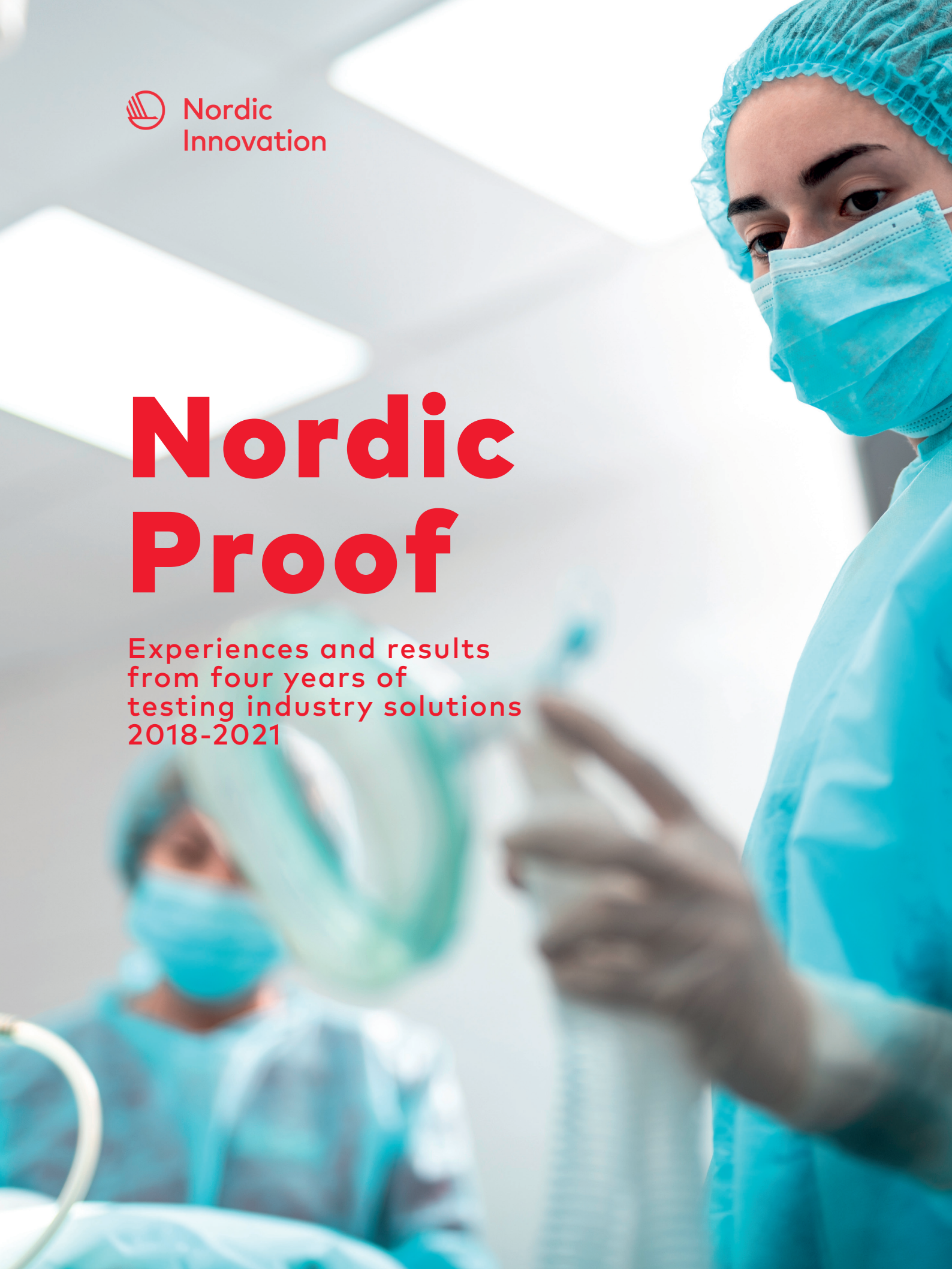


Nordic Proof

Experiences and results
from four years of
testing industry solutions
2018-2021





Nordic Proof final project report

Nordic Proof is a network of renowned health institutions and testing facilities in healthcare from the Nordic countries. The network provides an initial one-point entry for companies looking to test their ideas, products or solutions. Nordic Proof is administrated by Norway Health Tech on behalf of the partners.

The Nordic Proof project is co-funded by Nordic Innovation. The project partners are responsible for the content of this publication.

Front page photo

AdobeStock

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Summary

Nordic Proof partners have handled 600 incoming inquiries from the industry focusing on medical devices and e-health solutions in the period from 2018 to 2021. By committing the partners, developing the services, securing procedures, and organizing a series of events and communication activities Nordic Proof has settled as a true Nordic collaboration platform and an important gateway for Nordic companies and international companies looking for test sites in the Nordics.

Nordic Proof is a network of partners from renowned health institutions and testing hubs in healthcare in the Nordics. Our partners are leading facilities in the testing landscape and can test your idea, product or solution with quality and expertise. Together the partners provide testing in all phases of development including structured documentation.

The Nordic Proof network offers one initial entry point for contact with the test facility partners. Once your inquiry has been received, Nordic Proof will assign projects to the relevant facility(ies) depending on the type of service(s) you are looking for. The testing will take place at the most suitable site, and further contract will be made directly between the two parties.

Nordic Proof provides structured access to leading Nordic health institutions and testing hubs in the Nordic countries committed to world class health services.

This report is a short summary of the activities and results from four year of operation. We would like to use the opportunity to thank **Nordic Innovation** for their continuously support to our activity.

Nordic Proof, January 2022



Nordic Proof is a unique and valuable project that has reach far in the context of complex international cooperation in healthcare. It is very Important for governments to support it further on, because this is what every national innovation agency's wants, a forum that's actually up and running.

Olle Hillborg, Enhetschef DS Innovation, Danderyds sjukhus

Foreword

Nordic Proof was developed as part of Nordic Innovation test bed initiative 2015-2017. Launching the service in end of 2017 the partners had done an extensive co-creation process ending with a signed consortium agreement committing the partners with resources, quality of services and a joint understanding of the Nordic Proof strategy.

The pre-project was set up with work groups discussing joint procedures, standards, services, business models, branding, communication and maybe the most important, sharing of best practice for operation of a professional test-center for industry sponsored studies and co-development projects.

Since starting the collaboration in 2015, all physical meetings has been organized with a separate part for best practice sharing presenting each partner site (on site) and discussing topics of joint interest.

The consortium discussed early the need for resources to secure the daily operation and planning of Nordic Proof. Norway Health Tech was given the main responsibility as coordinator focusing on planning and execution of marketing activities, initial handling and follow up of incoming inquiries from companies, planning of partner meetings and handling of the budget.

Reducing the complexity executing the tests, Nordic Proof decided upon a business model where each test is contracted directly with the relevant partner organization.

Funding from Nordic Innovation has been instrumental to develop and adjust services, business model, procedures, network activities and communication strategy. From 2022 Nordic Proof has been restructured to adjust to a self-funding model with each partner paying a fixed annual fee.

The Nordic Proof partners see the need for extending the number of participants to our consortium. We believe it will be important to secure geographical presence in all the Nordic regions and to increase clinical expertise and services working with companies from early idea verification to clinical studies and even post marketed activities.

Since 2019 the consortium has started testing solution targeting primary care and consumer-oriented products and services in addition to products and solutions targeting the specialized health care.

Pictures from partner meetings in Oslo, 2019 and Helsinki 2018.



Marketing and events

Graphic profile

Development of a graphic profile including a catchy logo and a selected font was a priority when establishing the testbed network. Branding of Nordic Proof is crucial for attracting the desired attention and create trust among stakeholders in the ecosystem.



Website

The main marketing channel has been the [Nordic Proof website](https://www.nordicproof.org). The website contains the following tabs: About, Partners, Services, Cases, Events and Send Inquiry.

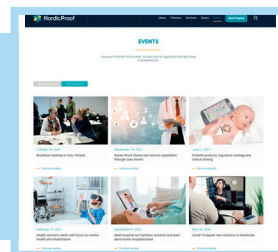
The **Nordic Proof partners** (=testbeds) are presented both through descriptive text and 30 sec. films. Trying to easy explain the core capacity and focus of the respective partners.

The **services offered** are visualized by using the same development- and test vocabulary as the healthtech companies are familiar with from their regulatory demands. See chapter "Services" for more details.

To have the healthtech companies easier understand how they can benefit from the testbed network we have profiled some of the **test cases** being executed through Nordic Proof. Professional story writers have been engaged to interview company and testbed respectively as well as writing the article. Se chapter "Cases" for more details.



The **Event subpage** is announcing all events organized by Nordic Proof. The ones interested can register directly from this page. Event presentations are made available under each specific event page afterwards. If it is a virtual meeting the streaming of the event is also made available there.

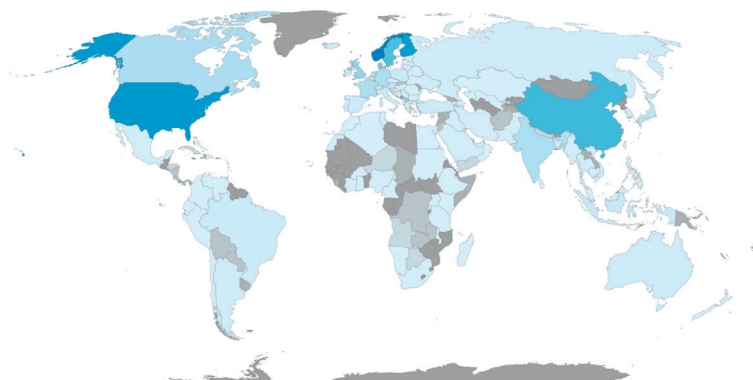


The **Send Inquiry** tab directs the reader to a fill in form which reach the Nordic Proof e-mail inbox once the send button is clicked.

www.nordicproof.org has attracted visitors to the website from all parts of the world. Below chart shows number of unique visitors scaling from 4 (light blue) to above 2000 visitors (dark blue) 2019-2021.

Country users

Norway	2007
Finland	1411
Sweden	866
Denmark	618
Iceland	50
Nordic	4952
World	1690



Events organized by Nordic Proof

Breakfast meetings, including one2one meeting opportunity between Nordic Proof partners and participating companies

Pre Covid-19 we organized breakfast meetings in the various Nordic capitals. Several of the Nordic Proof partners were present at each event. The events were divided in two sections. First the Nordic Proof coordinator and the Nordic Proof partners presented the services offered to the industry.

This first section often also included a guest speaker e.g. presenting a successful case story. The second section was set up for 10 minutes one2one meeting between the Nordic Proof partners and the present companies. Typically, 20-30 companies participated in these meetings. These events resulted in several new inquiries and service agreements.



Webinar and virtual one2one meeting opportunity

During Covid-19 we have continued the concept of breakfast meeting but in a virtual setting. These events continue to be well visited. Typically, more than 50 participants join these meetings. We arrange up to one hundred one2one meetings between Nordic Proof partners and participants during 1,5-hour period.

Naturally it is easier to reach more people when arranged online. We have also experienced quite a significant participation from outside the Nordics.

Participation at international exhibitions

Nordic Proof has a couple of times marketed the testbed services at international exhibitions:



HIMMS Europe, June 2019 in Helsinki

It is hard to measure the effect of exhibiting at international events. We did however not see many direct inquiries after exhibiting at HIMMS. However, the branding of Nordic Proof and Nordic Innovation should still not be underestimated.

MEDICA, November 2019 in Düsseldorf

Medica is such a huge exhibition that the way of getting attention is to approach companies you think might need the services we have to offer. And that is what we did. With the Nordic Proof brochure in hand. In addition to being available at the booth.



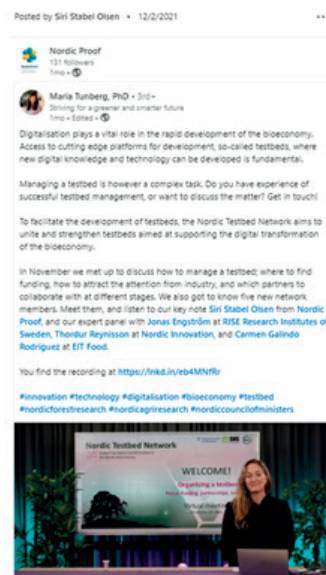
International events where Nordic Proof was invited

We have found it important to promote Nordic Proof and Nordic excellency also outside the Nordics. We have presented Nordic Proof in a large number of national and international meetings and events. Below is a short selection.

- a) Speaker at event arranged by The Texas Global Health Security Innovation Consortium (TEXGHS).
- b) The EU program Cross4Health run by Norway Health Tech, exhibited at final event May 2020.
- c) Nordic Health Virtual Market Entry Programme arranged by Nordic Innovation House Singapore, Sept 2020. Nordic Proof part of a Panel discussion.

Social media

- a) **LinkedIn** is the channel used the most. We utilize this channel for promoting events, informing about published case stories, promoting the Nordic Proof partners and displaying articles.
- b) **Facebook** is predominantly used to promote upcoming events. Some geographic targeting of advertisement seems to have paid off
- c) We have used **Instagram** to some extent during events.



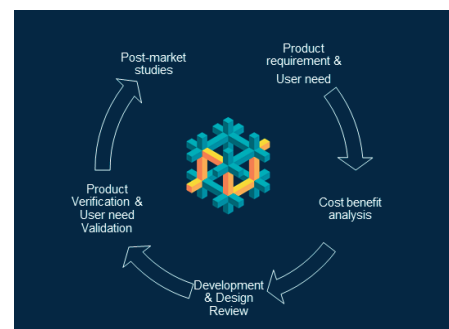
Direct e-mail marketing

We put quite a lot of effort in direct marketing though targeted e-mailings in the early phase. However, the outcome was very limited, and we find it much more effective to set up activities where we directly can match Nordic Proof testbeds and companies.

Services and execution of tests

In all communication we have between Nordic Proof and companies, we utilize the opportunity to explain the services offered. On our website we are describing and exemplifying how we can support the companies from very early-stage phase of understanding the exact needs for their solution in the clinics and further all through their development cycle. We connect our services to the design control and development process all medical device company are obliged to follow. The services offered by Nordic Proof is therefore expressed as shown below:

It is hard to see the text in the cut/paste clip from the Nordic Proof website to the right. But just to visualise that when you click on one of the development stages you will get a roll down menu exemplifying Nordic Proof services at that stage. The development stages are more easily read in the figure to the far right.



The various Nordic Proof partners differs in terms of clinical focus. And also if they act predominantly in primary care or in specialist care. This increases the probability of one or more testbeds having the capability of offering the service requested by the companies.

In some of the breakfast meetings and webinars we have the Nordic Proof partners present challenges and needs they have related e.g. specific clinical areas or infrastructure like home hospitalization. In this way we attract companies having products or solutions in development which potentially can meet those needs. It is always easier for the Nordic Proof partners to prioritize services in areas where they have unmet needs.

We experience that many of the inquiries we have is in the early phase of product development. We have limited inquiries for clinical investigations. The reasons might be a combination of several factors like e.g.:

1. the companies at that point already have a relationship with the relevant test partner through Nordic proof or other means and do not see the need for getting connected.
2. the healthcare providers have more streamlined processes for clinical trials of pharmaceuticals and less infrastructure and procedures for medical devices.
3. the healthtech industry is growing with many young SMB's. The SMB's do not always have the understanding of what is required from their side.

It is a continuous education of the companies to have them understand that the services are offered at a cost. And that the cost will vary a lot depending on the services to be provided.

We have however been able to develop one fixed price service. Namely a workshop. See content and process below. Workshop has also been possible to arrange virtually given Covid-19 restrictions. Here exemplified by company representatives from having a workshop with clinicians from Sunnaas rehabilitation hospital.

Fixed price workshop package



Content and process:

- Order the service package through our website
- Nordic Proof coordinator check availability of experts (2-3 experts per workshop) with relevant Nordic Proof partner(s).
- Nordic Proof coordinator create semi-structured interview guide with input from company.
- Selected Nordic Proof partner(s) recruit relevant experts.
- 90 minute workshop conducted with company and recruited experts at partner(s) test facility.
- Nordic Proof partner(s) write report with findings and recommendations.

Price:

€3000 for one workshop including the development of interview guide
€2000 per additional workshop

 NordicProof



It is also a challenge to provide optimal service for testing of e-health applications. None of the testbeds have fully developed set-up for a systematic approach for testing of a broad spectre of Software as a Medical Device (SaMD). It is also quite new to the companies as the Medical Device Regulation-MDR (2017/745/EU) coming into force May 2021 put much higher demand on the testing and documentation required for SaMD. Nordic Proof is not meant to be regulatory experts, but we have invited professional speakers who have shared their expertise in one of our events.

E-health or software solutions not defined, and CE marked as a Medical Device has similar challenges in terms of defined testing regime. Even though an e-health solution might fall outside the MDR it might still be a need for testing if such product is to be used or recommended by healthcare personnel. We make sure to have a regular communication with the Interoperability Project, also financially supported by Nordic Innovation, to synchronize our efforts to the benefit for both healthcare personnel and general citizens in terms of qualifying and rating solutions versus a defined set of parameters. Nordic Proof might play a role when testing is required for such non-regulated e-health products.



For us, the main challenge has been that the prospects have not included SW testing, and/or they have not realized (or had) the need for it. Difficult to bring our offering forward when they ask for a clinical study.

Jörgen Larsson, Kvalitetschef, Nordic Medtest

Process

Nordic Proof shall make it easy to reach several test best beds through a "one door in" and simple connection process.

Our process



a) Nordic Proof coordinator receive inquiry form automatically once "send button" is hit

b) Coordinator upload inquiry form content into the Nordic Proof backoffice system

c) All partners have access to backoffice system

d) Bi-weekly meetings with all partners. Discuss and match new inquiries from industry. Log conclusions and actions in backoffice system

e) Coordinator connect company with relevant Nordic Proof who can potentially provide the services requested

f) The dialogue and eventual agreement happen between Nordic Partner(s) and the company.

Simple 3 step process to explain to the companies what to expect.

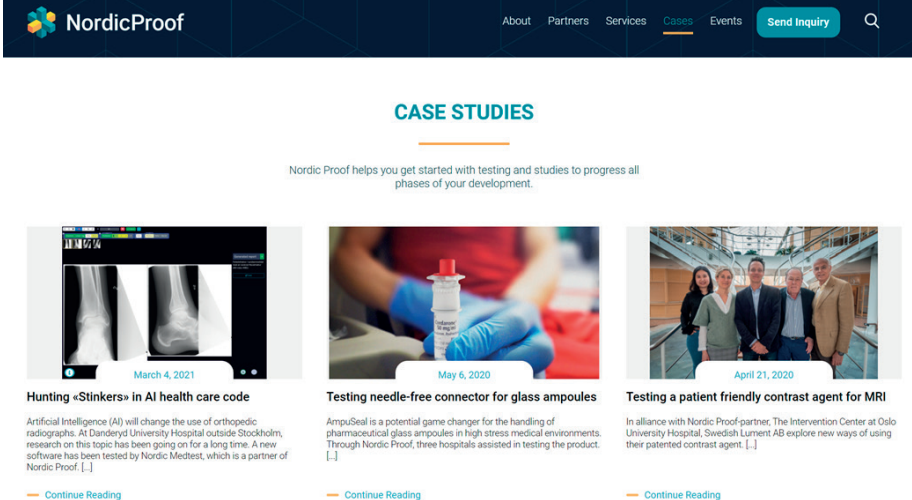
Operating process in the Nordic Proof consortium

Process action log	Start date	End date	Comments
Received incoming inquiry			
Initial contact (coordinator)			
Network inquiry sent out (coordinator)			
Internal network dialogue			
Testbed initial contact with company			
• <<testbed name>>			
Signed contract with testbed			
• <<testbed name>>			
Evaluation of activity			
• <<testbed name>>			
Dialogue closed			

Backoffice system for following up all the company inquiries.

Case example

To exemplify and promote the Nordic Proof testbed consortium we are sharing case studies at the Nordic proof website. We are using professional writers for this task. Some case studies are between a company and one testbed while others are between one company and several testbeds.



The screenshot shows the NordicProof website's 'CASE STUDIES' section. The header includes the NordicProof logo and navigation links: About, Partners, Services, Cases (highlighted), Events, and a Send Inquiry button. Below the header, a sub-header reads 'CASE STUDIES'. A descriptive line states: 'Nordic Proof helps you get started with testing and studies to progress all phases of your development.' Three case study cards are displayed:

- Hunting «Stinkers» in AI health care code** (March 4, 2021): Artificial Intelligence (AI) will change the use of orthopedic radiographs. At Danderyd University Hospital outside Stockholm, research on this topic has been going on for a long time. A new software has been tested by Nordic Medtest, which is a partner of Nordic Proof [...].
- Testing needle-free connector for glass ampoules** (May 6, 2020): AmpuSeal is a potential game changer for the handling of pharmaceutical glass ampoules in high stress medical environments. Through Nordic Proof, three hospitals assisted in testing the product. [...]
- Testing a patient friendly contrast agent for MRI** (April 21, 2020): In alliance with Nordic Proof-partner, The Intervention Center at Oslo University Hospital, Swedish Lument AB explore new ways of using their patented contrast agent. [...]

Each card includes a 'Continue Reading' link.

“

Without access to testing facilities at the Nordic Proof partners, we would not have products in the market.

Carl Christian Sole Semb, Independence Gear



“

We came in selling the product as if we were doing a sales pitch. We soon realized that the meetings were the most valuable to us if we sat back and allowed them to be brutally honest – almost prompting their most critical feedback.

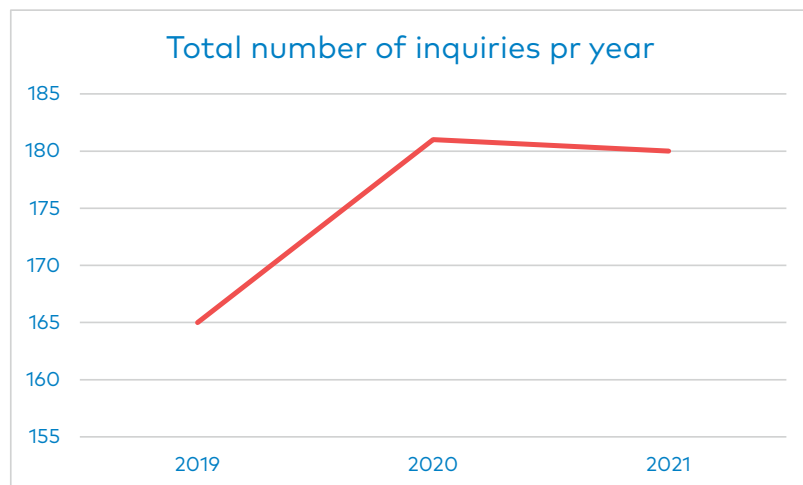
Marius Andresen, serial entrepreneur



Incoming inquiries

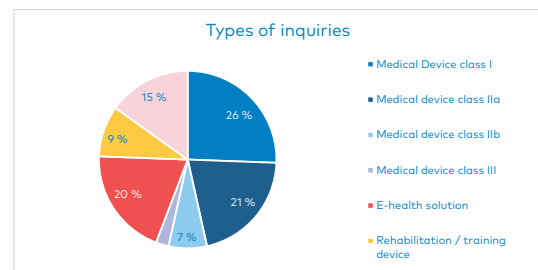
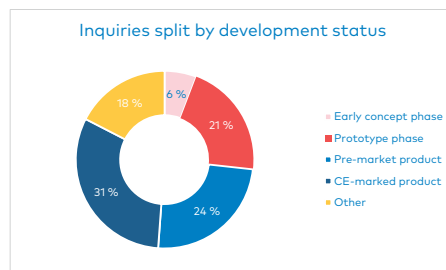
In total the Nordic Proof partners have handled 600 inquiries from companies during the project period. Of these inquiries 85% have been handled directly by the partners and 15% have been registered through the website of Nordic Proof. Building awareness and knowledge about the partners and their services has been one of the main purposes for Nordic Proof. Starting the Nordic Proof service in 2018 we had a goal of 300-500 inquiries during the project period.

Companies that register their inquiry at the Nordic Proof website have been handled by all partners in parallel and the companies have been introduced to an average of 2,2 partners interested in discussing their case one-to-one. Adjusting for the multiple of contacts pr inquiry the percentage of inquiries coming through Nordic Proof is 22% of total.



We see a growth in number of inquiries from 2019 to 2020 and a slight decline in 2021 (see figure above). Considering all issues with limited access to hospitals during covid and restrictions to travel, we believe the numbers will increase in the coming years when the situation is back to normal.

Below are two figures with statistics about types of inquiries and development status for the 22% inquiries registered through the Nordic Proof website. The figures show a diversity of inquiries both regarding types and development status.



Starting Nordic Proof, we expected a need for individual priced services based on the needs of the companies. This hypothesis has been confirmed and we experience a variety of needs and expectations. Nevertheless, we have developed a fixed priced workshop concept for companies that would like a product evaluation by clinicians, and we believe that it would be of interest to further develop and streamline this first dialogue with companies. Trials and verification studies will also in the future be custom made services with individual prices.

Results and effects

Nordic Proof has managed to establish as a **well-known gateway** for companies that would like to test and verify their products and ideas together with clinicians at Nordic hospitals and within municipalities. The **pandemic** has made it difficult to travel abroad and capacity and access at the hospitals also have been very limited for long periods. Nevertheless, we have managed to turn around and offer digital dialogue and focusing on products and services relevant for handling of the pandemic.

Our overall ambition has been to **professionalize** the testing service for industry and make sure to **streamline the process** of testing to avoid unnecessary use of resources both for the companies and for the health care institution. We experience that all Nordic Proof partners have continuously developed their services and capacity for industry collaboration. We see an **increase** in number of local, Nordic and international projects being set up by our partners.

Here are some feedbacks from the partners describing the main outcome of being partner of Nordic Proof:



Joint events and webinars with targeted meetings between SMEs and NP partners, sharing practical experiences and practices between network partners, gaining visibility for HUS activities in a Nordic network of partners and potential collaborators.

Pekka Kahri, Technology Officer, M.Sc
Helsinki University Hospital, Development group



Cooperation Between the Nordic countries are necessary to bring development in healthcare forward in a larger context. Together we can lift up important issues that are different in the different countries. It's important to get inputs from the different ways of work that we have developed through the years. We can pick up the best parts and develop our work from that. The products or services that comes out from successful cases within the partnership, have a bigger mandate to be spread in a larger scale, though there are competence involved from different Nordic perspectives.

Olle Hillborg, Enhetschef DS Innovation
Danderyds sjukhus



Nordic proof had three overall ambitions:

1. Bringing down barriers for testing and verification of new products and services.
2. Open up the Nordic as a home market for companies by making it easier to get insight and start collaboration with health care institutions abroad.
3. Increase number of companies testing their solutions in the Nordics.

Looking at the results from four year of operation we believe we have managed to address the ambitions and given many companies the opportunity to get their products tested and verified at Nordic hospitals.

There is still untapped potential for further development of the Nordic Proof offer and the testbed network. With new health tech innovations continuously being developed the need for relevant testbeds are crucial for further growth in the health industry. Some of the challenges and barriers which is important for Nordic Proof and the testbed partners to further address in the coming period are listed below:

- Most of the inquiries to Nordic Proof are for early development phase evaluations and we see a potential for more clinical trials being contracted. We believe continuous work will position the Nordic Proof partners competing with central Europe and UK as preferred locations.
- Many startup companies do not have the competence needed to plan their clinical investigation. This makes it challenging for the testbeds to deliver efficient services. Nordic Proof will continue to focus on knowledge building and streamlining the clinical investigation process.
- Limited public financial support to start-up companies for early-stage clinical evaluation prolong the ability to test out new innovations
- Limited infrastructure for testing of e-health solutions. Both with respect to e-health solutions falling inside and outside of the Medical Device Regulations 2017/745 (MDR)
- Lack of dedicated testbed resources are still an issue at several hospitals. Probably due to a combination of limited public funding for specific testbed activities and cultural "resistance" within the healthcare institutions towards healthcare-industry collaboration to bring forward new technology. Clinical trials for drug development are accepted and given priority. Trials and testing of medical devices and e-health solutions are evenly important for a sustainable health care service and need to be focused with the same priority.
- Lack of incentives (including financial incentives) for clinicians to set aside time for interaction with health tech companies is a barrier.
- With OuluHealth Labs as a good example we see new initiatives coming where municipal healthcare, specialist healthcare and universities coordinate their services and resources and meet the need for testing of integrated health care solutions.

Next steps

Ending the first four years of operation, Nordic Proof has recently discussed our strategy going forward. Beside operational tuning we would like to focus:

1. Increase uptake of new test cases.
2. Increase number of partners and collaborative partnerships with other organizations securing a strong footprint in all the Nordic countries.
3. Secure funding for continued strong development and operation of Nordic Proof.
4. Joint development projects of new services within clinical areas of strategic importance for Nordic Proof partners.

EU roll-out of Medical device Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) has already set a new agenda for clinical trials. Nordic Proof would like to contribute to position the Nordics as an attractive region for clinical investigations to the best for industry growth and development of new and better treatment.

We would like to invite for informal dialogue with potential new partners, and of course be available for companies that are looking for a testing site. Please get in contact with us!

On behalf of Nordic Proof



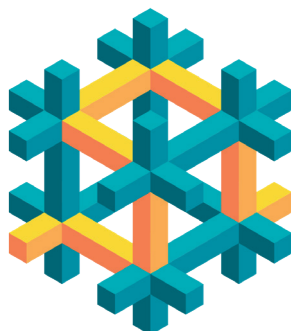
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