Acronym:	vINCI
Name:	Clinically-validated INtegrated Support for Assistive Care and Lifestyle Improvement: the Human Link
Call:	AAL 2017 "AAL Packages / Integrated Solutions"
Contract nr:	AAL-2017-63-vINCI
Start date:	01 June 2018
Duration:	36 months

D5.4. Exploitation and Standardisation

Nature[1]: R

Dissemination level[2]: PU

Due date: Month 24

Date of delivery: Month 24

Partners involved (leader in bold): **ICI,** MPU, UNRF, NIT, CMD, AUT, SAL, NIGG, CTR

Project Co-Funded by:

Project Partners:

Partner list:

No.	Partner name	Short name	Org. type	Country
1	National Institute for Research and Development in Informatics	ICI	R&D	Romania
2	Marche Polytechnic University	MPU	R&D	Italy
3	University of Nicosia Research Foundation	UNRF	R&D	Cyprus
4	National Institute of Telecommunications	NIT	R&D	Poland
5	Connected Medical Devices	CMD	SME	Romania
6	Automa Srl	AUT	SME	Italy
7	Optima Molliter (former Salvatelli Srl)	SAL	SME	Italy
8	National Institute of Gerontology and Geriatrics "Ana Aslan"	NIGG	R&D	Romania
9	CT Management d.o.o. (Comtrade) (former Comtrade Digital Services)	CTR	Large enterprise	Slovenia

5.4 Deliverable Revision History

Rev.	Date	Partner	Description	Name
1	11.01.2020	CTR	Idea	Gregor Molan
2	21.01.2020	CTR	Exploitation	Gregor Molan
3	20.02.2020	CTR	Standardisation, dissemination	Gregor Molan
4	01.06.2020	CTR	Resume	Gregor Molan

Chapter 6 Business plan – CTR - CT Management d.o.o Revision History

Rev.	Date	Partner	Description	Name
1	17.05.2019	CTR	Initial plan	Gregor Molan
2	19.07.2019	CTR	Merge with Connected Medical Devices docs	Gregor Molan
3	25.07.2019	CTR	Update of chapters' description	Gregor Molan
4	11.12.2019	CTR	Review	Gregor Molan
5	11.12.2019	CTR	Sent to review	Gregor Molan
6	04.01.2020	National College of Ireland (NCI)	Minor revisions to improve manuscript readability. Minor revision to SWOT chart. Added proposal on WaaS privacy policy for discussion.	Horacio González-Vélez
7	10.01.2020	CTR	Market overview	Gregor Molan
8	13.01.2020	CTR	Market overview	Gregor Molan
9	16.01.2020	CTR	Update with merge of other personal researches	Gregor Molan
10	01.06.2020	CTR	Resume of work until June 2020	Gregor Molan
11	10.06.2020	CTR	Update – published for vINCI	Gregor Molan

Chapter 7 Business plan - CMD - Connected Medical Devices Revision History

Rev.	Date	Partner	Description	Name
1	20.09.2020	CMD	Added Chapter 7 Business plan – CMD Connected Medical Devices	George Georgescu Tudor Dimofte

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Table of Contents

1. Introduction

Collected are reports about dissemination, exploitation and standardisation for the vINCI project. The first part of this document (Communication activities, Exploitation activities, Dissemination activities, Standardization activities) is published on the vINCI project web page https://vinci.ici.ro. The most important part of this document is Business plan and it is prepared as a special and separate document.

2. Communication activities

During the vINCI project there are weekly meetings between project partners to report about the work on vINCI project. These meetings are Skype meetings scheduled and stored in Google calendar. Beside that official meeting there are many other communication channels such as email, phone (skype) calls, and personal meetings.

3. Exploitation activities

3.1 Patents

There should be prepared potential patents for vINCI project results:

- Patents for protocols used for data collection
- Patents for data formats for collection of personal data for patients (elderlies)
- Patents for user interface screens provided for elderlies
- Patents for reliable data storage for personal data
- Patents for actions provided for patients (elderlies)
- Patents for questionnaires for patients (elderlies) feedback about the process
- Patents for questionnaires results evaluation

3.2 Exploitation plan

The most important part of the exploitation is the vINCI business plan.

4. Dissemination activities

Dissemination activities are:

- vINCI project web page https://vinci.ici.ro
- Articles and scientific communications https://vinci.ici.ro/dissemination/
- Personal business communications (not publicly available)

5. Standardization activities

Standardization of vINCI results is proposed at the end of vINCI project. The need for standardization is verified and proven processes that are executed during the vINCI project.

6. Business plan – CTR - CT Management d.o.o.

6.1 Executive Summary

Funded by the EU Active Assisted Living Programme, the vINCI project is developing an integrated and validated evidence-based IoT framework to deliver non-intrusive monitoring and support for older adults to augment professional healthcare provision. The vINCI services are designed to improve the quality of life for older adults living alone or in an elderly care institution (e.g. nursing home).

Quality of life improvements that are proposed with the use of vINCI service:

- Foster independence of older adults
- Increase quality of life for older adults living alone or in elderly care institutions

Proposed customers of the VINCI services:

- Family members / relatives
- Elderly care institutions (e.g. nursing homes)

Bottom line: **vINCI reduces costs and increases quality of life for older adults - it is the best price/performance solution to improve a quality of life of adults over 65.**

6.2 Wearable Medical Devices

As the smart watches are important wearable medical devices, Google with Fitbit acquisition on November 1st 2019 [9] was the important date for wearable devices market. Now, on the market of wearable devices are two the most important actors: Apple and Google.

6.2.1 Market Research Future from August 2019

This study about wearable medical devices is based on the extract from Market Research Future report [7] published on Medgadget weblog [6]. Facts are in following subchapters.

Segmentation of Medical Devices

Segmentation by type

1.   Diagnostic & Monitoring

2.   Sign Monitoring

3.   Therapeutic Devices

Segmentation by application

1.   Fitness

2.   Blood Pressure

3.   Heart rate

4.   Weight monitoring

5.   Other applications

Segmentation by usage

1.   Sport

2.   Patients

3.   Other usage

Wearable Medical Device Market Players

Companies for wearable medical devices ordered by report [7] published in August 2019.

1.   Apple

2.   Abbott Laboratories

3.   Basis Sciences

4.   Fitbit

5.   Garmin

6.   Jawbone

7.   Lifewatch AG

8.   Omron Corporation

9.   Philip Healthcare

10.   Polar Electo

6.2.2 Fortune Business Insights from August 2019

This study about wearable medical devices is based on the extract from publication of Fortune Business Insights [5].

Segmentation of Medical Devices

Segmentation of medical devices by report [5] published in August 2019.

Segmentation by product

1. Diagnostic & Patient Monitoring Wearable Medical Devices (2/3 of products)

    a. Activity Monitors/Trackers

    b. Smartwatches

    c. Smart-clothing

    d. Others (Biosensors, blood pressure monitors, glucose monitoring systems)

2. Therapeutic Wearable Medical Devices (1/3 of products)

    a. Wearable Defibrillators

    b. Drug Delivery Devices (Injectors, Patches)

    c. Pain Management Devices (TENS, EMS)

    d. Hearing Aids

    e. Others

Segmentation by application

1. Remote Patient Monitoring and Home Healthcare

2. Sports and Fitness

Segmentation by distribution channels

1. Retail Pharmacies

2. Online Pharmacies

3. Hypermarkets

Segmentation by geography

1. North America (USA, Canada)

2. Europe (UK, Germany, France, Italy, Spain, Scandinavia, rest of Europe)

3. Asia Pacific (Japan, China, India, Australia, Southeast Asia, rest of Asia Pacific)

4. Rest of the World

Wearable Medical Device Market Players

Companies for wearable medical devices ordered by report [5] published in August 2019. Xiaomi introduced some new perfect smartwatches in in early 2020 and therefor it is the most suitable smartwatch producer for vINCI clients. One of results of the rapid development of smart watches in 2020 is Galaxy Watch 2 with blood pressure and ECG technology that is compared to Apple Watch Series 5 [10].

1. Xiaomi, China
    a. Smartwatch: Amazfit Cor 2
    b. Smartwatch: Amazfit Verge
    c. Smartwatch: Mi Band 4
    d. Smartwatch: Amazfit Stratos Pace 2
2. Fitbit, USA
    a. Smartwatch: Fitbit Versa 2
3. Apple watch, USA
    a. Smartwatch
4. Samsung, South Korea
    a. Smartwatch: Galaxy Watch
    b. Smartwatch: Galaxy Watch 2
    c. S-Patch ECG monitor
5. Becton, Dickinson and Company (BD), USA
    a. Libertas wearable autoinjector
6. Ypsomed Holding AG, Switzerland
    a. Diabetes
7. Sonova, Swiss
    a. Audiological Care
8. Hologic, USA
    a. Planning to start with wearable devices
9. AiQ Smart Clothing
    a. Smart material for cloth
10. NeuroMetrix
    a. Quell: pain relief technology
11. Siemens Healthcare
a. Internet of Medical Things (IoMT)

6.2.3 Food & Beverage Herald Report from January 2020

The last study about wearable medical devices is based on the extract from publication of F&B Herald Inc from UK [8].

Segmentation of Medical Devices

Segmentation of medical devices by report [8] published in January 2020. It is another and slightly different segmentation comparing to previous segmentations.

Segmentation by type

1. Wrist-wear
2. Eyewear
3. Footwear
4. Neckwear
5. Body wear
6. Others

Segmentation by industry

1. Consumer Products
2. Healthcare
3. Industrial
4. Others

Segmentation by type

1. Smart Consumer Products
2. Healthcare
3. Industrial
4. Others

Segmentation by end users

1. Personal users
2. Enterprises

Segmentation by geography

1. North America
2. Consumer Products
3. Healthcare
4. Industrial
5. Others

Wearable Medical Device Market Players

Companies for wearable medical devices ordered by report [5] published in August 2019.

1.   Fitbit, USA

6.3   Competitive Advantage

6.3.1 The Largest Biotechnology and Pharmaceutical Companies

There are a lot of available capital in biotechnology and pharmaceutical companies to invest in wearable devices to improve quality of life of patients.

Table 1 Rankings of largest biotechnology and pharmaceutical companies by stock

Rank[N 1]	Company	Largest Market Cap (USD billions)	Market Cap in 2018 (USD billions)
1 ▬	Johnson & Johnson[P]	397.4 (Jan 2018)	346.1
2 ▬	Pfizer[P]	310.5 (Jul 2000)	259.7
3 ▬	Roche[P]	263.6 (Feb 2014)	209.3
4 ▲2	Merck & Co.[P]	213.6 (Nov 2018)	205.8
5 ▼1	Novartis[P]	275.2 (Jul 2015)	200.0
6 ▼1	AbbVie[P]	196.2 (Jan 2018)	146.3
7 ▬	Amgen[B]	143.0 (Jan 2018)	128.8
8 ▬	Abbott Laboratories[P]	130.2 (Dec 2018)	126.8
9 ▲1	Eli Lilly & Co[P]	131.2 (Feb 2019)	125.6
10 ▼1	Novo Nordisk[P]	159.6 (Aug 2015)	111.9
11 ▬	Sanofi[P]	151.3 (Sep 2014)	108.4
12 ▲2	AstraZeneca[P]	105.1 (Nov 2018)	96.2
13 ▲2	GlaxoSmithKline[P]	174.9 (May 2006)	94.8
14 ▼1	Bristol-Myers Squibb[P]	128.3 (Jul 2016)	85.0
15 ▼2	Gilead Sciences[B]	179.6 (Jun 2013)	81.6
16 ▬	Biogen[B]	111.7 (Mar 2015)	63.5
17 ▲3	Bayer[B]	129.0 (Mar 2015)	63.1
18 ▼1	Stryker Corporation[P]	67.6 (Feb 2019)	58.6
19 ▲2	Shire Pharmaceuticals[P]	62.0 (Sep 2014)	53.0
20 ▬	Takeda Pharmaceutical [P]	59.6 (June 2007)	52.9
21 ▼2	Celgene[B]	115.3 (Oct 2017)	46.6
22 ▼4	Allergan[P]	133.5 (Jul 2015)	46.2
23 ▼1	Illumina [B]	54.0 (Sept 2018)	44.1
24 ▼1	Vertex Pharmaceuticals[P]	49.1 (Sept 2018)	42.2
25 ▼1	Zoetis[P]	46.1 (Nov 2018)	41.4
26 ▼1	Regeneron Pharmaceuticals[P]	61.4 (Aug 2015)	40.3
27 ▼1	Astellas[P]	35.9 (Nov 2017)	23.8
28 ▲2	Eisai Pharmaceutical [P]	24.7 (June 2018)	23.0
29 ▬	Daiichi Sankyo [P]	27.9 (June 2018)	22.7
30 ▼1	Alexion Pharmaceuticals[P]	47.0 (Jul 2015)	21.7
31 ▼1	BioMarin [P]	24.0 (Jul 2015)	15.1
32 ▼1	Mylan [P]	37.2 (Apr 2015)	14.1
33 ▬	Incyte [P]	31.2 (Mar 2017)	13.5
34 ▬	Perrigo [P]	29.0 (May 2017)	5.5
35 ▬	United Therapeutics [P]	6.0 (May 2018)	5.5

Based on the list of world largest biotechnology and pharmaceutical companies by stock [4] in Table 1, here is the overview about wearable devices connected to these companies.

Johnson & Johnson

Research Study with Apple Watch

https://www.jnj.com/johnson-johnson-announces-research-study-with-apple-watch-to-help-improve-afib-outcomes-including-stroke-prevention

Pfizer

Collaboration with Fitbit

https://www.fiercebiotech.com/medtech/fitbit-enlists-pfizer-bristol-myers-squibb-to-bring-arrhythmia-detection-to-its-fitness

https://www.wearable-technologies.com/2019/10/bristol-myers-squibb-pfizer-alliance-and-fitbit-collaborate-on-afib-diagnosis/

Roche

Investment in a process

https://www.roche.com/about/priorities/personalised_healthcare/digital-biomarkers.htm

Merck & Co.

Leaders are Fitbit and Apple Watch, but Merck GHIF and other financial leaders are investing $40 million in TriNetX

https://medium.com/trinetx/can-your-wearable-computing-device-revolutionize-clinical-research-d884af1596a1

6.3.2 Competitor and Marketing Analysis

There are some existing smart watches and some other "wearables as a service" (WaaS) for older adults. Most of those WaaS are developed by mainstream global companies, and there are increasing new investments and resources for the WaaS.

Relevant existing smart devices and WaaS (as of 2019):

1. Apple Watch Series 4
   a. https://en.wikipedia.org/wiki/Apple_Watch
2. SmartSole
   a. http://gpssmartsole.com
3. MobileHelp Smart
   a. https://www.mobilehelp.com

4.   Medical Guardian

    a.   https://www.medicalguardian.com

Existing WaaS for older adults' activities:

5.   Charles Reed Anderson & Associates

    a.   http://charlesreedanderson.com

6.   EU funded project "Smart Service Power"

    a.   https://www.smartservicepower.de

    b.   https://ec.europa.eu/regional_policy/en/projects/germany/smart-technology-tested-in-germany-allows-older-people-to-live-independently

6.3.3 SWOT Analysis for vINCI WaaS
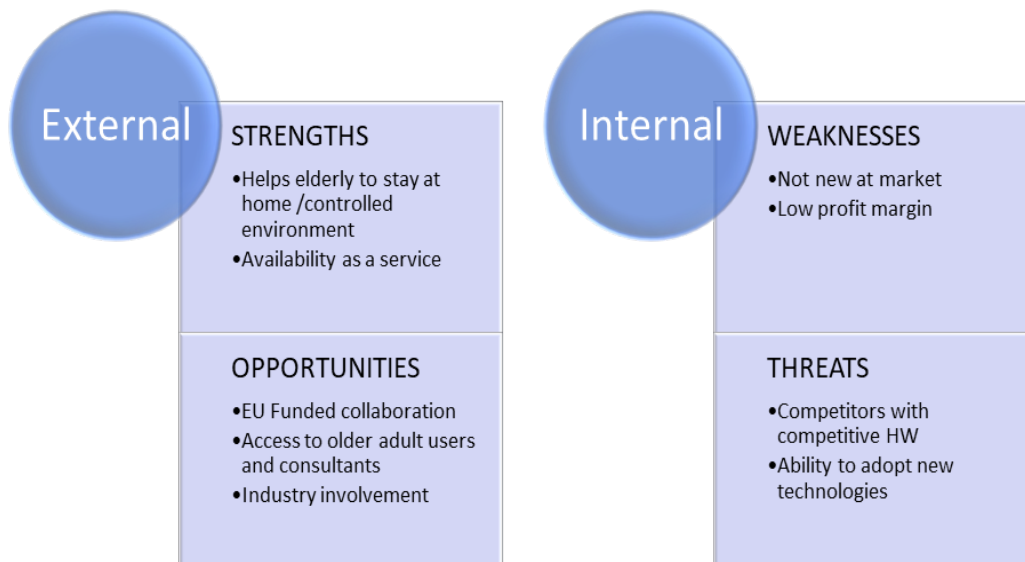
Figure 1 SWOT Analysis for WaaS

6.4   Mission Statement

The vINCI as a service provides high-quality and affordable lifestyle and supportive services to enhance the well-being of elderly with cost effective non-medical home care service, their caregivers, and to entire community.

6.5   Marketing Plan

6.5.1 Elevator Pitch

The same as it is proposed as the "Executive Summary".

6.5.2 Sales Presentation

Sales should cover customers different domains, including (but not restricted to) (a) Senior citizen homes, (b) Hospitals with geriatric specialisations, (c) Institutions for older adults (d) Specialised outlets. There should be a special focus on a horizontal marketing to cover all possible customer areas.

During presentations, the sales should be based on following items:

(1)   vINCI is providing an innovative partnership model

(2)   Part of new area of wearables as a service (WaaS)

(3)   Not limited for elderly care management

6.6   Legal

6.6.1 IP Management

vINCI participants will establish during the project implementation a separate joint ownership agreement, defining in concrete terms the allocation and terms of exercising their ownership.

6.6.2 CNC (Covenant Not to Compete)

Do we need to provide special notes for CNC - a clause under which each partner agrees not to enter into or start a similar profession or trade in competition against another partners?

6.7   Answers to Frequently Asked Questions

What problem does the vINCI service solve?

What niche the vINCI fills?

Who are the vINCI customers

What is the vINCI marketing for customers and sells channels?

What is the size of the market for vINCI?

What is the business model for the business (how will it make money)?

Who are the competitors and what is the plan to maintain a competitive advantage?

What is the plan to manage vINCI operations as it grows?

What are the risks and threats confronting the business?

What is the plan to mitigate risks and threats?

What are Comtrade's capital and resource requirements?

What are Connected Medical Devices' capital and resource requirements?

7. Business plan – CMD - Connected Medical Devices

7.1 Company and Summary

In general the company has a set mission to increase people's life quality through innovative solutions, which integrate technologies.

In particular, The Human Link (THL) brand aims to become a European integrator for the care of elders and people with dementia, bringing together families, patients, caregivers, the medical community and service, and equipment providers. The detailed visual form of THL, comprising the areas of interest is depicted in Figure 2.

Figure 2 THL Product Constellation (Source: Connected Medical Devices)

Until now, THL was perceived as a single wearable based solution for elder people and dementia patients. Looking forward, THL is now broadening its protective solution behind the wearable (the watch with a GPS tracker, with the software installed and the mobile App) towards an entire ECOSYSTEM of services whose Final User - the vulnerable person and his/her Family - is in the center, surrounded by needed support services.

The current CHALLENGE of the innovative company is to SCALE UP the business by successfully pivoting form a device-based solution to a software-base solution (a platform), developing, investing in add-on services that could bring revenues & profitability on the long term.

Therefore, the objectives of THL can be summarized as follows:

- On medium term (3 to 5 years) THL targets to become a recognized brand and a well know app/platform for the care and life quality improvement of the senior citizens, at European level.
- On long term (7 to 10 year), the company wants to expand its coverage and awareness over North America in first stage and Australia-Oceania plus Japan afterwards.

- On long term, THL vision is to become the platform of choice for caregivers and elders, who look for improving their quality of life.
- On medium term, the company targets to have 20,000 individual users (downloads) for the app and 3000 paying users, while on long term its vision is to reach 100,000 individual users and 20,000 paying customers (B2B+B2C users).
- By the 3rd year, THL will achieve breakeven point.

Worldwide, there are 50 mil people with related dementia and the average yearly cost of care for each family is $7,000. By 2050, the number will rise to 152 mil.

The Human Link (THL), the software based platform, aims to offer a better life to elders and patients with dementia in its mild to moderate stage by providing them more freedom while reducing their caregivers, healthcare professionals and families' level of stress and anxiety, while also decreasing costs of caring. Basically, offering the chance for improved quality of life at a lower cost, for elders and dementia patients.

The unique trait of THL, which differentiates it from any direct competition, is the fact that it's developed in co-operation with doctors, patients and professional institutions and offers an open platform where a wide range of two-way communication devices (patient – caregiver) based on the Internet of Things (IoT) paradigm can be integrated and soon it will integrate, among others, new features like patient/ caregiver support, support groups, and patient recovery.

7.2   Opportunity – What do customer want?

7.2.1 The problem

According to Eurostat, almost 20% of Europe's population is 65 years old or more and has a life expectancy of up to 85 years old, with the expectancy to enjoy healthy years only up to 75 years old, meaning that they still have many years ahead of them and they need to keep active and to have a healthy life to extend the number of healthy years and increase their quality of life.

Unfortunately, more than 30% of the elders aged 65 or more are living alone. Less of 10% of the same age group are economically active and less than 50% still travel. So, finding a solution to keep them active, independent, and mobile is very important.

The quality of life of older adults can decrease drastically if they don't live an active life. The VINCI project was aimed from the beginning to improve their lives by blending clinical know-how with technology. The project started around the concept of building the VINCI Kits, that contain multiple technologies that can track the activity level and the mood of the older adults, in order to have the possibility to intervene proactively in situations that can affect their wellbeing.

7.2.2 Who are our customers?

The customers are split into B2B and B2C.

The B2C customers are:

- Older adults (≥ 65 years of age) who do not have severe neurocognitive impairment, frailty syndrome, any other significant disability and who are independently living within their communities and who are interested in improving their health status and quality of life.
- Informal caregivers of older adults (e.g. relatives, family members).

The B2B Customers are:

- Hospitals with MCI patients (Private and Public)
- Professional caregivers - Daycare centers for older adults
- Nursing homes (Private and Public)
- Family doctor practices

7.2.3 `What do they want?

B2C:

Older Adults who do not have severe neurocognitive impairment, frailty syndrome, any other significant disability and who are independently living within their communities want to stay healthy for the longest period possible. These days they are more and more technology aware. Many of them own either a smartphone or a tablet that they use to stay in contact with their loved ones, to keep up-to-date, and to enjoy in leisure activities. They want a solution that can monitor their state of health and that can send them alerts, if they are in danger of having health issues. They can buy services on their own or they can influence their families to buy the services for them.

The informal caregivers (the family members) want to be able to monitor the state of health and safety of the Older Adults. They want to have a possibility to intervene if there are real or possible problems which can affect the state of health of the patients. Furthermore, because of the constant attention required by their elders, the family-caregivers end up losing their jobs, their social interaction and their health condition is overlooked. Therefore, they need to become more independent and pursue a normal social life (job, friends, hobbies, and healthcare), while still being able to monitor the health status of their loved ones. As mentioned above, taking care of the elders can also prove an important financial burden. Due to all these strong motivators, usually this category of users also identifies the commercial buyers.

B2B:

- Hospitals with MCI patients (Private and Public).

  The Hospitals want to use the system to monitor the activity and state of health of patients. They can be in closer contact with their patients creating an added

value to their services, and can also implement a long-term and continuous monitoring. Also, they could use the system in medical studies.

- Professional caregivers - Daycare centers for adults

  The professional caregivers and daycare centers for older adults want to differentiate themselves from their competition with the aim of growing their business. THL integrated system can help them demonstrate that their patients are cared for closer than their competition and can reassure the family of that. Besides creating comfort for elder's family, the care centers have also a very important responsibility over their patients physical integrity – we know from our clients that on many occasions the patients can wander off and get lost or even worse, have an accident and no one is aware or can react in due time to save their lives.

- Nursing homes (Private and Public)

  The nursing homes want to both differentiate themselves from their competitors with the aim of growing their business. They also want to be in closer contact with the patients when the patients are outside. Nursing homes can also establish a closer relationship to families of their patients and provide a more transparent care service.

7.3 The Rivalry on Target Market

7.3.1 Industry Rivalry

At this time, based on our research and discussions with professional, on the targets markets (especially those targeted on a short to medium term), we identified limited solutions for elder care which could be a direct competitor for THL. Therefore we consider the direct competition having a low impact on the project and for the time being the rivalry is at a low level. For example, with almost all our B2B and B2C customers, the original THL solution was the first solution of this type they ever employed or even heard of.

Still we were able to identify a couple of existing WaaS for older adults' activities, in Europe:

1. Charles Reed Anderson & Associates
   a. http://charlesreedanderson.com
2. EU funded project "Smart Service Power"
   a. https://www.smartservicepower.de

   https://ec.europa.eu/regional_policy/en/projects/germany/smart-technology-tested-in-germany-allows-older-people-to-live-independently

Profiting of this opportunity and considering that the bigger threat comes from potential new entrants in the market, as presented in the next sub-section, THL aims at using the current client base for quickly securing a safe starting base, and being able to quickly expand on a short time period (of course, also with the help of sales and marketing efforts).

7.3.2 Threat of Entries

We were able to identify a considerable number of existing assistive technology devices for seniors, which are also in development, or available in an initial form.

Startups and high tech:

- Embodied Labs Virtual reality solution which allows senior care providers and healthcare professionals to better understand the problems the elderly are facing
- Intuition robotics has the promise to redefine the relationship between humans and machines and propose digital companions. The digital companion agents are providing social AI entities that proactively interact with each user creating empathic experiences. The platform integrates any device with sensors and starts learning them.
- Ageless Innovation is producing smart pet Joy for All pet that can engage, delight, enhance meaningful connections, provide companionship, calm, sooth and most importantly promote happiness. The robotic cats and pups have sensors that allow them to interact with a human companion as they would with a live pet. The cat responds to touch, rolls over and utters 32 different types of purring sounds. The pup's heartbeat slows down if a hand is placed on its back.
- Neuro Rehab VR allows neurological rehabilitation and physical therapy in Virtual Reality. They use machine learning
- Toy Labs turns the toilet into source into health information TrueLoo has sensors that can determine who the user is. It then scans the toilet bowl to determine the size, color, consistency, frequency and shape of the excreta.
- **Vital Tech** is a cloud-based platform that improves the patient health and wellness through connected care. It integrates advanced biometric wearables, real time data collection and advanced analytics to provide actionable data to patients and care teams.

  Vital tech has Vital Care that integrates vital signs as heart rate, breath rate, blood pressure, step count and glucose. Vitals are collected through integrated BLE medical devices. By creating daily awareness of physiological data, seniors better self-monitor and can act quickly promoting self-care.

  With Nutrition Diary nutritional data is logged through voice inputs or simple barcode scanning. This data can be shared to stay on track with health goals.

With Medication reminders it is possible to set medication reminders by time of day, pushed to the patient's Vital Tech-provided tablet or sent to the Vital Band. Patient and clinicians can add and track medications, helping avoid adverse reactions due to prescription conflicts. Patients engage in their care plans by marking their medications as taken, skipped, or missed, helping adherence and improving the quality of care.

With Video calls and photo sharing allows Multi-user video calls for remote visits & Virtual Check-In eliminates unnecessary visits to the emergency rooms or physician's office.

With Messaging Services Patients communicate with their care teams through a HIPAA secure portal. Notes on care reviews and progress by the physicians can be pushed to the patients for review.

Vital Care Easily view your patients integrated health data from any smart device. Real-time and historical vitals, nutritional inputs and medication adherence are recorded to the patient record and viewed based on patient populations.

With Telehealth Vital Care allows multi-user video calls for remote health visits and Virtual Check-In eliminates unnecessary visits to the emergency rooms or physician's office. Messaging through the app allows the physician to prescribe care while reviewing the patient data in real time.

Vital Care also uses alerts and triggers. Pre-configured alerts are set for patients suffering from chronic conditions. When an anomaly is detected, physicians and care teams are notified and can reach out to their patients via our portal allowing all communications to be documented and archived.

Hardware and software:

Smartwatch with On-Wrist charging RFID and water resistance. The watch integrates with a platform that allows text and e-mail alerts.

7.3.3 Substitute competition

The substitute competition can come in THL's case from existing hardware providers and also service providers.

We were able to identify a large number of hardware solutions, which individually, can replicate parts of the intended THL solution. Therefore we consider these solutions a high threat of substitute. For example, we may expect an elder who already owns a smart watch which has daily and weekly health goals (calories, steps, heart activity) to consider that these are sufficient for their needs, and with the help of other technical elements (like Facebook groups to share activity results and a smartphone which can provide additional elements in connection with the watch) they could easily substitute a solution like THL, unaware of the additional benefits of our platform.

Nevertheless, these potential substitutes can actually become an ally of THL, considering that THL intends to be able to integrate a wide range of 3rd party IoT devices (smart shoes and smart watches among them).

Smart shoes:

- Xiaomi smart shoes $20 smart bracelet that integrates sensors is waterproof and has 60 days autonomy by using a coin battery
- Feetme released a connected insole called FeetMe Diagnosis which zeroed in on post-surgical evaluation, gait and patient analysis.
- E.VONE has created a connected shoe that features a falling alert system. Basically, these shoes cater to four types of users: the elderly, outdoor adventurers, blue-collar workers, and people who don't know when to stop drinking.
- Smart house solutions for elderly promise :
  - No more lost keys by using RFID
  - No more accidents due to the lack of light by integrating smart lights
  - Integration with apps and gadgets for entertainment and communication
  - Motion sensors and alerts
  - Voice controls
  - Health Monitoring

Smart watches

- Apple Watch Series that features a software-based "fall detection" system also allows its users to take Electrocardiogram (ECG) right on their wrist; thanks to a much improved heart-rate sensor, the Apple Watch Series 4 would only require a dedicated App to record heartbeat and rhythm for an ECG.
- Safelink – Uses the same Factory as CMD "SafeLink is well suited for the senior citizens, offering functions such as GPS tracking, SOS alerts and tracking from other devices. It's basically a 2G watch that features GPS tracking; it has what it calls "tailing mode", whereby the watch forces GPS location updates to happen by the minute', when necessary. It also has SMS notifications, allowing SMS alerts to be sent simultaneously to three separate contacts available. The SafeLink can also come in form of a Tracker Module, which can be worn anywhere else on the body. It works best as a GPS tracking watch, and it allows families and caregivers locate its wearer easily." (https://smartwatchesguru.com/best-smartwatches/ten-best-smartwatches-for-the-elderly-2019/).
- MobileHelp Smart - The MobileHelp Smart is a watch for adults that's simple to use, yet trendy; it doesn't look like you're carrying a medical alert bracelet, which in fact, it really is. It features GPS tracking, 4G cellular backup and a comprehensive country-based medical emergency monitoring. The hardware features a built-in two-way speaker, water-proofing and a long-lasting battery

life. With its free MobileHelp Alert App, fitness activities and heart-rate can be monitored and logged. Price $350.

- Freedom Guardian - The Freedom Guardian is a smartwatch designed by Medical guardian and it is one of the best senior smartwatches. It has a fine design that's discreet too, adjustable wrist bands, the black and white colorways, and large, oversized app icons are some of the little things that makes this device sleek and not utilitarian. It comes with GPS and Wi-Fi, both of which can be used for location tracking, it can also be used for reminders and alerts for medications and other tasks and events, there's even an alert system for when the device is running low on battery. There's also a text-to-speech function, allowing for seniors to keep in touch through SMS. The Freedom Guardian is geared towards active (and independent) seniors, providing them with little nifty features like the quick access to emergency services. However, this device doesn't have automatic fall detection, and the cost of subscribing to a medical monitoring on the device is a bit high.

- The UnaliWear Kanega Watch is a pretty solid smartwatch for the elderly, coming in a hardware that's functional and practical. It features automatic fall detection, GPS tracking, and on-call emergency assistance. It is primarily voice-controlled, which in a way makes it more intuitive for the older people it is hoping to cater for. The biggest advantage of the UnaliWear Kanega Watch is that it is capable of being used independently and doesn't need another device (like a smartphone) to work, this is welcomed by seniors who may not like to have a smartphone on them most of the time, it can connect with modern hearing aids. The hardware is water-proof and impact-proof, and it comes with a long-lasting, easily-replaceable batteries.

- Wonbo Q50 - The Wonbo Tracking Device is the cheapest entry in this of smartwatches for the elderly. Despite its cheapness, the device offers real-time GPS personal tracking and "one-click" emergency call alerts. It comes in a casing that's easy on the wrist and has a comfortable grip, it has a 0.96 inch OLED display that's very easy on the eye, making it easier for elders to see elements on it clearly. At just $19.99.

- Amazfit Bip Smartwatch -The Amazfit Bip Smartwatch is quite a total GPS tracking experience for the elderly. It comes with all the fitness and tracking functions needed. It features a heart-rate sensor and a multi-network tracking system. It has an always-on display that enables easy readability, and a battery life that can last up to 45 days on a full charge. It can easily be paired to a smartphone and push notifications from the phone onto its screen.

With regards to the **services** which could substitute THL, from country to country the approach on elderly health care is different. Specifically, for Mild Cognitive impairment and Elderly patients the approaches go from support groups,

neighborhood watch, smart bracelets, printed t-shirts, smart watches, smart shoes, wearables etc.

- Family Care: family members take shifts to give care to the elders, wanting to be personally involved in the life of the loved one and disregarding a solution like THL.
- Daycare centers for the elderly: places specifically built for elderly people where they can have daytime activities to keep them in shape and help them socialize
- At home part time caregiving: professionals come to the elder's home for a limited time a day and provides different services
- At home full time caregiving: professionals stay full time with the elder.
- Nursing homes: the elder is full time in the caregiving of professionals in a dedicated institution. The institution provides healthcare and social activities.

7.3.4 Buyer Power

Romania ranks 32nd out of 42 European countries in terms of purchasing power per capita, with EUR 5,881, some 60% less than the European average, according to the results of the newly released study "GfK Purchasing Power Europe 2019".

The purchasing power in Romania rose by 14% compared to last year, four times quicker than the average 3.5% growth in Europe.

Bucharest leads the domestic rankings with an average per capita purchasing power of EUR 10,452. This equates to 78% more money than the rest of the country.
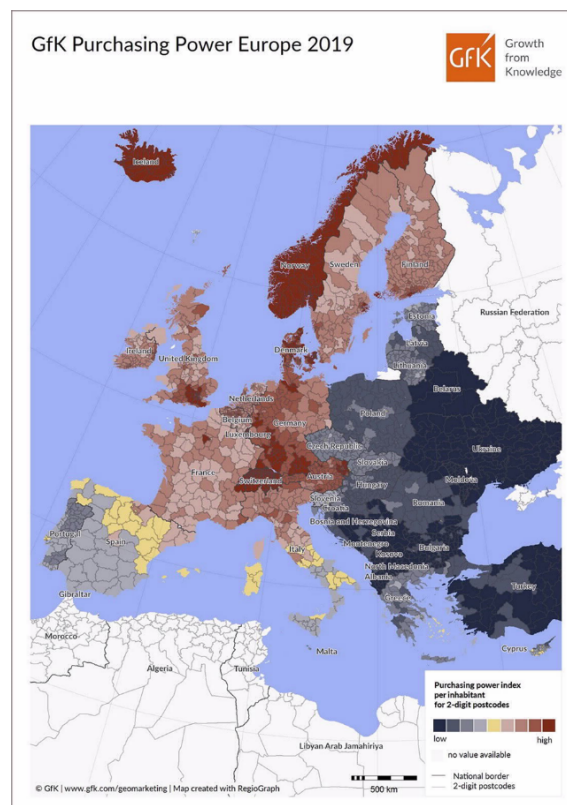
Considering this income level development for European countries, which are also the first target for THL development, we see an access to a high number of customers with a healthy level of income. Therefore, as long as THL proves the added value, quality of product, and affordability, we see a low threat in customers' negotiation power.

This should hold true for both B2B and B2C customers. As mentioned before, the clients which already interacted with the initial THL product, didn't have an idea about such solutions and proved themselves enthusiastic to employ such solutions, as long as these were affordable as well.

Probably, only at the point when similar solutions with THL will start flooding the target markets, the clients will also be able to choose and therefore get a higher negotiation leverage. But this is an issue rather related to rivalry on the market and the threat of new entrants, hence these will be dealt with the proper focus on the competition.

7.3.5 Supplier Power

One of the main reasons for THL moving away from being a hardware supplier to being a software platform supplier, was exactly to solve avoid supplier power and the huge capex and cash-flow pressure required by developing and stocking hardware. Until now, THL was dependent on the Chinese supplier which was chosen as the only supplier for the smartwatch, as part of the THL solution. THL made a step forward and developed its own Smartphone App for the watch, but the hardware was still supplied under the commercial conditions of the Chinese producer.

Once THL makes the step towards the software platform, the hardware suppliers will become complementary to the platform and in the future our aim is to make them compete for being present in the THL platform, in order to promote their products along with THL app and platform purchases or downloads. As a result, the hardware supplier threat will disappear.

For the platform and App development, the company has foreseen to employ own resources, more specifically its own team of programming engineers. So, on the product development and maintenance side we see limited to none supplier power.

The only side of THL which can become a threat can come from one of the partners' part of the vINCI consortium, in case they have unreasonable IPR protection and income expectations. Yet, as long as the Licensing Agreement coupled with the handling of IPR are correctly defined and agreed between the consortium partners, this will not be a threat to marketing the THL product.

7.4 Strategy Execution

Having in mind THL's vision, the set goals, and the fact that the strategy should be a link between the external environment, and the company's structures and systems,

further there will defined on which arenas THL wants to be a player, how it will achieve presence on the defined arenas, which differentiations will help it successfully enter the arenas, the steps needed to be taken to achieve the wanted goals, and finally how all these will combine in the economic logic that should drive forward THL's success.

7.4.1 Arenas Where the Product will Activate

As mentioned previously, THL is shifting from a device-based solution to a software solution, and therefore the main product category arena in which it is fitting is healthcare monitoring apps, with the major difference that THL intends to give also interactive advice, based on the user data input (depending of the number of tracing devise integrated). The app is one of the two main pillars of THL, the other important technical element being the cloud platform with the important role of integrating the data from different IoT devices and the app itself, with the goal of analyzing the data and producing high quality conclusion for the patient feedback and for improving patient's general health level.

Having the product category defined, we move forward to the type of customer segments. The opportunity arising in the elders' market segment, and therefore THL is targeting the elders as target user was already presented.

Nevertheless, while the user is clearly the elder, on the customer side, there is a further differentiation needed to be made. So, on one side, the elder himself can be also the customer, but on the other side, the company must consider other direct and indirect customer categories:

- The caregivers as direct customers and here we refer mainly to the family of the elder and the elder caregiving centers. These two being the paying customers as well.
- The caregivers as indirect customers, in this case referring mainly to family doctors and 3rd party family caregiver. In this case, the paying customer is still with the elder or elder's family, but we must be aware that the buying decision is triggered by the caregiver. The additional motivation of the doctors is also given by the access to the supplementary dashboard, by which they can have a "real time" monitoring of the health status of his patients. The advantage is two-fold, with a win-win situation: the family doctors has a closer communication with the patient, and a more continuous-time monitoring of the patient, most probably creating a higher number of consulting meetings (physical or tele-medicine), which should be translated in a higher income (e.g. in Romania, the family doctors are remunerated from the public healthcare budget based on the number of patients and the number of patient meetings); and the patients will benefit of a more preventive care, which should improve their overall health level and improve the quality of life.

Separate stakeholder categories, important to mention for the longer term development of the platform are:

- Technology producers: at this moment Vinci program uses devices which are in an experimental stage. The integration of data from the different devices is under technical and medical study. The resulted model can be extended by using a wider range of devices, from various producers (ex. Fitbit, Sony, Samsung, etc.). This way, the THL platform can work constantly with state-of-the-art devices and update the functioning models based on this technology.
- The healthcare and insurance companies: over a long term, this will become a target customer segment for the company, when the platform reaches a mature level and the set of data and processed information become relevant for healthcare companies. Nevertheless, at this stage, it is hard to evaluate the exact potential, as THL platform has insufficient collected data.

One of the strategic advantages envisioned by the switch from a device base solution to a software solution is also the capacity to quickly scale it at a wider geographical area. The mission states that THL aims at becoming a recognized European brand in the healthcare app category. Hence, for the medium term THL will start in the markets where there are already Vinci project partners and where the company has well established commercial relations. These first countries are:

- Romania, mainly through the partners CMD and Ana Aslan
- Greece, through CMD partners (e.g. National Greek Alzheimer's Association)
- Cyprus, with the help of University of Nicosia
- Poland, with the help of National Institute of Telecommunications
- Slovenia, with the main commercial partner Comtrade
- Italy, with the help of Optima Molliter and Marche Polytechnic University.

7.4.2 How It Will Get to the Arenas

For the geographical reach, as mentioned previously, THL will employ the help and support of existing Vinci program partners, for the first wave of European expansion.

Further, at a local level, THL will have to employ mainly marketing channels, for reaching the B2C customers, and sales capabilities to reach B2B customers.

The main marketing instruments are, of course on-line:

- Facebook, where the average age of users is higher than in other social networking platforms
- Google AdWords + well developed own website, as an important engine for creating B2C app downloads
- SEO optimization
- Partnering with Influencers and specific blogs

Off-line marketing will mainly refer to:

- Participation to specific event and congresses dedicated to elder's healthcare
- Targeted PR and marketing campaign, in certain periods and places.

Sales resources will be employed internally and will mainly focus on two categories of clients:

- Caregiving institutions – like private and public elders' care centers. Here some strategic alliances will be employed (ex. National Greek Alzheimer's Association, Romanian Association of Elder Care Centers).
- Doctors. In this category, THL mainly target General Practitioners (GPs). Older adults trust their GPs a lot, because their GPs know the health history of each patient, they usually also know the familiar conditions of each patient, and often, they also provide help and support to access some kind of social assistance services. In many European countries, the public health system relies on GPs who are represented by the national GPs' Associations, which operate at a national level. These associations, and similar actors in other countries, may be contacted in order to promote the advantages which THL platform can provide to older adults and the possibility for GPs to access the data collected by the system to better assist their patients.

Considering the sales targets, the sales team will target to employ medical reps.

An obvious collaboration channel will be also the various IoT producers that can integrate with THL platform

A potential channel, which is not that obvious for THL, are the insurance providers. The insurers are actively looking to expand their customer base, and such a platform like THL can be a perfect fit. On one side THL should be able to improve the general health level of a certain individual (through keeping him active and closer to his doctor), while providing data to the insurer, elements based on which the insurer better asses their risk, come up with better targeted (built-to-suite) insurance solutions for both elders and caregivers. On another side, the elders and the caregivers can benefit of superior security (better insurance packages) and lower costs, which ultimately, from THL's point of view, also translates into an increased quality of life.

Another target channel, which is also not evident, but is important, is represented by Gyms. More and more people aged over 50 are joining gyms (the average age in gyms is over 40 years). Furthermore, to keep members coming back for more, the gyms of yesterday have expanded their offerings with the latest and greatest trends in group exercise, from yoga to zumba and barre to kickboxing. More than two out of five health club members are involved in group exercise (https://www.creditdonkey.com/gym-membership-statistics.html). This is a perfect set-up, because gym clients are usually higher-income clients and are more likely to become paying customers for THL. In addition, THL has as a goal to create support group and competitive elements within self-selected social groups.

7.4.3 Differentiation

The main differentiation elements targeted by THL platform are of technological aspects:

- Flexibility, which refers to
  - multi-sided communication between doctors and patients or between different peer groups
  - technological possibility of integrating different IoT devices, to improve health reports and suggestions from the app.
- In the same line, this translates also in the customization capacity of THL. It can be used as an app alone, as an app with certain devices as an add-on, or the app together with the dedicated dashboard for the caregivers.
- Reliability of the technology is another aspect, as the technologies and platform are pretested during the Vinci program and pilot project.

Considering that THL aims at attracting customers ready to pay for the superior version of THL platform (with all reports and features), from design point of view, the target is to develop a product with a premium look, simple and easy to use.

On the pricing side, THL wants to reach scale through a free package, while also having premium features, priced accordingly.

7.4.4 Strategy Staging

It is important to acknowledge that at the moment when the start is considers (starting with 2021), through Vinci program THL has already the MVP and PoC stages concluded.

As a result, THL can focus on more on market development strategy, while in a first stage keeping more maintenance technical capabilities – platform updates, based on user reports and detected bugs.

Therefore, in the first year, THL will focus on creating a marketing and sales boost, in order to penetrate the market and create a steady foothold. The development of operating infrastructure will be done at a minimum requirements for the project (in terms of office support, office space, operational infrastructure, support services, etc.).

In the view that the first year efforts will insure a healthy paying customer base, with special focus of B2B customers, in the second year the company will focus this time on creating a proper infrastructure for THL, in order to be prepared for the next marketing and sales push. So, the platform is prepared for the envisioned intake of new customers. As we know from other market experiences, also success can lead to a business fall, if it's not properly prepared for the respective success.

Besides setting up basic office needs (accounting and financial, legal, office related, communication, etc.), THL will also increase in the second year the platform

development capabilities (for both research and development purposes and maintenance).

From the 3rd year, THL attention will refocus once again more on the marketing, sales and R&D efforts. Hence, these should significantly increase the customer base and income level, in order to create growth cycles.

The first 5 years will be dedicated to the European expansion. The first 3 years will focus on starting and expanding in the "partner markets" (Romania, Poland, Italy, Cyprus, Slovenia and Greece). Once THL proves that it is able to handle this international presence, it can further expand to bigger markets like Germany, France, Spain or UK.

7.4.5 Economic Logic

One of the advantages targeted by THL, when making the switch from a device-based solution to a software-based solution, is to be able to achieve scale at a faster pace and through that to achieve lower costs per customer. Once ready, the software platform is easily accessible by any smartphone or tablet user, though a simple download.

To help the creation of scale, THL will employ the freemium strategy. Therefore, anyone can access a basic set of features and also allowing it to easily spread among customers. In addition, a free use period of premium features will be given, in order to allow the customer to have an idea of the superior information and features the platform can give them.

In order to catch more of the paying customers, THL will have 3 type of subscriptions:

1. Basic -> where some additional platform features are available (TBD). The pricing level for it has to be set up to a monthly level of euro 5, which a general acceptable fee level for any non-free app (see subscription approach strategies for apps like kids development apps, Spotify, Netflix, amazon premium, etc.). The main scenario in this business plan considers a penetration between 6% and 12% of the basic subscription from the total number of downloads.
2. Basic + smart features -> is roughly the same set of information as for the first category, but for clients which also acquire and integrate IoT devices. Therefore they will have access to wider and more precise sets of data and analysis. The pricing level for it still has to be one within 'acceptable' customer expectations. The main scenario of this business plan is based on a euro 15/ month. THL actually aims to make this higher value category bigger than the basic category.
3. Basic full -> this will include all premium features of the platform and additional data generated with the help of integrated IoT devices. This will be positioned at a higher fee, of euro 30/ month and as a result, this premium customer segment is estimated to be at 3%-4% of the total number of downloads.

The customer base for the premium features is expected to be achieved also due to proprietary features of the platform.

An additional service that is expected to generate some income, is support services. This is expected to be employed only by B2B customers and premium B2C customers (considering the additional costs of euro 5/ customer). This will give the possibility to the client to benefit of immediate direct support (in a max time limit), while the other clients will only have access to automatic help technologies or general user manuals or Q&As.

7.5   Financial Plan

Based on the strategy and economic logic developed under the strategy execution, a series of financial assumptions and previsions were made, starting with 2021, considering that the technological development and testing within Vinci project is mainly due to be finalized during 2020.

First, we have a look at the foreseen evolution of income and costs evolution:
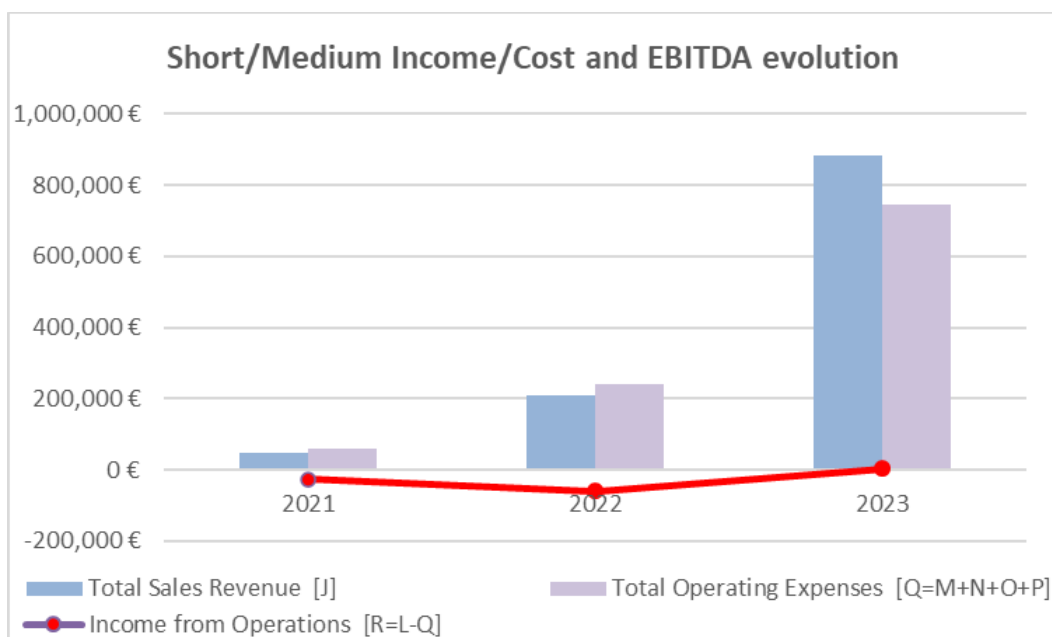
As visible in the above graphic, the project on its own is foreseen to have a cost structure higher than the income side, as logically the THL is focusing on catching the early adopter, through increased marketing efforts, while also investing in the platform fine-tuning and further development.

Once the early adopters come along and with the help of marketing efforts, the platform is expected to mature and by the 3rd year to reach operational breakeven point.

Nevertheless, even in this main growth scenario, the minimum estimated projecting financing required in the first 3 years, in order to reach the breakeven point and

employ the necessary resources to employ the reach the strategic targets, is estimated at a level of Euro 60 thousand.

Furthermore, the financial model shows that the operational profit is very sensitive to the number of adopters and implicitly the paying customer base. As a result, in a more pessimistic scenario if there is a drop of the customer base by 25%, while the resources acquisition and marketing targets remain the same (in order to keep the efforts of boosting the business), the financing need of the project would at least triple. Therefore, for comfort, a higher line/source of financing should be considered, in order to avoid project blockage and sufficient 'swinging' space for development.

As also specified previously, the economic logic is indeed to develop the business based on B2B customers, as these present a safer, constant and increased level of income per customer, especially considering the existing customer base and the market connections of the company. Hence, the financial result also shows an increased financial income from the B2B contract over the first 3 years. After the 3rd years, as long as the marketing and development efforts work as planned, it is foreseen that the B2C segment income, which is more important for scale development of the business, will catch up to the B2B income level and it should considerably overtake it by the 5th year.
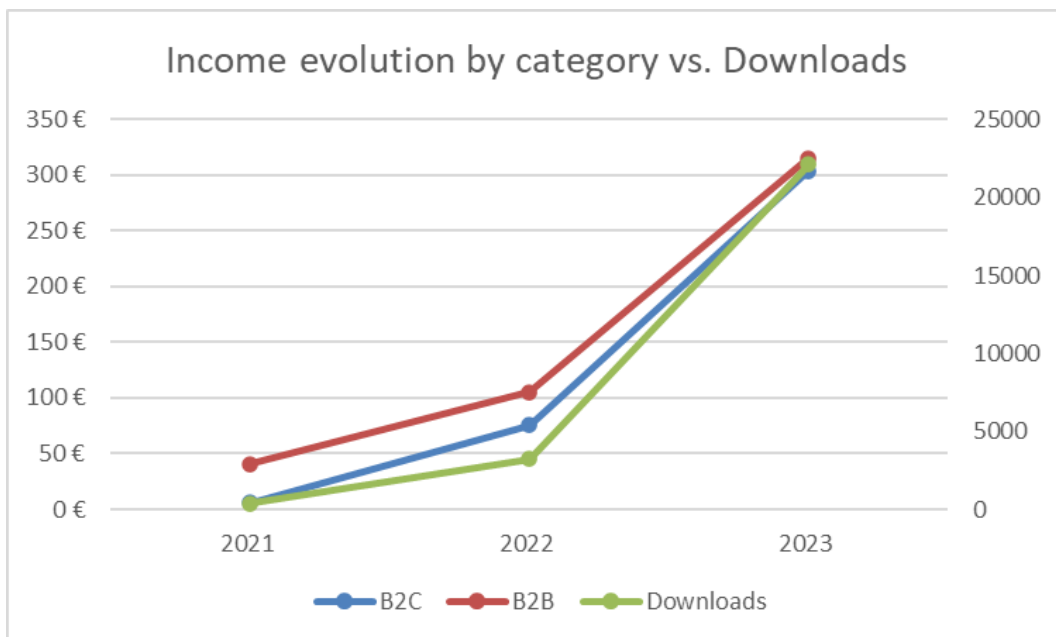
In detail, the financial plan foresees in the main development scenario that THL should reach a download level for the app above 20,000 mark. At this level, income from B2B and B2C would balance out at approximately euro 300 thousand.

On the cost side, the financial model reflects the strategy to have a focus on marketing and the further development efforts for the THL platform and app. As a result, these should reach together around 50% of the total operations and sales related costs.

Chart - Income Split Evolution
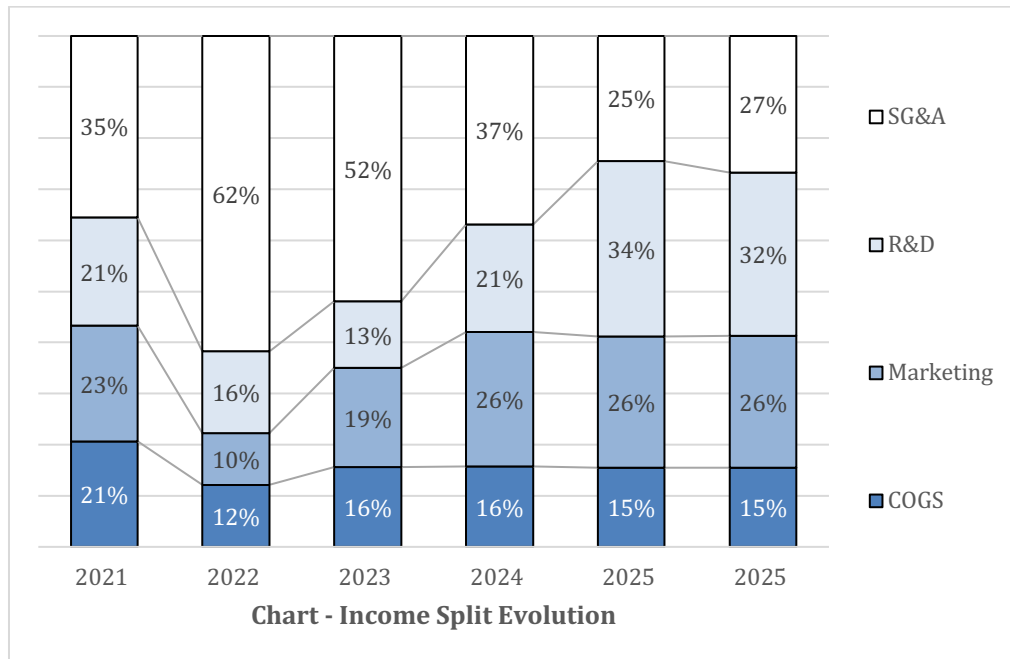
The same higher level of marketing costs is already foreseen from the first year of the project, as THL will need a strong boost to get a market grip. At the same time, in the first year the sales effort is in attention (reflected under SG&A category), to quickly secure the B2B customer base, which should insure the steady minimum income level.

Once THL managed to secure a base line, the 2nd year focuses on further establishing the basing resources to support the increasing operations, especially for the years to come. That's why the model shows a considerable increase of SG&A cost level in the first years, until the income level increases and this cost category is targeted to level out below 30% of the total costs.

R&D costs is mainly referring to employing THL's own dedicated team of programmers.

In the cost of goods sold category include IPR costs and general technical services for the platform (e.g. Amazon hosting, etc.).

It is important to mention that in the case of THL platform, as it is considered in this model, cost of goods sold should behave rather as fixed costs. In this case, as both COGS and SG&A categories are acting as fixed costs categories, once the sales pickup, the target is to level them to a maximum of 40% of the total cost. Nevertheless, for a project in full expansion, it is expected that the SG&A should still have a flexibility and follow sales curve.

7.6 The business model Canvas

The Human Link

Key Partners	Key Activities	Value Proposition	Customer Relationship	Customer Segments
Vinci Consortium Partners Doctors and healthcare units (for patient studies) ... KOL's IoT producers Insurance companies On-line markets	Development and selling of the THL App with the platform and the dashboard for doctors. Customer care Big data – medical statistics **Key Resources** Tech know-how Specialized sales team (tech/medical) Access to EU medical network Marketing – internal and outsourced; software development	**Product:** A singular innovative platform with an App, THL, which can integrate a wide range of IoT devices, so elders and caregivers can track health status, activity, health evolution, and connect with elder's family, doctors and other groups of friends; designed to improve quality of life and health conditions for elders and families, while reducing caregiving costs. **=> Keep elders safe, free, and with a higher quality of life, while providing comfort and security to elder's caregivers and informing the treating doctor about patient's medical status.**	Direct relation: On-line sale platform; direct interaction; on-line support; App updates Indirect relation: interaction insights from patient relation with doctors and specialized associations **Channels** On-line environment/ markets; caregiving centers/doctors for B2C; IoT suppliers; dedicated bodies (national associations; professional associations; opinion leaders); Gyms.	Families with elders or dementia Patients Elder Care Facilities and Hospitals Family Doctors Practices Profession Caregivers Long term: pharma producers; insurance companies.

Cost Structure	Main Revenue Streams
Up to 20% COGS More than 25% Marketing investment More than 30% R&D Up to 30% SG&A	Monthly subscriptions for App and customer support services. Basic – euro 5 Basic + smart features – euro 15 Full – euro 30 Customer support – euro 5

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