

# THE INNOLABS WHITE BOOK

SUPPORTING SMEs TO GENERATE COLLABORATIVE SOLUTIONS  
FROM ICT, HEALTH, BIOTECH AND MEDICINE SECTORS AND GET  
THEIR PRODUCTS TO MARKET FASTER



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## SOME FACTS ABOUT INNOLABS...



### INCENTIVISING & INFORMING

€4m was directly invested in SMEs

300+ start-ups and SMEs took part in 8 events across the EU

2 Open calls attracted 191 eligible proposals

### INNOVATION SUPPORT SERVICES

84 SMEs enrolled in two 9 month acceleration cycles with customized support

150+ Consortium support services provided

100+ external voucher



### IMPACTS

84 start-ups/SMEs with new products closer to market and enhanced credibility

€22m+ new public/private growth funds secured or planned by SMEs in 1<sup>st</sup> Acceleration Cycle alone

## 1 WHY INNOLABS MATTERS FOR SMEs

This White Paper shares with you the lessons learnt in the INNOLABS project in unlocking the cross-sectoral collaborative potential of SMEs from the ICT, Health, Biotech and Medicine sectors (IHBM). This represents an emerging market where the INNOLABS project supported SMEs to further develop personalised digital solutions (eHealth and mHealth) for older people in both rural and urban areas.

As a cluster driven project INNOLABS developed its activities based on the conviction that innovation thrives in specific companies and regions that build an ecosystem with the right conditions, competences and skills.

Start-ups and SMEs took part in the project because:

- they were taken seriously by the project and its partners,
- our experts believed in what the SMEs were doing and;
- both the partners and experts believed in the potential of the products/processes and/or services the SMEs were developing



The two nine-month Acceleration periods helped our companies validate their technical, commercial and business hypothesis, build credibility and become an attractive and well-structured opportunity for prospective future partners including large industry players, health care providers and investors.

So, with this White Paper we report on the e-health market, its challenges and opportunities, success drivers and triggers and end with a Call to Action. Hopefully this provides you with a concise read on a complex issue and supports the need for change and innovation.

## 2 THE DIGITAL HEALTH MARKET AND ITS DYNAMICS

The European Commission promotes and coordinates multilayered efforts for its citizens to have equitable access to safe, trusted and top quality digital care services. Transformation of health (and social) care, in particular, broader use of digital and artificial intelligence technology, will benefit patients and populations, health care systems and the economy. In particular, by enabling innovative approaches to independent living and integrated health and social care. But in achieving this vision, health systems and industry face some harsh realities.

**Healthcare** - Healthcare systems worldwide are confronted with the twin challenges of rising costs and increasing demand for better outcomes. Up to 20% of current expenditure in modern care systems can be categorised as either ineffective or wasteful. Meanwhile, health and social care systems have demonstrated stubborn resistance to the kinds of transformational improvement that have been witnessed in other industries driven by ICT advances. This is due to a variety of factors including the inherent fragmentation of care delivery by the silos within and between sectors and departments.

These issues are especially problematic in rural areas where there are fewer options in seeking care. Rural communities are more likely to have gaps in the underlying delivery system, with limited access to quality primary care, specialists, and, in some cases, hospital care. In particular, there are few incentives for clinicians, GPs and pharmacists to work in dispersed rural communities. Additionally, the cost of infrastructure and capacity is spread over fewer people. In terms of cost per head of population, rural care is more expensive and offers limited economies of scale. In this context harder to justify the assignment of additional resources without clear cost and value-based return evidence. Uptake of digital solutions can help in addressing operational shortcomings and unequal territorial distribution at lower costs than today, but this needs an outcome guarantee and clear implementation roadmaps.

**SMEs and start-ups** - The healthcare sector is a particularly challenging market for start-ups and SMEs. Getting approval of a new solution for reimbursement is cost- and time-intensive, therefore companies often abandon their innovation because time-to-market is too long, risky and costly. If you have a fully tested and Medical Device Regulation compliant product, you still need to assess and demonstrate the health economic value within a given healthcare system. This slows the speed at which start-ups and SMEs can get their products to market for two reasons (i) its implementation currently has minimal capacity to conduct the necessary assessments and (ii) the assessment processes seem to prioritise large corporations. And if you get to market, it seems easier to access individual consumers instead of health care institutions. Or to sell products abroad rather than locally or in the EU. While pre-commercial and value based procurement and health technology assessment can help navigate this obstacle, a fragmented local public procurement practice remains a major obstacle and extremely undermines the scale-up potential of innovative SMEs and start-ups.

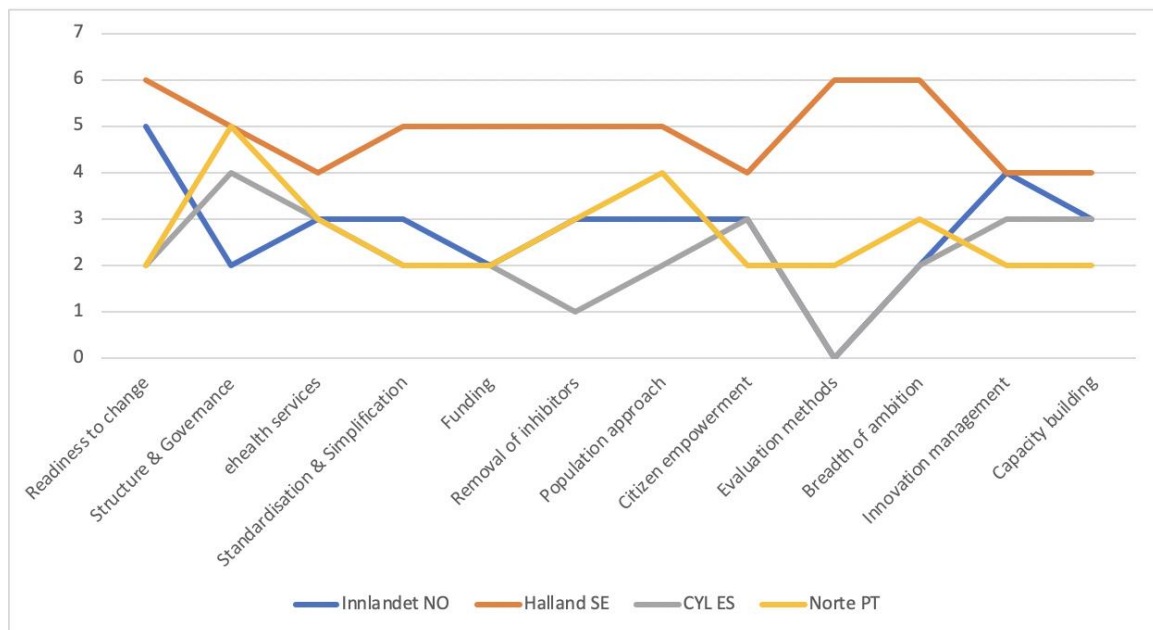
## CHANGING CARE MODELS AND INDUSTRY OPPORTUNITIES

To tackle the needs of ageing populations and management of chronic diseases including comorbidities, care models are moving from being hospital-centric towards closer-to home, more value-based and person-centric. A particular shift that has traction is integrated health

and social care. **It can be defined as those initiatives that proactively seek to structure and coordinate care for people in their own home environments, centred around their needs.** It can also be seen as both a design principle and a means to achieve person-centred, equitable access to services that are efficient and provide safe care through networks of organisations that provide a coordinated continuum of services to a defined population.

However, up-front investment is typically needed to cover the set-up costs and the costs of transition to a new care model (costs for buildings, facilities and ICT; costs for human resources, training/development and continuous technical support; costs of implementing innovations and organisational changes etc.). At the same time, there will likely be a time lag in achieving outcomes and sufficient scale to realise cost efficiencies. So, the 'return on investment' may only come in the medium to long-term. Consequently, public investment in new care models are considered to be high risk

The following graph summarises the maturity of integrated care in four regions against 12 criteria using the SCIROCCO self-assessment tool. It builds on the conceptual [Maturity Model for Integrated Care](#) developed by the B3 Action Group on Integrated Care of the European Innovation Partnership on Active and Healthy Ageing. Integrated care in each region is sufficiently mature to absorb new digital solutions. But, just as important is the ability of stakeholders in these ecosystems (health and social care providers, social enterprises, municipalities) to optimise and rearrange existing digital assets (data platforms, eHealth assets, mHealth apps, tools, medical technologies, methods, standards) and exploit these to improve the data stream and service value chains to ensure that the integrated care system can demonstrate value-based care delivery from an economic and outcomes perspective.



**Figure 1:** Maturity of integrated care system in 4 regions

The bottom line is that digitally enabled integrated care needs to be able to optimally support older people by addressing both their health and social care needs, while at the same time minimising service utilisation and expenditure. In this context, the fit between care systems

and digital solutions needs to take account of the maturity of integrated care at a sub-national level, their capacity to absorb new digital solutions and to better utilise current digitally-enabled assets.

Such insights are helpful but, in a demand-driven market, start-ups and SMEs need to identify and work with end-users (patients, professionals and informal carers) using approaches such as user-centred design to inform both product development and selling it. At ExtraMed 2019, a roundtable with frontline NHS staff answering the question: “does technology improve healthcare?”<sup>1</sup>. The main benefit identified was technology helping to free up time for more patient contact.

Freeing up time for more patient contact	That freed time for care and patient contact [and] which improves outcomes overall, was most valued.
Supporting better decision making	Can help to reduce human error and more accurate information supports better decision-making. Entries or changes can be monitored and flagged up immediately if they are outside accepted standards or ranges
Empowering vulnerable patients	Allows patients to have access to content that will better help them understand and be more involved in their care. If they are given access to simple systems that put them more in control of what happens to them in hospital they feel more empowered and engaged, which has been proven to support their recovery.
Proper integration and buy-in	To be most effective...[technology] needs to be used by “the right people, at the right time, at the right location, with the right training.” It seems that this is a tricky balance to find. [Also], there is a degree of fatigue and cynicism about technology projects. Taking an integrated, intuitive and evolutionary approach that respects the experience of those at the frontline, rather than disruptive and ‘big bang’ implementations is key.

## VALUE CHAINS AND BUSINESS MODELS

The competitiveness of an individual company depends on the competitiveness of the value chain to which it belongs. The Table on untapped business opportunities below shows an approach that regional innovation ecosystem stakeholders could use to incentivise SMEs and health care providers to collaborate more. With this the key element are ‘platforms for learning and co-creation’. This reflects a recommendation made by one of the interviewees: *co-developments is the key for future developments...[and that] living labs...are a very good basis for co-development activities.* (Senior Clinician FR).

What frames and drives digital health transformation needs to find better ways for how start-ups and SMEs can connect their products to care systems. A particular challenge for our emerging IHMB sector is that data processing must be in real-time and this demands new analytical technologies/data processing solutions including their automation. And this,

<sup>1</sup> <https://extramed.co.uk/does-technology-improve-healthcare/>

combined with MDR regulations and liability issues create significant challenges. As the CEO of an Italian Legal Partnership told us,

*The more we work in interconnected systems, the better we think about liability. For example, here are new decision support tools for clinicians. If they use data from different sources...who will be responsible if the wrong result is generated?*

Opportunity	Description	End-user	Options for monetising
Lack of accessible financing for needed investments in health care reform	Upfront capital from social impact investors, national promotional banks and European funding streams: ESIF, ESFI, EIB	Health care providers	<ul style="list-style-type: none"> <li>Improved provider performance reduces payer expenditures</li> <li>Financial partner shares in returns</li> </ul>
Lack of sufficient financial reserves for providers to take on risk in new payment models	Reinsurance or other financial support to limit provider risk	Health care providers	Knowledgeable/informed risk sharing through pooling risks across provider organisations (e.g. in a regional service network) or securitisation
Lack of accessible and relevant advice on mHealth and other care management tools across the care continuum and efficient partnerships between tool developers, SMEs and providers	Platforms for learning and co-creation including 'living labs'	<ul style="list-style-type: none"> <li>Health care providers</li> <li>Patients/advocates</li> <li>SMEs</li> <li>Researchers</li> <li>Investors</li> </ul>	<ul style="list-style-type: none"> <li>Blended HTA briefings and market assessments for public procurement staff</li> <li>User fees from developers</li> <li>Fees per purchase of developed tools from individual customers and provider organisations</li> <li>Royalties to clinics that validate the product</li> </ul>
Underused non-health data	Holistic data based on interoperability and new business intelligence	<ul style="list-style-type: none"> <li>Health care providers</li> <li>Tool developers</li> <li>Health Insurers</li> <li>Care entities from other sectors</li> <li>Researchers</li> </ul>	<ul style="list-style-type: none"> <li>Licensing fees</li> <li>Purchase fees from data analysis products</li> <li>Data sharing from federated databases</li> </ul>

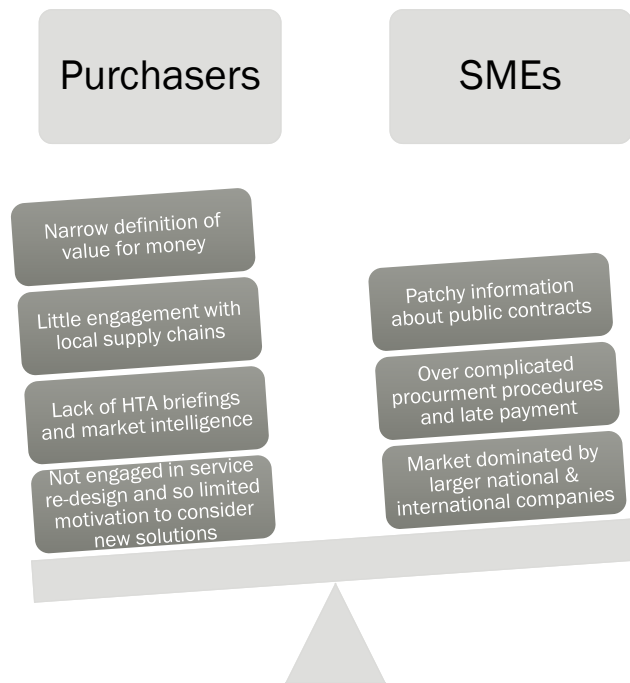
**Table 1:** Untapped business opportunities in changing health care delivery<sup>2</sup>

Just now, there are too few good use cases to show how collaborative value chains work best. As the CEO of a software development SME (LU) said: *Typically, the technology is developed first, and then we work to adjust to reality/practicality.* This reflects the lag between end-user needs, the readiness of start-ups and SMEs to address those needs and the willingness of health care providers to involve themselves in these product pipelines to help the diffusion and adoption of market-ready products and services. Patient involvement and co-creation models are essential for the emergence of viable and market adoptative future health solutions. It is suggested that we should think about good **use cases** to study the situation before we further develop the technology. For example, 200 projects have been supported in the past years from German funders, but none of the project solutions has reached the health care system.

Although few digital start-ups choose to pursue medical certification or clinical validation and trials, those who do seem to benefit from collaboration with health care providers. For example, Tilak Healthcare who sought certification of gaming software as a medical device. In summary, no dominant business models have yet emerged for digital health SMEs; very few successful solutions reached the digital health market and no full value chain is clearly established today.

<sup>2</sup> Adapted from: Pham H, McClellan M (2017) NEJM Catalyst © Massachusetts Medical Society

## PUBLIC PROCUREMENT



**Figure 2:** Barriers in attracting SMEs to public procurement opportunities

Innovation in public procurement is an underdeveloped enabler for regional innovation ecosystems and especially for SMEs<sup>3</sup>. Public procurement is currently re-emerging as the most sought-after instrument of demand-side innovation policies in Europe. Although public procurement is said to account for 17% of the EU's GDP (€2000bn) experience of SMEs in Portugal, for example, suggest that they are more likely to engage in pre-commercial and other innovative procurement initiatives if they are seen as risk-benefit sharing, non-complex and compatible. Examples of networks and initiatives that help to build mutual benefit relationships between SMEs and healthcare supply chain managers were medtecnet-BB in Berlin-Brandenburg and a NHS Passport Scheme by Groundwork in Liverpool/Manchester.

Figure 2 above summarises barriers that are (i) affecting the ability of regional and local health care providers to extend local procurement opportunities (ii) affecting the ability of SMEs to compete for public healthcare service or goods contracts (iii) affecting the ability of purchasers and SMEs to work collaboratively to extend local procurement.

<sup>3</sup> Watson J (2015), Health innovation enablers: foundations for sustainable investment in modest and moderate innovator regions. DanuBalt Project Working Paper 1. [http://danubalt.eu/wp-content/uploads/2016/05/Health-Innovation-Enablers\\_Working-Paper-1\\_v3.pdf](http://danubalt.eu/wp-content/uploads/2016/05/Health-Innovation-Enablers_Working-Paper-1_v3.pdf)

### 3 WHAT SMES WANT

INNOLABS cluster partners had a fairly good idea about what support start-ups and SMEs might need but refused to rely simply on their assumptions and experiences. And so, at the start of the project we talked with SMEs across the EU and drew on recent stakeholder workshops with SME owners in the EU13 as part of the DanuBalt project (2015-2016). Although a range of support needs were identified, five stood out:

1. Being able to 'plug and play' their product with end-users (patients and carers);
2. Dealing with the complexities and costs of IPR;
3. Accessing and blending the data their product generates with available patient data sources and;
4. Leveraging new public and private funds to help get their product closer to market.
5. Facilitated and streamlined access to key stakeholders and key opinion leaders to alleviate development and adoption of their offerings (See 'Connectivity to generate ideas' under Section 4 below to see how this need to addressed).

### PLUG AND PLAY PLATFORMS

Start-ups and SMEs need practical channels, procedures or work flows that a company with a new product can 'plug into' in order to test and validate the product and associated processes. Unfortunately, this option is not always available to them. This is not for want of trying:

*we are now working on a strategy of dealing with rare diseases...[but] there is no specific channel or specific work flow created for stakeholders [including SMEs] to join, to get involved...to think together these strategies* (Innovation Unit Leader, Regional Health Authority ES)

Resolving connectivity is critical. For a start-up or younger SME this matters because:

- Unless they are a spin-off from a profiled university-based research project (e.g. AssisTech, Gdansk) they will have low market visibility, solution credibility and user's trust
- Initial human resources and funding (self-invested, crowdfunding e.g. through the Capital Cell Platform, Spanish Centre for Industrial Technological Investment) are often limited but might be sufficient to provide proof of concept. So, being able to join a local test/validation platform set up between an innovation cluster and local health care providers can provide a SME with needed credibility to secure funds from dedicated funding lines (e.g. Catalan Institute of Funding) for prototyping with patients
- This also provides the momentum and capacity needed to certify products to comply with regulatory standards (ISO 13485:2016, CE Marking, EMA, FDA) that are necessary steps to enable market penetration.

However, providing such infrastructure means finding incentives for healthcare providers and their funders to collaborate and the perceived mindset of health care management is perplexing:

*I think there is an available market but because of this mindset of “I prefer to buy the big game player solution” [rather than] say okay let’s talk to a start-up” (Senior Manager, Technology Centre, ES)*

## UNDERSTANDING IPR

In discussion with SME owners, two issues emerged regarding Intellectual Property Rights (IPR): looking at alternatives to patents and lack of understanding of IPR as an obstacle to collaboration between healthcare providers, industry, academics and investors. There is some evidence that IPR can be a source of **conflict between stakeholders seeking to develop collaborations**.

*We had once explored working with a professor. We said we would like to collaborate with you but in order to take your compound into development we have to have rights to it. We cannot just develop your compound. So, what we would need is to sit down and decide on the terms on which you would transfer the ownership to us. So yes, you are still the inventor, you are still on the patent, we would compensate you for the rights to your compound. His answer was: but are those my compound? We said, well but this is how it works. For us to develop it further we have to take it from you one way or the another, so we can agree whatever payment you want, whatever terms or conditions we can negotiate but we have to have the right. He just did not get it. (CEO, Biotech SME PL)*

Actually, as one of our partners commented: *such conflicts are as natural as water in a swimming pool*. So, there was a lack of understanding about IPR that prevented this collaboration happening. That said, it was not clear if the Technology Transfer Office of the university was present in those initial discussions because this might have dealt with any misconceptions about background and foreground knowledge in IPR. Relatedly, in Pomerania, Campania and Castilla y Leon there is a perception among non-academics that university departments are ‘cathedrals’ to the older professors who can be very protective of their knowledge or other knowledge developed in their Department. This might act as a barrier to industry collaborations sought by younger researchers.

In Germany, a group of young innovators started a company and they applied for funding for the seed/initial phase. However, they did not get the funding first time around because they had not filed a patent. The reason the funding agency gave was that they also need a security represented by the filed patent. They tried again 6 months later, filed a patent in the meantime and now they have the funding!

That said, there are **alternatives** to taking the patent option. For example, a biotech start-up in northern Spain explained how they have decided to manage the intellectual property of a new algorithm they have created for cancer diagnosis. It has been developed by the company and is protected as a “trade secret”. Having assessed the possibility of patenting, for now they rejected this option, as this would force them to make public certain sensitive information. Their concern is that, despite being protected, this could allow potential competitors to analyze the structure of their algorithms and reach a series of conclusions that otherwise would be impossible. In addition, they said that “trade secret” protection allows them to shorten the time to market of new versions developed by the company. They argue that they will not have to

adapt to the terms of the various management of intellectual property (patent registrations). This should ensure a faster inflow of funds to the company. The bottom-line here is that nowadays it is very difficult, if not practically impossible, to patent an algorithm since it is considered an abstract idea. This is only possible if the algorithm is integrated into hardware or a product and then the system is patented.

## DATA ACCESS AND CONNECTIVITY

Patient data are distributed and are stored in different and heterogeneous repositories. For digital health solutions information from these data sources need to be integrated to allow an analysis of all relevant and complex data. To enable this process, it needs interoperability and flexibility of all connected systems. Reality shows that so far that even locally, different systems are not fully interoperable limiting full exploitation of the available data.

In the context of digital health solutions (ranging from mHealth apps to eHealth systems) a particular challenge for SMEs is **accessing existing data resources and delivering interoperability**. *This is critical to achieving critical mass and momentum in testing and validating a new solution* (CEO Biotech Start-up ES).

Partnering with public laboratories in order to build on existing data resources and integrate new datasets generated in the frame of a clinic-industry-science collaboration are an option. Patient sample cohorts hosted by the public laboratory partner(s) include: serum samples collected prior to therapeutic intervention and available for retrospective analysis; associated anonymised data about individual patients. Standard Operating Protocols (SOPs) used by public labs for various data production types help produce data and information in accordance to appropriate quality standards (ensured by consultation with existing information/resources, e.g. provided by BBMRI-ERIC, ELIXIR and CTMM TraIT).

Partners in such collaborations need to strictly obey European and national regulations for data security and personal data protection<sup>4</sup>. These guidelines are under review by the European Data Protection Supervisor for endorsement and will be implemented as soon as these are approved. If person-identifiable data are involved or if data are subject to ethical, legal or IP restrictions, the conditions need to be defined and agreed upon by the collaborating partners regarding which safeguarding mechanisms need to be implemented<sup>5</sup>.

In public laboratories, patient data is anonymised to protect privacy, and treated according to guidelines specified by local/national boards. However, the work of SME partner(s) is likely to be better accepted by clinic and scientific colleagues if the production process for the solution does not manipulate personal data. For example, this means the SME only have access to the patients' numbers and their levels of biomarkers. In a similar way, at the Labs they will analyse the blood samples, which are anonymised. In this context, **retrospective data can be used as a training dataset for assay testing and validation**. Prospective clinical validation draws on

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<sup>4</sup> More detailed guidelines can be provided by following the recommendations for the Code of Practice for Reuse of Medical Data in Scientific Research Projects that are developed in the eTRIKS initiative <http://www.etriks.org/project/code-of-practice-on-secondary-use-of-medical-data/>

<sup>5</sup> BioMedBridges Charter: Data management and sharing. Principles of data management and sharing at European Research Infrastructures. Version 1.0, 21 Jan 2014.

independent patient samples not used in the training dataset or that are collected in parallel with the collaboration for clinical purposes in compliance with national and local ethics criteria.

## LEVERAGING FUNDS

SMEs and third party stakeholders across our regions identified a range of problems with securing funds. For example, there remains a “*need to incentivise decision makers to enable digital transformation*” (Senior Expert, Big 4 Consultancy PL); “*funding does not incentivise SMEs...and public institutions have no spare cash*” (CEO, Biotech PL); “*make funding workable for SMEs*” (Professor, Translational Medicine, IT); “*we need venture capital*” (Finance Manager, SME ES); “*funds go to senior people and not younger people*” (CEO, Start-up ES); “*we are asked to help our health system to be more sustainable... sustainability is in order to serve the demand of the service and the low financing that they have*” (Researcher, Technology Centre ES).

Despite the market potential for connected medical devices, there is a disconnect between investors and investment opportunities regarding preferred returns on investment.

*The other thing that I think is difficult and I could see this ...that always surprises me. We are talking a little bit about public private enterprises or interactions. To me it is surprising that when you give an investor a choice to invest into something that has 50% chance of succeeding but the return is 2% vs. something that has 0.5% success but the return is proportionally higher, so you know the weighted probability is the same, they always go for something that has a high return but very low probability of success. So, in many cases in healthcare, except for drug discovery that always has this high return, you have relatively incremental returns with modest probability of failure, right? But this is something that investors do not like. I just don't know, it just always puzzles me but I just keep seeing that time after time.* (CEO Biotech PL).

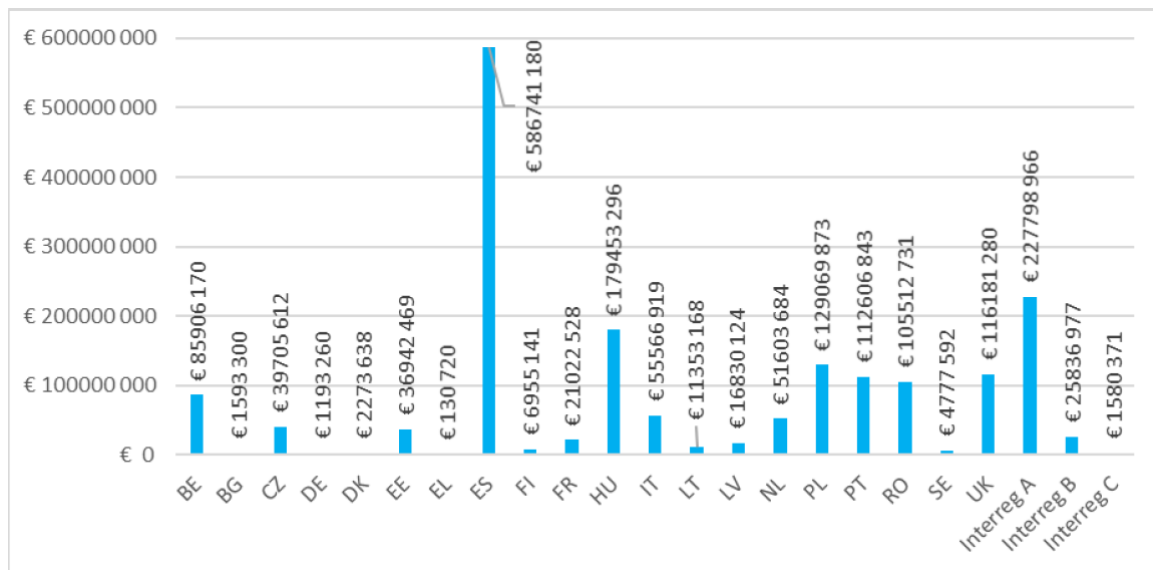
Elsewhere, we heard from a German Professor working in diagnostics that it is difficult to get Venture Capitalists interested in investing in diagnostics although there might be a higher chance to succeed with these innovations. The point to be made here is that this disconnected investor mindset is sometimes with the investor but also with the companies that manage investor assets. For this reason, regions looking to optimise clinic-industry-science collaborations (including the use of living labs,) need to extend these collaborations to investors directly.

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## EU FUNDING

European Structural and Investment Funds (ESIF) offer many opportunities to support health innovation, from the development of particular products to the enhancement of R&I infrastructure and the wider innovation environment. ESIF funded projects are aligned with the Cohesion Policy priorities (currently for 2014-2020). For example, Thematic Objective 1

(Strengthening research, technological development and innovation) and Thematic Objective 3 (Enhancing the competitiveness of SMEs)<sup>6</sup>.



**Figure 3:** Total budget of health R&I projects by Member State and Interreg programme

Most Member States have adopted ESIF Operational Programmes that support health innovation through these broader objectives, as well as through Investment Priorities related to ICT development (Thematic Objective 2). ESI Fund support for R&I must be in line with the regional or national smart specialisation strategies (RIS3), which is an ex-ante conditionality (i.e. a precondition for receiving financial support from the ERDF). By enabling each region to identify and develop its own competitive advantages, RIS3 aim to boost growth and jobs, and promote the creation of R&I clusters. To date, many RIS3 have identified health as a key area for specialisation. In addition to the ESI Funds, Horizon 2020 (H2020) is another major funding source for R&I.

Midway through the 2014-2020 funding period, €1.8 bn has funded 1,708 projects in 20 Member States in support of health innovation and R&I in health. Over half of these projects (56%) are in Spain, followed by numerous others in Italy, Portugal and Poland. Many relevant projects are also financed under the three Interreg cooperation programmes.

The vast majority of the health R&I projects target investment in products and processes at different phases of research and development and with different technology readiness levels (TRLs). Some projects target the development of R&I capacities and environments by supporting research infrastructure, clinic-industry collaboration and human resources in the

<sup>6</sup> ESI Funds for Health (2019), Investing for a healthy and inclusive EU, Final Project Report, DG SANTE

R&I field. Another group of projects aim to address key health and societal challenges such as the ageing of the population, through R&I of new and changing care models.

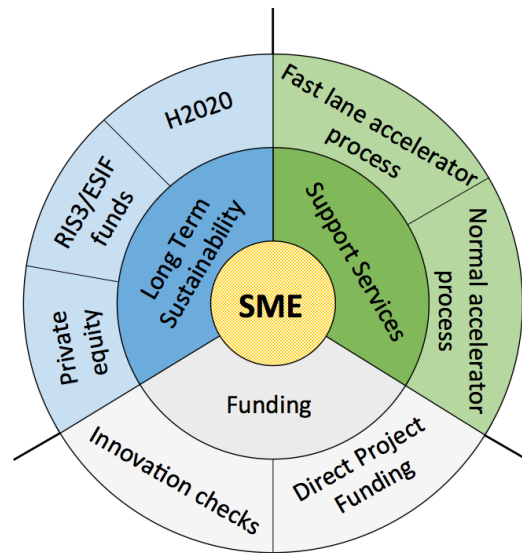
It is important to ensure that EU funding instruments for R&I (especially the ESIF and H2020) are complementary at a strategic level and that they adequately address R&I needs in the EU. Synergies between the ESI Funds and H2020 are crucial. For example, innovation should be supported along the whole process (from concept through research to commercialisation). Combining H2020, which focuses more on concept development, and the ESI Funds, which can support getting projects closer to market, is key to ensuring project longevity and returns on investment.

Despite this seemingly huge investment, the EU's research budget itself is still too small compared to public funding of research in competing economies such as the USA, Japan, China, or compared to the aggregate public funding of research in the Member States.

## 4 THE INNOLABS METHODOLOGY AND SUCCESS DRIVERS

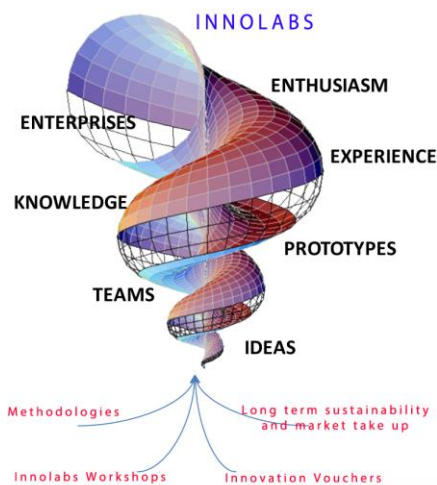
*When you are into a start-up for the first time in your life, you desperately need some kind of 'school for entrepreneurship': a place where you can learn what kind of barriers you are about to encounter and what dilemma's you irrevocably will be confronted with... In that sense INNOLABS was sort of a crash course for us (Co-Founder ORYX).*

In mobilising more than 75% of the total project budget (€4m) to provide direct innovation support for SMEs, INNOLABS encouraged integration of skills and competences among the funded SMEs operating in different sectors (IHBM). Working with European clusters, accelerators and intermediary organizations – all of them with depth experience in fostering innovation and fertilizing growth in their sectors and regions – helped deliver a large number of activities reinforcing SME competencies and creating new industrial value chains fostering the development of emerging industrial sectors in Europe.



**Figure 4:** Overview of INNOLABS actions

Through its programme, INNOLABS sought to boost cross-sectoral collaborations with the additional effect of offering opportunities for new knowledge combinations and innovation. The intent was to shape new products, value chains and industries and diversifying specializations patterns with high probability of boosting the economy from local to European in scope. In this process clusters partners (i) provided entrepreneurial support to SMEs, (ii) acted as cross-border bridge-builders and as catalysts for cross-sectoral collaborative projects by also (iii) created a favourable open space to promote value chain innovation using a systemic approach.



### SUCCESS DRIVER 1: CONNECTIVITY TO GENERATE IDEAS

INNOLABS support for SMEs was guided by an Acceleration Funnel Approach. A first step was providing the conditions for best ideas to thrive, through online and physical meetings and workshops. These ideas were then expected to coalesce in teams. For this INNOLABS provided both IT tools (matching portal) and facilitated physical encounters in major INNOLABS events (Hackathons in Gdansk, Berlin and Oslo, Ideas Contests in Barcelona and Paris, an Investors Day in Madrid and

a final event and Demo Day in Oslo). Some of these connected to larger events e.g. InfoShare in Gdansk or the FUTUR.E.S festival in Paris in June 2018.

The **Hackathons** were not only competitions, but also an opportunity for enthusiastic teams to get mentorship and guidance in creating new ideas from Mentors and Challenge Owners who can implement those ideas with them on the ground.



The funnel approach continued with two **Open Calls** supported by a matchmaking portal to enable SMEs to search for partners. The Calls sought applications from SMEs belonging to the Health, BIOTECH or Medicine sectors, to collaborate with the IT sector to offer innovative projects that would improve personalized health care especially for older people in rural and urban settings. In each Call, teams could select one of three challenges to focus the pitch for their solution application. 203 proposals were submitted (of which 191 were eligible proposals) and 84 projects were funded.

Finally, INNOLABS **Investors Day** in Madrid (26 June 2019) was an excellent opportunity for Startups and SMEs to meet investors specialized in Health. Participants were able to meet and connect with investors in person, to pitch their idea, network and compete to win cash prizes.

SUCCESS DRIVER 2: CUSTOMISED INNOVATION SUPPORT

One of the main challenges that INNOLABS addressed was that SMEs need help to generate, take up and better capitalize on all forms of knowledge, creativity, craftsmanship and innovation. Each company was allocated a **Key Account Manager (KAM)** to guide them through the Acceleration Cycles.

The provision of **needs-led, customised innovation services** was preceded by assessing where each SME was in terms of innovation practice and performance. Data was collected from SMEs using a benchmarking tool, the **Innovation Health Check** developed by Enterprise Ireland. It was an important instrument for self-assessment in order to evaluate the SMEs innovation process and that how this process is impacted by company culture, business strategy & structure, the company capability & resources. The identification of the main strengths and weaknesses helped the selection of the best fitting innovation support services for the SMEs.

The awarded teams are motivated but their starting point tends to be a focus on the product	With the IHC results they are quick learners about what support they really need	The ‘dark horse’ services that get traction with the teams: IPR and regulatory compliance
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As the CEO of Mentalab GmbH told us:

*Looking back, this 360°-analysis was enormously useful. In the daily grind of a startup, it is hard to see what is being done right, and what needs improvement. Therefore, the external view and advice of an unbiased specialist was very helpful in identifying easy-wins, as well as more complex, bigger issues to tackle. The IHC process not only identified points to improve on within the company, but also uncovered additional challenges that Mentalab would face going forward.*

Besides identifying where the companies needed support, the benefit of this exercise was that it allowed continuing a discussion between the company and their KAM on structural issues regarding where the company is at the moment and where it wants or need to grow. It provided a direction for future development, like a “future-roadmap” for newly established companies with fewer employees and without a sophisticated internal structure. The larger, older companies found it useful as a reference for their own direction of travel.

### SUCCESS DRIVER 3: GAINING CREDIBILITY, CAPACITY, SKILLS & MARKET READINESS

One of the most important roles of INNOLABS was that start-ups and SMEs who secured funding and support to further develop their products, gained credibility and an improved business image that aided discussions with bigger companies, potential investors or health care providers about further product development, testing and commercialisation. Specifically, the acceleration programme complemented SME resources, helping them finalise the technical design, further development of the product and testing the prototype in real environments. This led to reaching a higher level of market readiness, and helped companies shorten their time-to-market and optimise product development. In several SMEs the resources available also helped them to expand their working team.

The 9-month acceleration periods and how they were structured and delivered, clearly prompted the SMEs capacity to produce significant results:

- the innovation potential of the SMEs increased in several fields supported by IHC data collected pre- and post-acceleration
- improvement in business awareness was reported in several cases generating development of more realistic business plans
- many SMEs put in place or improved their innovation management strategy
- evaluation of their own product (or solution) against existing standards and regulations (like for medical devices, CE marking) was critical in helping projects progress.

Ultimately, a majority of the projects had their prototype ready to test by the end of the acceleration cycle. The finalised technology with a real product in hand, helped build confidence in these teams.

## EXAMPLES OF SUCCESS TRIGGERS BY THE SMES SUPPORTED

<b>Product development</b>	<p>During the INNOLABS acceleration cycle, we smoothly proceeded from a prototyping phase to a new one mainly focused on certification, IP protection and marketization (CEO Tech4Care).</p> <p>After the acceleration period we have achieved proof of concept in terms of technology and market. It gives us a real product that works, that the market wants and is willing to pay for the price that we ask. That gives us real, tangible value in our hands (CEO Ninthway)</p>
<b>Pivoting the business model</b>	<p>Identifying in time that there was a larger business opportunity than they had previously considered and acting swiftly to reconsider their approach and modify it, was a success trigger (EUROB KAM commenting on BioEcllosion)</p> <p>The company updated its business plan and improved its value proposition due to the market insight gained via the project activities and has adjusted its clinical strategy to meet the requirements of the cardiac surgeons participating in the interviews (INNOLABS blog by NHT)</p>
<b>Understanding the market</b>	<p>Start-ups cannot afford to make big mistakes...Therefore, we [worked] with EUROB on...detailed market research...EUROB created a very detailed report with interesting insights...All these insights were then evaluated by our team in order to adopt the ones which clearly can benefit our strategy. We challenged our own initial reports and that helped us a lot as we now can see from different perspectives our market strategy. (CEO /CFO Advantis Medical Imaging)</p>
<b>Leveraging funds</b>	<p>Advice from the Berlin Partner and INNOLABS resulted in concrete and well implementable steps that helped the company succeed in the local eco-system e.g. local startup grants for development-based cost reimbursement (CEO Mentalab)</p> <p>Cardiacs benefited from INNOLABS innovation services to prepare and submit an application to the EU H2020 FTI (Fast Track to Innovation) Programme. The application received a grant of €2,9 M, due, in part, to the market insight and company development achieved during the acceleration programme (INNOLABS Blog by</p>
<b>Final thoughts</b>	<p>It's been a nine-month rollercoaster since; we got nominated for best Dutch Health Innovation; won the title 'Best Small Dutch Start-up', partnered up with multiple institutions, had the chance to test and analyse the Dutch Olympic Softball team and secured 100K funding (Co-Founder ORYX Movement Solutions).</p>

## 5 A CALL TO ACTION

The purpose of this White Paper was to report on the e-health market, its challenges and opportunities, hopefully providing a concise read on a complex issue and establishing the need for change and innovation.

Despite best intent, health systems and regional innovation ecosystems tend to operate in a fragmented way and this is problematic for SMEs and for healthcare providers. Fundamentally, there is a need for a mindset change as a majority of hospitals and healthcare centers do not, deep down, seem very disposed to innovation. A related problem is the difficulty in testing, verifying, performing trials and deploying tech solutions in a sector with not-so-flexible legacy systems in some EU member states.

Accordingly, we wrap up this White Paper with a 'Call to Action' asking health, industry and trade ministries to work with intermediary authorities to support industry and health care providers in value creation and better services that can result from collaborative solutions between the ICT, Health, BIOTECH and medicine sectors.

Arguably, in the regions served by our partner clusters, government industrial and innovation policies (plus national and regional Smart Specialisation Strategies) are well suited to this emerging IHBM sectors collaboration. The main challenges for further growth and development in Norway and elsewhere are related to demand in the domestic market. Dealing with the main obstacles and barriers in the domestic market will strengthen the competitiveness of this IHBM collaboration. Lessons learned from INNOLABS show that start-ups and SMEs value cooperation with and delivering demand-led products and services to the public health and social care sectors that support digital care sustainably.

Attractive domestic markets for this IHBM collaboration will provide the basis for increased value creation and boost employment in local health economies. Working together, industry and care systems can contribute to achieving both health and industry policy goals.

**Unlocking the collaborative potential between SMEs and health care providers** – The starting point for IHBM industry sectors is good but there are still barriers that make it hard for start-ups and SMEs in these sectors to grow.

The most obvious challenge lies with health systems. Health systems are strictly regulated while healthcare providers struggle to manage with static and more heavily monitored budgets. The stakeholders (SME owners, clinicians, clusters) we have talked with believe that healthcare providers and their funders are at a tipping point: maintain the status quo where there are few incentives to optimise adoption of new solutions or see the challenges as opportunities to change the attitudes of management/decision-makers. Transitioning requires an attractive 'hook': new solutions that enable more affordable service delivery with improved performance - better patient and population outcomes. As it is, the politics of administration blocks innovation uptake. Organisations commission and adopt the wrong things so how to resolve this?

Practically speaking, a number of actions are needed to overcome such challenges. In Norway a case for action by relevant government ministries has been made to help make Norway an

ideal environment for health start-ups to develop<sup>7</sup>. This has been adapted to provide the following reference guide for partner clusters although some might be more advanced in bringing industry and health care providers together.

1. **Incentivise and resource cooperation** - Establish a stronger culture for contact and dialogue between business & industry and the public health & social care sectors responsible for integrated care

Emphasise the expectations of cooperation with the business sector in the assignment document (or similar) for the regional health authorities and in funding allocations to the underlying agencies providing integrated care

Submit a new national health strategy in which primary and secondary care integration, technology and competence are key elements

Continue to develop the funding system for hospitals in order to better support coherent digitally enhanced person-centred care pathways, use of new technology and innovation in service design

Utilise existing intersectoral fora as an arena of interaction for cooperation with the business sector

Assess how to develop innovation activities at local municipality level for integrated care services

Ensure that state and private funders develop their advisory services to municipalities and industry in order to stimulate innovation when building community care facilities including social housing

Facilitate management development in innovation and business development, and ensure its inclusion in current or planned executive management development programmes for providers of integrated care

2. **Good business conditions** - Work to ensure good business conditions in general, and for research and development in particular

Study the potential for utilising any spare capacity in existing laboratories and infrastructure for testing and piloting at universities, university colleges and hospitals by making it available to business and industry and assessing possible incentives to that end

Map the potential for increasing interaction with the IHB sectors in relevant parts of integrated care ecosystems at ecosystem, organisational and patient/informal carer levels

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<sup>7</sup> <https://www.regjeringen.no/contentassets/41435798a618491e902935a590967502/en-gb/pdfs/stm201820190018000engpdfs.pdf>

Put in place effective and coherent translational research pathways for key integrated care pathways to inform effective regional and cross-border value chains

Assess if national ministries for trade should take on a coordinating role in joint international marketing of individual industries and research environments

Continue work on increasing participation in EU programmes and take steps to enable local companies to participate in innovative procurements in other European countries

Perform a comprehensive review of the policy instruments in place for the business sector

Continue prioritising on business-relevant research and innovation, the high level of support to policy instruments with the highest degree of innovation and efficiency, and continue the focus on broad, nationwide schemes.

3. **Attractive partnerships** - Make the public health and social care sectors an attractive partner for business and industry specially in the context of person-centred integrated care

Right-skill basic researchers and clinical researchers to better translate ideas into viable innovation products for testing and eventual commercialisation in partnership with industry – and especially local SMEs

Submit an action plan for clinical non-pharmaceutical medical device trials in 2020

Establish 'one stop shop' for clinical trials (but distinguishing between pharmaceutical and non-pharmaceutical trials), by linking relevant national agencies more closely to business and industry through a partnership model

Study how a combination of different research and innovation policy instruments can contribute to a more coherent process towards the implementation of new technology and new solutions for integrated care services

Introduce indicators for measuring adoption of digital solutions to enhance service delivery and related data management by integrated care providers and consider implementation in a results-based funding system of research

Establish or enhance platform(s) for health data analysis to simplify access to health data for retrospective and prospective research and analysis purposes, while strengthening protection of privacy. Including enabling more active use of health data in the process of developing pharmaceuticals and medical technology

Ensure that Tech Transfer and Innovation Offices in national agencies and sub-national intermediaries (such as clusters and universities) have the ability to provide good regulatory advice to business and industry and the health service.

4. **Culture of entrepreneurship** - Facilitate more commercialisation of medical and health-related research and of ideas generated within the health and care sector.

Power-up public sector innovation capacity to support a culture of entrepreneurship that looks to better utilise resources and people skills in generating, adopting and diffusing digital health solutions and tools

Map how entrepreneurship is taught and whether it needs to be strengthened in the education of health and social care professionals

Consider incentives for commercialisation of research results in the public health and care sectors, and particularly consider implications for re-working hospitals as knowledge centres supporting closer to home care

Map whether better guidance is needed on intellectual property rights in the health industry or parts thereof

Provide financial support for SMEs and public health care providers to work together in preparing 'proof of need' and 'proof of concept' for new innovation products,

Prepare an action plan for female entrepreneurs, to be completed in 2020

5. **Smart Procurement** - Smarter procurement by integrated care providers

Treat investments in digital solutions (platforms, eHealth, mHealth, sensors, wearables, medical devices) as shared investment by integrated care providers to help make efficiencies of data sharing and associated models and tools, more accessible for under-resourced care ecosystems providing support for marginalized urban and dispersed rural communities.

Facilitate increased use of innovative public procurements for integrated care at national and sub-national levels

Support the chances of promising innovations being adopted with explicit attention to managing change at organisational and workforce levels in public health and social care providers.

Improve the ability of health care supply chain staff to make procurement decisions that are better informed by critical appraisal of HTAs and market intelligence regarding the purpose, efficacy and quality of new digital products (platforms, wearables, sensors etc

Increase capacity for Agile Health Technology Assessment at sub-national levels including mini-HTAs to overcome the common problems with classic HTA which relies on publications and large datasets. A particular focus should be on producing accessible briefings of emerging technologies with comparative cost and impact analysis with currently used technology

Regional health systems should define their own "economic footprint" as a basis for baselining current spending patterns for goods and services (what stays in the region and what goes out of the region) and then routinely monitor the contribution of their procurement activity to sustainable regional development.



# INNOLABS

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*The INNOLABS Project is coordinated by Norway Health Tech and run in collaboration with 7 other partners from across Europe.*

 Norway Health Tech	 <b>Berlin</b> Partner für Wirtschaft und Technologie	 bioscience
 biotecyl Cluster de salud de Castilla y León	 cap-digital Paris Region	 <b>EUROB CREATIVE</b> Intelligence on the move
 HCN OPTIMISING VALUE CHAINS FOR HEALTH AND INNOVATION	 Interizon	

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