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The report on health startups' experiences with testbeds, public procurement and regulations

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Inga Chernova, Alena Konina

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Abstract

The report describes health startups' experiences in three topics: testbeds, public procurement, regulation. The topics are part of the measures included in the Roadmap of the Health Sector Growth Strategy for Research and Innovation Activities that was published in December 2020.

In summer 2021, the startup community Upgraded carried out a survey for startups to map their experiences and development proposals related to testbeds, public procurement and regulation. A total of 35 companies responded to the survey. In addition, a total of 15 companies and 11 experts participated in the interviews. Three round table discussions were also organized between business and expert participants.

Testbeds, public procurement and regulation are important development areas for startups that are also closely linked to each other. It is important to develop an innovation-friendly environment. In the discussions with startups, the strengthening of the process between testing and procurement as well as the development of funding emerged as concrete proposals for further development.

Keywords	enterprises, means of livelihood, health sector, startups, testbeds, public procurement, regulations		
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Kuvailulehti

24.1.2022

Raportti terveysalan startup-yritysten kokemuksista testbedeihin, julkisiin hankintoihin ja sääntelyyn liittyen

Työ- ja elinkeinoministeriön julkaisuja 2022:6		**Teema**	Yritykset
Julkaisija	Työ- ja elinkeinoministeriö		
Tekijä/t	Inga Chernova, Alena Konina		
Kieli	englanti	**Sivumäärä**	63

Tiivistelmä

Raportissa kuvataan terveysalan startup-yritysten kokemuksia kolmessa aiheessa: testbedit, julkiset hankinnat, sääntely. Aiheet ovat osa terveysalan tutkimus- ja innovaatiotoiminnan kasvustrategian joulukuussa 2020 julkaistun tiekartan toimenpiteitä.

Terveysalan startup-yhteisö Upgraded ry. toteutti kesällä 2021 startup-yrityksille kyselyn, jossa kartoitettiin yritysten kokemuksia ja kehittämisehdotuksia testbedeihin, julkisiin hankintoihin sekä sääntelyyn liittyen. Kyselyyn vastasi yhteensä 35 yritystä. Tämän lisäksi yhteensä 15 yritystä sekä 11 asiantuntijaa osallistuivat haastatteluihin. Kolmessa aiheessa järjestettiin myös pyöreän pöydän keskustelut yritys- ja asiantuntijaosallistujien kesken.

Testbedit, julkiset hankinnat ja sääntely ovat startup-yritysten näkökulmasta tärkeitä kehittämisaiheita, jotka liittyvät läheisesti toisiinsa. Innovaatiomyönteisen ympäristön kehittäminen on tärkeää. Testauksen ja hankintojen välisen polun vahvistaminen sekä rahoituksen kehittäminen nousivat keskusteluissa esille konkreettisina kehittämisehdotuksina.

Asiasanat	yritykset, elinkeinot, terveysala, startup-yritykset, testaus, julkiset hankinnat, sääntely		
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Presentationsblad

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Rapport om startup-företags inom hälsobranschen erfarenheter av testbäddar, offentliga upphandlingar och reglering

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Referat

I rapporten beskrivs erfarenheterna från startup-företag inom hälsobranschen kring tre teman: testbäddar, offentliga upphandlingar, reglering. Temana är en del av åtgärderna i den färdplanen för Tillväxtstrategin för forskning och innovation inom hälsobranschen som publicerades i december 2020.

Upgraded rf, startup-gemenskapen inom hälsobranschen, genomförde sommaren 2021 en enkät till startup-företag. I enkäten kartlades företagens erfarenheter och utvecklingsförslag i teman testbäddar, offentliga upphandlingar och reglering. Enkäten besvarades av sammanlagt 35 företag. Dessutom deltog sammanlagt 15 företag och 11 sakkunniga i intervjuer. I tre teman ordnades också rundabordssamtal mellan företags- och sakkunnigdeltagare.

Testbäddar, offentliga upphandlingar och reglering är viktiga utvecklingsteman med nära anknytning till varandra ur startup-företagens synvinkel. Det är viktigt att utveckla en innovationsvänlig miljö. Stärkandet av vägen mellan testning och upphandling samt utvecklandet av finansieringen lyftes fram som konkreta utvecklingsförslag.

Nyckelord	företag, näringsgrenar, hälsobranschen, startup-företag, testbäddar, offentliga upphandlingar, reglering		
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PREFACE

The health sector growth strategy for research and innovation was published in 2014. In December 2020, the Government published an updated roadmap, which is intended to serve as a guideline for the development of operations in 2020–2023. The aim of the strategy is not only to improve people's health and well-being through the latest research and innovations but also to promote Finland's position as an internationally known pioneer in health research and innovation, investments, and new business.

Health and wellbeing startups are a special category of small innovative businesses. To start selling their solutions, usually they must go through extensive testing and validation and get certified. A lot of them develop products that can only be used in a highly controlled medical setting, thus warranting public entities as their customers. Upgraded, on a mission from the Ministry of Economic Affairs and Employment, set out to investigate how these startups go through the hurdles of testing environments, public procurement, and regulatory compliance to form a comprehensive overview of their experiences.

Upgraded ry (formerly HealthSPA ry) is a non-profit Association founded in 2012 for startups operating in the health and well-being sector. Our mission is to provide help and support to startups at all stages of growth so that no important innovations are lost. Our active and extensive community consists of more than 80 member startups and dozens of partners. We are building bridges between the actors in the health innovation ecosystem and enabling meaningful cooperation across national borders.

The aim of the project was to increase the understanding of the experiences and needs of Finnish health and well-being startups and other ecosystem actors, along with showcasing best practices from Finland and other Nordic Countries, and to introduce possible solutions to challenges from the following areas relevant to the roadmap:

- Testbed operations
- Public procurement
- Standards and regulations

In the first part of this project, we collected 35 responses from companies all over Finland. Next, we conducted in-depth interviews with companies and experts to gain a deeper understanding. Finally, we conducted three roundtables with companies and leading experts in the field to facilitate an open discussion on the topics.

The data was collected from both sides of each of the services/processes: from service providers and service consumers (here: public sector and startups, acting in different roles depending on the topic) and analyzed for the balance of the demand and supply on the market.

We would like to sincerely thank all our respondents, interviewees, roundtable participants, and consultants for their contribution to this project.

This report consists of six parts: this preface, the project overview, sections dedicated to each research topic, and a summary. The project was funded by the Ministry of Economic Affairs and Employment and delivered by Upgraded.

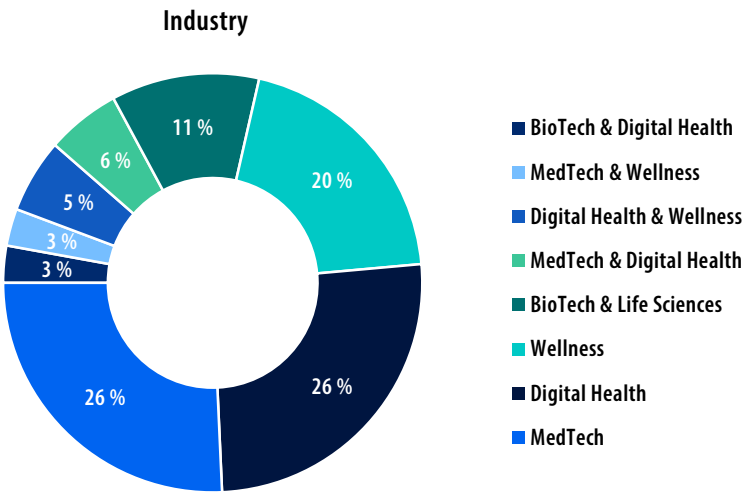
1 The project overview

1.1 The survey

The survey was conducted by means of a lengthy questionnaire (total of fifty questions), containing blocks on all three areas of interest. The questions are cited in Appendix 1. The questionnaire was disseminated by Upgraded and regional hubs through multiple communication channels with a goal to reach 200 Finnish health and wellbeing startups. 35 of them responded; some gave their responses to the questions in all three topics and some only in one or two sections.

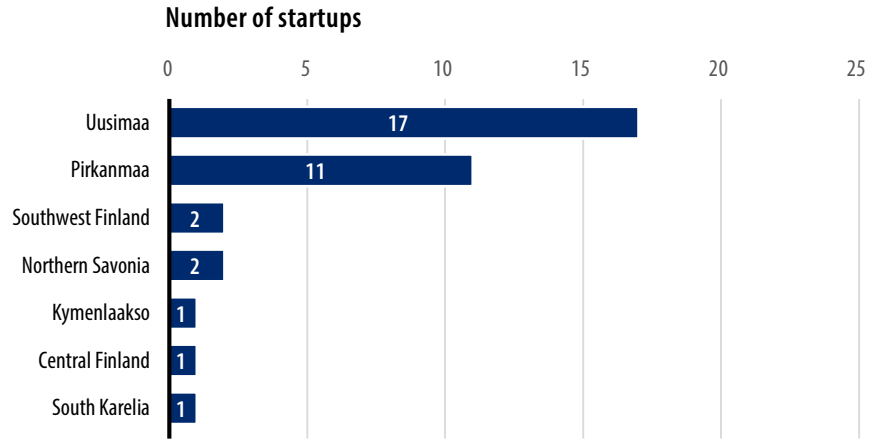
Figure 1 demonstrates the distribution of the industry sectors that the respondents self-assigned to. 26% of them reported belonging to the Digital Health industry, with the same number of companies belonging to MedTech. 20% self-identified as Wellness companies, 11% – belonging to the BioTech and Life Sciences sector. The rest is distributed across the combination of sectors: MedTech and Digital Health, Digital Health and Wellness, BioTech and Digital Health, and MedTech and Wellness.

Figure 1. The industry sectors that companies in our survey self-identify with.



Geographically, companies that responded to our survey reside in seven Finnish regions (Figure .2): Uusimaa (17 companies), Pirkanmaa (11), Southwest Finland (1), Northern Savonia (1), Kymenlaakso (1), Central Finland (1), and South Karelia (1). Only 20% of the companies were university spin-offs.

Figure 2. The geographical distribution of the companies in our sample.



As for the current company stages, most of the respondents chose multiple options with Traction being the most popular answer. A more detailed view of the responses can be seen in Figure 3. AI, information management, and telehealth are the leading technologies used by startups (Figure 4); on average, companies use 2,7 technologies in their operations.

Figure 3. The development stages of the companies in our survey.

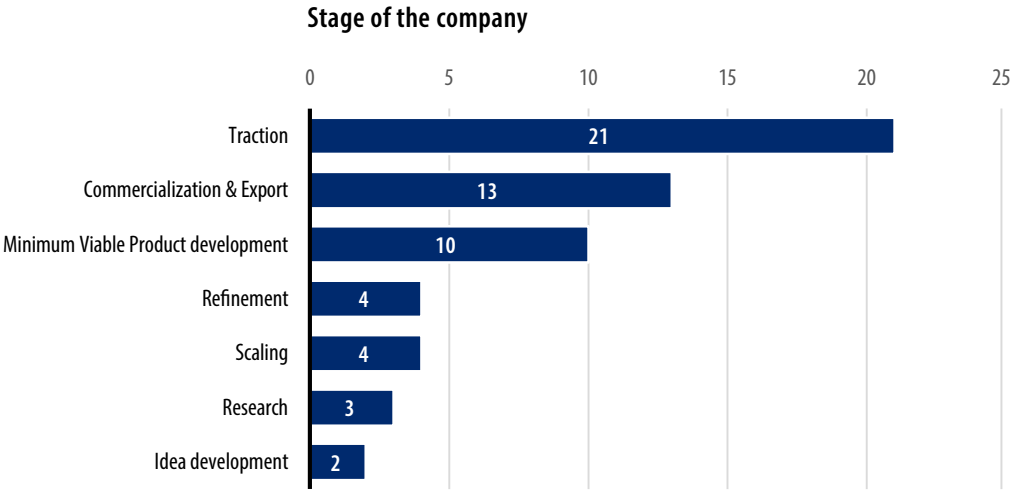
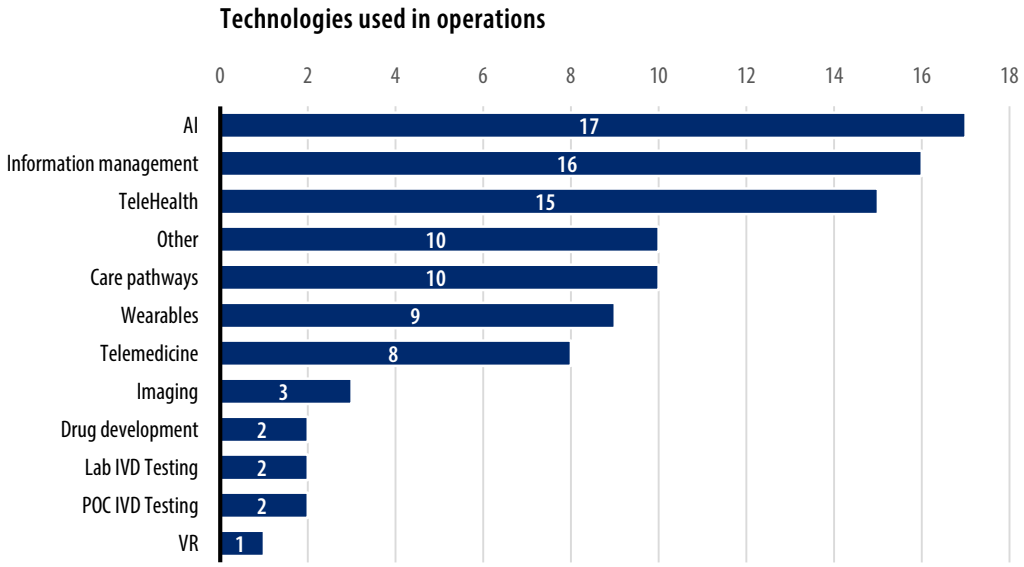
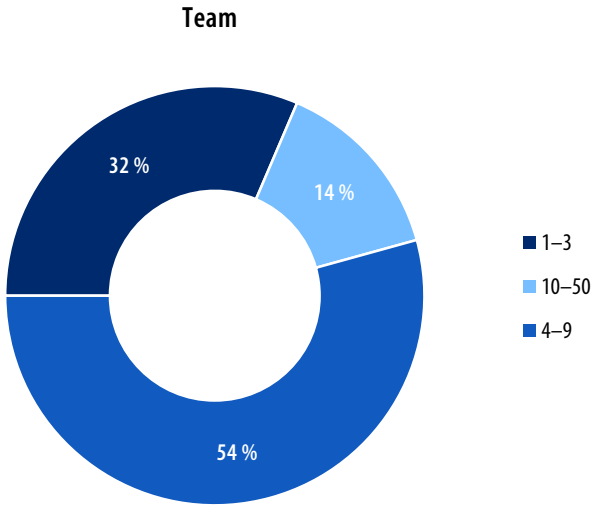


Figure 4. The technologies used in the startups' products.



55% of the companies in our survey have from four to nine employees, 31% – just from one to three, and 14% employ from 10 to 50 people (Figure 5).

Figure 5. The number of personnel the companies in this sample employ.



1.2 The interviews

We interviewed ten experts: four on testbeds, three on public procurement, and three on regulatory compliance, and fifteen companies: four on testbeds, seven on public procurement, and four on regulatory compliance. The interview questions are attached in Appendix 2. We do not include any identifiable information about the interviewed companies or experts to preserve their anonymity.

1.3 The roundtables

The roundtables took place online on September 14, 2021; they were organized jointly by the Ministry of Economic Affairs and Employment and Upgraded. 12-14 participants were personally invited to each of the roundtables (the participant list can be found in Appendix 3); they included both the experts and the startups for a more productive discussion.

2 Testbeds

2.1 Current state of affairs

A testbed is a testing and validation environment for a product, in which transparent, measurable, and replicable studies can be conducted to assess the product design and performance. There are approximately two dozen testbeds in Finland, both public and private ones, that provide testing and validation services to health and wellbeing startups: Kuopio Living Lab, Health Campus Turku, HUS testbed, Testbed Helsinki, HealthHub Tampere, OuluHealth Labs, SOTE Virtual Lab, Metropolia Proof Health, XAMK Active Life Lab, LAB WellTech, and others. They tend to cluster around university hospitals, municipalities, and universities of applied sciences and offer either generalized testing platforms for medical solutions or specialize in one area. For instance, Flavoria at Health Campus Turku exclusively provides food and eating experiences testing environment.

Business Finland is actively involved in building a testbed network in Finland to attract international investments and customers to the Finnish testing and validation market. They provide grants to both testbeds and startups (e.g., Innovation voucher) to help them grow and develop.

2.2 Survey results

14 out of 35 respondents had experience with testbeds. We will start by giving their overview first. Five of those companies self-identified as Digital Health startups, four – as belonging to the MedTech sector, two – to the Wellness sector, one self-identified as belonging to the BioTech and Life Sciences sector, one – to both Digital Health and Wellness, and one – to both MedTech and Digital Health. In our survey, the startups that used testbed services are based in Uusimaa (7), Pirkanmaa (4), Kymenlaakso (1), Northern Savonia (1), and South Karelia (1). 10 among them employ from four to nine people, three companies have a small team ranging from one to three staff members, and only one company is big enough to hire from ten to fifty people. As for the technologies in their solutions, they mostly rely on information management (7 companies), TeleHealth (7 companies), AI (6 companies), care pathways management (6), telemedicine (4 companies), wearables (3 companies), lab IVD testing and POC IVD testing (1 each), and other (4 companies). Nine companies consider themselves having reached the traction stage; we had six companies choosing Minimum Viable Product development option as their current description, five – the commercialization and export stage, three – refinement, and one – research.

The majority of the respondents in our survey (64%) have used the services of a testbed two or three times, with only seven percent testing in this setting once, and only one company coming back to a testbed more than five times (see Figure 6). It shows that testing in the healthcare and wellbeing industry is an iterative process; although not all companies choose to go that route, those that decide to use the services of a testbed become recurring customers.

Figure 6. The number of times the companies participating in this survey used a testbed.

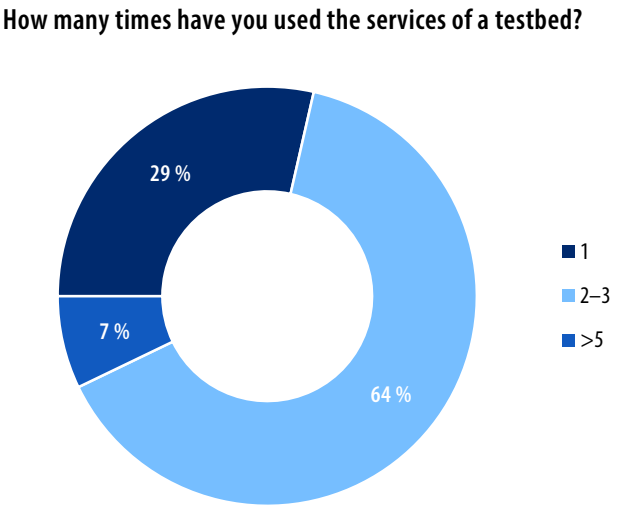


Figure 7. The product development stage of the companies using testbeds.

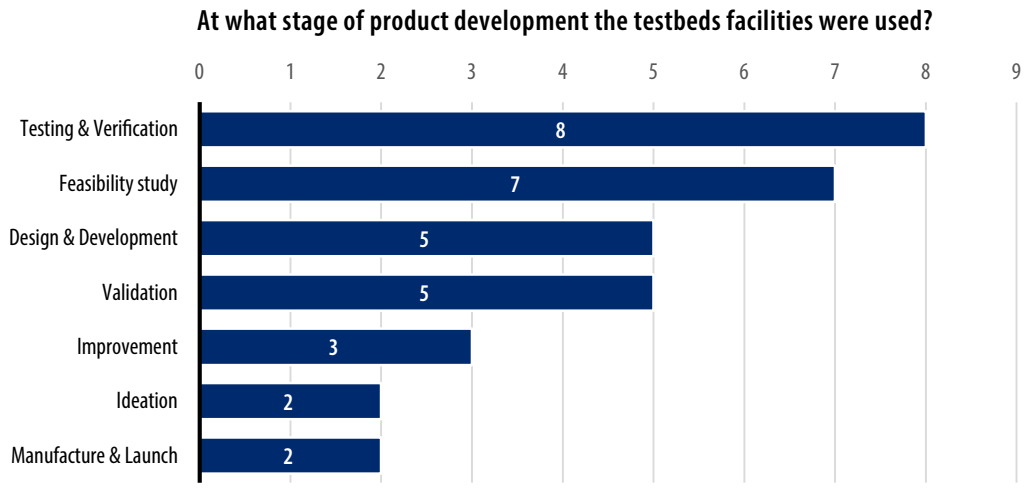


Figure 7 demonstrates at what product development stages companies choose to use a testbed. Two companies in our sample started as early as the ideation stage but most prefer to do it during the testing & verification stage. Most of our respondents have been using testbeds provided by a University Hospital or a Primary Healthcare Center (see Figure 8 for details). Startups use a variety of settings to test their solutions: institutional and specialized hospital settings and home-care facility setting seem to be the most popular options (refer to Figure 9).

Figure 8. The distribution of the testbed types.

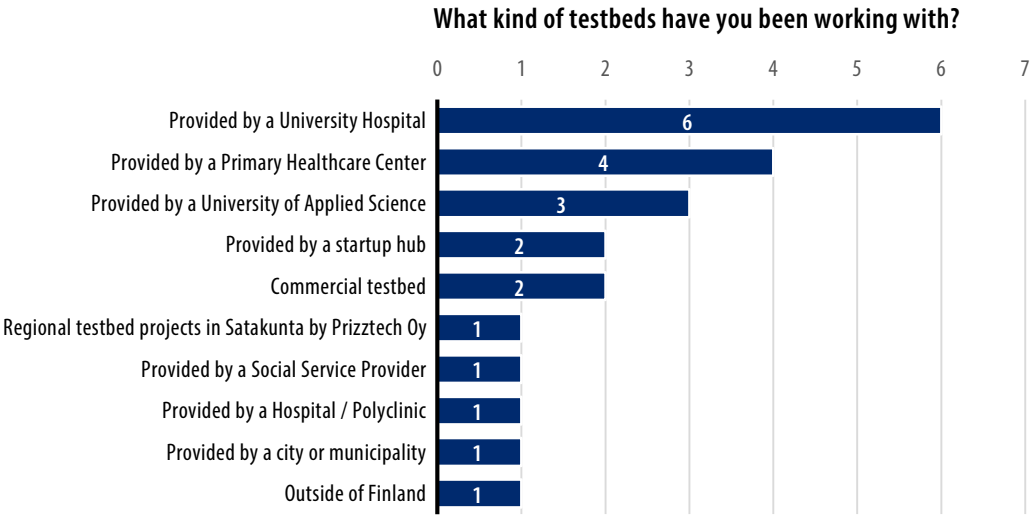


Figure 9. The testbed settings the companies in this survey used.

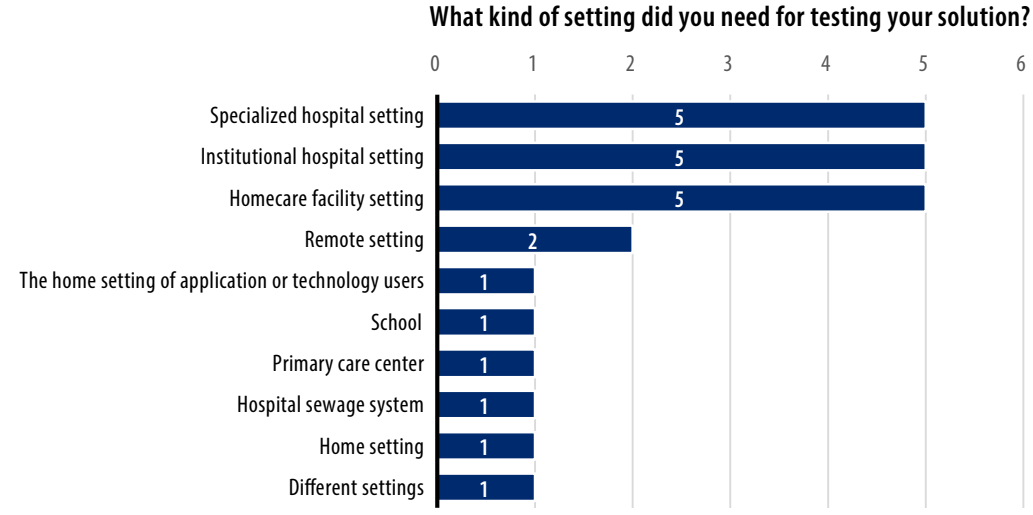
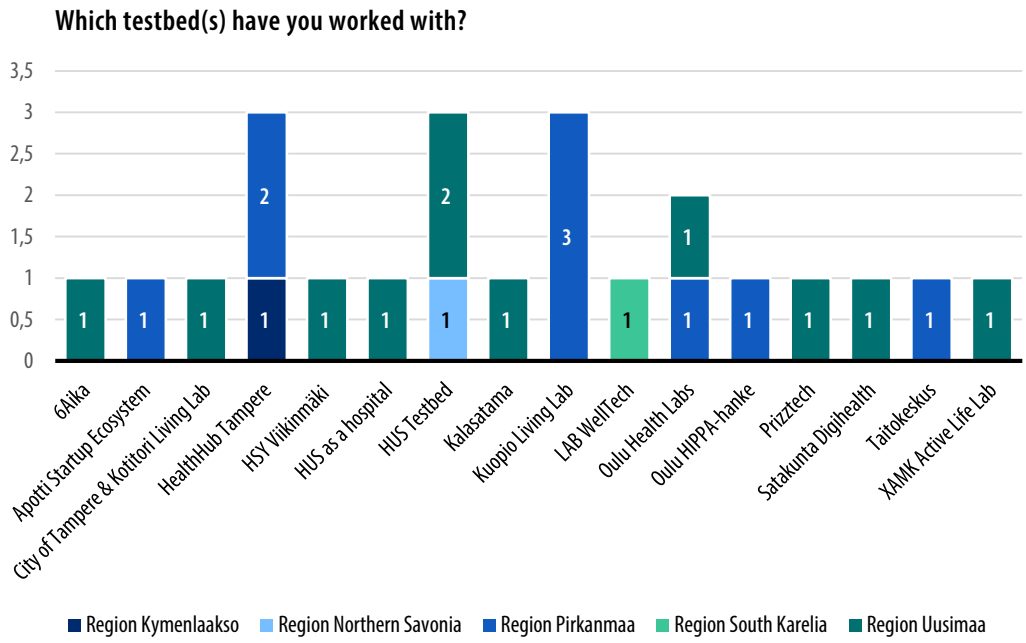


Figure 10 lists the names of the testbeds with which companies in our sample collaborated. It is interesting to note that the testbed location does not directly correspond to the company's headquarters. For instance, in our sample, there were three instances where Tampere-based companies preferred Kuopio Living Lab as a testbed, although there is more than one testbed situated in their city.

Figure 10. The testbeds companies used, based on their location.



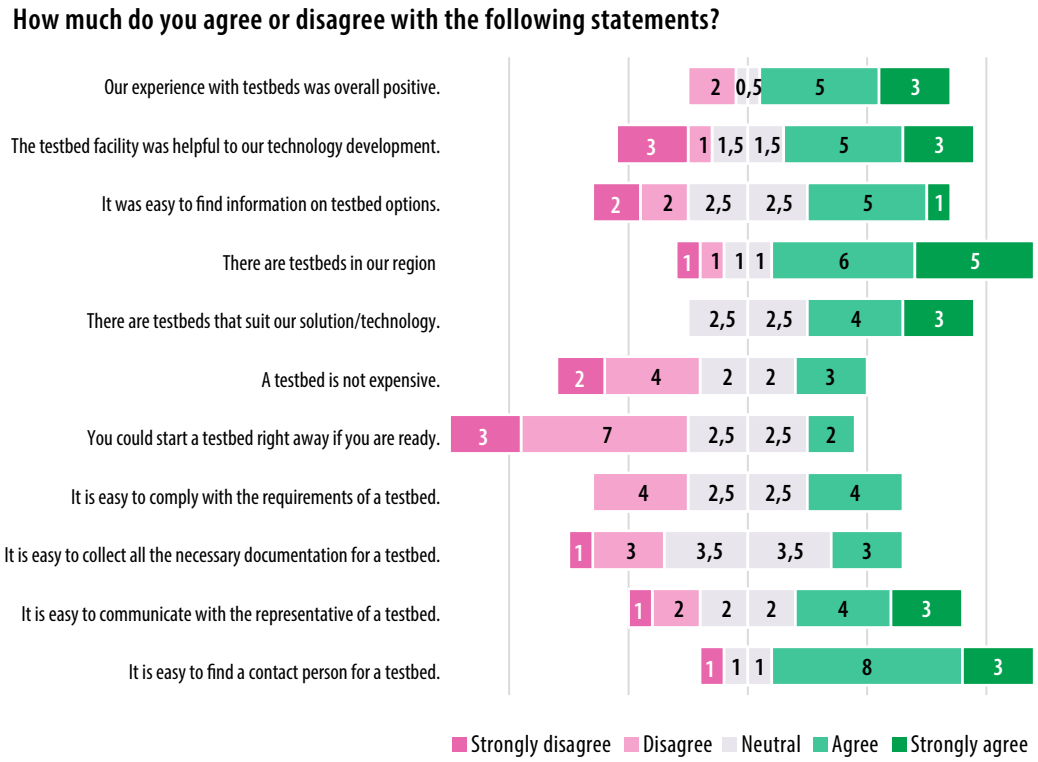
Companies report a wide variety of sources where they seek information about different testing environments in Finland:

- Events and networks (Business Finland, Upgraded, Nordic Proof, accelerators, and startup hubs)
- Social media (LinkedIn and Twitter)
- Business Finland Smart Life Program (2019-2022)
- Patent searching (PubMed)
- Secondary contacts
- Testbed representatives
- Hospitals

Not all companies chose to share the cost of their testing projects. Those that did, shared an amount between zero and 600,000 euro. It means that the mean cost of a testing project in our survey is 87,900 euro and the median cost constitutes 7,500 euro. Due to such variance and a limited number of responses to this question, we suggest taking the median as a reference point. We did not get a lot of responses pertaining to the cost breakdown but the ones we did specify that 50-84% of the cost is spent on personnel salaries. The company reporting an amount of 600,000 euro said that most of it is due to patent cost. It must be noted that two companies that took part in the survey indicated that the testbed services they used were free, and we even had one that was paid a thousand euros to perform testing by their ordering customer.

To get an overview of how positive or negative the experience with testbeds has been for startups, we asked the respondents to what degree they agree or disagree with a series of statements (please refer to Figure 11). We can see that companies did not report any strictly negative experiences. The most concerns are raised in regard to the preparation timeline while testbed location and the variety of services are appreciated the most.

Figure 11. Consensus on the statements related to testbed operations.



Among the major challenges that companies encountered while working with testbeds:

- complex information flow and communication in a multi-stakeholder project,
- lack of consolidated information on the various testbeds, and information on differences between those,
- a slow delivery process,
- the staff's workload preventing them from dedicating themselves fully to the project,
- the vicious circle of not being able to start validating the solution without certification and not being able to get certification without a testing and validation process complete,
- the lack of scaling strategy after the pilot,
- the lack of financial support after the pilot,
- the delays in project realization due to the Covid-19 pandemic, and
- culture barriers.

Although two of the fourteen respondents were very critical and said that they could not name any advantages to the existing testbeds in Finland, most have been able to list several. Startups characterize Finnish testbeds as cooperative and relatively easy to communicate with; they note that project implementation is straightforward and not bureaucratically burdened, and that testing facilities deliver what was promised. Testbed staff's attitude and expertise have been praised, as well as the quality of the obtained data and high credibility of the findings. Low cost, availability of funding, and information support from Business Finland have been mentioned as one of the key positives, although this opinion is not universal. References, networking, and contacts have been also listed as an added value of using a testbed in Finland, as have been the direct reach to real patients or customers and the collaboration side of the testing projects. Respondents convey that the feedback and development ideas they received were appreciated, along with more practical details such as location and working times.

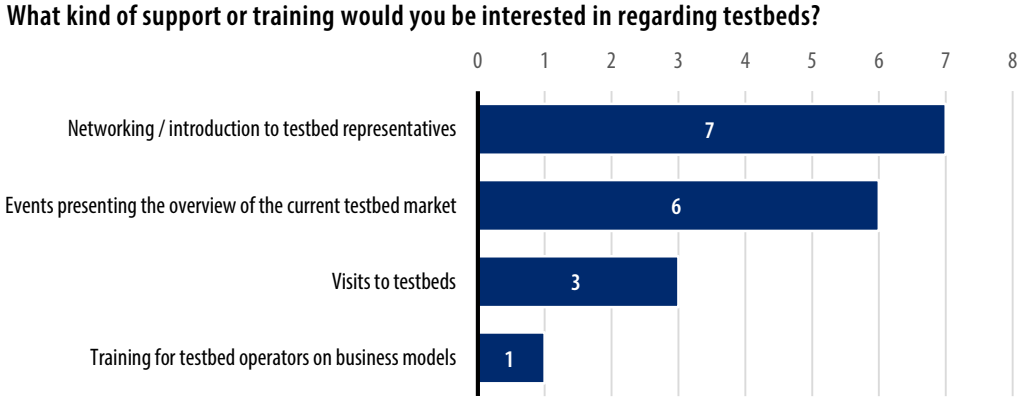
When asked what could be done to improve the situation, startups came up with **a** variety of initiatives concerning different aspects of testbed operations:

- To lower the testbed fees, or
- To reverse the current funding flow, suggesting treating pilots as an investment opportunity or collaborations between the testbed and the company, or

- To provide financial support in the form of a grant or a voucher to young companies for conducting testbeds. The respondents insist that this fee does not have to be big, and players inverting the cash flow already exist, giving the example of the Apotti ecosystem: "They see that it is highly beneficial for the healthcare organization to keep up to date on what's happening. They also understand the struggles early phase companies face with both funding and focus. Giving even a small fee to the startup to participate in collaboration with the healthcare provider truly makes a difference and shifts the thinking towards a more productive relationship."
- To devise a clear plan on scaling the product, from the startups' point of view, would be beneficial for both the facilities and the companies themselves. The final suggestions consisted of university hospitals acting as testbeds as part of their day-to-day operations, arguing that having a separate organization with its costs and without patients does not bring enough value.

In terms of support they would like to receive from the ecosystem players, most of our respondents would prefer networking and introductions to testbed representatives, closely followed by the option to attend events presenting the overview of the current testbed market (for details see Figure 12).

Figure 12. Support- and training needs related to testbeds.



Interestingly, as reported by the companies, the Covid-19 pandemic did not affect testbed operations in the same way. Some said that remote opportunities becoming more available was convenient for them. Some reported that it slowed the projects down or even made them stop completely because the staff was busy dealing with the outbreak.

2.3 Interview analysis

2.3.1 The expert perspective

We talked with five experts on the topic, mostly testbed coordinators and directors, and started the conversation by asking to describe the process that the startups have to go through to conduct testing. According to experts, generalized testbed in Finland receives applications either by direct contact or through a form on their website, usually from one to three per month. The testbed team then discusses the feasibility of the project and allocates the resources. The main discussion topics revolve around the best setting for the testing project and whether the candidate company is ready for a testbed. Testbeds tend to specialize more and more. For instance, the HUS testbed is more focused on late-stage validation and less on pre-clinical testing. It is important to find a correct match between the specialization and stage of the company so the project would succeed. The application process usually takes from two weeks to a month.

Experts noted that when the project is agreed upon, the startup team trains the healthcare personnel contacted by the testbed to use their product. When all the details are negotiated, the testing project can take any time between a day and twelve months depending on the project needs and complexity. The differences between testbeds show up first and foremost in the resources with which they operate. Bigger testbeds have coordinators and points of contact with companies while smaller ones must do without.

For a successful testing project, in experts' opinion, it is crucial to get the medical personnel involved. Testbeds report that both doctors and nurses are interested in a collaboration with companies but often do not have the time for it due to their workload. Some testbeds compensate the hospital staff they are working with.

From the financial side, some testbeds are run as a business, but this approach is not difficulty-free. Some testbeds do not charge the companies that have a big societal impact, the majority, however, charge a fee that starts from a few hundred euros and can go up to a hundred thousand. The price tag depends on the size and the specification of the project; some testbeds have an overt price list on their website, but some prefer to calculate the price for each company individually. The fee is often determined based on the staff working hours and facility and equipment rental.

To get funding for their testing project, startups can choose one of the two routes: private or public. They can pay for it themselves (however, they rarely do due to their limited resources) or obtain governmental support. Receiving funding from Business Finland is quite common (specifically, the Innovation voucher, 5,000 euros). Experts note that often companies are not even aware that such funding exists.

Some testbeds occasionally assist startups in applying for funding. They can also use a public project to provide funds for a testing project that fits their goals so long as they do not exceed a certain number of such projects. Another way of cutting testing costs is to team up with other companies and test several products in one project. Such a collaboration then must be carefully curated from the ethics perspective to make sure different startups' goals do not compete.

The biggest challenges for startups

Our interviewees point out that one of the biggest challenges when working with startups is their size and, consequently, their lack of resources. From the business point of view, it is easier for testbeds to work with bigger companies or apply for funding for research projects. Finding funding is difficult for a startup too because public players rarely subsidize this kind of service.

Another challenge for startups from their point of view is finding the right partner. In medical devices, the R&D process is quite established and the path to clinical validation is clear. When we talk about digital health, which often benefits from agile development, clinical validation can be challenging timewise. Finding the balance between testing and sales and marketing is tricky as well.

The list of challenges goes on and ties into regulatory compliance. Not all testbeds are ready to work with early-stage companies that are just starting to look into regulations. Some testbeds only work with companies already going through the regulatory compliance process and having their documentation ready. The experts that we talked to note that sometimes the startups have accumulated excellent knowledge on the solution over the years, tested on their own but do not necessarily have the insight into the medical world, rules, regulations, or different validation processes. The usual bottlenecks, in this case, are regulations, cybersecurity laws, medical records, and patient information. As for the Covid-19 pandemic, it slowed testbed operations significantly or completely stopped them.

The biggest challenges for testbeds

According to experts, working with small companies presents a challenge for testbeds. Some are trying to turn their testing project into a customer-finding mission while testbeds are not a mechanism for lead generation. Moreover, not having enough funding is a hurdle not just in itself: it also means that startups often cannot afford external help, for instance, consultations on regulatory compliance, which could save them time down the line by preventing them from knocking on the wrong door. Being young companies, startups do not always know where and how to get assistance.

Furthermore, scarce financial possibilities can lead to lower prioritization in the testbed operations. Testbeds organized within and in universities have their staff working on multiple projects and sustaining daily operations, which is not an optimal way to run a testbed. Adding to that, testbeds are not their primary function by law. Similar issues arise in close collaboration with hospitals: they tend to work slower than startups which can be frustrating for both sides, and the medical staff is always busy with other duties.

The biggest advantages for startups

The experts that we talked to suggest that testing a product is the best way to get a reality check for the company's product, a great learning opportunity that is controlled and reproducible. Involving real-life environments and users and tailoring the product to satisfy a real need is a source of important insights. In a testbed, it is much easier for a company to get the right personnel and correct procedures compatible with the healthcare system than testing on their own. The feedback form is standardized, becoming a precise and informative assessment tool. And if the solution is not working how it is supposed to, startups end up not investing time and resources into a product that is not suitable for the market.

Furthermore, by testing companies get their first reference that adds to their portfolio. If the testbeds have commercialization assistance, startups can bounce their ideas off the consultants. They can make cost structure and customer flow calculations to evaluate the idea in the long run.

The biggest advantages for testbeds

The experts note that working with startups is inspiring and encouraging. There is more room to help startups than with established companies because they are more flexible and receptive. It is also a possibility to get involved in building something big. Learning about the newest services and technologies is a learning possibility for testbeds, as is companies providing feedback on testing services.

Testbeds that are part of a university are required by law to communicate with and have an impact on the local business, and testbeds are one way of fulfilling that commitment. Sometimes a testbed case becomes a partner; it also opens ways for other collaboration avenues: joint publications, students getting an internship or writing a thesis based on a real-life scenario.

Best examples of a testing environment in Finland and abroad

- Oulu Health Lab: specialized and social care among others, full-time coordinators, hospital integration;
- Kuopio Labs: three organizations (the City side, the Hospital side, and the Applied Sciences University side) working together in a transparent manner, as is the case in several public testbeds;
- LAB WellTech: commercialization services.
- Intervention Center at the Oslo Hospital, Norway: numerous staff, special equipment but very expensive;
- Living Lab Eindhoven, the Netherlands: regulations allowing companies to have access to every technology and measurement equipment in a city, letting the city operate as a "sandbox" for companies.

Suggestions for improvement

Experts suggest that more cooperation in the field is necessary. Business Finland used to have a testbed network project that was beneficial to all the parties involved. It consisted of meetings and contacts which generated a lot of good buzz between testbeds. The project ended and left a gap; the existing testbed network needs a partner who could lead and not have a project deadline. The pandemic slowed things down as well with remote meetings not being nearly as profitable as their face-to-face counterparts. The European Consortium with Turku, Oulu, and Kuopio working together is a good start.

A better coordination could be useful in the future. Now the testbeds mostly operate geographically and are specialized in their own things. Specialization seems like the way to advance because it allows for better resource allocation. One suggestion is to work on abandoning the geographical principle altogether and do more referrals between testbeds according to their field of expertise.

Well-designed service provision with low fees would be ideal but it is challenging to organize with limited resources. Testbeds suffer from not being able to become self-sufficient. The goal would be to get these projects funded with minimum administrative overheads; there should be some way to provide funding in a more straightforward way, available with minimum extra bureaucracy. One way to find private funding is to be more involved by talking to investors and by networking (which can be a very long shot).

Bigger innovation vouchers for testing could help in this regard. Currently, they are usually a few thousand euros while an extensive testing protocol can require tens of thousands. Lowering Business Finland requirements so that more companies could be eligible for this

kind of grant could boost entrepreneurship. Finally, a strategic decision could be made to focus on startups more so testbeds could use more time to build those projects.

2.3.2 The startup perspective

We interviewed four startups that chose different routes for testing their product. Companies we talked to approached the testbed either through a web search or personal contacts. The positive experiences we gathered were related to the cost (if the testbed was offered for free), the free use of English, which reduces the language barrier for companies whose staff do not speak Finnish, the communication, and the attitude of the testbed staff. Some respondents conveyed that their projects were successful mostly because their project coordinator or partner from the hospital was enthusiastic about them. Based on the responses we got, a case can be made for choosing testbeds in smaller cities since bigger centers have a high workload, thus limited time for working with startups. Another big advantage for smaller companies who are just trying to make it on the market is a testbed tied into the purchasing or procurement process.

Not all startups we interviewed appreciate the existence of testbeds in the first place. They understand the necessity to evaluate the product performance in a real-life environment but would prefer to do it directly in the hospitals without the intermediary organizations. Instead, they believe that collaboration between startups, universities, and hospitals is extremely important and should be invested in by hospital districts and universities. Although the ecosystem is rather developed in Finland, medical practitioners are often absent from the dialogues, making testing more difficult later.

The biggest challenges of testing and validation in Finland

The respondents in our interviews were mostly critical about the business model and the disconnection of the testbeds from the production cycle. Startups go into trial, get validation, and start scaling but healthcare organizations have a small R&D budget, so companies feel like the results are not meaningful. There is no connection between testing and purchasing, which is a hurdle for small businesses that are desperate to get customers.

Moreover, companies feel like more established businesses should not be treated the same due to the disparity in the resources they possess. The Covid-19 pandemic also complicated and slowed down projects. For instance, for some startups, it was difficult to teach the staff how to set up and use the equipment without coming to them in person.

As for more practical challenges, the negotiation timeline seems to be an issue in some cases. From the startups' point of view, overly bureaucratized procedures hinder the innovation process.

The biggest advantages of testing and validation in Finland

According to startups, the Apotti ecosystem shows big promise because it allows building a bridge between testing and purchasing. Finnish testbeds are also easy to get in contact with, the response rate is decent. Trust enables better operations. Furthermore, there is money available through government agencies. Business Finland makes concessions and gives out innovation vouchers, which alleviates the issue of finding funding for initial testing.

Suggestions for improvement

Companies we interviewed suggested both structural and practical changes. At the high decision level, emphasizing the importance of research and private-public cooperation could be one step forward to a more startup-friendly testing environment. Moreover, integrating testbeds into the purchase or public procurement process is a logical next step in testbed development. One of the companies suggested an open self-service development environment where startups can sign up and test their solution.

On a day-to-day basis, an enthusiastic liaison between the companies and the hospitals would help a lot, as would events matchmaking companies with hospital representatives. It is difficult to know what hospitals need and discussing actual hospital needs could streamline innovation.

2.4 Roundtable summary

The roundtable on testbeds that Upgraded held together with the Ministry of Economic Affairs and Employment became a small forum where experts and startups could share their opinions on the topic. The discussion started with emphasizing the importance of testbeds as real-life testing environments for innovative products and their potential to attract investment to Finland. If Finland can show an extensive testbed network, it can be leveraged when inviting international capital. New testbeds keep appearing every year, showing momentum. The goal of Business Finland is to bring testbeds together and make

them work almost as one entity, and they are implementing programs and events towards this goal[12].

The definition of a testbed came into question next. The participants agreed that it is vague and needs refinement. Currently, it is not clear which testing environments and setups can qualify for testbeds and which cannot. What all testbeds seem to have in common now is that they provide a simulated environment for customers to test their solutions. However, some companies do not need real environments, they just want to bounce their ideas off and get feedback. The participants thus noted a mismatch between how public entities and companies look at testbeds: companies want to collaborate and cut the costs down, organizations need to communicate the results to the public and stay solvable.

The question of who should bear the cost of testing arose multiple times during the roundtable discussion. Startups obviously have very limited resources and letting them do the testing for free would boost their development. However, quite often public organizations cannot subsidize businesses by law. A compromise would be to keep the fees reasonably low and change the attitude of testbeds from providing a service to entering collaboration. The CleverHealth network shows promise in that regard.

The participants also discussed that testbeds are not viable without competent and motivated clinicians who have time to spend on innovations. There is no doubt that medical personnel do not have enough time to help companies to test their products. To remedy this issue, the attitude on the highest political level needs to change, facilitating 'creator culture'. It would be greatly appreciated if the government and the ministries encouraged and supported hospital collaboration with startups both financially and in terms of coordination.

1 https://www.businessfinland.fi/suomalaisille-asiakkaille/palvelut/ohjelmat/smart-life-finland/terveys-ja-hyvinvointialan-kokeiluymparistot-suomessa

2 https://www.businessfinland.fi/en/whats-new/events/2021/health-tuesday-get-acquainted-with-leading-finnish-health-testbeds

3 Public procurement

3.1 Current state of affairs

Public procurement is a process that aims to procure products and services for public organizations. In Finland, the Ministry of Economic Affairs and Employment drafts legislation related to Acts on public contracts and maintains HILMA, an online platform for advertising public tenders and calls (more information here[3]).

According to a Study on administrative capacity in the EU published in 2016[4], public procurement spending in Finland tends to be one of the largest in the Nordic countries in the EU due to the sheer size of the public sector and its role in the country's economy. Approximately 540 contracting authorities place their calls on HILMA.

Finland also has a recently developed specific mechanism for procuring never-before-seen solutions: innovative public procurement. It involves "the procurement of new or significantly improved goods or services that can help to enhance the productivity, quality, sustainability and/or effectiveness of public services" [5]. To facilitate this type of procurement and enhance the Finnish public sector's role as a leader of innovations, a Government Programme for innovative public procurement was launched in 2018. KEINO, the Competence Center for Sustainable and Innovative public procurement, is a part of this program, supporting public procurement experts in purchasing "a new or clearly improved product or service that is not yet being used widely"[6].

3.2 Survey results

16 out of 35 companies who replied to our surveys supply to the public entities and 12 companies not now but would love to in the future. 7 companies do not have experience with public procurement and skipped this section of the questionnaire. Thirteen startups

3 https://tem.fi/en/public-procurement

4 https://ec.europa.eu/regional_policy/en/policy/how/improving-investment/public-procurement/study/#26

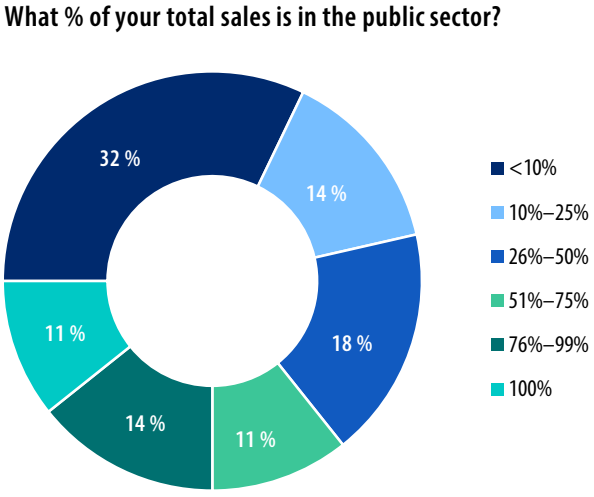
5 https://tem.fi/en/innovative-public-procurement

6 https://www.hankintakeino.fi/en/sustainable-and-innovative/what-innovative-procurement

in this section are based in Uusimaa, nine – in Pirkanmaa, two – in Northern Savonia, two – in Southwest Finland, one – in Central Finland, and one – in South Karelia. Nine of them belong to the Digital Health sector, eight to MedTech, five – to Wellness, two – to the BioTech and Life Sciences sector, while the rest self-identify as a combination of the above. Most startups in this sample are at the traction (16 companies), commercialization and export (16), or Minimum Viable Product Development stage (7); some companies add refinement, scaling, idea development, and research to this mix. Their solutions are mostly based on AI (16 companies), information management (15), TeleHealth (12), care pathways management (10), telemedicine (8), and other technologies (7). Seventeen companies have from four to nine employees on their staff, six are micro-businesses with one to three people in their team, and five are bigger companies employing from ten to fifty people.

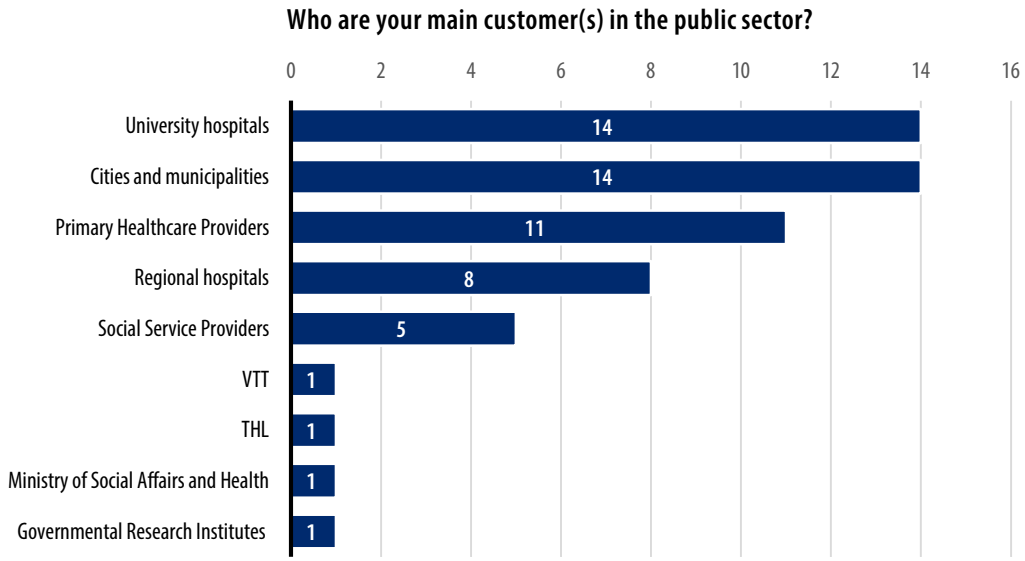
As shown in Figure 13, companies in our sample differ significantly based on the share of their sales to the public sector. A third of the startups that responded to our survey reported that less than 10% of their sales are to public entities. 11% of the companies supply to the public exclusively.

Figure 13. Distribution of the sales shares to the public sector.



University hospitals, cities and municipalities, and Primary Healthcare Providers are the most frequent customers from the public sector that health and wellbeing startups are selling to (Figure 14).

Figure 14. Startups' customers from the public sector.



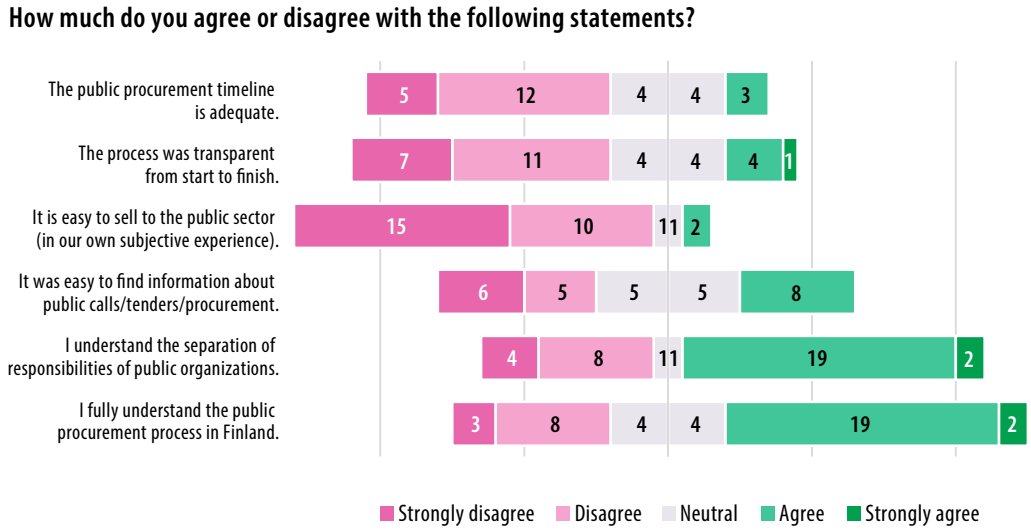
Participants in our survey mostly seek information about public procurement options either through their direct contacts, HILMA, or Business Finland.

We asked participants to rate a series of statements pertaining to public procurement. The sentences were worded in a positive way, and participants were asked to report if they agree or disagree with them. The results are presented in Figure 15. According to the answers, it becomes obvious that the topic is controversial and provokes a spectrum of emotions. The respondents in their majority have a clear understanding of the process and the structure of public procurement but are not happy with the timeline, lack of transparency, or how difficult it is to sell to the public sector.

We have also given our respondents the option to share their own challenges when working with public procurement that did not make it on the list. They noted that, as a young company, selling and collaborating in clinical research with a university hospital is a difficult process because they are often not included in the trial process and are expected to pay for it themselves.

The respondents also note that healthcare organizations are not well equipped for paying for truly innovative solutions or at least for those that were not previously used in hospitals, for instance, apps. They are not (yet) reimbursed by Kela, as medications would be, and not distributed like supplies required for treatment. Rules and regulations for medical device integration are also not as straightforward.

Figure 15. Consensus on the statements related to public procurement.

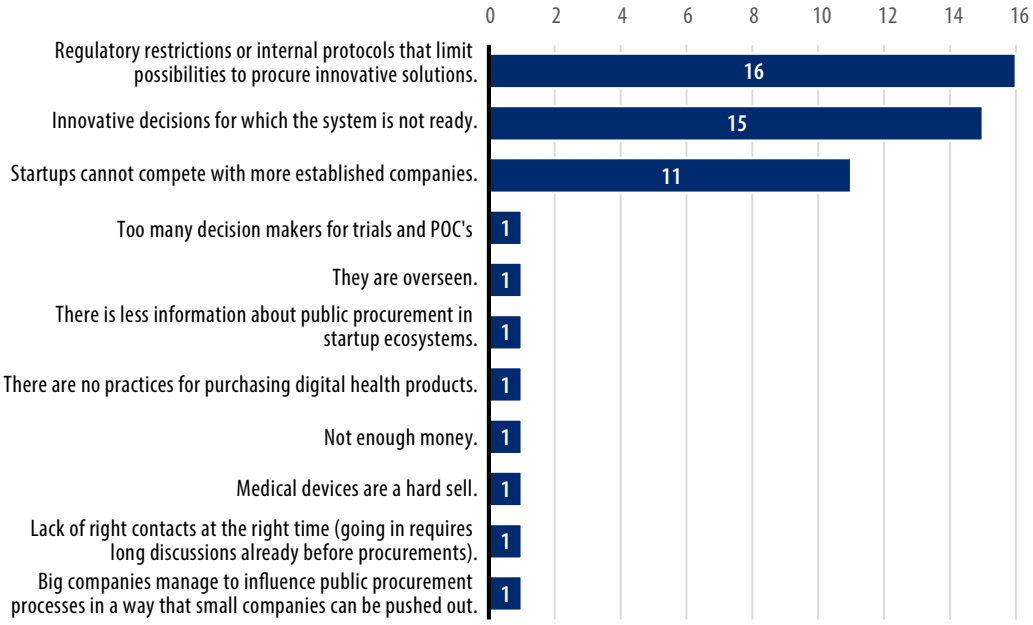


Another issue seems to be the lack of flexibility for fast decision-making even when it is required. All need to be first budgeted and then, in the best-case scenario, the purchase happens within a year. Participants report that at times the process is overly bureaucratic, and procurement experts often lack expertise in digital health. Public sector representatives are cautious about innovative public procurements and instead most often go for regular tenders, causing additional challenges.

Finally, appealing about the procurement decision can be equally difficult. Market law and a long complaint process are a burden for small companies. Some answered that bigger companies have been reported to appeal about the procurement decision even if they were not fit for the call and causing financial trouble for small companies and preventing competition.

When asked to specify what are the public procurement issues related specifically to startups, the companies in our sample listed regulatory restrictions or internal protocols that limit possibilities to procure innovative solutions and innovative decisions for which the system is not ready, closely followed by the opinion that startups cannot compete with more established companies. The respondents also suggested that startups are often overseen or pushed out during the public procurement process, lack funding and contacts, or have difficulties to sell innovative decisions (for a full list of possible issues see Figure 16).

Figure 16. Issues with public procurement related specifically to startups.



When looking for the best examples of innovative public procurement from their own experience, companies listed agreeing on the project details and planning beforehand, as well as the expertise of the procurers, as factors leading to success. As put by one of our respondents, "In our experience, the best cases of direct purchases [are] initiated by knowledgeable expert customers. It means, however, that the size of the cases is limited". The transparency that leads to corruption prevention and equal access was cited as the biggest advantage to the public procurement process in Finland.

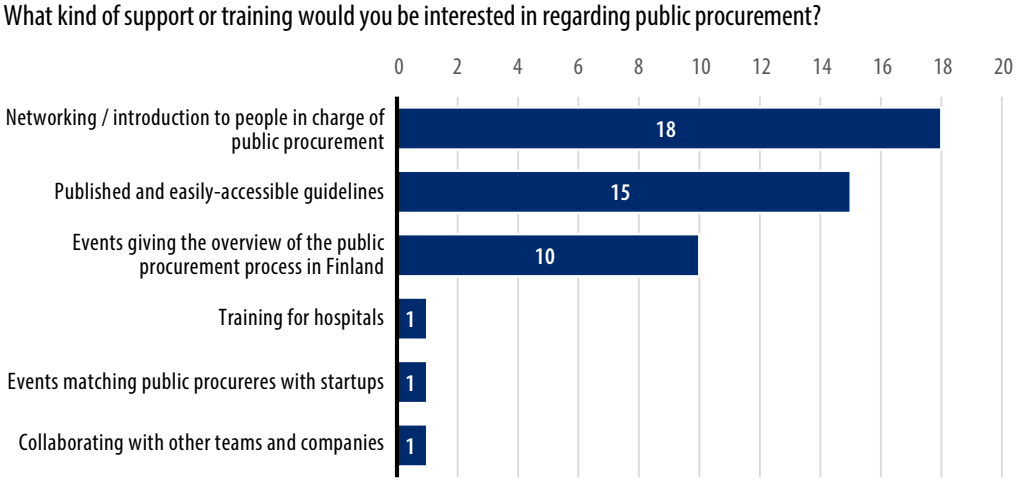
To improve the process, startups in our sample had the following suggestions:

- A change in attitude towards innovative procurement for a more positive one should be underway.
- Exclusive tenders for innovative products were cited as a way to improve the current situation.
- The focus of procurement should be on domestic innovation as a way to keep Finnish healthcare high in the ranking.
- Going even further, more incentives could be given to the hospitals to use products or services from the startup companies with the help of a donor (e.g., Business Finland).

- Making the decision process faster and more flexible would help smaller companies to succeed more often, as would adjusting the target cost for calls and tenders. It is hard for companies to offer their solution below the limit and stay sustainable and going above the threshold makes purchasing too difficult for the healthcare provider.
- Raising awareness of public procurement departments to testbeds and linking the two could create the right tunnel to innovation even for small companies.
- Organizing matchmaking events for procurers and startups based on the procurement needs would be beneficial for all parties. But raising awareness should not be limited entirely to public procurement departments. All stakeholders could benefit from mentoring, open dialogue, and clear guidelines on the process.

In terms of support and training on the topic of public procurement, companies that responded to our survey mostly chose networking, introductions to decision-makers, and published and easily accessible guidelines. Events giving the overview of the public procurement process in Finland gathered less support (see Figure 17). When given the opportunity to provide their own option, the respondents suggested training for hospitals, matchmaking events connecting procurement officers and startups, and collaborating with other startups to have a better chance of getting a tender.

Figure 17. Support- and training needs related to public procurement.



Startups reported that the Covid-19 pandemic has slowed down or postponed the public procurement process, making the resources scarce, the decisions more conservative, and the staff less available.

3.3 Interview analysis

3.3.1 The expert perspective

We talked to three experts in public procurements from different public organizations. There are two routes public organizations can take when trying to procure: regular procurement and innovative procurement.

Within regular procurement, the point of contact would always be HILMA, a national database for procurement. All public tenders are published there. Sometimes, before the tendering process, organizations may publish preliminary information. At the HILMA website, they publish the list of procurements that are coming, usually several months in advance. Certain procurements, however, do not make it to HILMA or are published too late for anyone to prepare and are spread through limited contacts. After the tender has been published, the organization is not allowed to have any discussions with the suppliers.

During the market analysis phase, it is the responsibility of procurement specialists to study the market and have multiple discussions over the criteria for the tender. Specialized teams procure in categories and normally discuss the procurement needs within their teams but can also use external consultants if necessary. Bigger organizations understand that sometimes the volumes they require for tenders are too big for upcoming companies and are trying to accommodate for their capabilities by splitting the tender into smaller calls. This strategy is in line with the latest EU recommendations for Finland on improving how funds are invested and managed.[7]

When it comes to innovative procurement, specifically tailored for procuring new solutions, the buyers need to evaluate if they are truly ready to procure something new. They can then contact Business Finland for allocated funding and consultations. If all the formal criteria is met, the procurers need to have a discussion with companies to understand reasonable goals and the level of innovation they can afford. They proceed with the interviews and market research. Keino can facilitate market dialogue if necessary.

7 https://ec.europa.eu/regional_policy/en/policy/how/improving-investment/public-procurement/study/#26

Generally, innovative procurement is a flexible process that is structured around a project proposal from a procurer.

The biggest challenges of public procurement in Finland

Experts noted that public procurement can be too slow for startups because they do not have the resources to wait. According to experts, many startups are only looking to do direct procurement (under 60 thousand euros) because they cannot follow the full public procurement protocol (open calls and tenders). But by only going after small purchases, they do not get contacts in local business and cannot get entrenched in the region, for instance.

Furthermore, when companies have their first client in the public sector and they go to the next, they must start the process all over again. The process does not get easier and takes as much time as with the first client. Those challenges encourage startups to choose to go private and then the public sector gets behind in innovation. The bureaucratization does not help either, as does not the tendency for the large buyers to choose large suppliers as well.

The biggest advantages of public procurement in Finland

The experts we interviewed note that Finnish public procurement is a big and stable market (34,5 billion euro, 18% of the GDP[8]) with numerous opportunities. When you get in and have a name there and enough references and start understanding how it works, it gets easier because there is not that much competition (which is a problem for public procurers but not for companies).

Suggestions for improvement

From the policy point of view, it is important to synchronize the available data and the procurement needs on the national level, have precise goals and come up with a roadmap and clear milestones. Clarifying the notion and coming up with clear guidelines on innovation procurement could benefit both the companies and the procurers.

Experts also feel like a change in attitude towards openness to innovation and companies' input is in order. Public entities could take part in the ecosystems to stay in touch with what is happening in terms of new technology. The procurement process is usually

8 https://ec.europa.eu/regional_policy/en/policy/how/improving-investment/public-procurement/study/#26

disconnected from the development stage; more can be done to address the issue. For instance, a connection between testbeds and innovation environments has not yet been exploited in relation to public procurement.

3.3.2 The startup perspective

To get a more detailed view of public procurement in Finland from the perspective of a small innovative company, we chose seven startups for interviews.

Two motives that came back again and again in the interviews we conducted, and that seem to shape the startups' experience with public procurement, are the timeline and the staff. If the project is on the shorter side (six months), startups evaluate it as reasonable and call the project a success. But even if we do not consider longer cases such as 3,5 years passing from the initial negotiations to a pilot, the time it normally takes for public procurement projects to come to fruition is often too long for a young company. According to interviews, bigger companies can afford to appeal to court when they were not chosen for the tender just to hinder competition, and startups must wait even longer while the procurement is on hold due to open litigation.

Companies note that the staff responsible for public procurement is important because a large share of the project's success depends on personal connections. Companies we talked to note that getting a project through is easier if the responsible persons stay the same throughout the procurement process.

The person in charge is important, but not as important as ten others involved in the process. Our respondents reported that public procurement has an overly complex structure of the personnel being in charge.

Finally, it is difficult for startups to even enter the competition: bigger ecosystem players have been reported to cooperate more actively with bigger, more established companies. Knowing the customer, in this case, public organizations, has worked for some of our respondents. They found that doing their homework by getting to know the procurement calendar (the time for budget negotiations, e.g.), process cycles and people helped them be more prepared for the tender itself.

The biggest challenges of the public procurement in Finland

Several challenges with public procurement have been mentioned during our conversations with startups. First and foremost, innovative procurement, which seemed like a glimmer of hope for companies with truly innovative solutions who were slipping through the cracks of regular procurement, is not nearly widespread enough to make a difference. Companies report that when it does happen, procurers are not proficient enough in the process: for instance, they are trying to write a long list of specifications for an entirely new solution.

Another issue raised by our respondents is that public procurement departments often do not have a strategy after they order a pilot. The purchasing falls through even after a successful pilot due to the lack of planning. On the other hand, the other reason that solutions are not being purchased after the pilot is the procurement law. The pilot is costing an amount that is under the limit, but the purchase would put the amount over the limit, making the procurer open a tender and invite the competitors of the company that did the pilot. It is not beneficial for the resources on both sides of the procurement. Smaller companies also lose when the procurers open a pilot but are putting the development costs onto the business. Bigger companies pay for the development and can participate in the tender with their new solution while startups would not survive this process.

Furthermore, healthcare providers decide to develop solutions from scratch although they should build platforms to integrate already developed solutions. Companies feel like they rather end up ordering a pilot because purchasing existing solutions is that much harder for them too.

The organizational culture has also received criticism from our respondents: some say that procurers are too cautious when it comes to committing to innovations and too set in their old ways choosing the same solutions and partners. Others point out that they do not feel welcome during the negotiations with procurement departments. Finally, tacit knowledge and tailored tenders (targeting a specific company) prevent startups from taking a larger part in public procurement. Bigger companies with more established relationships push smaller companies out of the competition.

The biggest advantages of public procurement in Finland

Our interviewees, albeit quite critical towards the existing public procurement setup in Finland, cited a series of advantages to procuring as a startup in Finland. Most see promise and highlight that the system is open and transparent, there are no barriers to sharing information and data. Some suggest that the process is fair and corruption-free. Startups also feel valued when they are consulted on their area of expertise.

Suggestions for improvement

Changing the attitude of public procurers was mentioned by every startup we interviewed for this project. Embracing innovation, quitting the old ways, being open seems to be the key qualities to successfully procure truly innovative solutions. "Let's experiment rather than be afraid", as one of the respondents said. A more open dialogue with suppliers should be used more often to really explore the options and discuss them, not to get more information about the competitor so the startups could be excluded from the actual call for tenders. Some respondents wanted to implement measures encouraging public organizations to purchase already existing solutions and making it easier for them.

Alternatives to the tender process could be discussed; for instance, a challenge where B2G that are part of a social impact trend could present their solutions to public entities. It would be much quicker than the tender process, and there are good examples of the sort in other regions and countries (Asia, the UAE; see examples here[9] and here[10]).

Companies note that reserving a share of procurement dedicated to only domestic companies would guarantee growth opportunities. Events connecting procurers and companies could also have a positive impact. Sharing tacit knowledge and opening the whole process could help companies who do not have previous experience in public procurement. More information on how to bid for the European tenders would also be appreciated. On a small practical note, a possibility to apply for tenders in English could make life easier for teams that do not have Finnish as their mother tongue.

3.4 Roundtable summary

The roundtable discussion centered around public procurement as a tool for innovation. Occasional innovative procurement is not enough, an innovation-friendly market needs to be created so companies can be invited to an environment where innovation is appreciated. Both the public entities and companies have much to gain from public procurement.

The participants first discussed positive experiences with public procurement. Startups mentioned that it was rather easy to get a paid pilot for an early-stage company. Public procurers do not always copy and paste tender requirements, for instance, the company revenue threshold, which allows smaller businesses to participate in the process. Detailing the procurement need before the start of the project contributed to better results, as

9 https://forumvirium.fi/en/finest-twins-mini-piloting-programme/#SmartCities

10 https://www.hub71.com/en/programs/the-outliers-doh/

witnessed by one of the companies. Participants discussed that early engagement and market dialogue were key because public procurement can signal their needs that way and companies can signal what their capabilities are.

Although getting a paid piloting project is rather easy, the participants shared testimonies that the transfer from the initial project to a permanent solution is the opposite. Pilots are an experiment in an ideal world where the constraints of the real world are not considered. University hospitals are curious about experiments without having the solution on how to scale those experiments. There should be at least a roadmap for scaling after a successful pilot which should be discussed before the pilot. Tailoring some tenders exclusively towards startups by eliminating the requirement for references could also allow them to be more competitive. The goal of this measure would be to build references for young companies.

Some participants pointed out that the problem goes even deeper. Healthcare providers have the R&D budget, but the procurers are not involved in the process. Two different budgets, R&D and procurement, are not interconnected. Staying on the funding topic, it has been noted that for many companies the limit that can be transacted is around the public procurement limit. The overhead on purchases makes it nearly impossible for those companies to enter tenders. A solution to this problem would be to introduce a fixed fee per month per patient. In this case, organizations would not need to procure every app, they would only have accreditation criteria and no procurement process required then, just fixed fee purchase. This solution, however, requires implementing a reimbursement mechanism for digital health solutions that involve applications. Subsidization, as is currently the case with medications, or standard purchasing as with other IT solutions that public organizations use.

It has also been noted that public healthcare develops new solutions where there are already good existing solutions. Participants suggested working on incentives to prevent public organizations from developing new products provided there is a good match already on the market.

A related issue that the roundtable's participants raised next is that public procurement often does not include evaluation or benchmarking of the solutions they use. So, there is not a way to compare the solutions based on evidence. This gap can be explained by stigma and shame related to showing non-satisfactory numbers. Clinicians do not want to share or show bad statistics. Even if the numbers are good, public procurement departments are reluctant to share all the data even though it could help define their needs better. Political decisions have a huge impact on public organizations: even if they want to share the data, political solutions may interfere. There can be lots of testing, but

appropriate evaluation of the solution is rarely done, although it could help become a reference point for decision-makers.

This brought the discussion to the competence of public procurers. The presence of a lawyer is strictly necessary to the procurement negotiation but those negotiations often do not include people who are specializing in the need that is procured. This problem is being addressed: HUS, for instance, is creating specialized teams within the procurement department. In smaller places, however, there is less know-how.

Innovative procurement requires special know-how in the field as well. The mission of Keino Competence Center is to facilitate the dialogue between companies and public procurement. They have training activities and are just launching an Innovation Procurement Academy which is a coaching program for public procurement organizations that teaches how to manage procurement needs and requirements. Although innovative public procurement seems to exist more on paper than in real life, as some participants would argue, the big ship of procurement is slowly turning in the right direction.

The discussion continued with the 'no one size fits all' procurement model. There are many ways to structure a tender, and the public procurement law allows for that flexibility if we are brave enough to use those opportunities. The law only regulates the how of the process and does not tell the organizations what to buy. Value-based healthcare relying on impact rather than pre-determined needs and concrete solutions could become a good addition to this strategy. When implementing the new roadmap and trying to change the attitude towards procurement overall, participants noted that it was important for the two ministries, the Ministry of the Economic Affairs and Employment and the Ministry of Social Affairs and Health, to align their policies so the outcome would not be one-sided.

4 Regulations

4.1 Current state of affairs

On 26 of May 2021, the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, known as MDR, amended the Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealed Council Directives 90/385/EEC and 93/42/EEC, known as MDD, after a year of transition period[11]. This EU-wide legislative act concerns every manufacturer, authorized representative, importer or distributor of medical devices in the EU and, thus, in Finland. Similarly, the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices repealed the Directive 98/79/EC and Commission Decision 2010/227/EU[12]. This ambitious project aims to protect the customer and puts patient safety and anonymity at its core. Finland is the place of residence of two competent authorities supervising the enforcement of MDR: Finnish Medicines Agency, Fimea, and SGS.

Exporting companies also need to comply with regulations adopted in the countries where they are distributing their products. For instance, if they distribute in the U.S., they need to satisfy the requirements of the Food and Drug Administration. Finally, they also need to comply with regulations from the industries that intercross healthtech.

The process of regulatory compliance may be lengthy and complicated. Here we take a deeper look into the startup journey on the way to get all the necessary certifications.

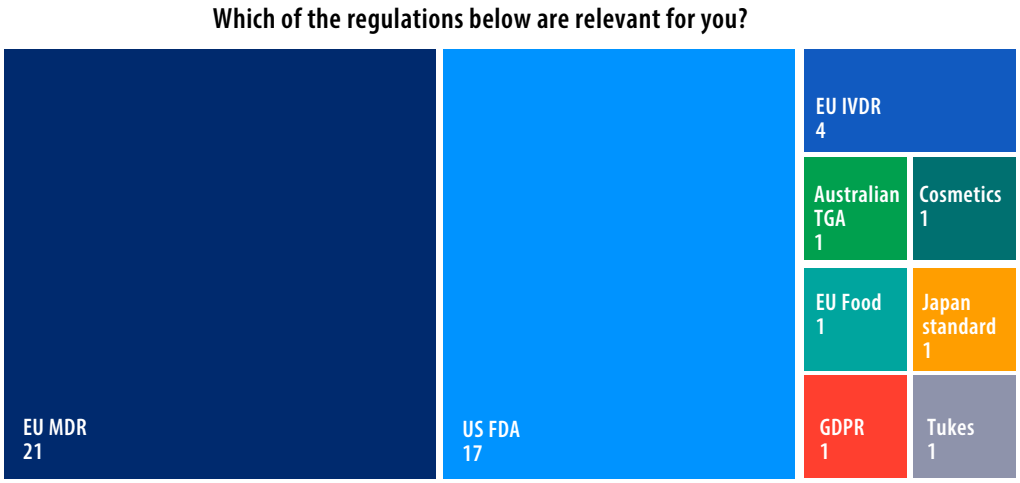
4.2 Survey results

25 out of 35 respondents must comply with one or more types of regulations, according to their assessment. Most of the companies we surveyed replied that the regulations relevant for them are the new Medical Device Regulation (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices) and the U.S. Food and Drug Administration (see Figure 18 for the full list).

11 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745

12 https://eur-lex.europa.eu/eli/reg/2017/746/oj

Figure 18. Regulations relevant to the companies in our sample.



Most of the companies required to comply with regulations in this sample belong to the MedTech (9 companies) or the Digital Health sector (8 companies, see the overview in Figure 19). Fourteen companies have from four to nine people on their team, seven – from one to three, and four – from ten to fifty (see Figure 20). They are mostly based in Uusimaa and Pirkanmaa (see Figure 21 for more details) and rely on Telehealth (13 companies), AI (12), information management (12), care pathways management (8), and telemedicine (8 companies) in their operations. As in previous sections, they mostly self-identify as being in the traction (13), commercialization and export (10), and Minimum Viable Product stage.

Figure 19. The industry sector of the companies going through regulatory compliance.

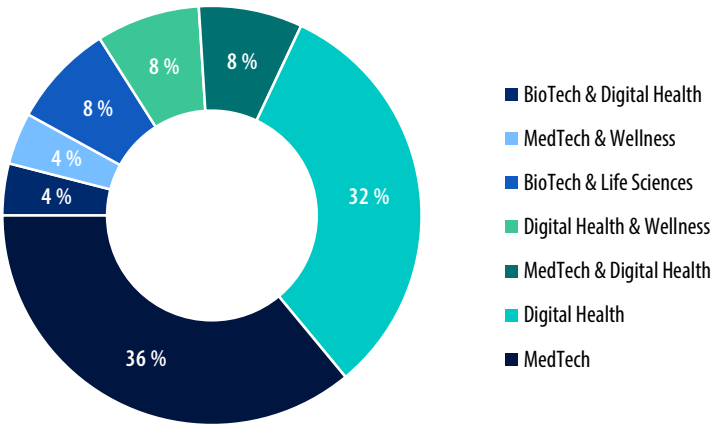


Figure 20. Personnel in companies going through regulatory compliance.

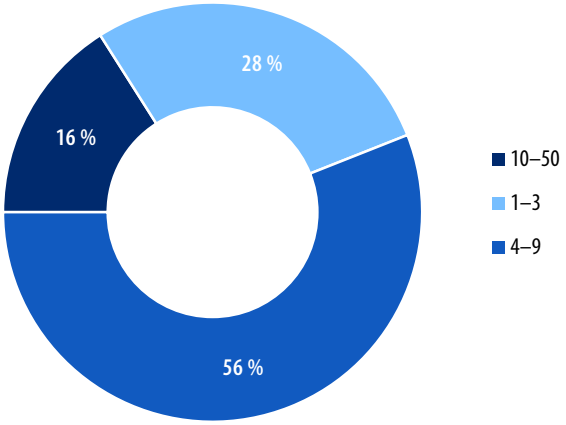
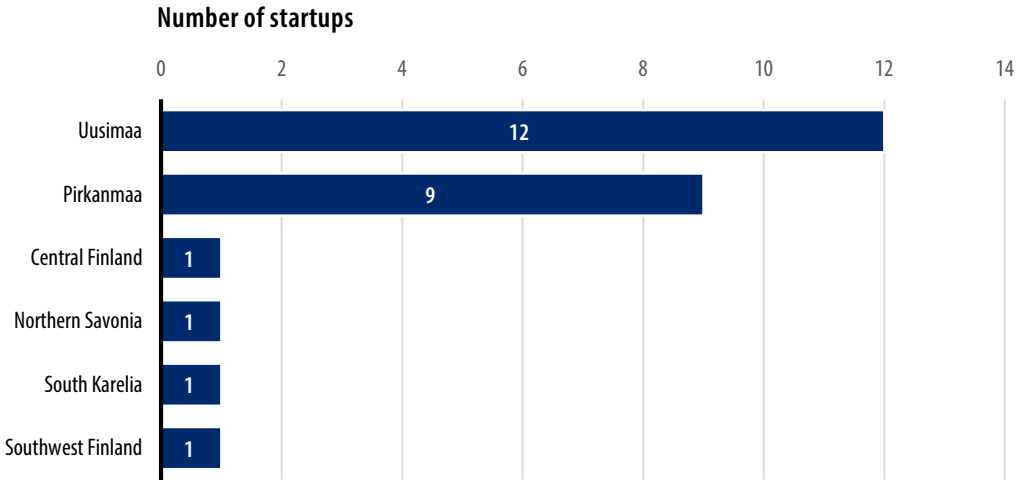


Figure 21. Regional distribution of the companies going through regulatory compliance.



Our survey shows that companies come well prepared for the hurdles of regulatory compliance: 80% of the startups in our sample had organized regulatory training for their team (Figure 22). Moreover, 56% have a member of the staff responsible for regulatory compliance, with 36% using external consulting services (Figure 23). Those who chose to do the training in-house either already had experience in regulatory compliance or self-taught it by doing and attending relevant discussions, events and courses at the HealthTech Finland Regulatory Affairs group, Health Incubator Helsinki, Business Tampere, HealthHUB Tampere, or on other platforms online. Resources provided by the European Commission were also reported to be helpful. Some companies have also chosen to have a full-time person with experience in regulatory compliance who takes the lead and trains other team members.

Figure 22. Response distribution on the question on regulatory training.

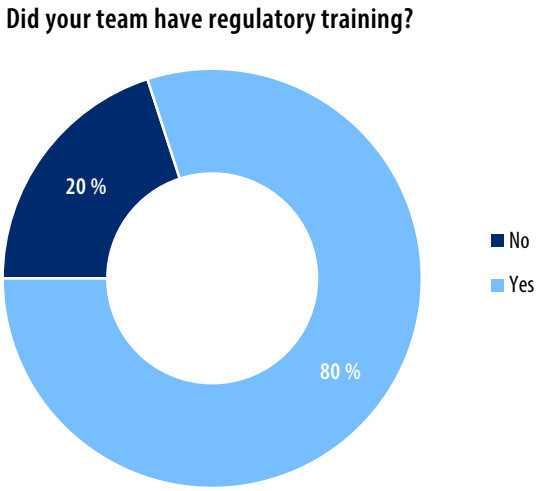
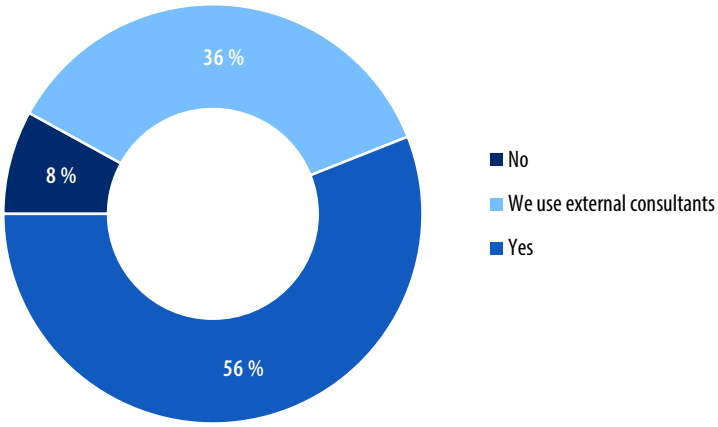
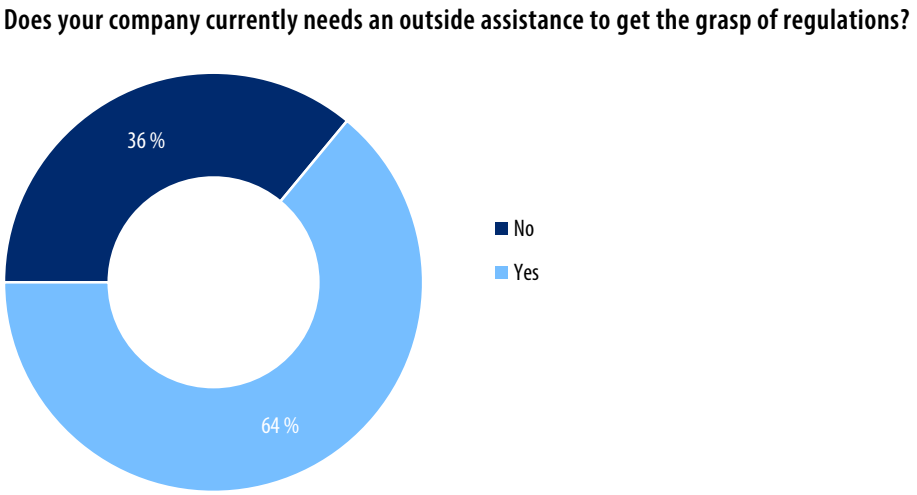


Figure 23. Response distribution on whether there is a person responsible for compliance in the team.



64% of the respondents admitted that they require outside assistance to get the grasp on regulations (Figure 24). Companies in our sample require assistance in practical matters, such as identifying the clinical evaluation type their product needs, a step-by-step walk through the certification process and the documentation or filing the reports on the results. Peer support and best practices exchange, as well as accessible information on notified bodies, is also greatly appreciated.

Figure 24. Response distribution on assistance needs.



Startups get information about regulations either online, through networking, or from external consultants. They mostly prefer to get information directly from Medical Device Regulation and FDA websites.

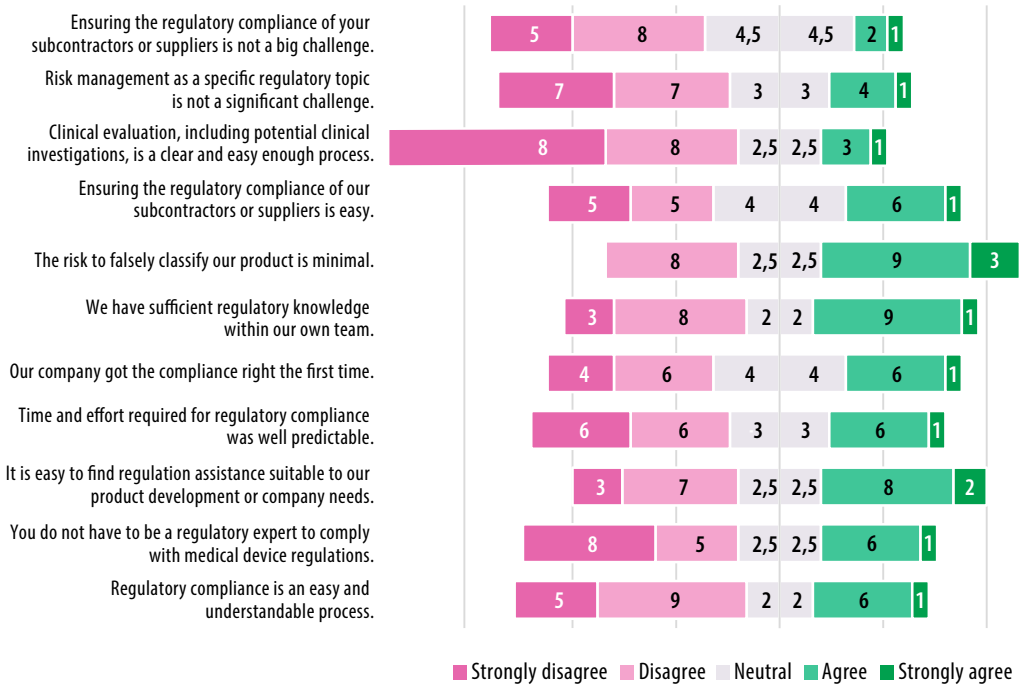
We asked the respondents to evaluate a series of statements pertaining to regulatory compliance. The statements are worded in a positive way and require assessments on a scale from 'Completely disagree' to 'Completely agree'. The results are presented in Figure 25.

The respondents find a lot of aspects concerning regulatory compliance to be challenging. For instance, the majority disagree or strongly disagree that clinical evaluation is a clear and easy enough process or that risk management can be dealt with effortlessly. It is peculiar that most of the respondents do not see the risk to misclassify their product as a significant risk, although it has happened before and entails substantial financial losses.

When asked to elaborate on challenges that were not mentioned on the list, the survey participants mentioned the lack of notified bodies for IVDR. There are only four in the EU, and all are fully booked for the foreseeable future. The cost of compliance came up as one of the hurdles startups find difficult to overcome.

Furthermore, it has been reported that a fully documented quality system quickly becomes a barrier for evolution, as adopting an improved process requires too much documentation and certification. Finally, although MDR is a relatively understandable text, it still has gray areas. A call for more guideline documentation has been mentioned in the replies.

Figure 25. Consensus on the statements related to regulatory compliance.



When asked to mention advantages in regulatory compliance if the company is registered in Finland, companies say that having two notified bodies is convenient considering that some European countries do not have any. The positive attitude towards startups at Fimea was stressed, which probably contributes to the reported good reputation that Finland has in the matter. Moreover, participants say that supporting networks are in place, it is rather easy to find consultants, and the hourly cost for consulting is lower in Finland than in the U.S.

Startups in our survey have suggested numerous ways to create more advantages and to improve the awareness and know-how of regulatory compliance in the Finnish HealthTech sector. Here is their full list:

- Providing more options for IVDR audit (more notified bodies or more staff in the current ones),
- Free public help to guide the first steps into compliance and introduce some relevant players,
- Training provided by professionals and peers,
- More practice-oriented assistance rather than general information,
- Encouraging companies to release their quality management systems as open-source information for best-practices exchange,

- Gradually building an ecosystem where information is shared and culture is grown,
- Financial support from Business Finland, ELY-keskus, or other similar players towards the certification in startups,
- Support in the regulatory compliance process from public healthcare players, especially university hospitals,
- Monthly meetings between startups and decision-makers,
- Online resources featuring freelance consultants and consulting companies.

24 out of 25 respondents did not notice the Covid-19 pandemic has complicated their regulatory compliance process; the one respondent noted that the pandemic had slowed down the compliance process.

4.3 Interview analysis

4.3.1 The expert perspective

We engaged with three experts to paint a picture of the regulatory compliance process in Finland. It is the same process no matter the size of the company, where safety and performance of the product are at the center. Multinational companies also struggle with this process, it is not an issue isolated to startups.

Regulatory compliance is highly contextual. It all depends on the technology and the product. If something similar is already on the market, it is much easier to comply. If it is completely new, it is more difficult. The companies have no choice but to know about the level of MDR compliance, but it would be beneficial if investors knew too when they decide to fund such companies. A lot depends on the team and their knowledge. Regulatory compliance can become one of the toughest topics in company operations.

The first step for the companies is to start understanding the regulations. They might start with two simple questions: Do we even want to go there? Is our product eligible to go to the market? If the answers are positive, then the key to success is taking small steps and not giving up. Then, when the startup has built up the knowledge base, they can start creating good quality technical documentation of their product.

Two elements come hand in hand concerning regulatory compliance: the product and the quality system that creates the product. Safety comes always first. Those two elements need to match, so the quality management system needs to be consistent and controlled.

The next stage consists of setting up a clinical evaluation, risk management assessment, and the balance between those two. When you consider the risks, you may come up with a lot of negatives, but when you consider the clinical results, evidence might say that the benefits outweigh the risks. This process needs to be documented too. In general, meaningful documentation, clear and sufficient, is essential. Therefore, it is hard to give an estimate of the time and cost an individual company would require completing the compliance cycle, everything depends not only on the product but also on how the company takes through the process.

After the company has:

- Assessed their product (Is it eligible for certification? Does it need to be certified at all? CE-marking does not always require a certificate.),
- Qualified their product (What type of regulation is applicable?),
- Performed clinical investigation (Do the benefits of our product outweigh the risks?), and
- Set up the quality control system and insurance system,

they can apply to the notified body, which will issue a certificate. The initial process takes upwards of a year. An auditing cycle is set up next; it renews every three years (sometimes five).

Experts agree that successful regulatory compliance requires special knowledge. That knowledge should not stop at the consultants, people responsible for the compliance, or the startup team: subcontractors and investors would largely benefit from it as well.

Since the Medical Device Directive has been replaced in the European Union by the Medical Device Regulation, it brought both positive and negative changes to the previous process. Among the advantages, we can cite patient safety as a core value. The MDR also added unprecedented layers of openness and transparency. Everybody has the obligation to report violations; all the information about vendors, risk-benefit evaluation, and the supply chain is available. Knowledge of regulations has become a marketing advantage. On the downside, especially for startups, MDR compliance is very costly. According to the new protocol, at least one person must be hired to follow regulations.

The biggest challenges for startups

According to the experts, the biggest challenges for startups when going through regulatory compliance are related to product qualification and classification. Regulation type or class chosen wrong could result in months of work lost for the company.

Classification is especially tricky for software because the standards are up for interpretation.

Experts note that the documentation requirements can be burdensome for young companies. Moreover, they need to get networked first and find established companies to help them out because when they start the R&D, they do not necessarily understand the length of the process.

Although MDR did generate positive change, its requirements might be harder than FDA requirements, for instance. At the national level, a lot of national legislation that deals with R&D and MDR requires compliance with the local legislation too. It is a complex system. For startups, it is not enough to understand MDR or IVDR, they need to understand the larger regulatory process which is inherently more complicated.

The biggest advantages of the regulatory compliance process in Finland

Experts note that Finland has quite skillful competent authorities that are easy to contact. The difference between the European countries is negligible; there are some national deviations, such as fees (average in Finland) or language requirements but they are not considered that significant. Once the company has gone through the regulatory compliance process in Finland, it can go to market in any European country. Successful compliance also represents a competitive advantage.

Suggestions for improvement

Experts that we interviewed suggest that more effort is needed to educate the companies at the early stage. Moreover, the information does not have to come solely from the notified authorities' websites. Testbeds could provide the regulatory considerations (advice) along with the clinical investigation to make it a more aligned process. There are CROs (companies who set up clinical investigations) who could join the testbeds and bring their expertise to the table.

The Ministry of Economic Affairs and Employment and the Ministry of Social Affairs and Health could bring people together and raise awareness on the topic. However, it should not be a one-sided process: startups should bring their issues to the relevant actors because that way things can be taken forward too.

According to experts, lobbying to avoid national legislation and recommending to only follow the European framework has been suggested as a means to simplify the process for companies.

4.3.2 The startup perspective

We interviewed four companies who have gone through the regulatory compliance process. Half of our interviewees have a regulatory expert on their team who takes care of regulatory matters and the other half of interviewees is going through the process alone or hiring consultants. Companies admit that it is a tiring and consuming process eased by the clear available guidelines. They note the shortage of experts on the MDR, and the unprecedented level of detail required to successfully pass an audit. Some note that Fimea, one of the notified bodies located in Finland, is sometimes too strict but serves the companies well. The required expertise is difficult to come by in the hospitals too.

Startups that we talked to try to use every source of information available; those who are more advanced in the process share their knowledge with the newcomers, which shows potential for cooperation.

The biggest challenges of the regulatory compliance process in Finland

According to companies, the transition to the MDR is not pain-free. For instance, currently, there is a long queue of companies wanting to do an audit and nobody to deliver them, as well as a queue to get a consultation with an expert. Waiting long periods before testing the solution can be detrimental to the startup's operations. Some companies also share that they do not know where to look for assistance.

Even though MDR development and adoption took a long time, its text is still up for interpretation. In some cases, startups mention not having clear guidance on what they should do. They share that it is difficult to comply without involving external consultants. Finally, the cost is a challenge for companies that do not have a lot of resources yet.

The biggest advantages of the regulatory compliance process in Finland

According to companies, compared to other countries, Finland has two notified bodies that can certify. The competition between the two decreases the prices for certification and audit. Many countries do not have a notified body and some have only one that could result in a monopoly over pricing. Health authorities are reported to be aware of the shortage of notified bodies and of the long queues and are already rectifying the situation. Another advantage for Finnish-speaking teams is the possibility to apply for compliance in the native language.

Suggestions for improvement

According to companies, better communication with the notified bodies and trying to eliminate queues are the main recommendations by the companies. There is also a need for a roadmap regarding the compliance prosess.

4.4 Roundtable summary

The roundtable discussion on the topic of regulatory compliance started with the changes that MDR brought when it replaced MDD. On the one hand, it reduced the uncertainty inherent to the previous regulation and brought alignment. On the other hand, it can be overly burdensome for the companies. The burden, however, can be alleviated by introducing knowledge as early as possible. It has been noticed that companies who started on the regulations early move to certification quicker.

The roundtable participants shared that the MDR project was developed with good intentions but might have been too ambitious. The competent authorities and notified bodies, and not only in Finland, suffer from a severe lack of specialists that cannot be filled right now. It is unrealistic to expect that the existing notified bodies can deal with the volume of the solutions that are currently in need of certifications. This is a transformation period; the one-year delay in MDR implementation helped but did not resolve the issue. The EU is working on a more effective solution.

When it comes to local issues, startups conveyed that requirements for OmaKanta integration keep evolving. According to startups, there is no market discussion, and the companies who are seemingly ready for the integration are prevented from completing it because the criteria keep changing. Currently the system is not scalable because the government has an unprecedented access to citizen data. Nevertheless, other Nordic countries have similar setups; a collaboration at the regional level could bring exciting outcomes to digitized healthcare.

The Ministry of Economic Affairs and Employment is encouraging innovation-friendly regulations, but more dialogue is needed to achieve the desired results. In a broader sense, the MDR and IVDR implementation into the Finnish law is still not clear. Right now, the companies must abide by those, but the MDR and IVDR texts are much more readable than Finnish legislation on the topic.

Competent authorities, although they cannot support the companies in the process financially, offer programs aiming to assist young companies. Associations, such as HealthTech Finland and Sailab MedTech Finland, organise meetings where they share knowledge. Business Finland and other players could join them in publishing guidelines for companies that are just forming. Raising awareness can help companies successfully comply with the MDR which in turn will make it a marketing advantage and help them export more. Thus, investments made by the Finnish people through tax money could be used to increase the Finnish market attractiveness.

5 Conclusions

The present study aimed to gauge the opinions of Finnish health and wellbeing startups on three topics relevant to their operations: testbeds, public procurement, and regulations. We put the findings in context asking the experts to comment on the topics as well.

We found that the three areas appear to be extremely interconnected, and vital for mutual existence. For example, regulatory compliance is obligatory for entering any market, including public healthcare, and is often required when applying for testing and validation in a testbed. At the same time, any solution gains competitive advantages after proper testing and with the reference data, and proper testing is required to be regulatory compliant. Having public sector as a client also serves as a reference. And the cycle goes on.

Thus, the main takeaways from this study are:

- there is an acute need in fostering an innovation-friendly climate,
- more measures are needed to build bridges between, for instance, testbeds and public procurement,
- a proper roadmap for startups, with a step-by-step description of going through testing, complying with regulations, and entering the market is needed,
- the link between testing and procurement is vital for innovation development,
- there is a need for funding after the validation stage of a product (development phase).

Appendix 1. Survey questions

A survey on testing and validation environments (testbeds), public procurement, and regulatory compliance for health startups.

Dear Health Innovators,

Upgraded ry, the Health Startup Association of Finland, is on a mission from the Ministry of Economic Affairs and Employment to study three areas that are relevant for companies in your industry: testbeds (testing and validation environments), public procurement and regulatory compliance. In addition to this questionnaire, the project will include deep interviews with stakeholders and roundtable discussions at a later date.

The project's objective is to identify the challenges you may be facing in these areas, along with best-case examples. Thus, we kindly ask you to invest a maximum of 30 minutes of your time to answer the questions below. Your answers will generate actual change – this is a great opportunity to affect the innovation infrastructure in Finland. The questionnaire will remain open until 27.6.2021.

Each section of the questionnaire covers one topic. If a section is irrelevant for your company, it may be skipped.

The project supports the implementation of the Health Sector Growth Strategy for Research and Innovation Activities and its updated Roadmap 2020–2023 (https://tem.fi/en/health-sector). The results of the survey will provide important and valuable information that will be used when conducting deep interviews and roundtables and bring insights to the final report as well. The final report will be presented to the Ministry in September 2021 and will also be available to startups.

Personal data usage memo: the Ministry of Economic Affairs and Employment is outsourcing the analysis and reporting of this survey to its partner Upgraded ry. Both organizations are committed to protecting the data and organizational secrets with utmost privacy. By participating in this survey, you accept that both the Ministry of Economic Affairs and Employment and Upgraded will be given access to the replies you give. The sole purpose for Upgraded to handle your data is to conduct research on three topics for the Ministry of Economic Affairs and Employment.

Your reply will be anonymous. However, should you be interested in participating in a deep interview for any of the topics, or in receiving the final report, please leave your contact email at the end of the questionnaire. Your email address won't be used for any other purposes than the ones mentioned above.

Thank you for your input!

Best regards,
Inga Chernova, Director of Upgraded

1. Overview of your company

1.1 What does your company look like?

1.2 How would you classify your company?
– BioTech & Life Sciences (incl. drug development and diagnostics)
– MedTech: device, diagnostics, subject to MDR
– Digital Health: software, wearables, subject to MDR
– A wellness product, not subject to MDR

1.3 What is the stage of your company?
– Idea development
– Research
– Minimum Viable Product development
– Traction (getting customers, partners etc.)
– Refinement
– Commercialization & export
– Scaling

1.4 From the list below, please tick all related technologies that apply to your company:
– AI
– VR
– Telemedicine
– TeleHealth
– POC IVD Testing
– Lab IVD Testing
– Wearables
– Care pathway planning and management
– Information management
– Drug development
– Imaging
– Other

1.5 How many people are in your team?
– 1-3
– 4-9
– 10-50
– Over 50

1.6 In what region is your company based?
– Lapland
– North Ostrobothnia
– Kainuu
– North Karelia
– Northern Savonia
– Southern Savonia
– South Karelia
– Central Finland
– South Ostrobothnia
– Ostrobothnia
– Central Ostrobothnia
– Pirkanmaa
– Satakunta
– Päijänne Tavastia
– Kanta-Häme
– Kymenlaakso
– Uusimaa
– Southwest Finland
– Åland
– Outside of Finland

1.7 Is you company a spin-off of a university research group?
– Yes
– No

2. Testbeds (testing and validation environments)

We are interested in gathering more information on the process startups have to go through when testing and validating their solutions, from establishing contacts with testbeds (testing environments) to seeing this process through.

2.1 Have you been engaged with testbeds (testing and validation environments) when developing your solution?
– Yes
– No (will skip the section)

2.2 At what stage of product development the testbeds facilities were used?
– Concept/ideation
– Feasibility study

– Design & development
– Testing & verification
– Validation
– Manufacture & launch
– Improvement

2.3 How many times have you used the services of a testbed?
– 1
– 2-3
– 4-5
– >5

2.4 What kind of testbeds have you been working with?
– Provided by a University Hospital
– Provided by a University of Applied Science
– Provided by a Hospital / Polyclinic
– Provided by a Primary Healthcare Center ("Terveyskeskus")
– Provided by a Social Service Provider (Elderly Homes, etc.)
– Commercial testbed
– Provided by a startup hub

2.5 What kind of setting did you need for testing your solution?
– Institutional hospital setting
– Specialized hospital setting
– Homecare facility setting
– The home setting of application or technology users
– Remote setting
– Other

2.6 Which testbed(s) have you worked with?
– HUS Testbed
– City of Helsinki Social and Healthcare Testbed
– Oulu Health Labs
– Kuopio Living Lab
– Health Campus Turku
– HealthHub Tampere
– Elsa Testbed
– XAMK Active Life Lab
– Metropolia Proof Health
– SOTE Virtual Lab
– Taitokeskus
– Other

2.7 Where did you seek information about different testing environments in Finland?

2.8 How much did it cost approximately in total (in EUR, with consideration of all costs: fee of the testbed, salary of your team related to testing, research and preparation to testing, other costs) per one testing cycle?

2.9 How much do you agree or disagree with the following statements? (From 'Strongly disagree' to 'Strongly agree')
- It is easy to find a contact person for a testbed.
- It is easy to communicate with the representative of a testbed.
- It is easy to collect all the necessary documentation for a testbed.
- It is easy to comply with the requirements of a testbed.
- You could start a testbed right away if you are ready.
- A testbed is not expensive.
- There are testbeds that suit our solution/technology.
- There are testbeds in our Region
- It was easy to find information on testbed options.
- The testbed facility was helpful to our technology development.
- Our experience with testbeds was overall positive.

2.10 Have you faced any other major challenges while working with testbeds that aren´t mentioned in the list above? Which ones?

2.11 Please name five advantages of testbeds in Finland.

2.12 What can be done to improve testbed operations in Finland?

2.13 What kind of support or training would you be interested in regarding testbeds?
- Events presenting the overview of the current testbed market
- Networking / introduction to testbed representatives
- Visits to testbeds
- Other

2.14 How has Covid-19 affected testbed operations, in your opinion?

3. Public procurement

We are interested in gathering more information on the process startups have to go through from testing and validation to securing public procurement contracts.

3.1 Is your company selling its service/products to the public sector?
- Yes
- Not at the moment, but would love to
- No, it's not our customer (will skip the section)

3.2 What % of your total sales is in the public sector?
- <10%
- 10%–25%
- 26%–50%
- 51%–75%
- 76%–99%
- 100%

3.3 Who are your main customer(s) in the public sector?
- Social Service Providers (e.g., Elderly Homes, etc.)
- Primary Healthcare Providers ("Terveyskeskus")
- University hospitals
- Regional hospitals
- Cities and municipalities
- Other

3.4 Where did you seek information about public procurement options in Finland (e.g., tenders, calls)?

3.5 Do you agree or disagree with the following statements? (From 'Strongly disagree' to 'Strongly agree')
- I fully understand the public procurement process in Finland.
- I understand the separation of responsibilities of public organizations and who is the decision maker for procurement process.
- It was easy to find information about public calls/tenders/procurement.
- It is easy to sell to the public sector (in our own subjective experience).
- The process was transparent from start to finish.
- The public procurement timeline is adequate.

3.6 Have you faced any other major challenges while working with public procurement that aren´t mentioned in the list above? Which ones?

3.7 What was the most successful case of innovative public procurement that you have experienced in your work? Can you describe what exactly went well (in comparison to other cases)?

3.8 In your opinion, what are the public procurement issues related specifically to startups?
- Innovative decisions for which the system is not ready.
- Startups cannot compete with more established companies.
- Regulatory restrictions or internal protocols that limit possibilities to procure innovative solutions.
- Other

3.9 Please name five advantages of the public procurement process in Finland.

3.10 What can be done to improve the public procurement process in Finland?

3.11 What kind of support or training would you be interested in regarding public procurement?
– Networking / introduction to people in charge of public procurement
– Events giving the overview of the public procurement process in Finland
– Published and easily accessible guidelines
– Other

3.12 How has Covid-19 affected the public procurement process, in your opinion?

4. Regulatory compliance

We are interested in gathering more information on the process startups have to go through to comply with medical device regulations.

4.1 Does your product need to comply with regulations in any market area (e.g. EU MDR/IVDR, US FDA regulations)?
– Yes
– No (will skip this section)

4.2 Which of the regulations below are relevant for you?
– EU MDR
– EU IVDR
– US FDA regulations
– Other

4.3 Did your team have regulatory training?
– Yes
– No

4.4 Do you have a member of your team responsible for regulatory compliance?
– Yes
– No
– We use external consultants

4.5 What kind of regulatory training has your team obtained? Or will obtain in the future?

4.6 Where did you seek information about regulations?

4.7 Does your company currently needs an outside assistance to get the grasp of regulations?

4.8 What kind of assistance?

4.9 Do you agree or disagree with the following statements? (From 'Strongly disagree' to 'Strongly agree')
- Regulatory compliance is an easy and understandable process.
- You do not have to be a regulatory expert to comply with medical device regulations.
- It is easy to find regulation assistance suitable to our product development or company needs.
- Time and effort required for regulatory compliance was well predictable
- Our company got the compliance right the first time.
- We have sufficient regulatory knowledge within our own team.
- The risk to falsely classify our product is minimal.
- Ensuring the regulatory compliance of our subcontractors or suppliers is easy.
- Clinical evaluation, including potential clinical investigations is a clear and easy enough process.
- Risk management, as a specific regulatory topic, is not a significant challenge.
- Ensuring the regulatory compliance of your subcontractors or suppliers is not a big challenge.

4.10 Have you faced any other major challenges related to regulatory compliance that aren't mentioned in the list above? Which ones?

4.11 When it comes to regulatory compliance, please indicate any advantages in having your company established in Finland (e.g., specific services, programs, networks, authorities etc.)

4.12 What can be done to create more advantages and to improve the awareness and know-how of regulatory compliance in the Finnish HealthTech sector?

4.13 Has the Covid-19 pandemic made it more difficult to comply with regulations, in your opinion?
- Yes
- No

4.14 If you replied yes, please elaborate on how the Covid-19 pandemic made it more difficult to comply with regulations.

5. Report

A report will be created based on the responses provided by the startups to this survey. Following the survey, we will conduct several deep interviews on the topics, with participants who are interested in elaborating on their particular case.

If you are interested in any of these options, please leave your contact email address in the next question.

5.1 Please share your email with us if you would like to receive the report and/or participate in a deep interview in the future (in the next 2 questions you will get to choose which of the services you would like to participate in)

5.2 Would you like to receive a report on the study?
- Yes
- No

5.3 Would you like to participate in a deep interview (30–60 mins) to discuss your personal experience in one of the areas (possible to choose several topics)?
- Yes, on testbeds
- Yes, on public procurement
- Yes, on regulatory compliance
- No

Thank you for your time and effort!

Appendix 2. Interview questions

EXPERTS

Testbeds

1. What is your role in the testing process?
2. Can you describe the usual process a startup goes through?
3. In your experience, what are the biggest challenges that startups are facing when going through testing/validation?
4. What are the biggest challenges that a testbed is facing when working with startups?
5. What are the main advantages of using a testbed for startups?
6. What are the advantages of working with startups for a testbed?
7. What is the best example of a testing environment that you have encountered (in Finland or abroad)?
8. What can be done to improve the situation in Finland, in your opinion?

Public procurement

1. What is your role in the procurement process?
2. Can you describe the usual process that a startup has to go through when selling to the public sector?
3. What are the typical/biggest challenges of innovative public procurement in Finland, in your opinion?
4. What are the biggest advantages of innovative public procurement in Finland, in your opinion?
5. What is the best example of the public (innovative) procurement process that you have encountered (in Finland or abroad)?
6. What can be done to improve the situation in Finland, in your opinion?

Regulatory compliance

1. What is your role in the regulatory compliance process?
2. Can you describe the usual process a health startup has to go through to comply with the most widespread regulations (EU MDR, IVDR etc.)?
3. What are the usual challenges that startups face during the process?
4. What are the biggest advantages of the regulatory compliance process in Finland, in your opinion?
5. What can be done to improve the situation, in your opinion?
6. Do you think that special knowledge is required to successfully go through the regulatory compliance process?

STARTUPS

Testbeds

1. Please describe your experience of receiving services of a testbed/testlab.
2. What went well and what went wrong?
3. What is the biggest challenge of testing and validation in Finland, in your opinion? Can you give an example?
4. What is the biggest advantage of testing and validation in Finland, in your opinion? Can you give an example?
5. What can be done to improve the situation, in your opinion?

Public procurement

For those who had experience

1. Please describe your experience of selling to the public sector. Who was your customer and how long did it take to go through the whole procurement process?
2. What went well and what went wrong during the process?
3. What is the biggest challenge of public procurement in Finland, in your opinion? Can you give an example?
4. What is the biggest advantage of public procurement in Finland, in your opinion? Can you give an example?
5. What can be done to improve the situation, in your opinion?

For those who had no experience

1. What is the main reason you don't sell to the public sector yet/not anymore? Could you elaborate?
2. Did you have any attempts to sell to the public sector? Can you describe your experience? What went well and what went wrong?
3. Who would be your perfect customer in the public sector? Do you know how to reach out to them?
4. What is the biggest challenge of public procurement in Finland in general, in your opinion? Can you give an example?
5. What is the biggest advantage of public procurement in Finland in your opinion, in your opinion? Can you give an example?
6. What can be done to improve the situation, in your opinion?

Regulatory compliance

1. Please describe your experience of regulatory compliance. Which regulations do you have to comply with and what was the process of getting the right certification?
2. What went well and what went wrong during the process?
3. What is the biggest challenge of the regulatory compliance process in Finland, in your opinion? Can you give an example?
4. What is the biggest advantage of the regulatory compliance process in Finland, in your opinion? Can you give an example?
5. What can be done to improve the situation, in your opinion?

Appendix 3. List of participants in the roundtables.

ORGANIZERS

Ministry of Economic Affairs and Employment, Upgraded - Association of Finnish Health Startups.

TESTBEDS

Moderator: Business Finland.

Experts: Health Capital Helsinki, Metropolia, Savonia University of Applied Sciences, Kuopio Living Lab, Spinverse, Business Tampere, Business Finland, Oulu Health Labs, Tampere Health Hub.

Startups: Epiheart, Phonolyser.

PUBLIC PROCUREMENT

Moderator: VTT Technical Research Center.

Experts: Kuopio Health, HUS, Health Capital Helsinki, Tampere Health Hub / TUS.

Startups: Sensotrend, Predicell, Orkestr, Movendos, Resistomap.

REGULATIONS

Moderator: Lean Entries.

Experts: Fimea, SGS, Business Finland.

Startups: Cerenion, Phonolyser, Epiheart, Tezted, Sensotrend.

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