

Denmark



The public health sector is increasingly turning towards digital health technologies to help...

- 1. Improve treatment outcomes and experiences
- 2. Fill in gaps where staff doesn't have the adequate time/capacity
- 3. Prevent the need for future treatment

- We also know that there are so many [health professionals] that want to invest in digital solutions, that parents can use at home...
 We've given two presentations for nurses in the Municipalities of Slagelse and Sorø.
 - Startup owner

(Translated from Danish)

- But if we look at in the clinic, it's like, we don't have enough time for this type of... we focus on the kid.... and parents don't get that many tools... So that was a short answer. We need more tools for parents.
 - Clinical Researcher

"The Needs Gap"

There's often a gap between the needs addressed by commercially developed products and the **actual needs** of the healthcare system.

Public-private partnerships around **co-development** seek to address this issue.

I guess the hypothesis is more that if we develop something together... we're not looking out on the market about: 'Okay, what kind of fits our needs?' Instead, we're saying we're commissioning the type of work and we're as a clinic involved in developing a device that we think we would like to implement.

-Clinical Researcher

While Co-development helps to bridge "The Needs Gap" – it also comes with challenges

It currently occurs in small-scale, ad hoc, hand-held setups that are resource heavy.

This makes it slower and more difficult to implement and scale these technologies down the road.





It's fairly easy to be able to run smaller studies and things like that. That's quite easy in Denmark, I think...

But it's very ad hoc, and so it's not something that's scalable in that way.

- Researcher & Startup owner (Translated from Danish)



[It] makes it very difficult for companies to do like, yeah, you might have one contact. So let's say I just have Michelle now at the Region H. But then what? We need to scale it, we can't develop this solution only for one region or one center, we want to scale and we want to have that input from the beginning from different places.

- Startup owner

"The Validation Paradox"

The public health sector doesn't take new technologies into use without **sufficient evidence about efficacy** (and often a convincing economic argument).

Evaluating the efficacy of new technologies often requires testing in the appropriate context within the public health sector - preferably at a large scale.

There needs to be some **clinical evidence** that it's a good idea. And maybe also some **economic evidence** that it's a good business case for the health sector to invest in.

In order to create that evidence, you have to have run **some big studies**.

-Researcher, Health Ecosystem Focus
(Translated from Danish)



It's my impression that if you really want to [have your product] in the public health system, it requires really convincing data.

So my take on it is... that we have to run a very **big study** that shows... that we actually can improve something or other for some patients.

- Researcher & Startup owner (Translated from Danish)

Focus on "The Big Study"

But the problem was [that] we were just in the beginning, and you need a lot more validation, so we need to do **the big study**.

-Clinical researcher

This leads to a 'chicken or the egg' type of problem between validation and use, prompting the question:

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How might we support the process of validating at scale earlier in the co-development process?

"The Resource Burden"

Running research studies on health technologies *in use* is extremely resource heavy.

Recruitment alone takes requires vast amounts of time and effort.

One clinical researcher shared with us the experience of recruiting pacemaker users in order to test and co-develop a new technology.

I myself have seen the limitations of the daily practice in terms of wanting to gather data in order to improve things. And there's just a huge mis-match and there aren't resources and time to do it.

- Clinical researcher (PhD)

(Translated from Danish)

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One researcher's recruitment journey





There's simply so many resources, time and energy that is required to do the research... Where you initiate all sorts of things but it's only a little percent that becomes one's dissertation. But they've done so many other things and most often it just lands in a lake at the end, even though so much was invested.

I've been responsible for all the steps the whole way through. So yeah, I have tons of knowledge and things that I've learned, and then it's just - "In the lake it goes!"- Packed away in a "forgetting book".

- Clinical Researcher (PhD)

"The Resource Burden"

For digital health startups with limited resources it can seem overwhelming to integrate their solutions with the public health sector.



That about getting started with the public health sector, I think that's really difficult sometimes.

- Researcher & Startup owner

(Translated from Danish)

I think we're like a lot of startups that don't really know where we should start with something like this... It feels a bit like something for those who have the extra energy.

It kind of needs to be integrated with the patient journal system in order to test it. And you can't just do that... It's a huge technical exercise, where we simply don't know where we should start...

- Startup owner

(Translated from Danish)

The Consequence?

Startups end up focusing on business models outside of the public health system to quickly establish revenue streams, thereby **limiting who can benefit from their solutions**.

There's also some private businesses in Denmark that offer health-checks, for example. So we don't get that from the public sector, but if you're employed in a good company in the private sector, then you often get offered a yearly or twice a year health check. So it's obvious that [our product] can be used there.

- Researcher & Startup owner

(Translated from Danish)

When you're sitting deep in the logistics of running your company, and you're a little startup, then it can feel less important than doing all the small jumps along the way that you think can earn you money faster. Even though it's the other thing that creates greatness in the long run. There's no doubt about that.

- Startup owner

(Translated from Danish)

Vision

(Work in progress)

Denmark as Living Lab seeks to democratize digital health innovation by establishing a digital infrastructure that supports collaborative development, validation and scaling of digital health solutions in the public health sector.



When you say "Living Labs", then I think a lot about these digital solutions... [that] should go out and **reach the masses** - the majority.

-Employee in a large company

(Translated from Danish)

Citizens are willing to contribute... They feel that it's their duty.

I'd almost say that it's a **duty** and a **necessity** in order to maintain one of the worlds best public health systems, that we citizens contribute – and without needing to have money for it... I really feel that it is a "citizen duty" in order to ensure that our health system can keep running and be really good and of high quality.

- Citizen 3

I think I have some kind of understanding that **it's important to participate**. That it's a kind of **"citizen duty"** you could say... It's something that you ought to be a part of.

- Citizen 2

It's kind of like, that you think: 'Okay, I think this research project is interesting and I think it makes sense and is important. Then I would be willing to sit and use a half an hour in the evening on my sofa. I really think that would make a difference.

- Citizen 4

To sum it up, our research suggests that...

- 1. Collaborative development is essential for making sure digital health solutions meet the most pressing societal healthcare needs.
- 2. Digital health technology must be **tested at a wider scale** during the development process to give more clear indications early on about efficacy. Validation can require **implementing** (at least partially) in existing contexts and practices.
- 3. Many resources could be saved by offering better support systems for recruitment, legal & administrative challenges, and secure data transfer during the research and development process.
- 4. Citizens are willing to contribute when **broader societal value** is clearly illustrated.

Main Challenges

- Scaling co-development of digital health solutions
- Validating during and implementation and use
- Reducing the resource burden through shared support infrastructure
- Recruiting the right participants to test the digital health technology
- Transferring data securely between participants and research group
- Identifying the right health professionals to help test new solutions
- Managing the administrative burden and legal challenges of engaging in public/private partnerships

Cases

Identified in Phase 1

Case 1: Fix my Pregnancy" (Working title)

Professor at KU - Department of Food Science

A behavioral study about pregnant women's eating habits. Pregnant women get support in the form of a community-based app and possibly a meal box and observations are made about whether or not the intervention produces the desired behavioral change.

Type of technology/study?

- App with interaction/community feature, tracking and information
- Intervention study/behavioral study



- Recruitment is difficult when people are otherwise healthy (preventive focus)
- GDPR limitations in developing a community-based app
- Compliance among participants when the study requires a lifestyle change

Needs

- Channel for recruiting the "right" pregnant women – at a national level
- GDPR compliant channels and/or systems for handling consent

Opportunities

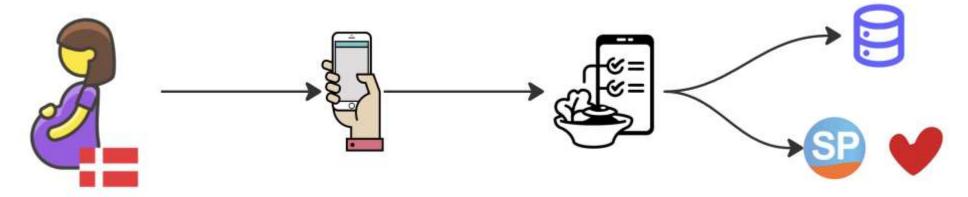
- Better opportunities for conducting "citizen science" or studies "in the wild" where it's possible to observe participants' behavior in their own context
- Being able to reach out to future participants when a clinical contact point isn't possible
- Saving resources otherwise used on developing a research set-up



Solutions

- Recruitment feature
- Easy deployment of app
- Legal foundation that is GDPR compliant
- Possible community feature

Case 1: Preferred User Journey



Pregnant women across Denmark (goal of 1.000) to participate in study

The participants are sent an app with recipes and more

The participants track various parameters

Researchers combine the tracked data with patient data from electronic journals (fx SP or Sundhed.dk)

Roadblock:

Missing a point of recruitment outside of the clinical setting

Roadblock:

No place to deploy the app in pilot version

Roadblock:

Compliance during the study is difficult – requires lifestyle change

Roadblock:

Missing relevant information about the patient's birth

Case 2: VentriJect

Aalborg University - Institute for Medicine and Health Technology, CSO of VentriJect

Precise estimation of VO2 max in less than 3 minutes via seismocardiography sensor. The solution is not integrated with the public health sector yet, but is being sold to private companies, that offer regular health checks for their employees.

Type of technology/study?

- Measuring device/device for use in a clinical setting (for example, with a doctor or other health professional
- Validation study (large scale)



- Entry into the public heath sector requires evidence and therefore, large scale validation studies in order to prove impact
- The company doesn't have enough resources to make a large-scale validation study

Needs

- Logistical support (enrollment, contracts, equipment delivery, and more)
- Research team consisting of trial manager & data scientists
- Ability to offer an intervention to study participants
- Identifying participants who will benefit most
- Communication platform for the general practitioners
- Data collection infrastructure

Opportunities

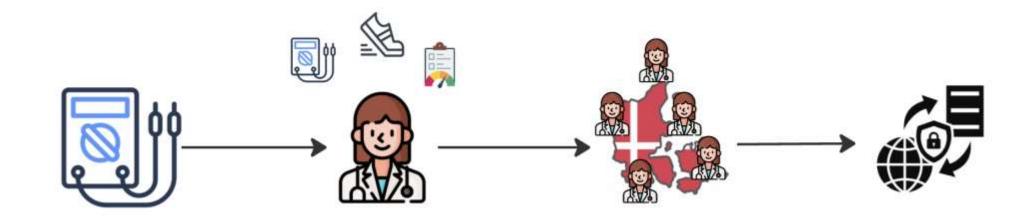
- Larger body of evidence by running a larger validation study
- New business strategy where the technology is able to be integrated with the public offering



Solutions

- Recruitment feature for health professionals (general practitioners)
- Logistical support
- Legal support
- Infrastructure for collecting and sharing data across the project team

Case 2: Preferred User Journey



The device should be tested in a clinical setting in order to understand efficacy and expand use A large-scale study requires collaboration with general practitioners, who can use the device, offer an intervention and measure impact The research setup must be expanded to doctors across Denmark to reach the necessary scale Test data must be shared securely between patient journals and the project's stakeholders

Roadblock: This process is anticit

This process is anticipated to be extremely resource heavy

Roadblock:

Lacks contact to relevant doctors who may be able to help with testing the device

Roadblock:

Lacks communication platform to coordinate between test sites

Roadblock:

Sharing test data currently requires twice the work from general practitioners

Case 3: AI app for parents of children with psychological challenges

Clinical Researcher and Psychologist at Region H's Psychiatric Department CEO/Co-Founder of Interhuman Al

New project, that will teach parents new ways of communicating with their children who are experiencing psychological difficulties via an app with emotionally intelligent AI. The app is to be tested and tailored towards this new type of use during a pilot study with Region H throughout 2025.



Type of technology/study?

- App (communication + AI)
- Validation study (small scale) and further development/tailoring to the clinical needs

Barriers

- Limited recruitment possibilities, since participants can't be in treatment at the same time as testing
- Limited scale, since the pilot is only running in one region
- Partnership agreements between the startup and the hospital administration

Needs

- Expanded clinical network for running the trial in other Danish regions.
- Expanded channels for recruiting
- Respect for anonymity in the recruitment process

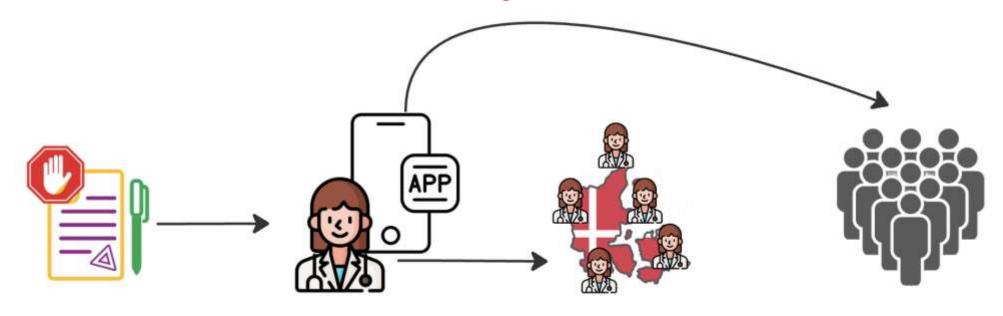
Opportunities

- Reach foundational evidence more quickly by running larger scale studies
- Minimizing implementation challenges by collaborating between regions

Solutions

- Recruitment feature
- Feature for recruiting relevant clinicians
- Legal support

Case 3: Preferred User Journey



A public/private partnership must be established before beginning a pilot-test

An existing app will be tested and adapted to the clinical context

The research setup must be expanded to similar clinics across Denmark to reach the necessary scale Recruiting citizens outside of a clinical setting would enable a wider pool of participants

Roadblock:

This process has already taken a long time and a lot of administrative resources

Roadblock:

The pilot test will only run at one clinic, limiting the scale

Roadblock:

It's difficult to acquire relevant contacts in similar clinics in order to test at a wider scale

Roadblock:

Lacking a mode of recruitment that honors anonymity for potential participants

Concept & **Desired Functionality**

What do we talk about when we talk about **Denmark as Living Lab?**

There's a lot of interest, but also a lot of different interpretations of what it will be...

If there was already a **communication platform**...
Then you could more easily get started.

-Researcher

(Translated from Danish)

We would of course really benefit from a database, for example, with people that were willing to test.

-Startup owner

(Translated from Danish)

[It] would be helpful if there was such a **platform** where we can, it's alright **legally to send a** request: Hey, would you like to participate?"

-Startup owner

(Translated from Danish)

I'd really like to use that **platform to invite** all pregnant women...

- Researcher

(Translated from Danish)

Working definition:

Denmark as Living Lab is a digital infrastructure that aims to ease the process of developing, validating and scaling digital health technologies by making it easier for researchers, clinicians and startups to recruit and engage a greater number of the right participants in developing new solutions

Focus on...



Digital interventions

Health apps Wearables & tracking devices Home monitoring Digital health information & communication AI based technologies



Pharmaceuticals

(Medicine only products)

Focus on...



Early-and middle stage development & pilot studies

Test & feedback for further development & evt. medical device approvals



Large scale clinical trials (RCT)

Data collection from private devices merged with public health data (can be added later)

Focus on...



Test & validation of new technology or new context

Public partner and societal value

Value & transparency for participants



Large-scale **survey** studies

Private sector **exporting value** abroad

No exploitation of public data and/or participants time

Two points of entry

1. Direct to citizens

For example, preventive projects without a patient focus

2. Through a clinical contact point

For example, adapting existing technologies to a new healthcare context

List of desired features

Direct to citizens

- Recruitment (citizens)
- Digital consent
- App deployment
- Project information & status updates
- GDPR compliant data exchange (from participant to researcher)
- Communication between project owner and participants
- Community (among project participants)
- Technical support

Through a clinical contact point

- Recruitment (health professionals)
- Communication channel between project stakeholders
- Shared data between project stakeholders
- Access to data from health professional's journal systems
- Legal support
- Technical support