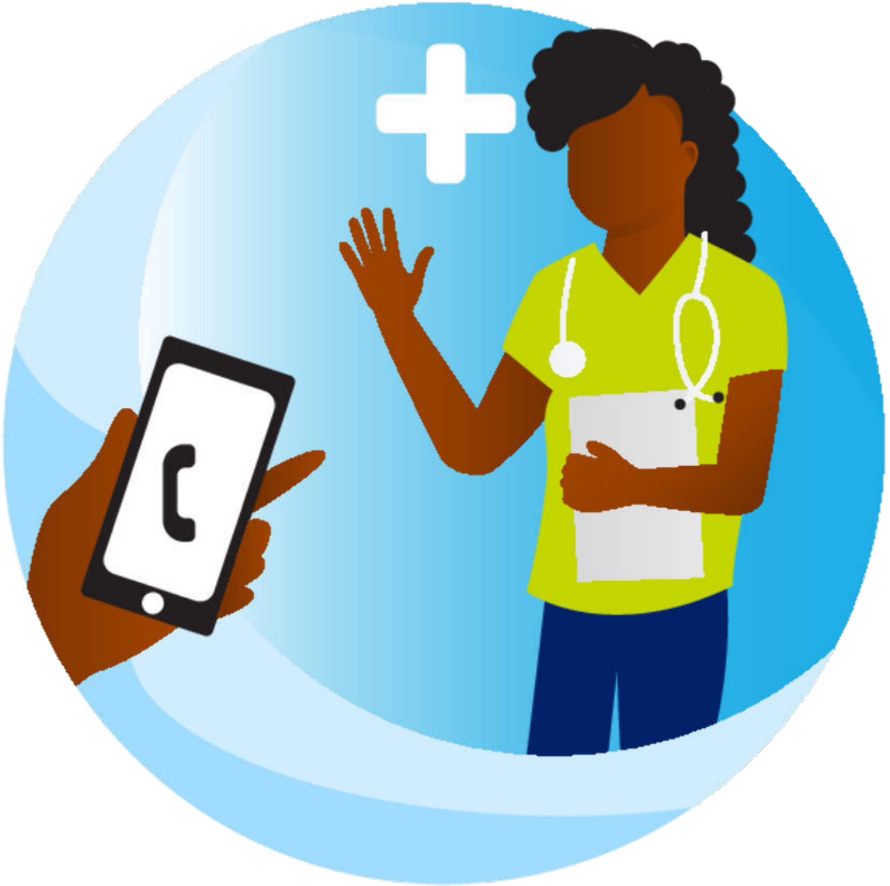

Prevention & HealthTech Study

August 2022 – Preliminary report for validation

Sub-study 2: Learning from successful business models

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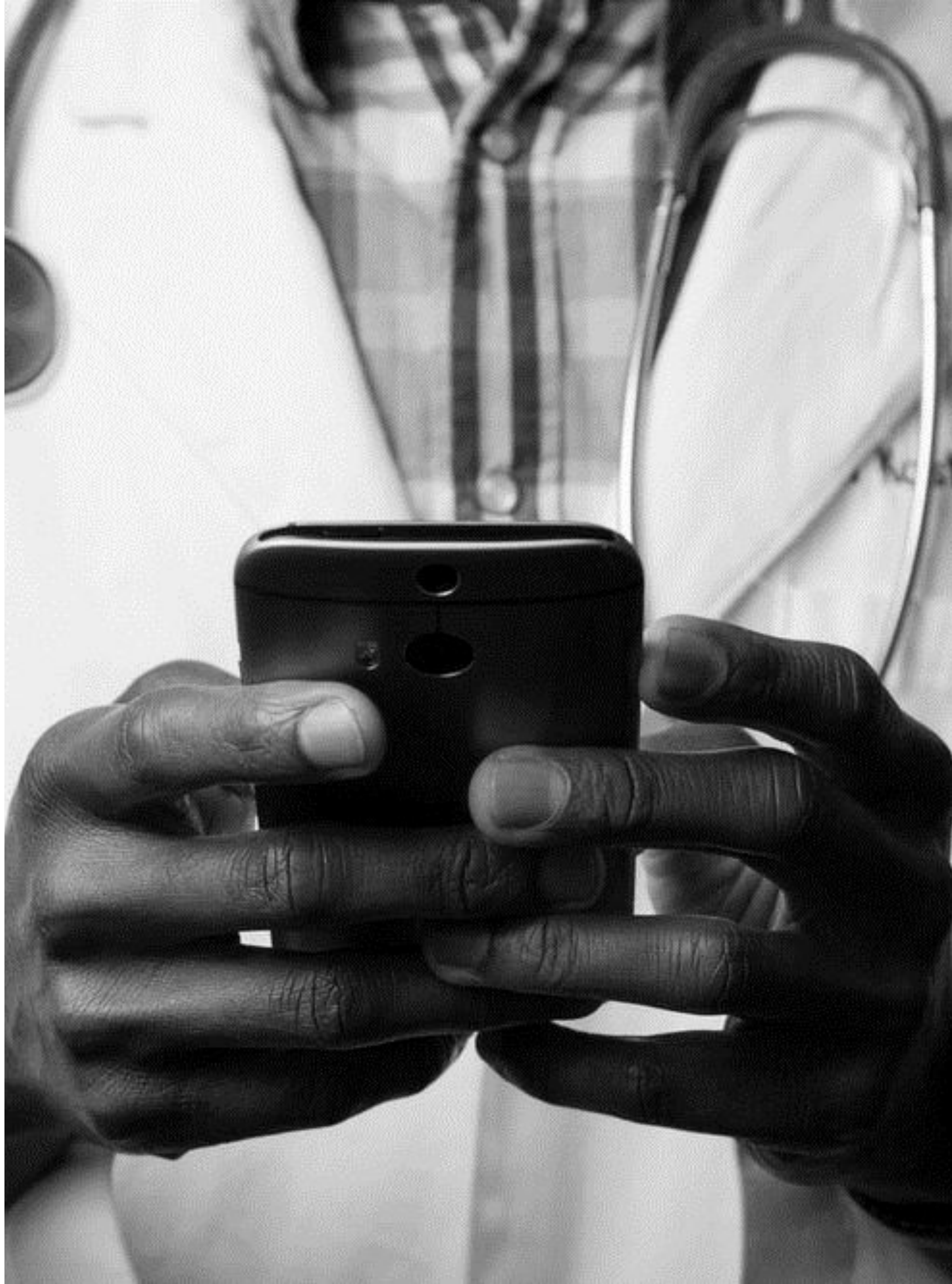
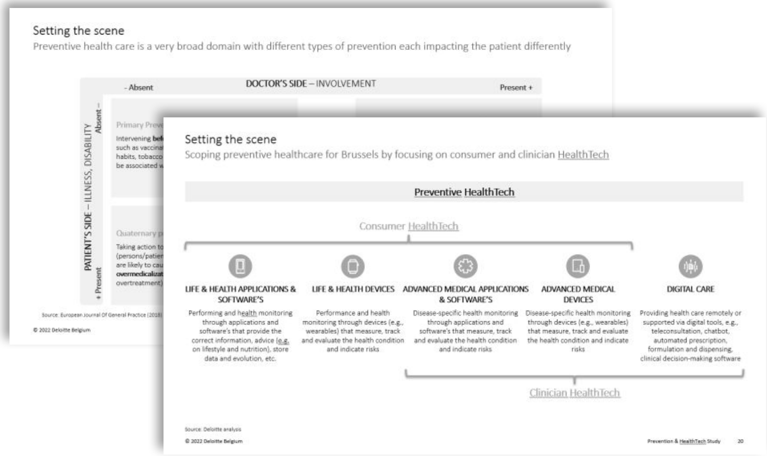


EXECUTIVE SUMMARY

Executive summary

In the first phase of the study, the market trends and opportunities were identified on the preventive care playing field in Belgium, Sweden & Germany, along with the key levers for a mature preventive care market

SETTING THE SCENE

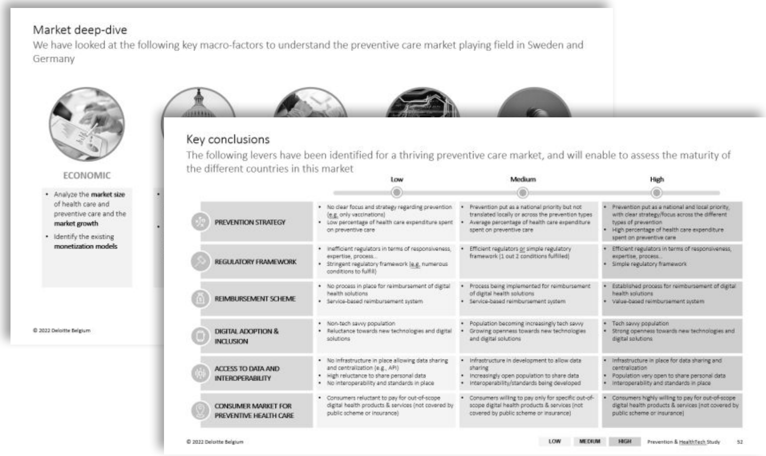


RESULTS

› Categorization of the **types of solutions** in the preventive care market

› Scoping of the preventive care market, with the decision to **focus the study on preventive HealthTech**

MARKET DEEP-DIVE



RESULTS

› **Analysis of the selected countries** (Belgium, Sweden, Germany) based on some key macro-factors: economic, political, sociological, technological, legal

› Identification of the **required levers for a mature preventive care market**

KEY CONCLUSIONS

RESULTS

› **Comparison of the selected countries** based on the identified levers

› **High level recommendations** on 1) what the government can do to promote prevention and 2) what the opportunities are for the private sector

Executive summary

The second phase of the study develops recommendations based on an assessment of the business model and key success factors of selected best in-class companies

Scope of the report

1 SUB-STUDY 1: INSPIRE

- Give overview of **market trends and opportunities** of the preventive health care market in Belgium, Sweden & Germany
- Identify the **levers for a mature preventive care market**
- Provide a **comparison between the selected countries** to assess the maturity of their preventive care market

2 SUB-STUDY 2: IMAGINE

- Identify and detail **~5 best-in-class companies** active in preventive health care of the respective chosen markets
- Assess their **business model proposition**
- Describe the **key success factors of their business models and lessons learned**
- Identify the **funding architecture** and **investment role of public agencies**

3 FINAL REPORT

- Consolidate the insights into a **final report and executive presentation** including:
  - **Market trends and opportunities** on the preventive care market – in general and in selected countries
  - Overview of **prioritized actionable business models**
  - Summary of **funding options**

Executive summary

Based on the theoretical Business Model Canvas and the research done in the study, we have identified 5 crucial areas that determine success of preventive HealthTech companies

Key Partners
The **external companies that will help the company to reach its goal** by e.g., funding the company, giving guidance, forming a strategic alliance with non-competitors…

Resources & activities
The **activities/tasks that need to be completed** to fulfill the company's business purpose and the **key resources** needed to carry out the key activities, e.g., talent, investment, equipment…

Value proposition
The unique solution (product/service) **of the company** for a problem faced by a customer segment, or that creates value for the customer segment.

Customer segments
The (groups of) **people that the company targets** and want to **sell its product/service to**, as well as the type of **relationship** the company want to establish with each of the customer segments.

PARTNERSHIPS
Collaborations with the **ecosystem players** to support (commercial) **development and implementation**

GO-TO-MARKET
Plan to **ensure market access** and to **deliver its unique value proposition** to customers and achieve competitive advantage (internal resources, target segments and characteristics, channels…)

Channels
How the company **communicates with and reaches out to their customers**, e.g., company website, social media, retail, distributor…

FUNDING
Private and public investment to support the activities of the company, through private investors, accelerators, public grants…

Cost Structure
The **costs** associated with **operating its business model**, e.g., development of product/software, R&D…

REGULATORY REQUIREMENTS
Regulatory information, processes and compliance including the requirements, rules, permits, regulation issued etc. to enter a market

Revenue Streams
The **sources from which a company generates money**, e.g., by selling their products and services to the customers/HCPs… and the potential **reimbursement scheme**

PRICING
Pricing model used by the company, and potential **reimbursement framework** in place (if applicable)

Executive summary

Based on the interviews and market research, the following success factors and challenges have been identified in the preventive care market

	PARTNERSHIPS	FUNDING	GO-TO-MARKET	PRICING	REGULATORY REQUIREMENTS
KEY SUCCESS FACTORS	• **Buy-in from KOLs** • **Health authority** promoting innovation (e.g., NHS) • Proximity of R&D partners enabling **fast implementation** • **Dedicated accelerator programs** for preventive HealthTech • **Data partnerships** for R&D	• Government with **innovation** in health care at the **top of its agenda** • Easy access to **public project funding, grants** • Access to **investors and accelerators** who understand health and tech	• **Adoption** amongst **HCPs** • Minimum level of **digital literacy and health literacy** among patients • **Commercial partners** with **network** in the field • **Talent** with the right expertise	• **Value-based pricing** model • **Simple and quick reimbursement** framework (e.g., DiGA)	• Easy **access to regulatory information** • **Simple and comprehensive** regulatory framework
KEY CHALLENGES	• **Access to** the right **corporates** and **start-ups** (e.g., MedTech focused) • **Access to health authorities** and **institutions** • **Resistance of KOLs** • Be able to easily **demonstrate the added value** of the solutions to **KOLs** • Finding **the right suppliers** (with required volume, expertise…) • Difficulty to **build a network** (e.g., hospitals, doctors, RIZIV)	• **Local funding** in Europe • Finding **investors with (preventive) HealthTech or MedTech knowledge** • **Limited number of private investors** in Belgium (compared to e.g., the US) • **Limited amount of funding/investment** in Belgium (compared to e.g., the US) • **Limited support from public** agencies/authorities	• **Conservative** nature of **health care system** (and HCPs) • Market requires **a lot of evidence** and **promotion** • **Health care** financing does not promote adoption of preventive solutions • **Access to patient** and **digital/ health literacy** • **Limited data** available from clinicians • **Regulatory** process (i.e., MDR) is **unfamiliar** to start-ups • **Direct marketing** not always allowed • **Access to skilled talent** (e.g., profiles with biomedical and technological experience)	• **Mismatch between existing type of financing** in health care sector (fee-for-service) and in prevention (value-based) • Hard to identify the **right pricing point** (across countries) and **validate value of preventive solutions** • **Reimbursement** process is **lengthy, uncertain** and **fragmented** in Europe • **Lower reimbursement tariffs** in Europe compared to the US • **Limited reimbursement** existing for **hardware** and **more advanced products** (e.g., only covers low and medium risk of MDR classification)	• **Fragmentation of prevention** across different regulatory bodies and levels in Europe • **Access to right expertise** to successfully apply/comply with regulations • **Access to local information** (i.e., different language(s) and applications)

Executive summary

Public authorities, including Lifetech.brussels, can play an important role in the development of the preventive care market and success of HealthTech companies

HOW PUBLIC AUTHORITIES CAN MAKE A DIFFERENCE

PARTNERSHIPS | **FUNDING** | **GO-TO-MARKET** | **PRICING** | **REGULATORY REQUIREMENTS**

SUPPORT FROM DEVELOPMENT TO COMMERCIALIZATION

Funding:
- Provide guidance in funding and **grant application processes** (including reporting, follow-up)

Go-to-market:
- Provide a **platform/initiative to effectively** and **efficiently run trials** in Brussels
- Provide guidance on specificities in entering **different EU countries**

Pricing:
- Provide guidance (center of excellence) on **reimbursement frameworks** for preventive HealthTech

Regulatory requirements:
- Provide guidance on **regulatory and legal aspects** (market analysis, market access, roadmap)
- Develop or give access to **center of excellence** (e.g., MDR)

CONNECT THE ECOSYSTEM OF PREVENTIVE CARE

Partnerships:
- Create a platform/initiative that **connects start-ups and different stakeholders** of the ecosystem in order to foster (public-private) collaboration (e.g., social impact bonds initiatives)
- Develop (MedTech) **network for early-stage** start-ups and scale-ups to ensure knowledge sharing

Funding:
- Connect with **investors that have (preventive) HealthTech experience** (e.g., Earlybird, Eightroads, Rockhealth)
- Setup specific **preventive HealthTech incubation program** that also provides access to other relevant int'l programs (e.g., Plug and Play Roche)
- **Access to corporate partners** for development projects or commercialization

CONNECT PRIVATE ORGANIZATIONS AND TALENT

- Develop **talent agency** connecting students and young professionals to start-ups

WORK ON THE BASIC DETERMINANTS OF HEALTH

- Improve **digital inclusion and health literacy for health care** (i.e., elderly)
- Leverage the **diversity of Brussels** (e.g., access to minority groups)

FOSTER ADOPTION

- Raise **awareness across the population** and encourage **adoption** of new preventive solutions **amongst HCPs**

Executive summary

HealthTech companies, active in the preventive care market, can respond to the growing market by leveraging the right partners and investors

HOW COMPANIES CAN SET THEMSELVES UP FOR SUCCESS

PARTNERSHIPS

LEVERAGE STRONG COLLABORATION WITH HCPS

- Demonstrate the impact of the preventive solutions and the **benefits for HCPs** through 'champions'

BUILD A NETWORK OF COMMERCIAL PARTNERS

- Consider commercial partners with an existing **distributor network with strong expertise** in the field to act as an accelerator for go-to-market

GO BEYOND HEALTHCARE PROVIDERS AND PAYERS

- HealthTech providers should also **consider** to target and/or **partner with private insurers** and **also companies (B2B)** to gain access to a larger pool of users

FUNDING

INVEST IN THE RIGHT PARTNERSHIPS

- Look for investors and partners who know both **technology** and **health care**

GO-TO-MARKET

DEVELOP AN AGILE SOLUTION

- **Radical focus on user-friendliness** to improve digital inclusion
- **Focus on interoperability**, allowing your solution to work with or even be integrated as-a-service into other HealthTech platforms / solutions

RAISE AWARENESS ON PREVENTIVE SOLUTIONS

- Find local public partners who promote **prevention** and the existing solutions, along with the (long-term) benefits
- Be **transparent** about the company's **use of (personal) data** in your consent mgmt.

CREATE REWARD MECHANISMS TO FOSTER ADOPTION

- Motivate users by rewarding them with **short feedback and insights**
- Combine the administrative or day-to-day monitoring with **gamification** to maintain the consumer's attention

PRICING

BALANCE VALUE-BASED PRICING VS ALTERNATIVES

- **Avoid lowering your price-point to 'buy the market'** as it will reflect on consumer perception of quality and value
- **Value your solutions based on alternatives** it replaces, but within an acceptable range

REGULATORY REQUIREMENTS

FIND SPECIFIC HIGH-QUALITY ACCELERATOR PROGRAMS

- Look for accelerator programs that are of high quality (e.g., with proven track record) and **dedicated to your field** as the public or private partners can bring **complementary expertise** and guidance to successfully go through the regulatory process

METHODOLOGY

Methodology

The second phase of the study consisted of three main steps, from identifying best-in-class companies to developing recommendations

STEP 1: IDENTIFICATION OF 'BEST-IN-CLASS' COMPANIES

- **Long list of potential best-in-class companies** based on investment and revenues, leveraging CrunchBase database
- **Additional desk research** to identify the companies active in preventive care
- **Triangulation** using other sources (qualitative information) to identify successful/growing HealthTech companies

See detailed methodology on page 13

STEP 2: ANALYSIS OF BUSINESS MODELS

- **Desk research** to understand the business model of the selected companies, i.e., their value proposition, market approach, cost and revenue streams, funding and pricing…
- **Interviews with stakeholders** (8) of the companies to identify key challenges and success factors
- **Interviews with patients and health care practitioners** (HCPs) (4) within the therapeutic areas of the companies

See overview of interviewees in appendix

STEP 3: RECOMMENDATIONS

- Elaboration of recommendations for **regional authorities/government** – how can they develop the preventive care ecosystem?
- Elaboration of recommendations for **Brussels-based companies** - what should they do to become a successful company?

Methodology

We have combined desk research, qualitative/quantitative analysis and interviews with companies and patients to build a clear understanding of the success factors and challenges in the market

Quantitative desk research	Qualitative desk research	Interviews
- Funding raised - Number of investors - Sales - Revenue range - …	- Partnerships of the company - Value proposition - Communication channels - Connection towards customers - …	- Insights on the company's business model - Key challenges - Key success factors - Lessons learned - …

Interviews

indigo, CardioSecur, Maron Trachte, moveUP, PRECURE, *Diabetic patient*, *General practitioners*, CardiacSense, FibriCheck, Gabi, GWA Hygiene, Tiro.health, BlueCall, *Cardiac patient*

Methodology

The selection of best-in-class companies consisted of two main steps

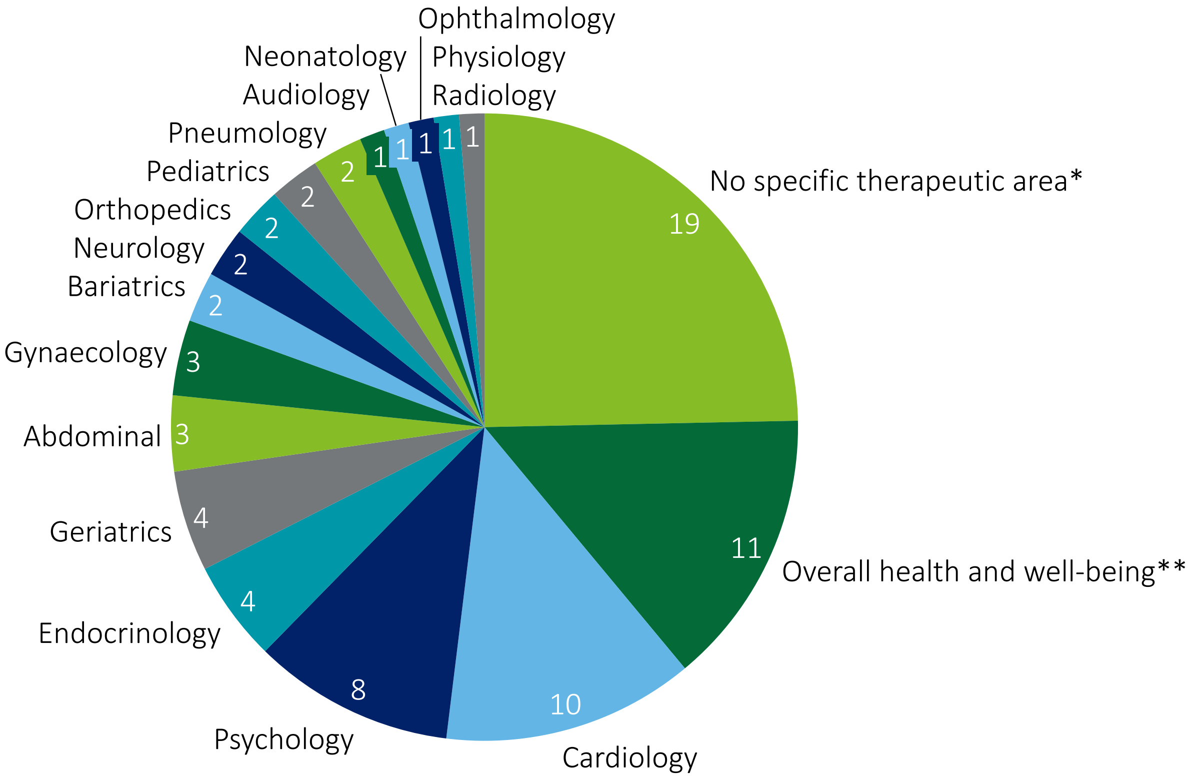
STEP	CRITERIA	OUTCOME
STEP 1: LONG LIST OF POTENTIAL COMPANIES	• Creation of a long list of potential best-in-class companies based on the following criteria: **Number of employees**: 1-50 **Total funding raised**: > $ 1M **Estimated revenue**: $ 1M - $ 10M **Type of company**: For profit **Industry**: Health Care, Health Diagnostics, Personal Health, mHealth, Home Health Care, Alternative Medicine, Assisted Living, Assistive Technology, Biopharma, Child Care, Cosmetic, Surgery, Diabetes, Dietary, Supplements, Elder Care, Electronic Health Record, Emergency Medicine, Fertility, Genetics, Medical Device, Nursing and Residential Care, Nutraceutical, Nutrition, Outpatient Care, Psychology, Pharmaceutical, Rehabilitation, Therapeutics, Wellness, …	Sweden - 64 companies Germany - 63 companies Belgium - 36 companies Israel - 60 companies
STEP 2: SHORT LIST	• Desk research to identify the **companies active in preventive care** • **Triangulation using other sources** on the most successful HealthTech start-ups/scale-ups in the different markets	Belgium - 17 companies Germany - 28 companies Sweden - 17 companies Israel - 9 companies
STEP 3: INTERVIEWS	• **Selection of the best-in-class companies** based on funding and therapeutic area to be interviewed	**Belgium - 4 companies** **Germany - 2 companies** **Sweden - 1 company** **Israel - 1 company**

COMPANY ANALYSIS

Company analysis

Of our short list of companies active in the field of preventive care, a large number offer cardiology solutions

Distribution of (shortlisted) companies per therapeutic area



*No specific therapeutic area e.g., patient management tools, tele-consultation…
**Overall health and well-being include vitamins, food supplements, healthy habits…

Observations

Based on interviews with companies, HCPs and patients

- **Adoption of preventive HealthTech solutions in general practice is low,** main applications are in cardiology (specialist-led), psychology (emerging) and non-disease specific applications for diseases mgmt. (GP-led e.g., therapy compliance)
- Patients are **generally reluctant to pay for new solutions**, unless clear added value, user friendly and/or reimbursed. **Younger patient populations are very open to test** new (preventive) HealthTech solutions
- **Solutions for physicians** (e.g. ECG) are **more often covered by reimbursement frameworks**, while solutions for patients are usually not (current frameworks do not foresee these types of solutions yet)
- In terms of **cardiology solutions**, we observe **monitoring devices** (watches, wristband, adhesive electrodes…) **usually connected to a software/application** available to the customer and the physician – potentially the family
- These solutions allow more and more **'at home monitoring'**, enabled by consumer wearables and medical devices
- An important challenge for companies developing pure medical devices is to **differentiate themselves from more basic ('gadget') solutions** (e.g., Apple Watch) – in order to do that, they leverage more specific equipment such as sensors with higher sensitivity

Company analysis

We observe three different types of funding models

DILUTIVE	NON-DILUTIVE	
PRIVATE INVESTORS	**PUBLIC FUNDING**	**COMMERCIAL PARTNERS**
ROCK HEALTH, Episode 1, EIGHT ROADS, EARLYBIRD, IMPACT (SOCIAL, LOCAL & GREEN INVESTING), CAPRICORN INVESTMENTGROUP …	Service Public Fédéral FINANCES / Federale Overheidsdienst FINANCIEN, AGENTSCHAP INNOVEREN & ONDERNEMEN, Vlaanderen is ondernemen, innoviris.brussels we fund your future, Wallonie recherche SPW	TERUMO, Medtronic, Cochlear, janssen, PHILIPS, epihunter, Baxter …

- It is crucial to find investors with **not only tech but also preventive MedTech and HealthTech expertise** since this requires a **long-term vision** and **expected returns**

- Public funding acts as a **market validator for innovation** and is often an **accelerator to receive private funding**, especially in the early stages
- Public project funding is crucial to **engage in development partnerships with companies**

- Commercial partnerships represent another important source of funding, for example through **milestone payments**

Company analysis

End-user perspective

Patients' perspective

<u>Willingness to use</u>

- **Young patients tend to be more open-minded** towards (preventive) HealthTech solutions
- **The level of technology** in treating patients **varies greatly** between doctors
- The **opportunity to test out a new product** can have **persuasive effects** on patients

<u>Conditions to use</u>

- **Physician encouragement is crucial for the adoption** of a new preventive HealthTech solution
- **Software products** that can be linked to **existing (familiar) products** are preferable
- **Patients are reluctant to pay for new solutions** without reimbursement, unless there is significant evidence of added value compared to incumbent products

Health care practitioners' perspective

<u>Adoption of HealthTech</u>

- **Limited adoption of HealthTech solutions** (especially software) amongst GPs
- Adoption in general practice depends on
  1. **Product pilots to familiarize** physicians with products and show added value in practice;
  2. **Endorsement from specialists** (e.g., Cardiology);
  3. **Integration of products** within central and regional **programs** (e.g., screening)

<u>Conditions for application</u>

- **User experience** i.e., **ease of use** also for older and less digital literate patients (e.g., treatment adherence)
- **Interoperability** i.e., **ease of integration** with **electronic patient records** and **other** administrative and medical **tools/devices** used in practice (e.g., offer software-as-a-service)

Overview of selected best-in-class companies

We have interviewed a series of companies active in preventive care, across different therapeutic areas in the selected markets

Company	Description	Country	Funding	Founding Year	Revenue	Type(s) of Prevention	Therapeutic Area(s)
indigo	› **Indigo** develops the world's first invisible sensor for people living with diabetes to address their need for accurate glucose monitoring with improved user experience		€ 45M	2016	$1M - $10M	› Tertiary › Quaternary	› Endocrinology
FibriCheck	› **Fibricheck** is a medically certified screening and monitoring application on prescription for the detection of irregular heart rhythms, including atrial fibrillation		$ 12.8M	2014	$1M - $10M	› Tertiary › Quaternary	› Cardiology
Gabi	› **Gabi SmartCare** is an innovative, patient-centric digital solution with personalized data and predictions to improve children's care (better monitoring, diagnosis, and prevention)		€ 3.7M	2017	$1M - $10M	› Secondary › Tertiary	› Pediatrics
moveUP	› **MoveUP** develops and commercializes digital therapeutics solutions which uses continuously collected data to directly personalize the treatment of the patient		€ 3.6M	2015	Less than $1M	› Tertiary › Quaternary	› Orthopedics
CardioSecur	› **CardioSecur** creates and sells products and services for mobile health with focus on instant cardiac monitoring		€ 7.5M	2008	$1M - $10M	› Secondary › Tertiary	› Cardiology
GWA Hygiene	› **GWA Hygiene** is a digital assistant that monitors the hand hygiene behavior and prevents hospital infections		$ 2.8M	2015	$1M - $10M	› Primary	› Infectious diseases
BlueCall	› **Bluecall** developed a digital empowerment toolkit for organizations, HR and leaders to manage their employee's mental wellbeing		$ 1.5M	2016	$1M - $10M	› Primary › Secondary	› Psychology
CardiacSense	› **CardiacSense** enables continuous, long term, ambulatory and non-invasive monitoring of life critical functions which enables accurate real time diagnostics of various medical conditions		$ 17.7M	2009	$1M - $10M	› Secondary › Tertiary › Quaternary	› Cardiology › Bariatrics › Geriatrics…

*MoveUP was included in the study to ensure the participation of a Brussels-based company

Overview of key success factors and key challenges

Based on the interviews and market research, the following success factors and challenges have been identified for preventive HealthTech companies

Key Partners | Resources & activities | Value proposition | Customer segments | Channels | Cost Structure | Revenue Streams

FUNDING

- Success factor: Access to **governmental support** and (public/private) **investors/accelerators** who understand health and tech
- Challenge: **Limited number** of Belgian **investors** (with preventive HealthTech knowledge) and limited amount of **funding**

PARTNERSHIPS

- Success factor: **Access to the preventive ecosystem** (R&D partners, accelerator programs, KOLs…)
- Success factor: **Authorities** promoting prevention and innovation
- Challenge: Difficult to **connect** with the **right stakeholders in preventive care and build a network**

GO-TO-MARKET

- Success factor: **Adoption by HCPs** and a sufficient level of **digital/health literacy** for patients
- Success factor: **Commercial partners** with the right expertise and network
- Challenge: **Conservative** and risk-averse **health care system** and **HCPs**
- Challenge: Limited **access to skilled talent** and to relevant **market data**

REGULATORY REQUIREMENTS

- Success factor: **Simple and comprehensive** regulatory framework, with easy **access to regulatory information**
- Challenge: Access to the **right expertise** and to **local information** on the different regulatory bodies and levels across Europe

PRICING

- Success factor: **Value-based** pricing model with **simple reimbursement process**
- Challenge: **Complex** and lengthy **reimbursement** process (fragmented in Europe)
- Challenge: Difficulty to **justify value of preventive solutions**, especially in the current **fee-for-service financing model**

Identified challenges

Identified success factors

Deep-dive per company – Indigo

Indigo, as a MedTech scale-up in clinical stage, is facing certain challenges, including access to large investors and to skilled talent, as well as the complex reimbursement process for its solution

Key Partners

- Public investors (EU, VLAIO)
- Universities (Ghent University)
- Private investors/accelerators (Fund+, Ackermans & Van Haaren, Thuja Capital, PMV, Capricorn Partners, imec.xpand, Qbic)
- …

! Lack of **network of MedTech-focused companies**

! Challenging to **get access to large investor groups.** Belgium is **a small market,** with limited **number of MedTech investors** and limited **amount of funding/investment**

Resources & activities

- Total funding amount: € 45M
- Number of investors: 14
- Number of employees: 45 (LinkedIn)
- The diabetes management is transformed by exploiting ground-breaking nanophotonics technology

! Challenging to find **talent with scientific and business experience** (go-to-market) in medical devices

! Challenging to find **the right (technology) suppliers** (e.g., start-ups/scale-ups have low volumes)

Value proposition

- A next generation solution for continuous glucose monitoring (CGM) – called a continuous multi-metabolite monitoring system (CMM)
- It provides people living with diabetes access to information on their glucose and other metabolite levels at any given time, without requiring them to wear an external device on their body
- Inserted under the skin, the CMM sensor is invisible to the naked eye and will connect securely and wirelessly to mobile devices via Bluetooth

Channels

- Health care practitioners
- Hospitals
- Online (site)

Customer segments

- Diabetic patients who want to monitor their glucose monitoring continuously (B2C)
- Family and caregivers of diabetic patients who want to follow-up the glucose monitoring continuously (B2C)
- Endocrinologists and other HCPs in the need for remote monitoring of their patients (B2B)
- Secondary market: therapeutic areas that could benefit the continuous monitoring of metabolite levels (e.g., nephrology, cardiology)

Cost Structure

- Main costs are linked to the development of the technology

Revenue Streams

- No revenue stream yet - estimated commercialization year is 2025
- Future sales of the medical device to health care practitioners and hospitals
- Long process to get reimbursement in Europe (e.g., the US have reimbursement in place for implantations and explantations, but not all European countries have that in place and lower reimbursement tariffs in Europe)

! **Long and complex reimbursement process** since every **aspect of the product** needs to be **reimbursed separately** (e.g., implantations and explantations)

Note: Indigo is an early-stage company, currently in the clinical stage
Source: www.crunchbase.com ; www.indigomed.com

! Identified challenges
Identified success factors

FibriCheck

Deep-dive per company - FibriCheck

FibriCheck has defined its biggest challenges around building the right partnerships and having access to the right resources

Key Partners

- Public investors (Flanders, European Regional Development Fund, Greater London Authority)
- Private investors/ accelerators (Imec, BlueHealth Innovation Center, Digital-Health London Accelerator)
- Public health care organizations (NHS)
- Private health care communities (EIT Health, EIT Digital)
- …

! Challenging to find the **investors with the right Medtech/health care knowledge** (differences between HealthTech and Tech investors), e.g., Earlybird, Eightroads, Rockhealth

! Challenging to **get access to corporate companies and other start-ups** to learn from

Resources & activities

- Total funding amount: $12,.8M
- Number of investors: 3
- Number of employees: 27
- Gathers data via the light sensors of a smartphone or smartwatch

! Challenging to find the **right resources**

! Challenging **to get access to the ecosystem and KOL's to perform pilot periods**

Value proposition

- A medically certified screening and monitoring application on prescription for the detection of irregular heart rhythms, including atrial fibrillation
- A software-only solution that only requires the user to place his/her finger on the camera of the smartphone or on the light sensors of a smartwatch to measure the cardiac rhythm anywhere and anytime
- All the information is automatically shared with a medical professional in order to get a faster diagnosis, resulting in an adequate treatment plan

Channels

- Health care practitioners (cardiologists)
- Online (site) and in Apple store, Google Play

Customer segments

- Cardiac patients who want to monitor their health (B2C)
- Cardiologists in the need for remote monitoring of their patients (B2B)
- Package service in the application (B2B2C)

! B2B is challenging due to the **resistance of the KOL's** and the **lagging encouragement** from HCPs

Cost Structure

- Main costs are linked to the development of the software and sensors

Revenue Streams

- Sales of Quompium* in 2020: € 2.25M
- Sales of application to customers
- Two level of services: €6.99/month or premium €24.99/month
- Part of level M2 of RIZIV's mHealth validation pyramid, meaning the app is not yet reimbursed but meets the high ITC requirements set by beMedTech, e.g., Data Protection

! Challenging to get reimbursed because the **MDR classification of mHealth (and DiGA) goes up until class IIa** – medium risk and FibriCheck is level IIb

Source: www.crunchbase.com ; www.dnbhoovers.com ; www.fibricheck.com

*Quompium has two products: FibriCheck and Extra Horizon. FibriCheck makes use of the Extra Horizon solution, which is a scalable medical backend solution that offers faster time-to-market and time-to-regulatory for third parties

! Identified challenges

Identified success factors

Deep-dive per company – Gabi SmartCare

In its efforts to transform pediatric care, Gabi SmartCare faces several challenges, including the limited access to data on the pediatric market and the limited adoption from health care practitioners

Key Partners

- Public investors/accelerators (Blue Knight – initiative between BARDA and J&J Innovation, Digital Attraxion, DGO 6)
- Hospitals (Children's National Hospital in the US, HUDERF and ISPPC CHU de Charleroi)
- Private health care organisations/communities (Biopôle, EVOLUTiON Medtec, Matrix requirements)
- Pharmaceutical companies
- …

Resources & activities

- Total funding amount: €3,7M
- Number of investors: 3
- Number of employees: 7
- The Gabi band, worn on the upper-arm, monitors the child's main vital signs
- Gabi analytics is an AI-powered, cloud-based platform that processes and structures the collected data and detects health events

! Challenging to find **human resources/talent** with the right background

Value proposition

- Aims for better monitoring, diagnosis, and prevention in pediatric care
- The Gabi band is a wearable device that collects data
- Gabi analytics gives HPCs a real-time, personalized and predictive health assessment report
- The Gabi Monitor App sends notifications based on a customized alert protocol and allows parents to share additional information with their physician

! Very limited access to **data on the pediatric market**

Channels

- Health care practitioners (pediatrics)

! **HCPs more conservative** than in the US, hindering adoption

Customer segments

- Parents who want to monitor their children's health (B2C)
- Pediatrics in the need for remote monitoring of their patients (B2B)
- Researchers in the need for remote monitoring of patients for research purposes (B2B)

Cost Structure

- Costs linked to their technology R&D and the building of wearables

Revenue Streams

- Sales in 2020: € 266.45K
- Currently obtaining medical certification and preparing commercial launch in Europe and the US
- Sales of the cloud-based Gabi platform to health care practitioners
- Sales of the Gabi Baby Band to customers/health care practitioners

! Challenging to **find the right pricing point** based on the customers' willingness to pay

! Challenging to **measure and prove the impact of prevention**

! Limited reimbursement frameworks for **hardware products** (compared to e.g., software solutions), and **differences per country**

Source: www.crunchbase.com ; www.dnbhoovers.com ; www.gabismartcare.com

! Identified challenges

Identified success factors

Deep-dive per company - MoveUP

Although MoveUP has reached the M3- level of reimbursement in Belgium, the experienced process presents different obstacles

Key Partners

- Sickness funds (Partena, Helan)
- Insurance companies (Ethias)
- Public investors (S.R.I.B. - G.I.M.B., European Regional Development Fund)
- Hospitals (CZ Nederland)
- Public health care associations (Lifetech.brussels)
- Private health care communities (MedTech Flanders, EIT Health)
- …

! Challenging to **build a network within the ecosystem** (e.g., hospital, doctors, RIZIV)

Resources & activities

- Total funding amount: €3,7M
- Number of investors: 5
- Number of employees: 7
- Gathers data via activity meter and application

Value proposition

- Comprehensive digital solution that offers personalized monitoring remotely through an activity meter (wearable) and application, before/after surgery
- Allows for easier and more efficient rehabilitation to prevent complications, as well as increased patient involvement in the recovery process
- Provides correct information at the right time and offers low-threshold contact with physician (7/7 availability)
- Personalized exercise schedule and follow-up by orthopedic surgeon or physiotherapist

Channels

- Health care practitioners (orthopedic surgeons and physiotherapists)
- Online (site) and in Apple store, Google Play

Customer segments

- Patients who are to undergo or have undergone orthopedic surgery (B2C)
- Orthopedic surgeons and physiotherapists in the need for remote monitoring of their patients (B2B)
- Identifying patients needs through patient-reported outcomes measures (PROMs)

! Difficult to **directly reach customers**, due to **limited open-mindedness** of the Belgian market

Cost Structure

- Main costs linked to the development of wearables

Revenue Streams

- Sales in 2020: around € 369K
- Revenue generated through sales of applications to health care practitioners, and warranty for the activity tracker that is paid by the customer (when device is not returned)
- MoveUP is part of the M3- level on mHealth validation pyramid - in the process of providing social-economic value and temporarily financed by NIHDI

! **Complex reimbursement systems in Europe and Belgium** – 6 years for MoveUP to reach the M3- level (Belgian market still based on fee-for-service)

! **Experienced difficulties during the reimbursement process in Belgium**

> Difficulty to measure outcomes/value of prevention
> Conservative measures used today for HCPs (e.g., survival rate vs PREMS/PROMS, satisfaction rate)
> The product can't be sold during the trial period, which takes a long time
> The collaboration with NIHDI is not easy which can lead to intense discussions

Source: www.crunchbase.com ; www.dnbhoovers.com

! Identified challenges
Identified success factors

Deep-dive per company – CardioSecur

CardioSecur enables patients to perform their own ECG and provides physicians with reliable data; however, its adoption strongly depends on the buy-in of HCPs and the reimbursement framework in place

Key Partners

- Hospitals (Charité, Helios Klinik Wuppertal, Rhön-Klinikum, Staufenklinikum Schwäbisch Gmünd, Universitätsklinikum Heidelberg)
- Universities (University of Applied Sciences Fliedner in Düsseldorf)
- Physicians and partner practices
- Health Insurers (AXA, REBECA Health Care GmbH, Novitas BKK, BKK Atlas Ahlmann)
- Corporate Partners (Center for Telemedicine in Bad Kissingen (ZTM), Bambus Life, Machtfit)
- Soccer team (SV Darmstadt 1898 e.V.)

Resources & activities

- Total funding amount: $7.5M
- Number of investors: 5
- Number of employees: 10
- Gathers personalized ECG-data using 4 adhesive electrodes attached to the chest

Difficult to get **reimbursement** for the ECG patient solution as regulation doesn't exist for this type of solution

Value proposition

- Professional ECG system that offers remote cardiac monitoring through adhesive electrodes and is implemented in a personalized application, CardioSecur Active
- The data can be connected to a physician through the physician's application, CardioSecur Pro (data platform to facilitate the physician's diagnosis)
- The ECG report, including direct feedback, can conveniently and securely be viewed and shared at any time
- CardioSecur measures 15 leads (viewpoints) of the heart, while a standard ECG only measures 12
- It records complex arrhythmias and life-threatening circulation disturbances

Channels

- Health care practitioners (cardiologists, general practitioners, on-call physicians)
- Online (site) and in Apple store, Google Play

Customer segments

- Cardiac patients who want to monitor their health after having a heart attack, arrhythmias or unclear symptoms (B2C)
- People who want to monitor their health to keep their cardiac risk in check (B2C)
- Cardiologists, general practitioners and on-call physicians in the need for remote monitoring of their patients (B2B)

Difficult to prove the added value of **CardioSecur compared to 'gadget' solutions** (e.g., Apple watch)

Risk-averse physicians towards the adoption of new technologies

Cost Structure

- Main costs linked to the development of application and electrodes
- Pricing for end customers based on monthly subscription including new disposable electrodes every 6 months or by one-off purchases; pricing for physicians based on one-time purchase of the CardioSecur Pro and single purchases for the disposable electrodes

Revenue Streams

- Sales in 2020: € 0.87M
- Sales of the application CardioSecur Active and adhesive electrodes to customers
- Sales of the application CardioSecur Pro to health care practitioners
- Sales of the Ambu BlueSensor P/Q/R Disposable Electrodes to health care practitioners
- Sales of the CardioSecur Protection Case to customers/health care practitioners, used to store the CardioSecur ECG cable and disposable electrodes

Complexity to be covered (reimbursed) by health insurers in Germany due to the difficulty to measure the benefits of prevention

Challenging to set a price due to **different levels of willingness to pay** amongst countries

Source: www.crunchbase.com ; www.dnbhoovers.com ; www.cardiosecur.com

Identified challenges

Identified success factors

Deep-dive per company – GWA Hygiene

GWA Hygiene develops assistants that monitor the hand hygiene behavior and prevent hospital infections

Key Partners

- Investors (MIG Verwaltungs AG and High-Tech Gründerfonds, Dräger)

Resources & activities

- Total funding amount: $2.8M
- Number of investors: 3
- Number of employees: 24 (LinkedIn)

Value proposition

- Digital assistant that monitors the hand hygiene behavior and prevents hospital infections
- A system of sensors, called "NosoEx", will check for each professional group how well hand hygiene is applied through anonymous recording by simply walking by, so that adjustments can be made where necessary
- Data-based feedback in the form of evaluations and reports will get to the ward staff via encrypted connection to the NosoEx data
- It provides reusable infrastructure for other applications and NosoEx has a flexible sensor module for various dispensers

Channels

- Hospitals (doctors, management, board…)

Customer segments

- Hospitals willing to optimize the use of hand sanitizers and prevent hospital infections (B2C)

! German hospital landscape is still in the early stages of digitalization, and user friendliness very limited

Cost Structure

- Main costs are linked to (further) product development and market penetration

Revenue Streams

- Sales of NosoEx to hospitals
- Sales of infrastructure (densor module) to hospitals
- Upgrading existing infrastructure and work processes with NosoEx to hospitals

Source: www.crunchbase.com ; www.dnbhoovers.com ;

! Identified challenges
Identified success factors

BlueCall

Deep-dive per company – BlueCall

Most partnerships BlueCall is helping organizations to manage their employee's mental wellbeing to reinforce self development

Key Partners

- Company clients through e.g., campaigns and other collaborations (Rituals, KICKS, Samsung)
- Investors (Soläng Invest, PunktB,Sting)

Resources & activities

- Total funding amount: $1.5M
- Number of investors: 8
- Number of employees: 33 (LinkedIn)

! In the light of the COVID crisis, BlueCall had to **adapt its tools and techniques** to enable managers/ HR **to help employees remotely**

Value proposition

- A digital solution for organizations to manage their employee's mental wellbeing to reinforce self development to individual's specific needs
- Through digital anonymous coaching sessions with professional therapists, customized after the employees' individual needs
- Easily accessible help, Monday to Sunday between 07-23, and guaranteed contact with a therapist within 24 hours
- Digital tools for self-help, like activities, articles, trainings and daily check-ins in the app increase mental health knowledge and lead to positive behavioral changes
- Digital tools for managers and HR, to help them improve their leadership and get better at supporting their employees through the ups and downs

Channels

- Company leaders
- Online (site) and in Apple store, Google Play

Customer segments

- Companies willing to invest in the mental health of their employees (B2B)
- Insurance companies that want to offer their clients digital mental coaching (B2B)

! With the economic impact of the COVID crisis, companies **down-prioritized the issue of mental health** or are less able to act on it

! **Difficult to show the value** to clients because it is in the long term

Cost Structure

- Main costs are linked to development of the software
- Pricing for end customers based on yearly subscription (price negotiated) including certain number of free therapeutic sessions and access to all facilities of the application

Revenue Streams

- Application itself is free
- A certain number of therapeutic sessions per year for employees/clients are paid by the organization, price agreed upon with BlueCall
- An extra 45-minute session for employees/clients or a session for people with no access to free sessions costs 495 SEK (~€ 47,65)
- Revenues between 5-8 million

Source: www.crunchbase.com ; www.dnbhoovers.com ; www.bluecallapp.com

! Identified challenges

Identified success factors

Deep-dive per company – CardiacSense

CardiacSense has just launched their Medical Watch and faces the challenge of differentiating itself from more basic watches on the market

Key Partners

- Private investors
- Angel investors
- Commercial partners (*see distributors in Channels*)

Channels

- Distributors (e.g., Arseus Medical in Belgium, Gamida in Israel) that are targeting/working with physicians, hospitals, insurers and researchers, direct customers (online)

Resources & activities

- Total funding amount: $17.7M
- Number of investors: 2
- Number of employees: 35
- The technology is supported by the combination of the traditional electrocardiogram (ECG) verification and state-of-the-art PPG technology (photoplethysmography)

Show the added value of this purely medical watch, compared to more basic watches in the market

Value proposition

- The CardiacSense Medical Watch is an all-in-one device that detects heart arrhythmias and continuously monitors all the vital signs
- It can be used to detect Atrial Fibrillation, heart attack, sleep apnea, gait patterns to predict increased fall risk, and to monitor chronic diseases
- The CardiacSense Wristband is specially designed for in-hospital use, eliminating the tangle of tubes, wires, cables and cords
- The CardiacSense chip enables other manufacturers to create their own medical device that measures the vital signs by implementing the chip
- The system also contains software in the form of an external application and a platform linked to the CardiacSense cloud services. These enable users to stream data in real time, store and share measurement histories, request reports of analytical health data, and leverage integration with third-party applications, control centers and telehealth services
- The physician has access to all the raw data that is stored in the cloud application and gets a real-time notification when the watch detects a problem
- Alignment with health care standards to ensure reliability and accuracy

Customer segments

- Consumers and health and fitness enthusiasts who want to monitor their vital sign to keep their health in check (B2C)
- Patients who are in the need of medical grade vital sign tracking during rehabilitation at home, chronic diseases, fall detection… (B2C)
- Physicians and the medical community in the need for remote monitoring of their patients (B2B)

Cost Structure

- CardiacSense is part of the M1- level on mHealth validation pyramid, is a CE-certified medical device and is currently in the advanced stages of FDA certification
- Received financial and non-financial governmental support due to the strong innovative ecosystem in Israel (e.g., Office of the Chief Scientist)

Revenue Streams

- No revenue stream yet - start commercialization in July 2022
- Sales of the CardiacSense Medical Watch to customers/health care practitioners
- Sales of the CardiacSense Wristband to health care practitioners/hospitals
- Sales of the CardiacSense chip to manufacturers
- Price of the watch in Benelux: €686,40 ; Israel ₪2.700

Generally, **reimbursement only covers** a small portion of the development costs

Source: www.crunchbase.com ; www.dnbhoovers.com ; www.cardiacsense.com

Identified challenges

Identified success factors

RECOMMENDATIONS

Recommendations

What can Belgium do to develop the preventive care market?

GOVERNMENT & PUBLIC AGENCIES PUSH

What can the government and public agencies do to develop the preventive care ecosystem?

Connect the ecosystem of preventive care

- Create a platform for companies to **connect with the different stakeholders in the ecosystem** in order to foster (public-private) collaboration (e.g., social impact bonds initiatives): investors with health/MedTech knowledge (e.g., Earlybird, Eightroads, Rockhealth), health organizations, practitioners, KOLs, specific incubators and accelerators
- Setup **preventive HealthTech incubation program** that also provides access to other relevant int'l programs (e.g., Plug and Play Roche)
- Develop or provide access to **networks around specific topics/expertise** e.g., MedTech companies, early-stage companies

Support from development to commercialization

- Ensure **knowledge sharing** and provide **guidance through market studies and center of excellence** on specific topics, e.g., on European reimbursement processes, regulatory and legal aspects (including MDR), existing funding and grants, roadmap for start-ups
- Provide a platform for companies to **test new preventive HealthTech solutions in a pilot trial** (early development phase) and **in a real life setting with KOLs and consumers** (commercialization phase), e.g., by partnering with innovative hospitals

Connect private organizations and talent

- Establish **talent agency connecting students and young professionals to start-ups** e.g., through partnerships with universities and student communities
- Organize **networking events connecting start-ups to experienced workers** with the right scientific/technological/medical background

Foster adoption of preventive care solutions

- Raise **awareness across the population** of existing solutions and their benefits, as well as (personal) data usage and transparency
- Encourage **adoption amongst HCPs** – this will be a key factor in driving patient adoption of preventive care solutions (B2B2C)

Work on the basic determinants of health

- Work on the key determinants of health for the Brussels region, such as **digital inclusion** (i.e., elderly and minority groups) and **health literacy**, to be able to act on health prevention
- **Promote the power of diversity** as Brussels can provide access to a variety of patient segments (e.g., 170 different languages)
- **Tailor communication to the target audience** (often vulnerable), with the right information (to avoid overload of information) through trustworthy people in real contact with the population and able to speak different languages

Recommendations

What can Belgium do to develop the preventive care market?

PRIVATE SECTOR PULL (1/2)

How can private companies be successful in the preventive care market?

Leverage strong collaboration with HCPs	› Adoption amongst HCPs was identified as a **key success factor for patient adoption** of new preventive HealthTech solutions › Collaborate with HCPs by demonstrating the **impact of the preventive solutions** (investment needed in value-based studies), the ease of use and the added value for them through 'champions'
Build a network of commercial partners	› Consider commercial partners with an **existing distributor network with strong expertise in the field** to act as an accelerator for go-to-market
Go beyond healthcare providers and payers	› **Consider** to target and/or **partner with private insurers** also **also companies (B2B)** to gain access to a larger pool of users more rapidly than by adopting a B2C strategy
Invest in the right partnerships	› Look for **investors** and **partners** who know both technology and health care
Develop an agile solution	› Develop a solution by focusing on **user-friendliness** to improve digital inclusion › Ensure **interoperability**, i.e. allowing your solution to work with or even be integrated as-a-service into other HealthTech platforms /solutions - the multitude of existing solutions and platforms makes it complicated for physicians and hospitals to adopt new solutions

Recommendations

What can Belgium do to develop the preventive care market?

PRIVATE SECTOR PULL (2/2)

How can private companies be successful in the preventive care market?

Raise awareness on preventive solutions

- Find **local public partners** who promote prevention and the existing solutions, along with the (long-term) benefits
- Be **transparent** about the company's **use of (personal) data** in your consent mgmt., a still significant barrier to the adoption of new technological solutions

Create reward mechanisms to foster adoption

- Motivate users by rewarding them with **short feedback and insights**
- Combine the administrative or day-to-day monitoring with **gamification** to maintain the consumer's attention

Balance value-based pricing vs alternatives

- **Avoid lowering your price-point to 'buy the market'** as it will reflect on consumer perception of quality and value
- **Value your solutions based on alternatives** it replaces, but within an acceptable range

Find specific high-quality accelerator programs

- Look for accelerator programs that are of high quality (e.g., with proven track record) and **dedicated to your field** as the public or private partners can bring **complementary expertise** and guidance to successfully go through the regulatory process

APPENDIX

List of interviewees

Name	Company	Role	Country	Contact
Amnon Blanca	CardiacSense	Vice President of Business Development at CardiacSense		amnon.blanca@cardiacsense.com
Bieke Van Gorp	FibriCheck	Co-Founder & COO at Extra Horizon/FibriCheck		bieke.vangorp@fibricheck.com
Charles-Eric Winandy	moveUP	Director at MoveUp		charles-eric@moveup.care
Christoffer Linder	BlueCall	Sales Manager at BlueCall		christoffer@bluecallapp.com
Jonathan Baut	Gabi SmartCare	Co-Founder and CEO of Gabi SmartCare		jonathan.baut@gabismartcare.com
Petra Ojala	Precure	Chief Operating Officer at Precure		petra.s.ojala@gmail.com
Tim Bechtold	CardioSecur	Finance and Procurement at CardioSecur		tim.bechtold@cardiosecur.com
Tobias Gebhardt	GWA Hygiene	Managing Director at GWA Hygiene		tobias.gebhardt@gwa-hygiene.de
Tom Segers	Indigo Diabetes	Vice President of Business Development & UX at Indigo		tom@indigomed.com
Andries Clinkaert	Tiro Health	Co-Founder Tiro.Health and PhD researcher KULeuven		andries.clinckaert@tiro.health
Julie PAPAZOGLOU	Cabinet Maron	Cabinet Maron		jpapazoglou@gov.brussels
Jos Peters	-	General practitioner		-
Pieter-Jan Geusens	-	General Practitioner		-
Cédric Segers	-	Diabetic patient		segerscedric@outlook.com
Anonymous	-	Cardiac patient		-