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Early stage MedTech **spin-off** from Capital Region and Technical University of Denmark

Early detection of critical complications …

… in **high-risk patients** using **real-time, AI** enabled patient monitoring

Current manual monitoring practice in hospitals (outside the ICU) doesn't work

Way too many unexpected complications

30%

unexpected critical
complications

3rd

leading cause of
death (surgery),
WHO

1:20

deviations
detected today

4-6 days

Prolonged stay in
hospital after
complications

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Ineffective patient monitoring comes at significant cost

Manual monitoring causes stress and takes time

- Complications lead to intensified treatment and prolonged admissions

- Nurses spend way too much time on ineffective monitoring

- Unpredicted events create a stress-full environment

4-6 days
Patients who experience severe adverse events after abdominal cancer surgery stay longer in hospital

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150.000 DKK
Estimated average cost of severe complications
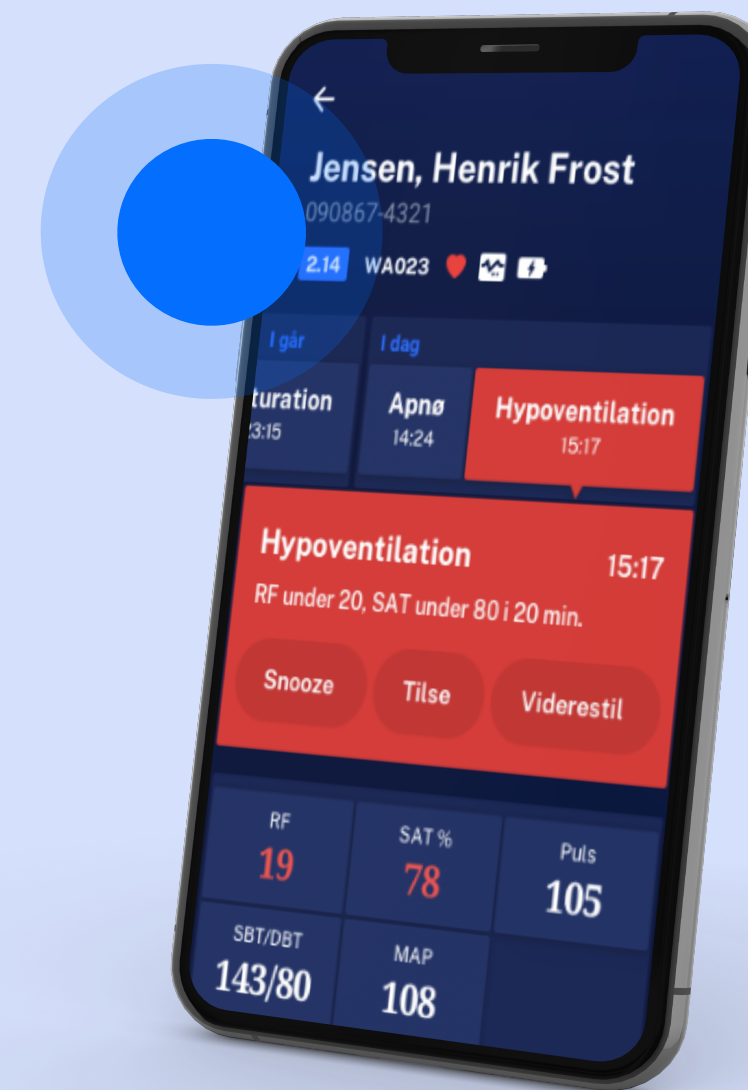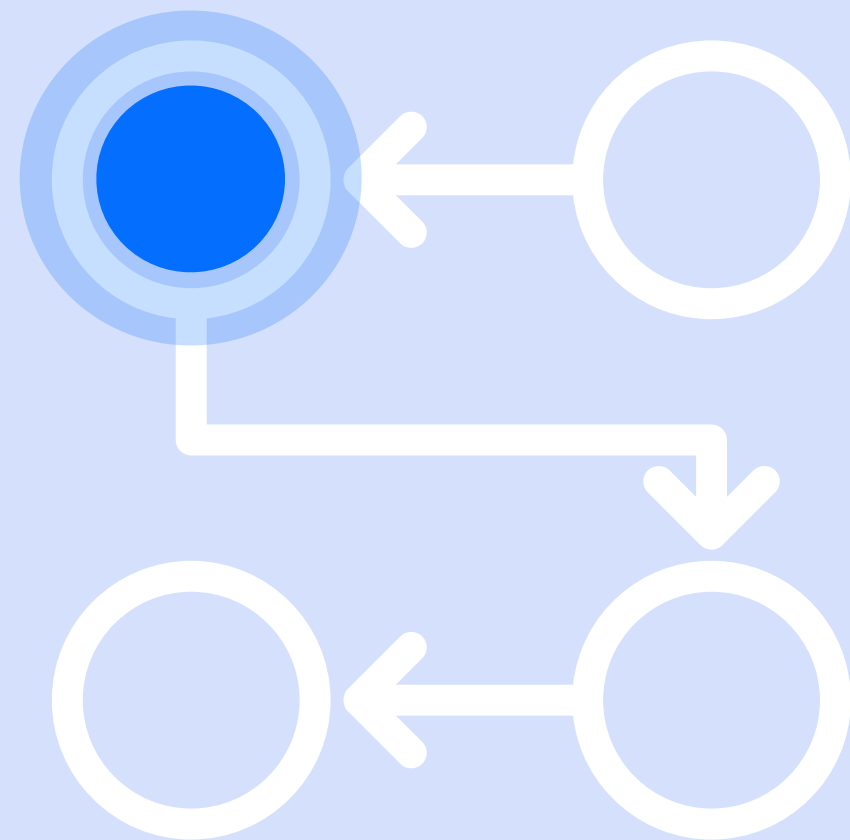
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Vision: From infrequent manual monitoring to 24/7 AI based early warning of complications

Our solution:
AI enabled patient monitoring in the hospital ward (not ICU)

Based on standard vital sign patterns from marketed wireless sensors, mathematically and medically modelled **AI algorithms** interpret complex vital sign patterns and translate consistent deviations into clinically meaningful & predictive alerts

Simple **intuitive interfaces** provide unique overview of patients so nurses can focus and **REACT** when needed

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Even 1st generation WARD 24/7 gives +12 hours to change patient outcome

Uncomplicated colon resection

Dizziness and feeling weak

WARD alert: Two dimensional AI interpretation detects deteriorating circulation

CT scan reveals anastomotic leak

Re-operated

Day 1

Day 2 02.00

Day 2 14.00

Day 2 21.00

May 2020

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The future:
Detect complications earlier
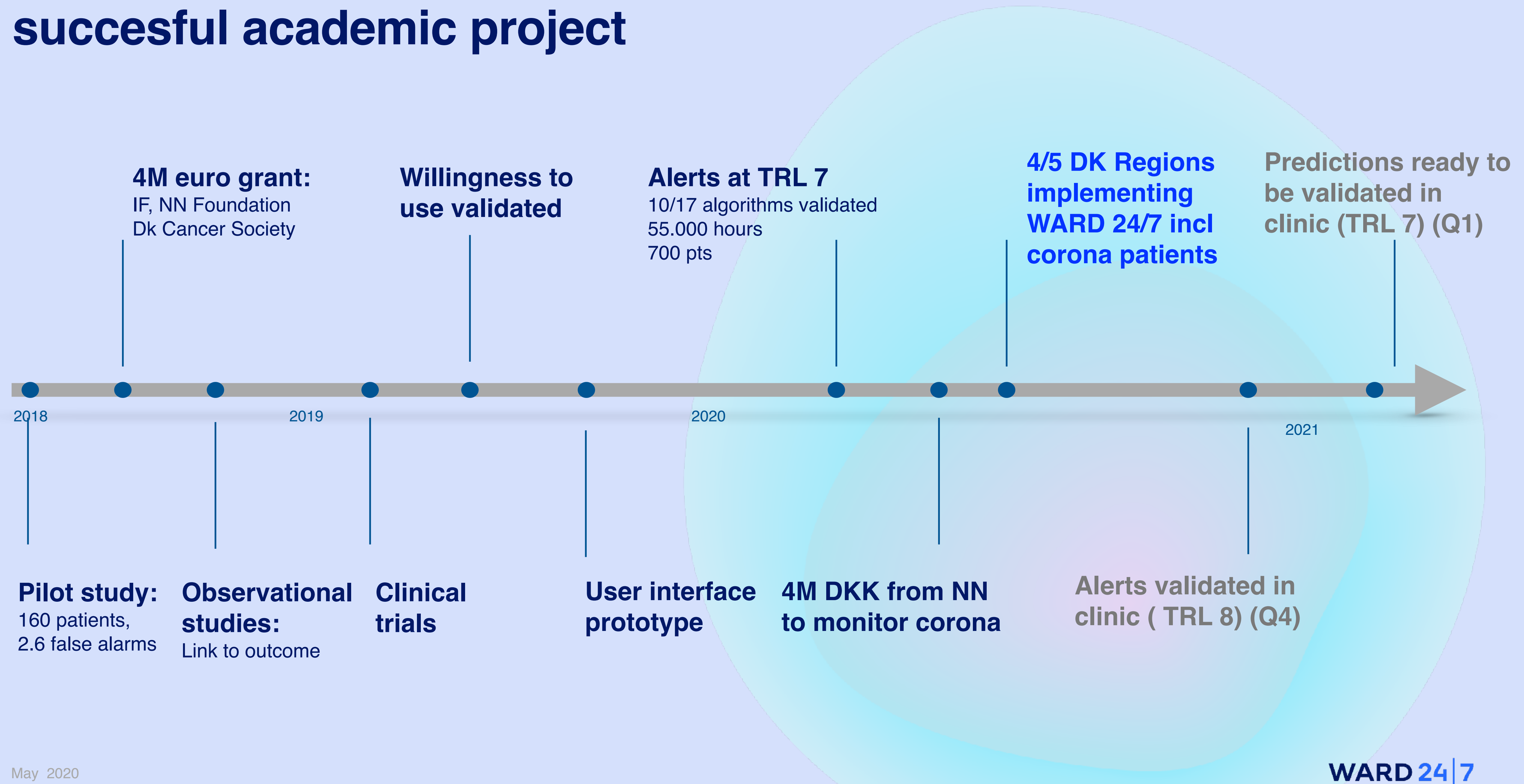
Helping patients get the best care

Helping nurses know when to act

Helping hospitals save costs

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WARD 24/7 is a spin-out from a well-funded and succesful academic project

4M euro grant:
IF, NN Foundation
Dk Cancer Society

Willingness to use validated

Alerts at TRL 7
10/17 algorithms validated
55.000 hours
700 pts

4/5 DK Regions implementing WARD 24/7 incl corona patients

Predictions ready to be validated in clinic (TRL 7) (Q1)

2018

2019

2020

2021

Pilot study:
160 patients,
2.6 false alarms

Observational studies:
Link to outcome

Clinical trials

User interface prototype

4M DKK from NN to monitor corona

Alerts validated in clinic (TRL 8) (Q4)

May 2020

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The invention is likely to be patentable

DTU patent advisors have agreed to initiate patentability and novelty search

Advisors have indicted it is likely that WARD algorithms can be patented as a "computer implemented invention"

Patent agency currently conducting patentability assessment and novelty search expecting result early Q2 2020

Patent strategy and timing await result of novelty search and further analysis of IP space

WARD 24/7 ApS has first right of first refusal to in-licence the algorithms developed in the academic project

WARD 24/7 has <u>right of first refusal</u> to in-licence and commercialise the scientific algorithms
- Preliminary term sheet currently being drafted by DTU and University of Copenhagen

WARD 24/7 is equally founded and owned by the 3 original inventors
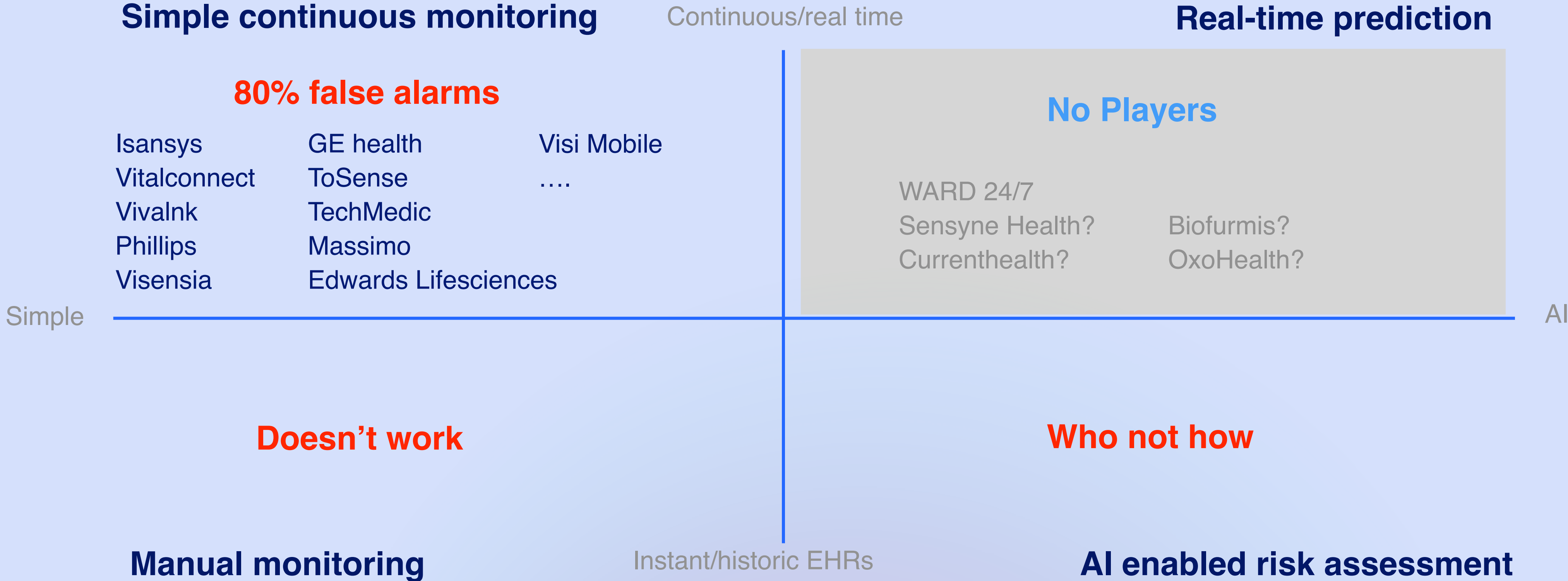- Angel investor has invested DKK 400.000 in 5% of the company

WARD 24/7 ApS looking for funding to commercial the WARD clinical support system

WARD 24/7 has been selected to be funded by and participate in the BioInnovation Institute Business Acceleration Academy in Q2 2020.

Is currently looking for pre-seed funding to develop the algorithms according to regulatory standards and launch the product

No players have the capacity to develop real-time prediction yet

Simple continuous monitoring   Continuous/real time   **Real-time prediction**

80% false alarms

Isansys	GE health	Visi Mobile
Vitalconnect	ToSense	….
Vivalnk	TechMedic	
Phillips	Massimo	
Visensia	Edwards Lifesciences	

No Players

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Sensyne Health?   Biofurmis?
Currenthealth?   OxoHealth?

Simple

AI

Doesn't work

Who not how

Manual monitoring   Instant/historic EHRs   **AI enabled risk assessment**

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Most companies give insufficient attention to the nurses workflow and user-experience

"The best IT experience I have had in the hospital world"

"Nice to have something 'nice' in a public hospital"

User validation research clinical trial prototype

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Our advantage

Broad range of clinical complications = reality

Mathematical modelling + medical modelling = **new medical knowledge**

Patient access through alliance with university hospitals

State-of-the art user interface

4 M Euro public grant funded scientific modelling

Current assessment is that the invention is **patentable**

Real time prediction is not easy to copy

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Substantial market size & peak sales potential

25 B USD

Patient monitoring device market 2023 (cagr 5.7%)

150-350 M USD

Patient subscription **peak sales potential**

Assumptions:
2M curative beds US+EU12, 25% eligible, 10 USD per pt per day, 10% market share, 80% occupation

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Business model

Multiple device company collaboration w easy calibration
Use fee per patient per day + service

Market entry

Market entry in large academic hospitals
Initial focus on isolation and innovation

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Commercial road map

Clinical trial data collection

"Commercialise" our current RCT set up that we use to develop algorithms. Help pharma collect and analyse data in exploratory or post-marketing trials .. Corona focus

2021 launch

In-hospital patient monitoring with alerts

Develop state of the art, intuitive, digital, dynamic patient monitoring visualisation - launch in partnership with innovative design partner and medtech/ or device partner

2022 approval and launch

In hospital <u>predictive</u> clinical support system

Develop and launch the world's first predictive patient monitoring system

2022/23 approval and launch

Out-patient monitoring (post discharge & remote monitoring)

Continue development of intelligent algorithms and device set up to fit remote predictive patient monitoring system. Perhaps the biggest potential for WARD 24/7.

2023/24 approval and launch

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Specific entry opportunities offer ways into a very broad market

30% of patients have unexpected critical complications

· Most medical specialties can be targeted (except high-dependency wards)

· Target is: largest non ICU wards at the largest hospitals in EU and the US, who recognise nurse scarcity and prolonged hospital stays as a priority

· **Market penetration driven by unmet need, PE data, outcome data, device partnerships, HCP endorsement, attention to nurse interaction**

Several opportunities for targeted market entry

1. Hospitals with many patients in isolation (Corona)

2. Private hospitals prioritizing state of the art equipment

3. Newly built hospitals looking to implement new work flows

4. Public/private "hospital innovation" projects focusing on implementation of AI and digital technology

5. Hospitals driven by insurance companies (US)

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SAMD/SAAS revenue model

Value of service is fewer critical complications and cost saving of shorter stays, fewer ICU admissions, less treatment; potentially less nurse resources

SAAS pricing suggestion 10 USD per patient per day
- based on informal benchmarks

SAMD/SAAS - revenue model includes
· Sub-licence fee + calibration fee - to partners
· Opstart fee
· Subscription per bed or per patient
· Maintenance fee
· Access to anonymised data for learning
· New versions
· Training - innovation fasciliation

LARGE Peak sales potentiel (USD, only subscription)

20	565 M	1.131 M	1.809 M
		300-700 M USD	
10	282 M	565 M	900 M
	25%	50%	80 %

Basic assumptions:
25% -50%-80% eligible/relevant
10-20 USD per pt per day
80% occupation
20% market share
2 M acute hospital beds EU 12 + US

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Funding needs in 2020 towards first launch end 2022

Product development
Clinical data
Quality system
Software development and validation
Front end development and validation
Build support system

Business development
Funding
Legal
Partnerships
International clinical pilots
Launch

1-1.5 M Euro ?
Pending state of regulatory compliance assessment, incl clinical data, quality system, software and front end cost assessment

Ready in May 2020

Business development: 0.5 M Euro
1 CEO
1 SW engineer
1 Medtech business developer
1 Clinical manager

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Product roadmap towards first launch 2022

Planning

Product development

Business development

Planning

Data

Front-loading

Develop quality system

Develop software to regulatory approval

Finalise & validate frontend

Clinical validation

CE and FDA approval

Support setup & device calibration

International pilots & Launch

Next generation

Scale up

6 months 2020	**2021**	**2022**	**2023**
Soft / Angel / Pre-seed	Pre-seed	Seed / Bridge	Bridge / Series A

Funding needs	0.1M Euro	0.4M Euro	0.4M Euro	0.4M Euro	0.4M Euro	**1.7 M Euro**

May 2020

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A complimentary team

Helge Bjarup Dissing Sørensen
Assoc. Professor MSK, PhD
Founder & CTO

Christian S. Meyhoff
MD PhD
Founder & CMO

Eske K. Aasvang
MD PhD
Founder & CRDO

Betina Langemark
MSc
CEO

Artificial Intelligence
Bioengineering

Anaesthesiolgy
Patient monitoring
Intensive care
Clinical research

Anaesthesiology
Post-surgery care and
complicaitons
Clinical research

20 years big pharma & biotech
Novo Nordisk, Abbvie,
Astra Zenaca
Strategy, BD, R&D, operations

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"PS

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An acute unmet need has emerged:
Manual monitoring of Covid-19 patients is even more catastrophic than for "normal" patients

Dramatic
lack of staff

Risk of
contamination
with each patient
interaction

Very unstable
patients -
unpredictable
clinical path

**Health system
capacity
insufficient to
manage the peaks**

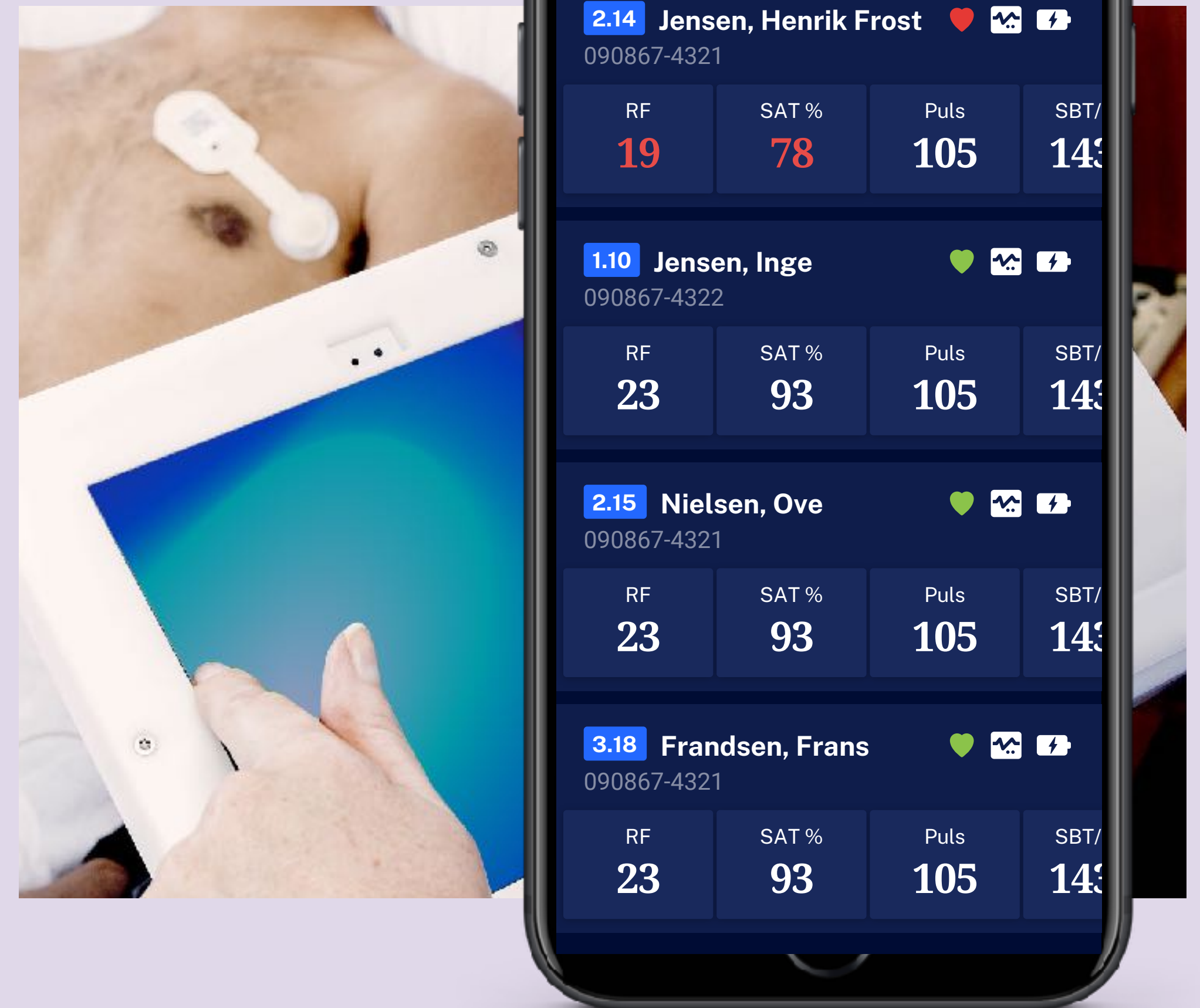**An opportunity for fast track development and approvals ..**

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We have a unique possibility to make a big difference right now

Our founders are involved in setting op the acute corona practice in two of Denmark's largest hospitals.

They see first hand the need to optimise monitoring of corona patients. And could not bear to not use the system they know will help. They attracted a 500.000 euro research grant to implement WARD algorithms for corona patients in Denmark. They start using the equipment in March. And the AI in May.

WARD 24/7 would make a huge difference for corona patients and hospital staff right now. With funding to finetune algorithms setup up, finalise software development and get regulatory approval, we have an opportunity to start helping more patients in and outside Denmark already in wave 2!

Two of our founders on national news 25 March 2020

The real big advantage is that we don't have to go to the patients to see how they are doing. We can monitor their vital signs from a distance. This means we can use less protective equipment.

Professor of infectious medicine, Ole Andersen

https://nyheder.tv2.dk/samfund/2020-03-26-kunstig-intelligens-skal-overvaage-corona-patienter-i-stedet-for-sygeplejersker

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Thank you for your attention.

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Please don't hesitate to contact us

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