on these services in order to help businesses grow bigger and more viable.

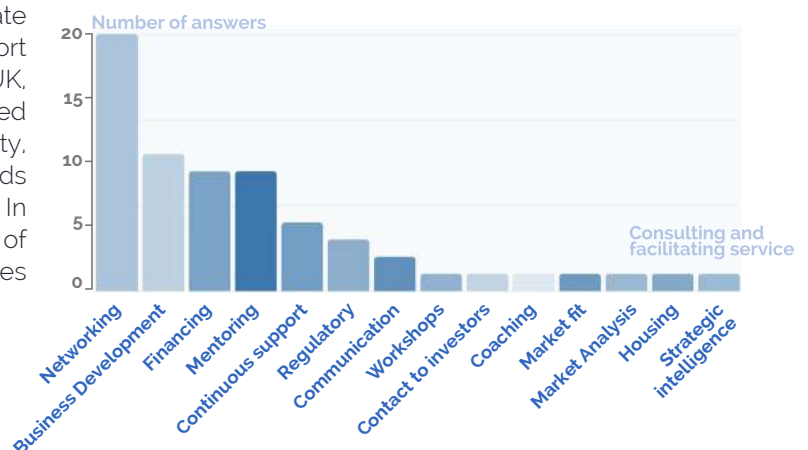


Figure 9. Most used and valued consulting & facilitating services

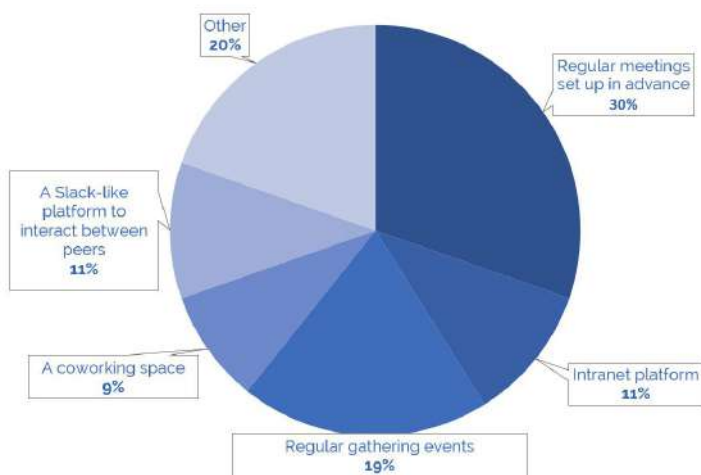


Figure 10. SMEs' most suggested proposition for improvement of incubation/acceleration programmes

In the survey, the consortium proposed new tools to help improve the incubation and acceleration experience. The feedback to those are shown in the pie chart above (Figure 10). Every idea was generally welcomed, companies are always looking for new tools that could impact their growth.

Concerning market target, the answers reveal a common trend: SMEs want to enter new markets close to their home region. One of the rationale behind these answers is that the geographical proximity of the market enables a company to have a better control over their pricing strategy thanks to the minimum costs involved in the transportation^[19]. Indeed, "Small and medium-sized enterprises are more at ease if the market is near, just few kilometres away from their own productive locations."^[20]

The most quoted countries (it was an open answer question) are those bordering the company's home country. A collaboration between clusters in bordering countries could thus be an asset.

Depending on the structure and the investment potential of the company, the markets to be targeted are not the same. While already mature companies, which present consistent and stable results, can tackle more emerging (and therefore riskier) regions such as Latin America or Asia, SMEs making their first experience abroad prefer to invest in bordering countries. The latter, thanks to their proximity in terms of culture and regulations, will make it possible to have a first positive experience of export and to establish their credibility.

Henri Baissas, Deputy Managing Director of Ubifrance, recalls that these target markets can also constitute "interesting gateways: a first step in the United Kingdom, for example, facilitates entry into the Commonwealth countries, a presence in Portugal can lead to Brazilian markets."

Companies offering innovative products or services prefer to invest in mature markets such as Japan or the United States. SMEs located in Europe and wanting to trade with neighbouring countries will not encounter large obstacles.

With the Schengen Space, products can be sold without custom procedures for example. Europe is indeed an ideal ground for the internationalisation of European SMEs.

The above is supported by the following statement: "Another option is to extend the geographic coverage of an acceleration or incubation structure. Some established operators rely on increasing internationalization to attract and compare more candidates. In 2017, 49% of A&Is offered international programmes (45% of them offer one to three programmes), either through partnerships with foreign entities or with foreign locations, and examples include NUMA (France), TechStars (U.S.), and Merck Innovation Center (Germany). After duplicating their programmes in several American cities, A&Is such as Dreamit Ventures, Dogpatch Labs, and start-up Bootcamp pursued their rapid expansion beyond national borders, enhancing their profitability. TechStars began its expansion in Europe and later acquired the successful European accelerator Springboard"^[21]

Nowadays, half of the incubators in the world offer internationalisation programmes. This allows them to increase profitability, and also to be more visible at international level. This can be seen as a win-win situation for all, SMEs and incubators and accelerators. A benefit of clusters of any sector is therefore to build up connections with foreign clusters near-by.

Supporting the above, another result of the questionnaire shows that SMEs are targeting customers and partners close to their current market (Figure 11 and 12). Companies answering the Peer2Scale-Health questionnaire were coming from France, Belgium, Spain, and Germany. It is obvious from the results in the graph below that they target customers is Europe in general, but more specifically close countries like the Netherlands and the UK. Only a few are willing to venture further, to the USA or Asia.

In a recent monitoring survey carried out by ITC for the Fifth Global Review of Aid for Trade, 'access to information about export opportunities' was ranked first out of nine areas in which SMEs would value improvement: 64% of the surveyed SMEs listed this factor as one of their top three priorities, while for large firms the figure was 44%. Inadequate provision of business information by public or private associations is a well-recognized market failure, which increases costs and barriers for the entry of SMEs. Giving access to information is key in order to create a successful partnership between SMEs and clusters.

In another study published by the European Commission in December 2007, "Supporting the internationalisation of SMEs", the commission stated that despite the fundamental principle of free movement of goods, many companies still face technical barriers when exporting to another Member State. Authorities often require that goods coming from other Member States are to be adapted to national technical rules. Cases presented at the EICs prove that this issue ranks 1st in the SME complaint list. This is particularly relevant in the case of business services. If mutual recognition was used, bilateral trade

in commercial services would increase by 30 to 60%. The Commission has tabled a proposal for a regulation, which will require national authorities to duly justify their decision in case they deny market access.

A major problem throughout Europe is a fragmented regulatory landscape: fiscal, complaint resolution, regulations in consumer transactions etc., which affect all companies but particularly those with services and retail. Greater uniformisation would provide a boost to trade. The same argument applies when SMEs want to find business partners. They are looking for partners close to their current market. This is a good opportunity for clusters and European-funded consortium projects. Finding clusters to collaborate in a project is always easier when

they are adjacent countries. Moreover, European projects like Peer2Scale-Health involving clusters from different countries allow to broaden their network of peers, and open their internationalisation programme possibilities.

Target market – Customers

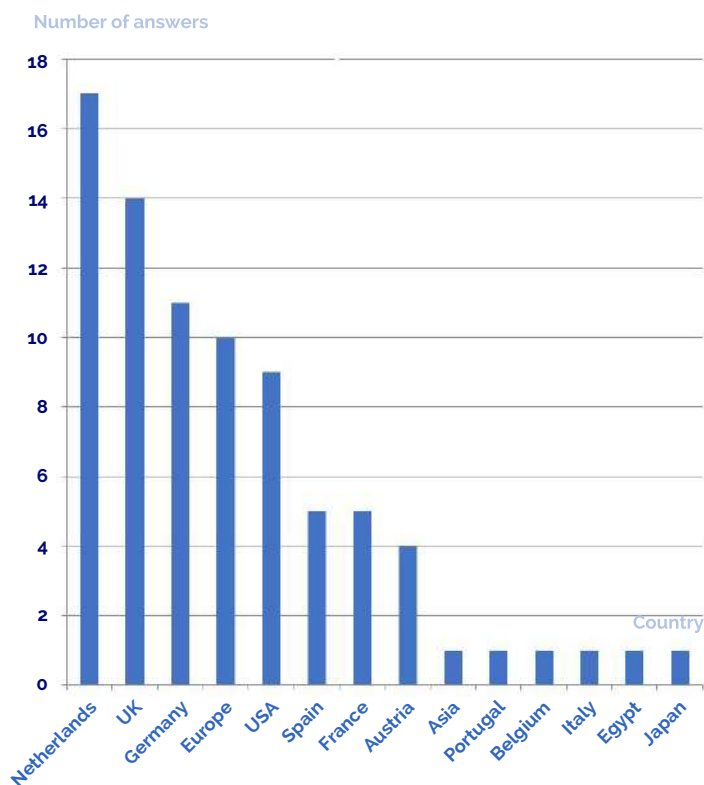


Figure 11. Targeted markets to find customers

Target market – Partners

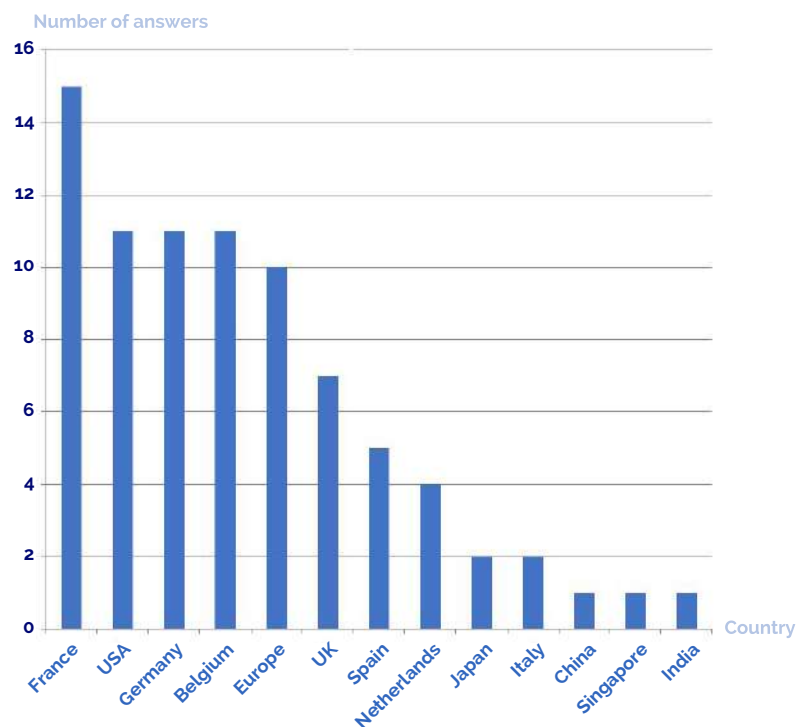


Figure 12. Targeted markets to find partners

As a summary, the results of the survey support the following statement from 'SME competitiveness Outlook' published by ITC in 2015: "Clusters can help SMEs to improve their productivity, innovation and overall competitiveness. What makes clusters potentially beneficial to SME competitiveness are the opportunities of 'collective efficiency', derived from both positive external economies and joint actions. For policymakers, clusters offer the opportunity to better streamline strategic intervention by providing an essential lever for policymakers to design and implement policies to improve SME competitiveness and their upgrading prospects, and help them overcome some of the barriers to internationalization."

2. SME FEEDBACK ON PEER2SCALE-HEALTH

Another part of the questionnaire focused on the feedback of SMEs on the Peer2Scale-Health project. After reading a short presentation of the project and key elements to understand its goals, participants answered a number of questions.

SMEs are convinced that the project has the potential to help them network with experts, investors, and peers from foreign countries, hire competent staff that they might not be able to find in their geographical area, and get help in overcoming regulatory, legal and commercialisation issues in foreign markets that they do not know so well, nor their clusters. Companies feel that this project could help them overcome barriers they are facing in their development.

Concerning the amount of money start-ups are willing to pay to participate in an inter-cluster A&I programme, answers vary between 1,000€ and 20,000€ with a mean value of 8,000€. Emphasis is placed on the importance of added value greater than costs. This data should be

viewed in relation to the time that SMEs are prepared to spend in such a programme. On average, they are willing to dedicate 1 month in total (on a full-time basis).

On the communication side, SMEs seem to be aware of the various instruments offered by their cluster to help them scale-up and they acknowledge the information offered.

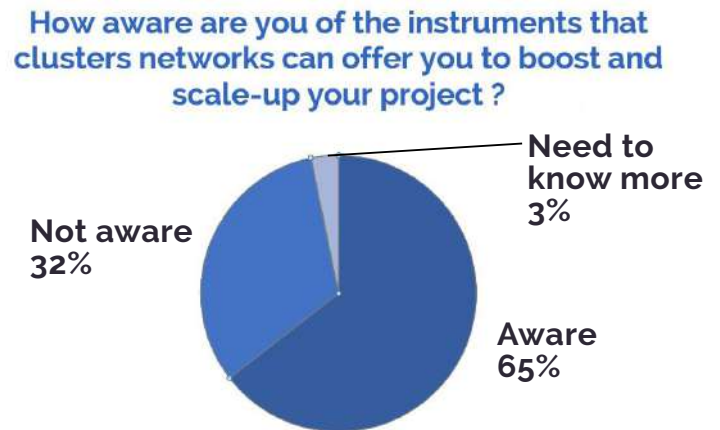


Figure 13. SMEs' awareness about the tools provided by their cluster network

II. MAIN FINDINGS FROM PEER2SCALE-HEALTH WORKSHOPS

WORKSHOP I – LILLE (ROUND TABLE)

The first workshop was held during the MedFit event in Lille on June 26th 2019. It gathered representatives of the four partners involved in the Peer2Scale-Health project and the project advisor from the European Commission. This first peer-review action was used to describe the partners' good practices: instigator, path taken, progress made, evaluation of the impact, actors involved, context of creation, etc. These elements were crucial to understand the potential for replication or adaptation in other ecosystems and settings as well as to set a basis for future common service(s).

Main findings:

- There is a clear diversity in the partners' expertise, international networks, scope of activities and reaching out capabilities, which is reflected in the SWOT analysis (page 18-19).
- Partner agencies and programmes are structured differently.
- The project is in line with the European Commission, encouraging to connect innovation agencies from different regions across Europe with the objective of enhancing existing innovation programmes and establishing new innovation support instruments for SMEs (see also Workshop III for additional information).

WORKSHOP II – BARCELONA (CREATIVE WORKSHOP)

The second workshop of the Peer2Scale-Health project, held in Barcelona on October 21, 2019, was a 2-hour simulation of Design Health Barcelona (d-HEALTH Barcelona, managed by Biocat), a postgraduate programme to develop entrepreneurs and future leaders in healthcare innovation. The workshop allowed its participants and the Peer2Scale-Health consortium members to experience a full cycle of health innovation, following the Biodesign methodology created by Stanford University: from the need to the solution. An audience of 47 persons participated in the workshop, forming nine multidisciplinary groups that identified different unresolved clinical needs, designed minimum viable solutions (from the concept to the prototype) to address them, and created business models for bringing them to the market.

Main findings:

- Multidisciplinary teams have a comprehensive view of the different opportunities and risks that may arise during the development and deployment of a business idea. Indeed, questioning the needs of a new target segment in a new market is definitely relevant to ensure the best product market-fit possible and to expand successfully.
- It is extremely important to validate that the unmet need a team intends to work on is real. The single biggest reason for SMEs failure is the lack of a realistic market need for their product.
- Teams must first design a Minimum Viable Product (MVP) that presents in a very simple manner the final

marketable product. The MVP envisions that the early adopters (customers) can test and provide feedback of a basic version of the product to allow the team to collect the maximum amount of validated learning with the least effort in order to improve the product proposal.

- It is fundamental to have a target-audience focussed pitch that describes in a clear and concise manner what you are solving and how you are solving it. A good pitch is instrumental to help SMEs to get funding, as well as to recruit the best employees, to on-board attractive co-founders, mentors, and advisors, and to refine their business idea.

WORKSHOP III – BRUSSELS (THINK TANK WITH THE ECOSYSTEM)

Besides reflecting internally on the SWOT of our consortium to address the complex challenge of raising entrepreneurship skills in health entrepreneurs and SMEs, and in line with the Twinning+ methodology, we found it relevant to also exchange with external actors on this question. For this, we involved scale-up digital health and medtech companies as well as experts in the EU and local financial scale-up support, in order to nourish the interesting debate surrounding the scale-up process. This was achieved during a third 2-hour workshop of the Peer2Scale-Health project, held in Brussels on January 30, 2020.

The objective of this workshop was threefold:

- Identify the challenges associated with an expansion strategy and how to overcome them.
- Figure out how the European Commission can financially support scale-up companies in their expansion strategy.
- Understand which criteria need to be fulfilled for an investment fund to validate the next round of funding.

Main findings:

Expansion strategy and associated challenges

For most companies, growth is not a deliberate choice but a must for survival in a strong competitive environment. It requires a strong spirit.

Experts identified four relevant paths for company growth:

- **Internationalisation:** The company can expand through entering new geographical markets via careful strategic planning or pure opportunity. Nevertheless, it should not underestimate the challenges associated with the specific regulatory, legal and operational requirements of each market, be it a country or even a specific region or state. Hence, significant time should be set aside to analysing the various parameters and gain precise knowledge of the field while being reactive and flexible.
- **Adjacent markets:** Entering Neighbouring countries markets and focusing on new customers is a powerful approach to maintain a competitive advantage while

tapping into new revenues. However, following a structured roadmap is key to avoid scattering human, time and financial resources and optimizing even sustaining the impacts sought.

- Dedicate sufficient time to identifying what would be the unanswered or implicit needs of the (potential) customers;
- Strategically analyse why these needs are currently not or under-addressed, what exactly triggers speed adoption and market penetration. Given the competitive advantage of the company and its strengths, which segment looks most attractive to meet a specific need? Stay focused is key to avoid a dilution of the company's legitimacy;
- Investigate externally and brainstorm internally for potential solutions and associated risks;
- Prioritize, challenge and shape solutions with the help of your carefully selected Board members;
- Get the right team in place with complementary talents and backgrounds to tackle these adjacent markets;
- Build up and utilize appropriate networks.

- **Product expansion:** Developing new products for an existing customer segment might require the company to develop additional skills as diversification might imply a strategic shift from product to service delivery. At the same time, this (unexpected) shift could uncover an immense scalability potential for the company and reinforce its scale-up strategy.

- **Commercial model:** Growing might entail switching from direct sales to using channel partners (distributors, value-added partners, digital sales etc.) to shift a company's attention back to the core business, as long as it fits the information and servicing needs of the customer. In any case, the company should first assess if (1) there is a true selling opportunity, (2) it can compete in terms of product-market fit and sales resource requirements, (3) it can win when it comes to executive credibility, corporate compatibility and political alignment, (4) it is worth winning the deal in terms of short-term revenue, profitability, degree of risk, future sales and strategic value of the deal (i.e. leveraging a customer to access other market segments).

Clusters can play an important role in ensuring that companies are aware of these challenges, and in stressing the importance of following a structured roadmap to avoid losing energy in this quest for growth.

EU Funding opportunities for companies going through the scale-up process

Through its European Innovation Council, the **EIC Enhanced Pilot** supports fast track disruptive and market-creating innovation coming from high-potential innovators, entrepreneurs, small companies and scientists willing to scale-up internationally. These projects are usually considered as too risky for private investors or benefitting from insufficient market response.

If you are an innovative researcher with an idea for the next breakthrough technology, you should apply to the **"Pathfinder"**.



PATHFINDER:
Researchers, technologists

- ▶ For radically new technologies emerging from collaborative research
- ▶ Grant funding of up to €4 million (100% of costs)
- ▶ From proof of concept to demonstration of commercial viability
- ▶ Access to EIC coaching and mentoring services
- ▶ Majority of funding is open (no predefined themes). Strategic breakthrough technologies are also supported (challenge-based)

Two complementary instruments help bridge the financing gaps entrepreneurs are confronted with when going from the idea to the market take-up:

- The **EIC Pathfinder** supports projects from early technology to pre-commercial development with grants;
- The **EIC Accelerator** supports projects from the pre-commercial to the market and scale-up process through grants and blended finance;

If you are a start-up, SME, entrepreneur with a business plan to develop and scale up a high-risk innovation, then the **"Accelerator"** is the right way forward for you.



ACCELERATOR:
Start-ups, SMEs and entrepreneurs

- ▶ For development and scaling up of high risk innovations by startups and SMEs
- ▶ Grant funding of up to €2.5 million (70% of costs)
- ▶ Option of equity investment of up to €15 million
- ▶ Access to EIC coaching and mentoring services, pitches with corporates, VCs, etc
- ▶ All funding is open (no predefined thematic areas)

The EIC Pathfinder 2020, for example, promotes the development of digital twins for life sciences in order to help physicians and nurse practice on digital organs before facing real-life situations.

Ready for the next round of investments?

Comprehensively, growth investors (i.e. series B) do not seek for the same signs of potential in a scale-up business than early-stage investors (i.e. seed funding and series A) do for start-ups.

Companies getting into the scale-up process should carefully considerate the following aspects:

- **Long-term view:** The needs of investors strongly differ from customers' needs. The pitch should be adapted accordingly and demonstrate the company's sustainable growth potential based on concrete data and realistic long-term milestones.
- **Clarity:** It is important for a company to be able to explain in a simple yet complete and realistic way what will drive success and why funding is needed to accelerate growth.
- **Financials:** Even though the problem-solution fit, product-market fit, team member composition with complementary expertise etc. are still key, later stage

investors often have a corporate finance background, hence will assess an opportunity based on robust financial metrics and ratios (ROI, customer acquisition cost, customer lifetime value, margins, solvency rates, scale, etc.) as well as consistent KPIs and performance metrics.

- **Create demand:** Companies in the growing phase should maximize investments aimed at selling the solution, instead of developing the product.
- **Equity funding:** Scale-up companies should ensure that there is enough equity capital on the balance sheet compared to borrowed capital, as it would avoid creditors to foreclose on a loan in case performance does not meet expectations. It will also ease the attraction of new capital.
- **Management:** Scale-up companies should assess if they have governance capabilities or if they better look for people having these skills to pilot the business and maintain optimal relationships with all the surrounding actors.

KEY FINDINGS FOR CLUSTERS

Clusters and innovation agencies play a role of intermediary for investors as they give visibility to the companies and legitimate their growth potential through adequate coaching on the abovementioned aspects. Clusters could help SMEs, both on the strategic and operational levels in their local environment, but also in a context of further collaboration between ecosystems.

At strategic level

Entrepreneurs are on a journey. Clusters can help them anticipate what will come next and encourage them to ask for help with expert guidance. Connection between ecosystems can also be key to ensure that scale-ups bring disruptive innovation to the market at a much faster pace and with a true societal impact.

At operational level

Entrepreneurs can benefit from the deep understanding that clusters have of the local ecosystem, hence translate theoretical knowledge into practical knowledge, such as:

- Identify key actors, key investors, key opinion leaders
- Scout the right ecosystems to explore
- Attend relevant sectorial conferences
- Hire the right profile

B. Challenges of SMEs and recommendations on how clusters can assist

Based on the results obtained from the survey, the workshops and other activities carried out in the framework of Peer2Scale-Health, the consortium has identified the main areas SMEs find challenges and obstacles in: network building, access to knowledge, access to funding and financing, and internationalisation, along with some other specific aspects related to business development. The following section lists recommendations for clusters to facilitate the scaling-up process of SMEs by helping them overcome these challenges.

I. NETWORK-BUILDING

Working towards building a strong network of relevant connections is a crucial factor for the success of healthcare SMEs entering the scale-up process. Networking sets up a comfortable and easy to access space where SMEs get to talk to relevant stakeholders from the sector that might otherwise be hard to contact, such as KOLs, peers, mentors, investors and potential customers, and collaborators, among others. As already mentioned, SMEs normally do not have the time and staff resources to systematically build the appropriate knowledge and network base themselves. For this reason, healthcare acceleration programmes should ideally provide accessible networking spaces to help SMEs build a multifaceted network of high-quality contacts, establishing connections with:

- **Peers** - to access relevant information, gain perspective and increase industry expertise, given the fact that they might have gone through the same issues before.
- **KOLs and other key players** - to gain an understanding on a healthcare product's life cycle as well as the requirements to access the market.

- **Investors** - to build strong and long-term relationships with relevant expert and financing networks to secure the funding needed to take the SME to the next level.
- **Mentors** - getting their feedback, advice and encouragement guides SMEs toward smarter decisions and can have a large impact on their growth.
- **Industrial/cooperation partners** - to maximise a healthcare SME's return on R&D investments and gain affordable access to technology.
- **Patients/end-users** - to iterate and improve healthcare products and services. They can play a critical role in helping SMEs prioritize the potential applications to their technology.
- **Talent** - to meet and recruit future team members. This is crucial to push the business in a positive direction and facilitate its scaling up.

Building long-term relationships with these stakeholders (especially investors and mentors with entrepreneurial background) and matching them carefully with entrepreneurs is decisive to provide SMEs with high-level acceleration support, since it establishes an atmosphere of trust between them. It is also advised to include alumni in the mentoring network, as they can provide a unique perspective on how to best benefit from the programme.^[22]

Many acceleration programmes require participants to conduct a number of discovery interviews (e.g. around 100) with key stakeholders, a practice that has proven to be effective to understand the real needs, the hurdles to overcome, and the buying dynamics of their customers. Offering training on proper interviewing techniques can be of added value to participant SMEs.

Initiatives to match business needs with innovative technologies presented by start-ups are also of great

value for SMEs. This can be a great opportunity for start-ups to identify new potential applications for their technologies, and in some cases, it can even allow them to pilot the technology under real conditions once a match is identified.

2. ACCESS TO ACTIONABLE KNOWLEDGE

Training is an important component of running an effective business and it is the primary driver in building and reinforcing an SMEs' functional, technical and organisational competencies to make their business successful, not only at the beginning, but also in the scale-up process.

By accessing learning opportunities on essential areas, such as communication skills, market access, international regulation, intellectual property, product-market fit, and funding, SMEs can learn the most important capabilities to make their business consistent and strengthen their chances of long-term success. Healthcare clusters have the potential to either provide training and coaching for SME managers on key topics, or to connect them with the right training providers. The main areas SMEs need to gain knowledge on are:

- **Business economics/entrepreneurship** - learning some basic aspects of business, such as business models, organisational development, accounting and resource management is crucial for SME development and growth (especially for entrepreneurs with a background as academic scientists).
- **Master sales** - healthcare entrepreneurs also gain from learning how to prospect, drive sales, reduce rejection rate close to prospects and streamline the sales process for scalability.
- **Content marketing strategy** - training on content marketing is crucial to build brand awareness and trust, generate leads and new links and strengthen customer loyalty.
- **Communication skills** - oral and written communication proficiencies are imperative to share entrepreneur ideas and present them clearly, both to investors and customers (the pitch content should vary accordingly).
- **Digital skills**: The transformation of the health systems involves adopting digital technologies that need to be integrated into SMEs personnel skills.
- **Market access/international regulation** - SMEs in a scale-up process must gain insights on foreign markets before drawing their international strategy, studying the different regulations and ecosystem mechanisms in order to ensure a smooth expansion.
- **Intellectual property** - entrepreneurs in these fields need to gain a broad knowledge on the different ways in which they can protect their innovations, including patents, trademarks, design protection, trade secrets and privacy rights, etc.
- **Funding/financing** - SMEs in the scale-up process benefit from comprehensive knowledge of the different private and public funding mechanisms available, including investment, public grant and reimbursement

opportunities, among others.

- **UX design** - healthcare SMEs should take customer feedback into account early in the process and get the appropriate tools to collect this constructive feedback on a regular basis (especially if the company is tapping into adjacent markets or customer segments).

Several studies conclude that most entrepreneurs favour on-site, in-house coaching and training. This helps them build personal relations with the mentors and coaches, which plays a crucial role in creating trust between them. Off-site training, on the other hand, has some advantages as well, including that foreign entrepreneurs do not have travel and accommodation costs, which facilitates having an international cohort in the programme. For online programmes, it is recommended to gather the entrepreneurs at least twice (once at the beginning and once at the end of the programme), hence facilitating peer-to-peer learning and allowing the entrepreneurs to build connections in the ecosystem of the programme.^[22] In order to monitor the progress of the participants, it is imperative to provide clear objectives and agree on a set of KPIs and milestones at the beginning of the programme.

According to a study carried out by Hello Tomorrow in partnership with Bpifrance in 2019, start-ups which are close to market entry consider personalised coaching by mentors with an entrepreneurial background and other experts to be the most effective learning practice. Critical feedback and tailored working sessions appear to be the most valuable methods. On the other hand, master classes, forums and seminars have a higher impact on early-stage start-ups. This kind of one-size-fits-all training should focus on topics of interest to the entire cohort, such as pitch training, funding opportunities or legal matters. Learning processes in such programmes must be adaptive and agile, focusing on applicable knowledge and problem-solving skills, and it is imperative to give entrepreneurs enough time to apply the learnings to their start-up and work continuously on it.

Finally, it is a good practice to offer training not only during the programme, but also afterwards. It is a recommended practice to offer online forums on industry-relevant topics for current and previous participants of the programme, establishing an open space for them to meet and continue benefiting from the programme.

3. ACCESS TO SMART MONEY

Successful healthcare companies generally need to invest a significant proportion of their revenues in R&D. This is a big challenge for start-ups at an early stage, which have little to no turnover, high risk, long timelines, and extensive costs to cover, making it difficult for them to secure private investments. At this stage, finding funds is a matter of survival for start-ups. Governments and development agencies are stressing the importance of creating an investment-friendly legal and business climate, rather than SMEs raising funds from individuals or investment

firms in an independent manner. Governments favour the appearance of "investment facilitators", a role that can and in some cases should be assumed by innovation agencies, who provide SMEs with more than just specific tools or investor contact lists.



A combination of trainings, advice, and marketplaces can be provided to facilitate the interaction between SMEs and investors. The aim is to diagnose the financial situation of the company and create an optimised funding scheme through the knowledge of the local and European finance and funding ecosystems. Regarding the financing itself, the first step is usually to orient young SMEs towards non-dilutive financing such as grants, subsidies, bank loans and prizes obtainable through public calls and contests. Alongside with these non-dilutive funds, clusters can connect start-ups with angel investors for a first dilutive financing. These funds must enable the start-ups to take their product and progress through the R&D phase, achieving their Minimum Viable Product, and support them in the de-risking process in order to make the business attractive for investment funds and a venture capital funding round.

Usually, clusters support SMEs towards a seed funding round and occasionally towards series A, as it is the case in the Eurasanté Acceleration programme and the initiative "The Investment Readiness Series", led by Biocat. These initiatives must be planned carefully to ensure a valuable encounter for both parts. It is a common belief that young SMEs should be introduced to investors at the end of the acceleration programme, where they are in the best possible shape. However, many studies conclude that this is not ideal. Instead, it is recommended to engage VCs at a much earlier stage in the programme, leveraging on their expertise in order to de-risk the start-ups together with other mentors from the beginning and allowing them to assess the progress made by the start-up throughout the programme. This also builds a stronger relationship between entrepreneurs and investors, which works in favour of a potential investment. It is even recommended to invite investors to participate in the selection of the programme participants, hence taking into account what they are looking for from the very beginning.

Another possibility to help SMEs move forward and increase their pipeline of products at shared costs, hence

satisfying some of their financing needs, is to connect them with potential technology co-development partners, who work at shared risk. While it is not common practice, there are some clusters that become shareholders of the start-ups in exchange of their services or direct investments. This is the case for the Nordic start-up accelerator Accelerace (Denmark), which offers seed funding at the completion of its acceleration programme.

Finally, clusters might also want to work towards raising awareness on competitive funding opportunities. This can be done through a series of actions, including the dissemination of calls for projects and other funding opportunities, the support in the creation of a project consortium, and the participation in micro-financing projects, among others.

4. MARKET ENTRY – GOING INTERNATIONAL

Internationalisation is one of the main options for companies aiming to enter the scaling-up process. For this, SMEs often rely on the support of mentors, consultants, and clusters, which are some of the best-connected players in the ecosystem. According to a study carried out in 2017 by ministries and agencies in the Baltic Sea Region for the initiative BSR Stars Innovation Express, the most helpful activities to support internationalisation, as reported by SMEs, are: 1) General networking and access to new international contacts and cooperation partners, 2) Access to market information, benchmarking, and inspiration, and 3) Exposure to new opportunities and new partners in other sectors or application fields. ^[23]

In acceleration programmes, it is fundamental to implement an international customer perspective from the very beginning, taking into account the different specifications in domestic and international markets. Clusters should have an in-depth understanding of their ecosystem's needs for internationalisation, using the inputs from their stakeholders to develop a clearly defined strategy with a broad consensus and backing. Conducting surveys to funnel international expansion needs can be a very valuable instrument for clusters to gain insight into the current needs of SMEs in the sector and spot emerging trends, helping them to better adapt their support services and draw their internationalisation strategy. The lack of such strategy can easily lead to high resource expenditure with little impact. In order to measure the performance of this strategy, it is fundamental to define a clear set of KPIs from the beginning.

Some traditional tools, such as market analysis, road mapping, and technology forecast, can be useful to gain a better understanding of the targeted foreign markets. However, establishing connections with international clusters and other experts appears to be the best way to learn about the market and gain access to the right stakeholders (see next section). Attending international fairs and conferences and participating in international collaboration projects is also a common and recommended

practice, not only to give visibility to the ecosystem as a whole, but also to expose the capabilities of its SMEs and to identify potential development or commercial partners for them. By way of illustration, HighTechXL, a Dutch high-tech start-up accelerator launched in 2015, provides their accelerates with tickets to international business exhibitions and fairs. Another example is the Strasbourg-Boston innovation initiative, aiming at giving entrepreneurs willing to scale-up their business access to the European and USA markets and ecosystems. This programme focuses on business development, business matchmaking activities, thematic virtual workshop with a main focus on developing leadership and investor readiness, and pitch sessions are regularly organised between the two cities.

Joining large innovation networks can also be extremely beneficial to facilitate the internationalisation of SMEs. A good example of such networks is EIT Health, a consortium of over 200 partners from leading businesses, research centers, and universities from across 15 EU countries. EIT Health has launched a wide range of international innovation support activities across Europe, including business incubators and accelerators, training and education programmes, and innovation driven research projects. Being a member of the EIT Community grants access to cluster entities and their members to this massive network of partners and initiatives.

Additionally, healthcare entrepreneurs often do not have the time and staff resources to stay on top of all national and international industry news and trends, which is why it is important for clusters to take an informant role. For that, they need to stay up-to-date in the healthcare industry, disseminate any relevant information to their ecosystem, and screen the most suited international events and conferences.

5. OTHER CHALLENGES

• Product development and validation

The R&D process is key as it determines the true value of a product or solution, transforming ideas into practice. In that regard, SMEs need to design an attractive structure of the product as well as focus into its functionalities, utility, and reliability, as it will be the trigger for attracting future customers. To help SMEs in this stage, clusters can offer them the possibility to initiate relationships with academic and industrial partners with whom they can associate in order to advance the product development phase, particularly on topics such as feasibility, proof of concept, prototype design, and even final product development.

Concerning the validation support, clusters can provide access to mentoring and experts. They will support and advise the SMEs on the design of the trials, tests, and studies needed to ensure the compliance of the requirements of a marketable solution (clinical trials, toxicity tests, market access studies, among others) as well as the most suitable settings to conduct them.

• Regulation compliance and IP protection

Regardless of the sub-sector (biotech, medtech, digital health, etc.), all health SMEs have in common that they operate in a strongly specific and regulated environment. Given their connections and their intrinsic knowledge on the local health system, clusters are in a good position to support and advise SMEs on legal and regulatory topics, such as reimbursement criteria, national and European relevant agents, and laws applicable to their product. This helps SMEs to define their time-to-market, allowing entrepreneurs to have a clearer picture of the milestones they will have to reach before effectively commercialising their solution.

Another major subject for SMEs is the IP protection and regulatory strategy. Clusters can offer support in this area by providing individual coaching or group training sessions on topics like patent filing, freedom to operate studies and CE/FDA marking. Moreover, clusters can, on the one hand, advise the almost-incorporated projects on legal matters, such as the legal status of the company, founders' shares, or the obligations in accordance with local laws. On the other hand, clusters can also help spin-offs to define possible licensing agreement strategies of the assets created at universities or research institutes.

• HR management

Having a good human resources environment is fundamental for SMEs. A successful company is not just having a great and top-sales product. Indeed, the basis of a powerful company is achieving a good management of its human resources, having talented employees and being able to keep them engaged and committed.

Clusters could play a major role in leading the SMEs to achieve the abovementioned goal. Clusters can deliver training sessions or connect the entrepreneurs to appropriate consulting services, supporting them in some aspects of the recruitment process, such as the writing and dissemination of job offers, and the selection of the best candidates. Once this process concludes, clusters can help SMEs to integrate new employees, and set up a friendly and comfortable work environment and job culture.

Clusters can also support SMEs in their HR management by setting up matchmaking events to match SME HR needs with potential candidates. Given their wide network of contacts, members, and connections, clusters are in a good position to attract the right candidates for these events and help SMEs gain visibility.

Finally, working closely with research and development teams at universities has proven to be an effective practice for acceleration programmes. This way, they stay in touch with a wide network of faculty and students that may become collaborators or employees of the companies arising from the programmes in the future.

• Access to infrastructures

Clusters are aware of the financial constraints pressuring

young SMEs at the beginning of their lifetime. Despite managing small teams, entrepreneurs can require desks and office space, normally inside cluster facilities, at competitive prices. This service is usually accompanied by access to conference and meeting rooms, and other amenities (access to internet, copy centres, telephone services, kitchen rooms, etc.). Entrepreneurs appreciate the flexibility of these offers as they can gradually adjust the size of the occupied space to suit their needs and financial capabilities, starting with co-working spaces and later accessing private offices, suited to the size of the company. In some cases, SMEs can require virtual offices to establish their company with minor costs rather than physical facilities.

Biotech and medtech companies can also require dedicated spaces, equipment, and reagents adapted to their business, which comes at a cost. These necessary investments are not systematically affordable during the early-stage phase. Therefore, clusters owning this type of spaces and making them available for a reasonable price are considered to be a very attractive opportunity for life sciences entrepreneurs. An example is the Medtech Atelier® initiative, led by lifetech.brussels. Often after participating in the virtual incubator programme offered by BioM, start-ups gain access to laboratory and office space at the local incubator building.

• Ecosystem awareness

In this globalised world it is common for SMEs in the healthcare sector to work internationally or with an international approach from the very beginning. Despite that, before focusing too much on markets abroad, it is imperative for innovative healthcare SMEs to understand how their own national or local ecosystems work. Clusters have the opportunity to keep them informed and update them of any relevant novelties in the ecosystem, such as new regulations and trends or opportunities, changes in customer patterns, and possible emerging market niches.

By using different communication tools (targeted mailing, newsletters, social networks, flyers, etc.), healthcare clusters can provide SMEs with all the relevant information regarding collaboration projects, new events and initiatives, emerging trends in the sector, calls for projects, and other opportunities. Having a constantly updated agenda of events and opportunities can be instrumental for SMEs to stay in the loop. Additionally, through the elaboration of reports, infographics, articles, and other types of documents, clusters can identify and disseminate the ecosystem trends and other relevant data. Moreover, apart from elaborating internally the mentioned dissemination documents, it is important for healthcare clusters to give visibility to other relevant newsletters and media publications that can be helpful to SMEs.

C. How can cluster consortia such as Peer2Scale-Health address the challenges of scale-ups?

1. NETWORK-BUILDING

Tackling the challenge, that clusters are often generalists or focusing on a specific sub-sector, a cluster consortium pools complimentary expertise, networks, and activities, providing more valuable, internationally relevant and diverse services, which meet the various individual SME needs for scaling-up. Through a consortium, clusters can share contacts, including experts, mentors and peers, who already operate successfully in a certain field, which may be underdeveloped in other regions, to facilitate the access of international SMEs to that specific (sub-)sector.

2. ACCESS TO ACTIONABLE KNOWLEDGE

For effective coaching, also taking global developments into consideration, clusters also benefit from sharing their experts with other clusters, e.g. by organising joint international trainings involving SMEs from other cluster regions, or by recommending their own experts for trainings organised in another cluster region. To scale-up into a different (sub-)sector, SMEs also need coaching about hidden opportunities from experts who are up-to-date with global developments. For this, consortia of clusters with different sub-sector specialisations can

facilitate such scale-up trainings, e.g. by providing health-IT seminars for the other clusters.

3. ACCESS TO SMART MONEY

Demand-orientated cluster consortia are effective coordinators of SME funding programmes, taking the bureaucratic load of the SMEs, making funding better available for SMEs, and bringing together European SMEs with similar and complimenting interests.

Clusters might want to share investors and pitching events. The obvious benefit is the critical mass of potentially interesting SMEs for the investors. However, cluster-investor relations are based on trust with regards to the quality of the pitches and SME technologies, and with regards to confidentiality, so that investors are not overly approached by money-seeking SMEs who are not in their investment focus. Thus, joint pitching events require a careful preparation including pitch training and pre-selection of suitable pitching candidates matching them with the specific interest of each investor.

There is a large variety of funding and financing opportunities across Europe. The more clusters share their list of programmes they are aware of, the more

comprehensive the information for SMEs can be. Ideally such a database of updated funding and financing opportunities is coordinated by established organisations such as EEN or ECCP, who are also close to the European Commission and their funding programmes.

A lot has already been achieved in numerous cluster-consortia across Europe, also with regards to scale-up support. However, the information and tools developed are hardly known by SMEs, partly because they have only little time spare to scout for potentially useful information, partly because the results of such programmes are not easily found. A comprehensive and easy-to-search database for such results would be a valuable tool, which also clusters could utilise for the benefit of their SMEs.

4. MARKET ENTRY – GOING INTERNATIONAL

A cluster consortium can accelerate scaling-up into European markets by each partner providing certain pre-matching or soft-landing packages to the SMEs of the consortium partners' regions. Since this is time-consuming, it is crucial to clearly define the scope of such services according to the specific resources available to each cluster partner. It is also important that each partner benefits from such a cooperation, i.e. that there is interest of SMEs in all partner regions to enter the other markets. A number of such European market entry schemes and support-initiatives already exists, but they need to be mapped and made simpler to be identified and used.

Clusters often represent their region and industry sectors at international conferences – a luxury, that SMEs can only do in a limited way. Cluster consortia have thus the advantage that they can scout for and select the most beneficial events and fairs, and perhaps even join forces to take a group of European SMEs to such events, or organise scale-up sessions at large conventions.

When focussing on connecting ecosystems, automatically an "internationalisation of clusters" is taking place, scaling-up the involved ecosystems themselves by changing the language of regional events to English, inviting international experts, inviting international peers and SMEs etc.

5. OTHER CHALLENGES

• Lobbying and tapping into European networks

Lobbying is an important tool to improve government public funding mechanisms and initiatives. Healthcare clusters can work towards influencing government policies at national and international level, individually or by joining together, in order to address the major funding challenges faced by SME managers in their scale-up process. This can be achieved, for example, by demanding more targeted financing schemes.

If a cluster cannot face particular challenges alone, e.g. in finding funding for SMEs or doing lobbying work for SMEs at European level, it can capitalise on existing

networks, such as CEBR. Here, clusters work together in so called SIGs (special interest groups) on selected topics, e.g. purchasing schemes, cluster lobbying at European Commission, microfinancing etc. Any member can take a topic to the CEBR community, identify other clusters also interested in this topic, and start a SIG, which runs over one to max. two years, and works on practical solutions.

It is important that the European Commission acknowledges the essential role of cluster management organisations as intermediators for EU funding projects, as disseminators of information (regarding grants, platforms, databases, events etc.) provided by the EC and addressed to SMEs, as training bodies for scale-ups, and as experts on highlighting current challenges related to SME funding, especially with regards to life science scale-ups, which require larger sums. Thus, more future grant schemes should consider cluster organisations as eligible partners, dedicated and substantial cluster-consortia support programmes should be run, and SMEs should be able to allocate some of their grant money to cluster management organisations for coordination support.

• Critical mass

Consortia can bring together a critical mass of SMEs:

1. to attract global investors, also to attract buyers, hospitals, integrators, patients, and increase access to these actors;
2. to set up collaborations with international hot spots (e.g. Boston) in order to create business acceleration "gateways" for European SMEs;
3. to tap into larger pools of EC funding for more substantial and thus effective SME support schemes coordinated by clusters.

As a high-level support tool for scale-ups, clusters can join together – perhaps under the umbrella of the European Commission – to form an international Advisory Board to give regular advice to high-potential SMEs from the health sector. Initiatives in this direction are currently ongoing in the EIT Health programme.

In order to set up a joint, global internationalisation approach for the European life science sector, cluster consortia could work towards an alignment of regional, national, and European policies and initiatives, including a clear common future strategy.

D. Recommendations

Challenge	Answer as individual innovation intermediary	Answer as a consortium
1. Network-building	<ul style="list-style-type: none"> • Create open spaces for networking with multiple stakeholders, including alumni and KOLs, at early stages in the programme (see pg. 31) • Encourage SMEs to conduct discovery interviews to initiate new contacts (see pg. 31) • Launch initiatives to match business needs with innovative technologies to detect new potential applications (see pg. 31) 	<ul style="list-style-type: none"> • Build an international network of contacts by sharing experts, mentors and peers with other clusters (see pg. 35) • Send peers and other actors (who already operate successfully in a field) to other clusters less developed in a specific (sub-) sector (see pg. 35)
2. Access to actionable knowledge	<ul style="list-style-type: none"> • Critical feedback and tailored working sessions appear to be the most valuable coaching methods (see pg. 32) • SMEs specially value mentors with entrepreneurial background (see pg. 32) • Masterclasses, forums and seminars should focus on topics of interest to the entire cohort (see pg. 32) • Facilitate adaptive and agile training during and after the programme (see pg. 31) • Give entrepreneurs enough time to apply the learnings to their start-up and work continuously on it (see pg. 32) 	<ul style="list-style-type: none"> • Organize joint international trainings involving SMEs from other cluster regions (see pg. 35) • Facilitate coaching about hidden opportunities from experts who are up-to-date with global developments (see pg. 35)
3. Access to smart money	<ul style="list-style-type: none"> • Provide a combination of trainings, advice and marketplaces (see pg. 32) • Firstly, orient start-ups towards non-dilutive funding/financing (see pg. 32) • Engage VCs at an early stage in the programme (even in the selection of candidates) (see pg. 32) • Engage potential technology co-development partners who work with shared-risks models (see pg. 32) 	<ul style="list-style-type: none"> • Open pitching/investment events to reach a critical mass of potentially interesting SMEs (see pg. 35) • Prepare these joint events carefully, including pitch training and pre-selection of candidates (see pg. 35) • Create a common list of identified funding and financing opportunities (see pg. 35)
4. Market entry / Going international	<ul style="list-style-type: none"> • Establish relationships with clusters and other innovation agencies (see pg. 33) • Join large innovation networks (such as EIT Health) (see pg. 33) • Implement an international customer perspective from the start of the programme (see pg. 33) • Conduct surveys to funnel SME international expansion needs and spot emerging trends (see pg. 33) • Disseminate/screen any relevant information regarding international trends and events (see pg. 33) 	<ul style="list-style-type: none"> • Provide certain pre-matching or soft-landing packages to the SMEs of the consortium partners' regions (see pg. 36) • Define clearly the scope of such soft-landing services (see pg. 36) • Scout for and select the most beneficial events and fairs (see pg. 36) • Join forces to take a group of European SMEs to such events, or organize scale-up sessions at large conventions (see pg. 36)

5.1. Product development and validation	<ul style="list-style-type: none"> • Provide clear objectives, KPIs and milestones to monitor the progress of participants (see pg. 34) • Facilitate connections with academic and industrial partners (see pg. 34) • Offer support/advice in the design of trials, tests and studies to ensure regulatory compliance (see pg. 34) 	
5.2. Regulation compliance and IP protection	<ul style="list-style-type: none"> • Offer sessions on regulatory aspects, including national and European applicable laws, CE mark/FDA approval and reimbursement criteria (see pg. 34) • Offer individual coaching/group training sessions on patent filling, FTO studies, licensing deals, etc (see pg. 34) 	
5.3. HR management	<ul style="list-style-type: none"> • Set up matchmaking events with potential candidates (see pg. 34) • Provide training and coaching on topics related to recruitment processes/team management (see pg. 34) 	
5.4. Access to infrastructures	<ul style="list-style-type: none"> • Facilitate access to virtual/physical spaces at competitive prices (see pg. 34) • Give access to equipment, reagents, conference and meeting rooms (see pg. 34) 	
5.5. Ecosystem awareness	<ul style="list-style-type: none"> • Use different communication tools, including targeted mailing, newsletters, social networks, flyers, constantly updated agenda, etc (see pg. 35) • Provide relevant information on collaboration projects/calls, events, reports and other opportunities (see pg. 35) 	
5.6. Lobbying and tapping into European networks		<ul style="list-style-type: none"> • Demand more targeted financing schemes to address the major funding challenges faced by SME managers (see pg. 36) • For challenges that cannot be faced individually it is recommended to capitalize on existing networks, such as CEBR (see pg. 36)
5.7. Critical mass		<ul style="list-style-type: none"> • Bring together a critical mass of SMEs to 1) attract diverse actors (buyers, hospitals, integrators, etc), 2) create business acceleration "gateways" in international hot spots, 3) tap into larger pools of EC funding (see pg. 36) • Form an international Advisory Board to give regular advice to high-potential SMEs (see pg. 36)

As a general conclusion, the value clusters can bring lies both in their internal expertise and their ability to create relationships with partners in the health ecosystem. This complete integration in their environment enables the expansion of the number of services offered to SMEs, creating the perfect ground for growth.

This DOP is more than the result of a one-year peer learning exercise. Rather, it is a means to spark new discussions between the members of the consortium and other parties interested in these topics in the European cluster landscape. Please, do not hesitate to contact the consortium partners.

VI. References

II. Introduction

- p. 5**
[1] <https://www.oecd.org/cfe/smes/ministerial/documents/2018-SME-Ministerial-Conference-Plenary-Session-1.pdf>
[2] <https://www.forbes.com/sites/neilpatel/2015/01/16/90-of-startups-will-fail-heres-what-you-need-to-know-about-the-10/#a1594a066792>
[3] <https://dictionary.cambridge.org/fr/dictionnaire/anglais/incubator>
[4] <https://dictionary.cambridge.org/dictionary/english/accelerator>

- p. 6**
[5] <https://www.clustercollaboration.eu/cluster-mapping>
[6] The "Biological Sciences" filters englobes all the other sub-filters and a structure can be tagged with multiple sub-filters.

- p. 7**
[7] <https://sifted.eu/articles/these-are-the-best-healthtech-accelerators-in-europe/>
[8] https://ec.europa.eu/eip/ageing/news/top-healthcare-accelerators-europe_en
[9] <https://www.labiotech.eu/tops/biotech-incubators-europe/>

ACCELERACE ACCELERATOR, DENMARK:

<https://www.accelerace.io/accelerator/>
<https://www.accelerace.io/biotech/>
<https://www.accelerace.io/medtech-health-care/>
<https://www.accelerace.io/digital-health/>

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<https://www.babraham.com/accelerate-babraham/startup-babraham/>
<https://www.babraham.com/accelerate-babraham/scaleup-babraham/>

HEALTH2B HEALTHTECH ACCELERATOR, SWEDEN:

<https://www.health2b.life/who/>
<https://www.health2b.life/#team>
<https://www.health2b.life/how/>

EIT HEALTH, EUROPE:

<https://eithealth.eu/>
<https://wildcard.eithealth.eu/about-wild-card/>
<https://eithealth.eu/what-we-do/accelerator/>

III. The challenge: giving the right support for an efficient scaling-up

- p. 9**
[10] https://cordis.europa.eu/programme/id/H2020_INNOSUP-05-2016-2017
[11] <https://ec.europa.eu/easme/sites/easme-site/files/Paper-Twinning-advanced-methodology.pdf>

- p. 10**
[12] <https://www.oecd.org/sdd/business-stats/eurostat-oecdmanualonbusinessdemographystatistics.htm>
[13] <http://www.ecosysteminsights.org/scaleup-companies-create-most-of-southeast-asias-new-jobs/>
[14] https://scaleit.biz/wp-content/uploads/ScaleIT_backable-scaleup_EN2016.pdf

V. The SMEs

- p. 24**
[15] https://ec.europa.eu/growth/content/models-reduce-disproportionate-regulatory-burden-smes-0_en
[16] <https://grantedltd.co.uk/funding-blog/what-is-trl/>
[17] <https://grantedltd.co.uk/funding-blog/what-is-crl/>
[18] http://www.wsl.be/matmax/home_d.php?lang=en

- p. 26**
[19] <http://www.economicwebinstitute.org/essays/proximitytrade.htm#adv>
[20] <http://www.economicwebinstitute.org/essays/proximitytrade.htm>
[21] Roland Berger revisiting the market for innovation

- p.31 & 32**
[22] <https://www.hello-tomorrow-bpifrance-1.pdf>

- p. 33**
[23] <http://klaster.lt/wp-content/uploads/2017/05/ModelsforinternationalizationofSMEsthroughclusters.pdf>

VII. Glossary

A&I

Acceleration & Incubation

AI

Artificial Intelligence

B-2-B

Business to Business

B2C

Business to consumer

BBSA

Brussels Business Support Agency

BSR

Baltic Sea Region

CE mark

Conformité Européenne

CEBR

Council of European BioRegions

CEO

Chief Executive Officer

CERCA

Network of Research centers of excellence in Catalonia

CIMIT

Center for Integration of Medicine and Innovative Technology (Boston)

CRAASH

Commercialization Readiness Assessment and Accelerator for Solutions in Health

CRL

Commercial Readiness Level

CRO

Clinical Research Organisation

DOP

Design Option Paper

EC

European Community

ECCP

European Cluster Collaboration Platform

EEN

European Enterprise Network

EIC

European Innovation Council

EIT

European Institute of Innovation and Technology

ERDF

European Regional Development Fund

ESIF

European Structural and Investment Funds

EU

European Union

FDA

Federal Drug Administration

FTO

Freedom to operate

HIBSTER

Health Innovation Bootcamp by Eurasanté

HIMSS

Healthcare Information and Management Systems Society

HR

Human Resources

HRM

Human Resources Management

INNOSUP

Horizon 2020 programme to test new approaches for better innovation support through funding opportunities for innovation actors across Europe

IP

Intellectual Property

IPF

INNO-Partnering Forum

IPO

Initial Public Offering

ITC

International Trade Center

KOL

Key Opinion Leader

KPI

Key Performance Indicator

MVP

Minimum Viable Product

NOME

Nordic Mentor Network for Entrepreneurship

OECD

Organisation for Economic Co-operation and Development

PoC

Proof of Concept

R&D

Research and Development

SIG

Special Interest Group

SME

Small and medium-sized enterprises

SWOT

Strengths, Weaknesses, Opportunities and Threats

TRL

Technology Readiness Level

TTO

Technology Transfer Organisation

UX design

User-centered design

VC

Venture Capital