HORIZON 2020
The EU Framework Programme for Research and Innovation

CAPABLE

Cancer Patients Better Life Experience

Grant Agreement No. 875052
Start Date: 01/01/2020 (48 Months)

Deliverable No. 8.4

Exploitation plan and business models V1

Due Date: [31/12/2021]
Submitted On: [28/12/2021]

Coordinator	University of Pavia (UNIPV)
Deliverable Lead Partner	Universidad Politécnica de Madrid (UPM)
Contributing Partners	UPM
Contact	Prof. Silvana Quaglini
Email	silvana.quaglini@unipv.it
Website	www.capable-project.eu

Deliverable Type		
R	Document, report	**[X]**
DEM	Demonstrator, pilot, prototype	
DEC	Websites, patent fillings, videos etc.	
OTHER		
Dissemination Level		
PU	Public	**[X]**
CO	Confidential (Consortium members including the Commission Services)	
CI	Classified Information (Commission Decision 2015/444/EC)	

This deliverable is a part of a project receiving funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 875052.

Table of Contents

Versions History 4
Executive Summary 5
1. Introduction 6
2. Exploitation plan 7
3.KER 1: Overall Capable system 11
3.1 Characterization of the result 11
3.1.1 Problem 11
3.1.2 Alternative solution 12
3.1.3 Unique Selling Point USP - Unique Value Proposition UVP 13
3.2 Exploitation roadmap 16
3.3 Risk assessment 20
3.4 Use options 25
4. KER No. 2 CAPABLE technological stack for Digital Health products 26
5.KER 3: Digital therapeutics for cancer self-management 27
5.1 Characterization of the result 27
5.1.1 Problem 27
5.1.2 Alternative solution 27
5.1.3 Unique Selling Point USP - Unique Value Proposition UVP 27
5.1.4 Description 28
5.1.5 "Market" – Target market 28
5.1.6 "Market" – Early Adopters 28
5.1.7 "Market" – Competitors 28
5.1.8 Go to Market – Use model 29
5.1.9 Go to Market – Timing 29
5.2 Exploitation roadmap 29
5.2.1 Actions 29
5.2.2 Roles 30
5.2.3 Milestones 31
5.2.4 Financials Costs 32
5.2.5 Revenues 32
5.2.6 Other sources of coverage 33
5.2.7 Impact in 3-year time 33
5.3 Risk assessment 33
5.4 Use options 37
6.Conclusions and future works 38

List of Figures

Figure 1: adaptation of the CeHeres process to the CAPABLE activities 6
Figure 2: Organizational map for the commercialization of KER1 18
Figure 3: Organizational map for the commercialization of KER3 31

List of Tables

Table 1: CAPABLE KERs overview 7
Table 2: analysis of the alternative solutions 12
Table 3: metrics used to inspect the KER1's competitors 15
Table 4: proposed action for the exploitation of KER1 16
Table 5: milestones for the exploitation of KER1 18
Table 6: costs for the exploitation of KER1 (€) 19
Table 7: initial estimation of revenues for KER1 20
Table 8: risks related to the partnerships 21
Table 9: risks related to technology 21
Table 10: risks related to the market 22
Table 11: risks related to the IPR and legal issues 23
Table 12: financial and management risk factors 24
Table 13: regulatory risks 24
Table 14: proposed action for the exploitation of KER3 29
Table 15: milestones for the exploitation of KER3 31
Table 16 costs for the exploitation of KER3 (€) 32
Table 17: initial estimation of revenues for KER1 32
Table 18: risks related to the partnerships 34
Table 19: risks related to technology 34
Table 20: risks related to the market 35
Table 21: risks related to the IPR and legal issues 35
Table 22: financial and management risk factors 36
Table 23: regulatory risks 36

Versions History

Version	Date	Author	Comments
1.0	10th October 2021	UPM	First table of content
2.0	20th October 2021	UPM	First draft of the KERs
3.0	13rd November 2021	UPM	Revised version of the KERs
4.0	30th November 2021	UPM	Completed draft version of the document
5.0	15th December 2021	UPM	Final version of the document

Executive Summary

The document presents the first version of the exploitation plan and business model of the CAPABLE project. At this stage of the project the Consortium proposed to focus on the exploitation of 3 Key Exploitable Results (KERs), they represent a first analysis of joint commercialization of the following services:

- Overall CAPABLE system: a mobile health solution to monitor cancer patient during the treatment.
- Technological stack for Digital Health products, to develop novel solution in the field of digital health leveraging on the methodological approach and software re-adaptability of the project.
- Digital therapeutics app for cancer self-management. An adaptation of the overall system to provide an app for cancer patient communities.

1.Introduction

The project proposed to adopt a framework for the uptake of the e-health solution called CeHRes, introduced in the first WP8 deliverable (D8.1, chapter 5.1). This methodology proposes a unique iterative process for the phases of development of an e-health solution. In this process WP8 used the results from WP7 (system evaluation) and WP2 (system specification) to craft an exploitation plan and business model according to the stage of the project and to the project innovation potentials. The following schema summarizes the main activities and dependencies in the different steps of the CeHeres method.

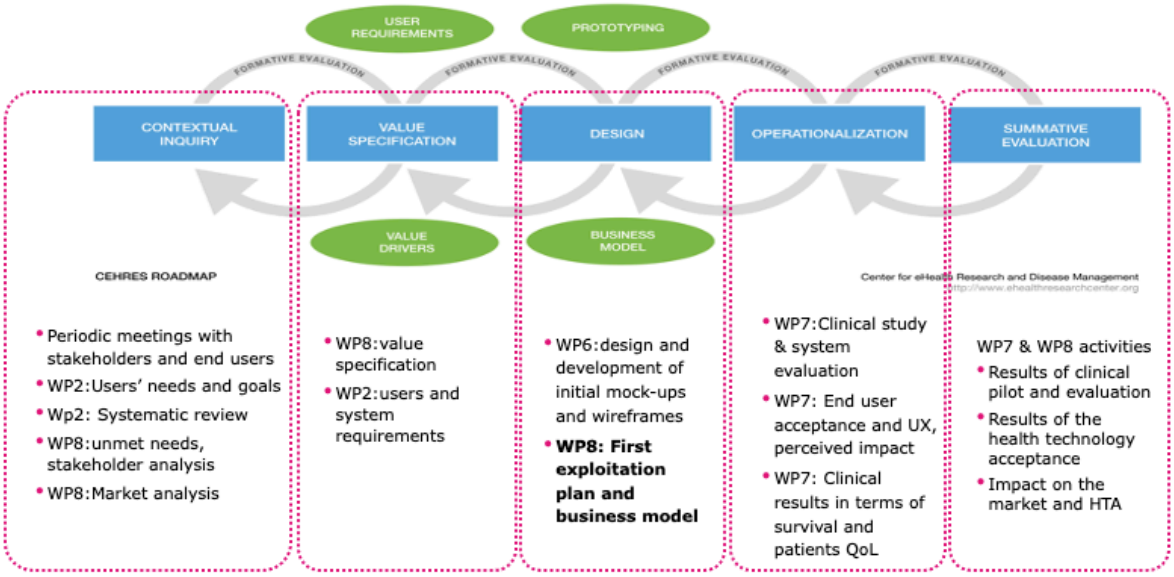

Figure 1: adaptation of the CeHeres[1] process to the CAPABLE activities

The process of definition of the exploitation plan and of the business model has been supported by *Horizon Result Booster* (HRB). HRB is an initiative backed by the European Commission which aims to maximise the impact of research projects funded by FP7, Horizon 2020 and HE. The CAPABLE consortium decided to apply for HRB support, which was approved, and HRB organized 3 workshops with the Consortium to refine the exploitable results and show a possible methodology to craft a proper value proposition, business characterization, risk analysis and exploitation roadmap.

The document presents in the next section the exploitation strategy, introducing the process of identification of the 3 Key Exploitable Results that have been described in section 3, 4 and 5. The document finishes with a conclusion chapter that shares the actions for the next period.

[1] https://www.utwente.nl/en/bms/ehealth/cehres-roadmap-toolkit/

2. Exploitation plan

The exploitation plan for the reported period focused on the definition of commercial routes of 3 joint Key Exploitable Results: KER1, KER2, and KER3.
The process of the selection of the KERs has been described in D8.3 (see section 3.3) and, as mentioned above, was refined together with the HRB support (Module C: *Assisting projects to improve their existing exploitation strategy*).

Table 1: CAPABLE KERs overview

		Exploitation schedule/ Target TRL (Technology readiness levels)				
KER	Description	End of project	1 year after	2 years after	3 years after	4 years after
1	Overall CAPABLE system	TRL6	TRL7	TRL7	TRL8	TRL9
2	Technological stack for Digital Health products	TRL6	TRL7	TRL8	TRL9	TRL8
3	Digital therapeutics for cancer self-management	TRL6	TRL8	TRL9	TRL9	TRL9

This initial focus on the KERs and not in a more general exploitation (considering not only commercial exploitation but also individual exploitations) has been agreed as a strategy to early identify, define, and analyse the opportunity during the project and properly decide the strategy and actions during the project as well. Being the KERs technological components depending on the results of the final clinical study in terms of health outcomes, user experience, accurateness, and robustness of the system, part of this work has been done making specific assumptions on the value of the proposed KERs. Just at the end of the clinical study it will be possible refining the value proposal according to the obtained results.

Thanks to the methodology proposed by the team of Horizon Result Booster the KERs have been defined under different aspects:

- Exploitation intentions, i.e., the CAPABLE consortium share the position on the exploitation interest on the specific KER.
- Business characterization to describe the problem, the proposed solutions, the market, and the competitors.
- Use options, i.e., definition of the best exploitation route for the KER.
- Risk analysis to assess the risks and actions to mitigate the risks.
- The exploitation roadmap, to identify actions for the implementation of the business case and estimation of revenues and costs.

The exploitation intentions of the 3 KERs can be grouped in the following table:

		Participation in KER			
Partner	**Interests**	**Contribution to the KERs**	**1**	**2**	**3**
UNIPV	licensing, know-how transfer contracts, research and development contracts, participation to future projects to increase this KER TRL to help bringing this KER to the	development of the case manager software component background expertise in knowledge elicitation for guidelines formalization	Y	Y	Y

	market, organisation of focus groups				
UH	Support the commercial exploitation via a license	Explanation and documentation of the approach	Y	Y	Y
BIOMERIS	Biomeris can do dissemination by releasing (in form of open source) the Capable OMOP-FHIR implementation to the OHDSI-OMOP community	development of the Data Platform component expertise in OMOP CDM, OHDSI toolset, harmonization procedures and FHIR	Y	Y	Y
AMC	AMC can exploit the role of the Capable system in a FAIR ecosystem, i.e., benefitting from and contributing to other FAIR resources.	Collaborate and consult with customers on maximizing the FAIRness of future instances of the Capable system	Y	Y	Y
IBM ISRAEL	IBM Research can support via a license; additionally, they can present the Capable Demo to customers /collaborators and if there will be potential interest, we could return to the consortium to generate the relationship. It will be possible to exploit the overall system in new EU projects that they will participate in.	Explanation and documentation in of the approach	Y	N	N
BITSENS	Bitsens will be happy to exploit with its parts that are the UI, as an integral part of the overall system; this is a new market for Bitsens so no geographical preferences or restrictions due to the virtual nature of the product	The UI (front end) for patients and caregivers, including the backend component which will be connected to other components of the system	Y	N	Y
PUT	PUT is interested in exploiting the created components within the overall CAPABLE system both commercially (by offering licenses to interested institutions) and scientifically (by participating in other projects, founded by EU or local grant agencies).	(1) Development and maintenance of the Virtual Coach software infrastructure, process and decision models. (2) Development and maintenance of the Sensors module. (3) Involvement in advertising efforts and activities.	Y	Y	Y
ICS MAUGERI	ICSM can exploit the Overall Capable system in a real-life scenario and it can provide feedback on the usability from both	ICSM is involved in the overall system requirements definition. Requirements were collected via interviews with both patients and healthcare	Y	N	N

	clinicians and patients points of view.	professionals. ICSM is involved in the clinical trial activities (protocol design and pilot study). ICSM participate in the UX validation.			
NKI AVL	It will be possible to exploit the overall system in the participation of funded research projects.	NKI is an important contributor of sharing knowledge/intellectual capital and having access to the users of the system (patients and clinicians). NKI is involved in the overall system requirements definition. Requirements were collected via interviews with both patients and healthcare professionals. NKI (researchers and clinics) is involved and contributes to the development (content) of a system of symptom monitoring, guideline modelling, UX validation and clinical trial activities (protocol design and pilot study). NKI contribute to the development of an AI prediction model.	Y	N	N
DEONTICS	Provisional answers: Commercial licensing of components (primarily PDSS) for clinical use. Licensing of the Deontics engine and APIs for use as a back-end engine for decision support within the system.	Provision of the backend DSS engine. Development of Physician DSS component (Integration of Deontics DSS into CAPABLE system as a component, and incorporation of probabilistic and goal-based techniques into CIG-based DSS)	Y	Y	Y
AIMAC	AIMAC is interested in developing the app to support its activities. More in detail, the most relevant aspects are: 1. better inform the patient by means of constantly updated and personalized information on the patient's needs 2. educate patients to adopt behaviors that fight cancer	AIMAC provides the app with information on cancer and lifestyles in an appropriate language for patients and their care givers. It contributes to designing a user experience capable of creating value for the patient. AIMAC helps testing the app with the patients.	Y	N	Y
UPM	UPM would like to exploit the Capable results in the Spanish Market thank to the network of hospitals and relevant stakeholder operating in the Market.	UPM is committed to guide the Consortium through the exploitation of the Overall Capable system	Y	Y	Y

	(hospitals, industrial partners etc). It will be also possible to exploit the overall system in the participation of EU founded project.				

In the next sections the reader will find the description of the KERs: 2 KERs are presented in detail according to their level of maturity at this stage of the project (KER1 and KER3), while KER2 will be briefly introduced in this document and then further elaborated in the next period. All the KERs must be considered as an initial proposal of the potential exploitation routes of the overall CAPABLE system. The business cases will be continuously evaluated and refined in the next period of the project and aligned with the individual exploitation plan of the partners.

3.KER 1: Overall Capable system

3.1 Characterization of the result

3.1.1 Problem

Cancer is the leading cause of death for people under 70 years in most of the countries worldwide, accounting for nearly 10 million deaths in 2020. Cancer is a complex disease that causes late and long-term side effects due to the malignancy of the condition and the treatment; this reduces the quality of life of the patient and families and generates a significant social and economic burden. Cancer is the leading cause of death for people under 70 years old in most of the countries worldwide, accounting for nearly 10 million deaths in 2020. In many cases the cancer patients receive a treatment (e.g., immunotherapy, chemotherapy) to be followed out of the hospital; and it is crucial to accurately follow-up the treatment response, the overall cancer evolution and the patient's side effect. If a patient is having a good evolution, it will have periodic visits every 3 months. The duration of the visit is around 20 minutes, which in some cases is not enough to address all the issues of a patient. In the following, a list of problems is reported

PB1 for the hospital: **lack of time to spend with each patient**
During the visits the health professional collects information from the patient and eventually requests additional lab tests to better investigate the health status.
From a visit to another the health professional is not informed on the evolution of the disease and on the possible onset of side effects or signs of deterioration of the health status.
PB2 for the hospital: **improve symptom monitoring.** To better manage the treatment, it is crucial to know the onset of symptoms, when it appears, the grade and explain to the patient what to do and decide if this can be self-managed by the patient at home, or if it requires further visits and clinical interventions. The classical follow-up model is based on (i) periodic visits, which sometime is not necessary, and (ii) unscheduled visits, triggered by certain reported symptoms, which might be scheduled before the persistence or the worsening of the health conditions of the patient. The overall knowledge of the disease evolution in outpatient settings is also requested to better understand the physiological response of the patients.
PB3 for the hospital: tracking patient status remotely. In standard care the oncologists have no access to the health status of the patients at home. This information would be crucial to better understand the evolution of the treatment response and side effects as it would save time during the visits requested because of the onset of a symptom.
PB4 for the hospital: **improve adherence of cancer treatment**. The adherence to the treatment is the key for a successful therapy. The hospitals nowadays rely on the patient's feedback during the visit. There is a need to support the patient at home to foster the adherence.

Additionally, there are specific barriers for the adoption of new digital health technology:
PB5 for the hospital: Hospital staff might be hard to teach / convince to use a new program: Current standard health care organizations are not considering the required additional resources for the use of the telemonitoring services, and the work is not recognized as part of the clinical processes.
PB6 for the hospital: Not enough Good IT systems in hospitals, they are usually old and cumbersome: Additionally, there are difficulties to integrate new systems to the Health Care Record of the patients.

In the digital market of oncology there are companies that are already providing tools for the diagnostic (based on imaging of genetic data), or support for Electronic Health Records. In case that they would enter in the digital therapeutics market they can face the following problems:

PB1 for MedTech companies: Complexity of the cancer treatment domain. The complexity of the cancer domain depends on the complexity of the disease, of the treatment's options, side effects and the need to harmonize this with the clinical guidelines.
PB2 for MedTech companies: MedTechs initially focuses on hospital needs, now there is a need to create services for patients at home. This is a growing market. The companies would like to Increase market share and increase visibility.

At this stage we consider the following KPI to be used to monitor the performance of the solution:

- KPI1: duration of the visit (20min follow up, 30 min first visit).
- KPI2: side effects of patients during cancer treatment.
- KPI3: time spent by the health professionals (nurses and oncologists) using the CAPABLE system.
- KPI4: Quality of Life of the patient (which will be the primary endpoint of the clinical study) .

3.1.2 Alternative solution

There are three alternative solutions:

1. Standard Care (NO tele-monitoring system, just phone call to follow-up the patients)
2. Competitors (Kaiku Health[2], Bioformis[3] etc)
3. Patient can decide to find information in the Web and eventually download and pay for an app to have support (e.g. Chemowave[4]). In some hospitals (also in NKI) the doctors recommend downloading an app for self-management of specific symptoms (e.g. UNTIRE[5]).

The following table shows how the alternative solutions solve the problems presented in the previous section.

Table 2: analysis of the alternative solutions

	Lack of time for visit	**Improve symptoms monitoring**	**Monitor patient health**	**Improve adherence**	**Additional workload of digital services**
Capable	We expect to reduce visits number and duration	Instant feedback to the patient and request of follow up to the health professional	Collection of PREM and PROM and physiological data using wearable sensor	Digital service to promote the adherence to home therapy, suggestion on how to manage moderate symptoms	CAPABLE will add a workload for nurses. This is minimized by a stratification approach based on alert generation
Standard Care	Visits are the only opportunity to get information from	This depends on how patients perceive the gravity of the	This is possible during the visits.	Health professional can give proper instructions but then	After the visit routines usually the health professionals update the

[2] https://kaikuhealth.com/
[3] https://biofourmis.com/
[4] https://chemowave.com/
[5] https://untire.me/

	patients. With the pandemic also phone calls have been used to remotely assess patients	symptom and react to that. Also, it is important that patients remind past symptoms during follow-up visits.		this depends on how the patient stick to the recommend ation	Electronic Health record
Competi tors	The benefit of the remote follow-up is to reduce the visits time and frequency	Symptom's reporting is supported but not all the system implements the guidelines recommenda tions	Competitors collect health information. Many just focus on cancer related information and not on the overall wellbeing of the patient	Many competitors state that the solution improve adherence	Competitors are not mentioning the added workload for the health professionals
Self-manage ment app	During the visit the patients could share the evolution of the symptoms using an app (e.g, Chemowave)	Many apps just support the symptom report, but no feedback and suggestions are given to the user		The use of a diary might improve the adherence	No additional workload for health professional

3.1.3 Unique Selling Point USP - Unique Value Proposition UVP

- Many system implement guidelines, but CAPABLE is the only one that is flexible, because new guidelines can be added without affecting the code.
- Support for remote symptom management. Triage of mild symptoms and promotion of self-management according to clinical guidelines.
- Prediction of disease trajectory / treatment response
- Patient empowerment and support related to lifestyle, emotional distress, information need based on clinical evidence
- Building upon psychological theories (Fogg behavioural change theory)
- Reliance on approved standards (PROforma for representing guidelines, HL7 FHIR and OMOP for communicating and representing data) makes CAPABLE a solution well suited to clinical studies where clinical knowledge and data should be openly shared with the research community.

Our Service Helps hospitals who want to improve the efficiency of the visits and overall follow up of cancer patients during the treatment phase. And, unlike hospitals, we prefer to delegate patients to self-manage the collection of information using digital tools or not.

The CAPABLE service can support the hospitals by providing a tool to monitor symptoms and physiological status in the patient's home, follow the clinical guidelines and provide recommendation to the patients in case of no critical situations and alert the health professionals in case that a specific attention to a patient is required.

3.1.4 Description

The CAPABLE solution is a state-of-the-art digital technology to foster the outpatient management of cancer. It targets patients and oncologists. The patient system is composed of a patient app (Android) and a smartwatch (Asus VivoWatch) that are used to gather physiological and health information (Patient reported experience and outcomes - PREM, PROM) to monitor the health status of the patients during a specific cancer treatment (e.g., immunotherapy). The app provides guidance on how to manage side effects and suggests behavioural modifications to promote the overall wellbeing of the patients, improving their quality of life. The oncologists can remotely follow up the health status of the patients and use a clinical decision support system that implements the current clinical practice guidelines (Computer Interpretable Guidelines) for the management of therapy and side effects; the system also provides prognostic tools to assess the disease trajectory and the treatment response.

3.1.5 "Market" – Target market

- TAM (Total Addressable Market / Total Available Market): The overall digital therapeutics market was in 2018 of 2,24 billion and it is expected to be 9,64 Billion dollars by 2016. This market includes all the digital solutions for wellness and disease management. We consider that the specific cancer market could be 1% worldwide. This sector is not including other specific cancer markets related to diagnostic and medical treatment.
- SAM (Serviceable Addressable Market or Served Available Market.): we consider that the CAPABLE service could reach the EU market with a specific focus on the Spanish, Italy, Polish market.
- SOM (Serviceable Obtainable Market or Share of Market): specifically considering the 3 geographical regions, Lombardy Italy, Madrid community in Spain and in Poznan community of Poland.

3.1.6 "Market" – Early Adopters

We have an initial contact list that we need to exploit to check is they could be early adopters:

- UPM has an agreement with the hospital network of Madrid (SERMAS) and it can try to contact them to make some tests.
- PUT has just started cooperation with one of the hospitals in Poznan. While the core cooperation is focused on data integration and analysis, the hospital also has an oncology ward and clinic and PUT can initiate contacts related to preliminary tests of the CAPABLE system (this would require a localized translation of the system).

Another activity that is planned for the next period is to make a survey for hospital managers to understand the situation across different hospitals in Italy, Spain, and Poland. This will help us to better identify early adopters. At this stage they think that there are few cases in Europe of hospitals using a service like CAPABLE.

3.1.7 "Market" – Competitors

For this KER an initial market analysis has been reported in D8.1 and D8.2. The work has been updated. The document is available to the following permanent URL:

https://docs.google.com/spreadsheets/d/1Ow6u4zPvcyjoDaM79JoOHQYMXa1ng4b7/edit#gid=1889730072

In this market analysis 15 products have been inspected and metrics have been considered to characterize the product and the company and to know the functionalities available as the following table summarizes:

Table 3: metrics used to inspect the KER1's competitors

Product info	**Functionalities**	
Company, Product, Location, In the market from Technical solution Wearable sensors Wearable Proprietary Technical approach Data storage Development language/Tools AI/Prediction EMR Integration Standard Use of Guidelines FDA or CE Mark # Treated Patients Target Profile (End Users) Related of Cancer Type of Cancer Stage of Disease Based on Previous Clinical Studies Price Website	Home Monitoring Symptom Reporting Symptom / treatment recommendations insert symptom photo Education Material Social Connection Therapy Symptom Own Cancer Education Nutrition Support Physical Wellbeing Mental Wellbeing Quiz Activity (capsule) Pharmacology (daily planning) Vital Parameters Lifestyle data Export/Import Data Messaging Clinical Application Clinical History Current Stage of cancer	Insert (Add) Patient Day Hospital Treatment Management Insert/Modify Treatment View Treatment Insert Parameters View Vital Parameters Insert Symptoms View Symptoms Insert Imaging Records Insert Blood Results Book Visit View Visit Messaging Questionaries Recommendations Nutritional Support Questionnaires

From the analysis CAPABLE differentiates from the competitors to be a comprehensive solution that covers all the functionalities and proposes an integrated care approach like the platform Living With[6] that gives access to different health professionals (nurses, psychologists, dieticians), implements the clinical guidelines as other 8 competitors. No one of the competitors supported personalized treatment for kidney or melanoma cancer as CAPABLE does. Just two competitors support all the types of cancer just because the solution focuses on providing the support to a specific therapy (e.g., chemotherapy) like Appli Chimio[7] or to a specific side effect like Untire app. **There is a clear opportunity for CAPABLE to differentiate for the capacity to support other types of cancer. Artificial intelligence represents another additional opportunity for CAPABLE, the prognostic model will have the advantage to be unique for the target population.**

3.1.8 Go to Market – Use model

[6] https://www.livingwith.health/
[7] https://play.google.com/store/apps/details?id=com.bepatient.appchimio&hl=es&gl=US

The use model is to provide a service in a public or private cloud according to the preferences of the hospitals. The costumer will pay a year subscription based on the number of clinical units, health professionals and patients that will use the system.

Additionally, the costumers will pay a fee for the deployment of the CAPABLE technology in a private cloud inside the hospital infrastructure. The fee will include hardware costs and deployment of the technology service.

The use model will be linked to the following services that will add value and will improve the costumer's experience.

- Commercial and financial service to close contract with the clients. Every costumer will be followed by a commercial agent that will follow-up all the pre and post purchase processes.
- Creation of customer support and training service. The new costumer will have access to training services to be used to build the technological skills of the health professionals to use the CAPABLE system and train the enrolled patients.
- Additionally, it is possible to purchase specific learning courses for a group of patients in the case that the hospital cannot afford the training of the patients.
- Deployment and maintenance: these are ancillary services linked to the CAPABLE server. The costumer can decide to use the service using a cloud solution or to deploy in the intranet of the target hospital. The service will support the customer to choose the best solutions and will be able to sell to the clients dedicated servers to be used for the intranet option. Service then will include all the activities to set up the CAPABLE service.
- Management of end user devices (sensors, mobiles) during the purchase of the service the client will be able to decide to purchase wearable sensors and mobile phones to be provided to the patients. This use model will purchase the devices to the specific provider and manage the logistic to deliver to the client

3.1.9 Go to Market – Timing

Considering the proposed use, we plan to go to the market after 3-4 years after the project.
The first year and half will be dedicated to the Medical Device certification and then it will be possible to offer the service in an internet cloud. The commercial services and the costumer support will be necessarily set up, the rest of the services (device managements and training, internal cloud support) will be available at the 3rd year.

3.2 Exploitation roadmap

3.2.1 Actions

The following table shares the list of actions to commercialize the KER1. The table also proposes an initial candidate that can be the responsible of the task. The assignation has been done considering the skills, knowledge and contribution shared in the CAPABLE project. This proposal will be refined in the next period.

Table 4: proposed action for the exploitation of KER1

	Start	End	Initial candidate
Agreement of collaboration in the Joint Venture	1	6	UPM
Agreed business strategy and business model	1	8	UPM
Creation of joint venture and agreement of level of participation of the partners	1	8	UNIPV
Participation in research programs	1	10	UNIPV, UPM

First research contract to perform a medical study and certify the system	1	15	UNIPV, UPM
Deployment of the CAPABLE service	1	15	BIOMERIS
Pre-order of user devices	1	15	BIOMERIS
Set up of logistics, costumer care service	15	20	BITSENS
Preparation of the documentation for ethical committee	15	20	UNIPV, UPM
Preparation of documentation for Certification as Medical device	12	18	UNIPV; AMC
Execution of the first clinical study	24	36	BIOMERIS
Certification process	30	45	UNIPV, AMC
Registration of the company as manufactures registry	30	35	BIOMERIS
Consolidation of the Business plan	12	36	UPM
IPR management, transfer of licence to the JV	24	36	UPM
Marketing activities	12	36	BITSENS
Creation of a sales department	24	48	IBM, DEONTICS

3.2.2 Roles

The roadmap of the exploitation will be supported by the partners listed in the previous table. The initial idea will be to set up a Joint Venture (JV) with the following organizational map that considers 4 main activities of a company: operations, sales, design, and marketing.

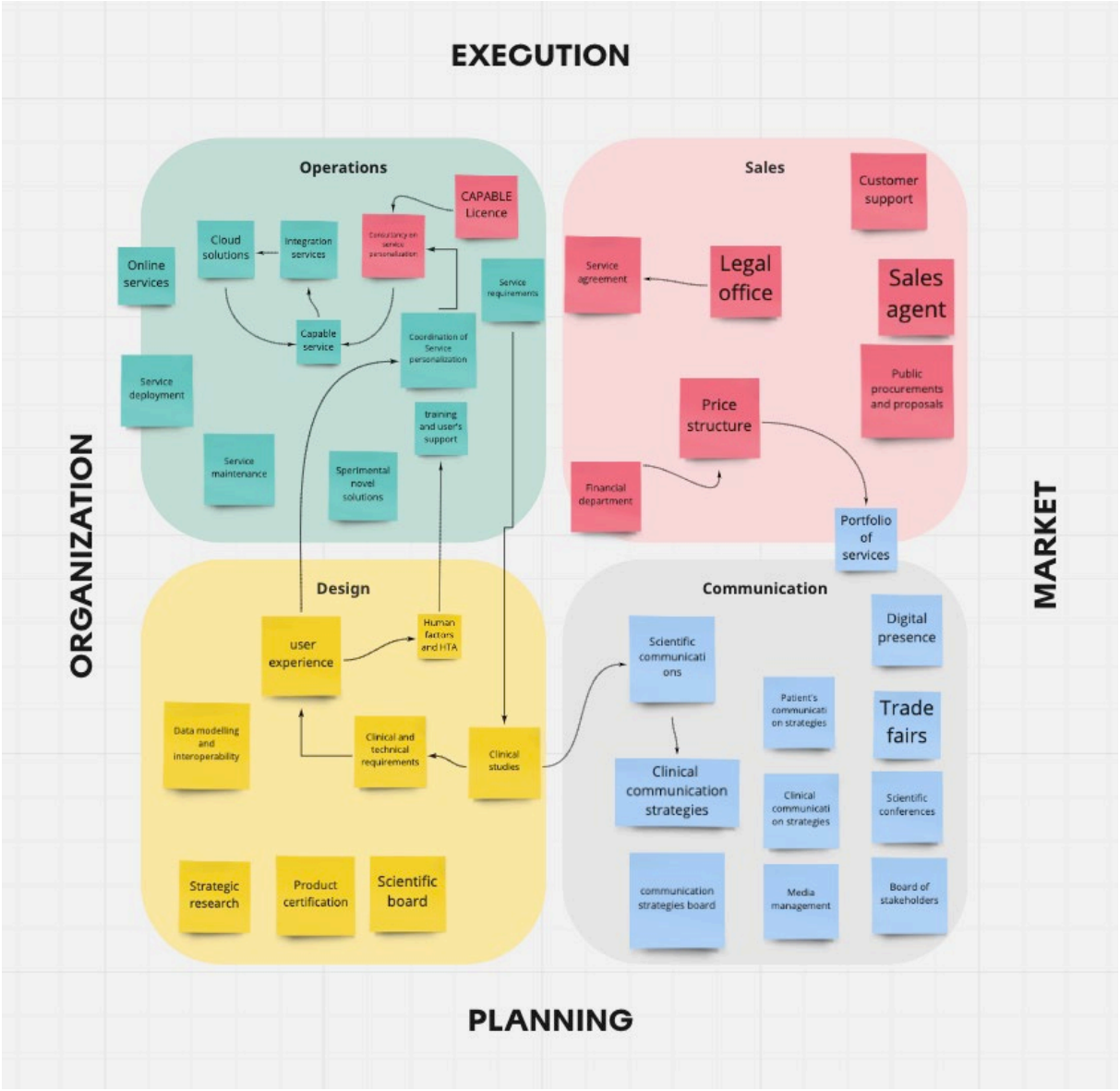

Figure 2: Organizational map for the commercialization of KER1

The JV will be supported by the companies of the Consortium, while the rest of the partners (no companies) will have a collaboration contract according to their expertise. The Role of CEO is still under discussion.

3.2.3 Milestones

WP8 proposes the following milestones to be achieved after the project to reach the commercialization of the KER1.

Table 5: milestones for the exploitation of KER1

Milestones	Months after the project	Means of verification
M1: agreements and JV creation	8	Existing of a legal entity, signed contracts
M2: funded project	15	Gran agreement

M3: service available	15	Service is available in the cloud
M4: Clinical study finished	36	Study registration number, copy of ethical approval, informed consent, existing data in the CAPABLE platform
M5: CAPABLE is certified as MD	45	Final documentation from Evaluation Agencies
M6: Final business plan	48	Document of business plan
M7: Marketing and sales activities are ready	48	Presence in 2 markets / conferences. Service portfolio, Web Page

3.2.4 Financials Costs

The following table breakdowns the estimated costs for the exploitation plan. This is an initial estimation that will be iteratively refined and detailed in the next deliverables of WP8.

Table 6: costs for the exploitation of KER1 (€)

Cost	Description	Total	Year 1	Year 2	Year 3	Year 4	Source of funding
Joint venture set up and contract	taxes, legal and admin consultancy	**20000**	20000	0	0	0	Supported by partners , proportional to shareholder
Deployment and maintenance of Capable service	Hosting and developers	**100000**	40000	40000	10000	10000	R&D funded project
CAPABLE service personalization	Collaboration with UPM, UNIPV, UoH, PUT, AMC	**120000**	10000	60000	30000	20000	R&D funded project
Logistics and costumer care	Network of collaborator for logistics and deliver of device and solve technical problem of the users	**60000**	0	20000	20000	20000	R&D funded project
Company webpage	Cost to set up a web page	**10000**	10000	0	0	0	Supported by partners
Marketing activities	Digital advertising, position in the search engine and social network feeds.	**30000**	0	5000	10000	15000	Supported by partners
Device purchase	Purchase of 200 devices for users	**40000**	10000	30000	0	0	R&D funded project
Certification documents and taxes	taxes, legal consultancy	**30000**	5000	10000	10000	5000	R&D funded project
Capable license		**30000**	10000	10000	10000		Supported by partners
Set up sales department	set up of office and hiring of senior agent	**80000**	0	0	20000	60000	Support by Companies
	Total	**520000**	105000	175000	110000	130000	

3.2.5 Revenues

The following table describes an estimation of revenues:

Table 7: initial estimation of revenues for KER1

Type of income	Description	Year 1	Year 2	Year 3	Year 4
R&D project	Project to support a clinical study and to perform the device certification.	150000		200000	150000
Start-up seed funding	Funding to accelerate the company		100000		
First contact with one hospital	First official contract with one hospital			100000	
R&D project	Second R&D research as a service provider, 2/3 hospitals				200000
Second contract with hospital	Second contract with an hospital				60000

3.2.6 Other sources of coverage

The certification will allow to grow from TRL6 (as stated in the grant agreement) to TRL8. For that it is required to perform a clinical study and certify the platform as a medical device. It is crucial to get some R&I grants to sustain the costs of these activities.

3.2.7 Impact in 3-year time

The impact will be the improvement of the QoL of patients that undergo cancer therapy (e.g., immunotherapy, chemotherapy), better use of resources in the oncological clinical units, early intervention to manage the side effects that may impact the overall evolution of the treatment response.

Impact related to the EU call of Capable (SC1-DTH-01-2019)

- Emerging data driven analytics and advanced simulation methods to study causal mechanisms and improve forecasts of ill-health, identification of disease trajectories and relapse; (KPI: number of deployed solutions, number of patients and health professionals using the solutions)
- Better and faster means of high-quality response to prevent or timely address development of new medical conditions and/or improve the quality of life; (KPI: number of early reported side effects)
- Better knowledge for improved patient counselling as well as to improve follow-up of patients; (KPI: improved knowledge of patients on cancer management)
- Novel information on health maintenance, onset and course of medical conditions with a view to optimise prevention and treatment; (KPI: number of deployed solutions and number of patients using CAPABLE)
- Improved quality of life after cancer treatment, strengthening personal confidence and enhancing employability; (KPI: QoL improvement according to the clinical study results of year 2023)

Other societal impacts

- Job created: 1 new Company with 2-3 employers fully dedicated
- Turnover of 1-2M€ /year

3.3 Risk assessment

A systematic risk analysis has been performed considering different factors related to partnerships, technology, market, legal and financial. At this state the situation is between action and control, in which there are two crucial activities that are managed by the Consortium:

1) The early process of certification. At this stage the Consortium is dealing with the preparation of the documents needed for the approval of the pilot study. In particular they are the DPIA (Data Process Impact Assessment) and the notification of the system to the national health authorities, which is necessary for using a medical device that is not yet certified with the CE marking.
2) The management of the user's acceptance. The studies performed so far demonstrated that Capable is an acceptable solution for patients and health professional. But the Consortium still had to wait the final clinical studies when the technology will be used for a longer period.

There are other critical risks that are related to the post-project phase (related to the possibility to have customers) that at this stage can be mitigated refining the value proposition to be sure to attract the interest of hospitals.

The following metric have been used to classify the risk:

- Description of the risk
- Criticality, the degree of criticality of the risk related to the final achievement of this Key Exploitable Result rated from 1 to 10 (1 low- 10 high)
- Probability of risk happening, rated rate from 1 to 10 (1 low - 10 high)
- The potential intervention to mitigate the risk
- Estimated Feasibility/Success of Intervention, rated from 1 to 10 (1 low- 10 high)
- Conclusion according to the 3 estimated values (criticality, probability, and success of intervention) the risk is then classified as control, action, no action, or warning.

The following tables show the risks related to different aspects, the team, the technology.

Table 8: risks related to the partnerships

#	Risk Description	Criticality	Probability	Risk Grade	Potential intervention	Success of Intervention	Conclusion
1	Not all the partners are committed to exploit their component for the Overall CAPABLE system	*8*	*6*	**48**	Meeting to clarify the position of every partner. Signed document of commitment for the exploitation	6	**Control**
2	Difficulties to agreed joint exploitation participation	*8*	*8*	**64**	Agreed before the exploitation activities the participation of every partner	*6*	**Action**
3	Misalignment of the exploitation strategy between partners	*5*	*5*	**25**	Agree the strategy before the starting of the joint exploitation	*9*	**Control**

Table 9: risks related to technology

#	Risk Description	Criticality	Probability	Risk Grade	Potential intervention	Success of Interventi	Conclusion

						on	
4	Low adherence and usability of the system	*7*	*6*	***42***	during the course of the project we are going to make UX studies	*9*	**Control**
5	System did not show clinical benefits	*6*	*5*	***30***	Clinical study during the project	*9*	**Control**
6	Technology becomes obsolete	*6*	*7*	***42***	Periodic update of the platforms	*8*	**Control**
7	Artificial Models are not reliable	*6*	*6*	***36***	Improve the performance of the model acquiring more data, a backup can be to not include the models in the system and leave them just for research purpose	*6*	**Control**
8	Patients may not want to use the proposed mobile and wearable platforms (if different than what they normally use and prefer)	*5*	*6*	***30***	Collect patient feedback during clinical study, extend platform support in the final product (?)	*9*	**Control**

Table 10: risks related to the market

#	**Risk Description**	**Criticality**	**Probability**	**Risk Grade**	**Potential intervention**	**Success of Intervention**	**Conclusion**
9	Difficulties to find a client	*8*	*10*	***80***	increase marketing activities and distribution channel	*3*	**Warning**
10	Big player entering in	*6*	*7*	***42***	Differentiate CAPABLE service from	*5*	**Between Control**

	Europe as competitor				the bid player service		**& No Action**
11	Product requires too much investment on the customer side (dedicated servers, devices for patients)	*7*	*7*	***49***	Consider cloud-based deployment (software-as-a-service?), gracefully degrade functionality if no wearables are used (rely on sensors built in the phone)	*7*	**Control**

Table 11: risks related to the IPR and legal issues

#	Description of Risks	Criticality	Probability	Risk Grade	Potential intervention	Success of Intervention	Conclusion
12	Conflict of IPR	*2*	*3*	***6***	IPR is managed in the project. Every partner will have clear idea of ownerships	*9*	**Control**
13	A competitor copy the CAPABLE service	*5*	*7*	***35***	Register trademark, copy-right the software . Patent is not possible	*8*	**Control**
14	Legal problem to operate in the health care sector (certifications , quality of service)	*4*	*6*	***24***	Early consultancy to reduce level and bureaucratic barrier to operate in healthcare sector. BIOMERIS and IBM have experience on that	*8*	**Control**

Table 12: financial and management risk factors

#	Description of Risks	Criticality	Probability	Risk Grade	Potential intervention	Success of Intervention	Conclusion
15	Marketing and distribution fails due to a weak strategy	*7*	*9*	***63***	Revise the strategy	*6*	**Action!**
16	Marketing and distribution fails due to a lack of resources	*7*	*10*	***70***	a.) Adapt strategy to low-cost activities b.) Dedicate staff more specifically	*2*	**Warning;**
17	No cash flow to maintain the service and the staff	*7*	*8*	***56***	Ideally the business should start with a research grant that would give the opportunity to feed the initial business activities	*5*	**Between Action & Warning**

Table 13: regulatory risks

#	Description of Risks	Criticality	Probability	Risk Grade	Potential intervention	Success of Intervention	Conclusion
18	Product encounters difficulties in the CE process for Medical Device	*7*	*8*	***56***	Starting on MDR requirements earlier than originally planned to ensure that the product is ready to start the certification process shortly after the end of the project	*7*	**Action**

3.4 Use options

At this stage the option could be the direct exploitation of a group of partners that commercialize the CAPABLE solution through a joint venture. This will be further discussed in the next period and also indirect exploitation routes might be explored.

4. KER No. 2 CAPABLE technological stack for Digital Health products

This KER is based on the idea to leverage on the software architecture to build a technological stack to create new services in the field of digital health.
The CAPABLE technological stack consists of loosely coupled components whose efforts are coordinated thanks to state-of-the-art technologies. It relies on frameworks and principles of design that facilitate standard-based data sharing, integration of modular components, health information exchange and an easily extensible architecture. These aims are accomplished using the OMOP common data model for data persistence and standardized procedures for data analysis, HL7 FHIR for both intercomponent and intersystem information exchange and integration, and full compliance to FAIR principles through rich sharable open datasets that are metadata-enhanced.
CAPABLE architecture itself benefits from the adoption of these technical principles allowing it to function as a distributed system, relying on two central components, namely, Data Platform and Case Manager providing respectively centralized semantically unambiguous data storage and workflow orchestration.

This solution can be attractive for ICT companies operating in the field of e-health, mobile health, digital interventions, or therapeutics that must face the problem of the technical complexity of the design of digital health solution due to:

- complexity of the medical problem
- complexity of knowledge representation
- complexity of the compliance to health standard
- complexity of the process of certification as a medical device.

In the market there are different ways to support digital companies that want to craft next digital health services in the area of digital health:

- Specific consulting companies
- Platform providers with services adaptable to the context of health. These platforms in general provide support to data representation, interoperability, management of informed consents (e.g. Microsoft Health Cloud), some of which are focused on security and data access (Health.Node) and other to the creation of workflow for clinical studies and Clinical Report Form (eCRF) as REDCAP[8] and CASTOR[9]. CAPABLE differentiates for the possibility to manage complex clinical workflows and execute clinical guidelines and enhance the data management with a transparent support of the clinical decision.

Other relevant stakeholders that might be interested on this type of solution could be researchers willing to quickly prototype a solution in the field, electronic medical record vendor, MedTech companies and finally it can be used as a medical informatics tool for education in Universities and Medical schools.

[8] https://www.project-redcap.org/
[9] https://www.castoredc.com/

5.KER 3: Digital therapeutics for cancer self-management

5.1 Characterization of the result

5.1.1 Problem

The diagnosis of cancer is overwhelming in all human dimensions (physical, mental, social, etc). Patient would like to stay informed on the disease progress and know better the side effects. Living with cancer requires patients managing different lifestyle challenges related to mental and physical wellbeing (managing stress, anxiety, depression and physical problems, follow a recommended dietary regimen, perform physical activity) that are even more difficult during the treatment phase due to the detrimental toxicity of the cancer treatments (e.g., chemotherapy, radiotherapy, immunotherapy). Patients would like to relate to people with similar conditions and share experiences and suggestions. On the other side it is also important to provide contents and proposed activities that scientifically demonstrated benefits to the patients.
The following unmet needs have been identified:

- Cancer patients treated at home experience many problems during the treatment.
- Hospitals cannot always address all the patient requests. The medical support is provided during the follow-up visits or in case that the health status is worsening, and the patient requests an unscheduled visit.
- Patients use the internet as a source of information and many times, they access unreliable information. There is a need to have access to trusted information.
- Patients need to be in control of their health status to better report to the health professional the evolution of symptoms, physiological data, and QoL information.
- Patients would like to know the experience from similar patients to get information on how to face the daily difficulties (e.g., managing anxiety, side effect symptoms, knowing the reference sites for specific treatments, etc).

5.1.2 Alternative solution

Nowadays there are three alternative solutions:

- User receives information from their doctors, whenever there is a new situation, they have contact that provides the right counselling. Instructions are given orally and using medical report forms and educational material in digital or paper format. No specific tool is provided to follow the evolution of the patient when is at home. The educational material in many cases is not tailored for the specific needs of the patients.
- People find information on the internet. In this case the quality of the information depends on the capacity of the user to find a trustable source of information.
- People download an app. Also, in this case there are many available apps but just few of them have been clinically validated and/or contains trusted sources of information. Very few apps offer the support from a patient's community.

5.1.3 Unique Selling Point USP - Unique Value Proposition UVP

The CAPABLE app is a companion for cancer patients at home. It provides all the information that a patient may need during the cancer journey. The app provides a set of functionalities to report the health condition and to receive immediate feedback on what should be done. In case of a non-critical situation the app will provide feedback following the clinical guidelines and trusted information, for the critical symptoms the app will suggest the patient to refer to the oncologists. Furthermore, the app will suggest specific activities to improve some aspects of the user's lifestyle (diet, physical activity etc). The app features can be summarized as follow:

- Community of patients clustered by same type of disease stage, personalised information related to treatment and management of side effects
- Counselling for the management of moderate, mild symptoms according to clinical evidence and guidelines
- Personalized coaching system to provide specific intervention to promote physical activity, sleep hygiene and mental wellbeing.
- Possibility to export the data and generate a detailed report with the evolution of the disease and the performed activities of the user.

5.1.4 Description

The CAPABLE app is a personal digital coach that promotes the self-management of light or mild symptoms of cancer therapy. It is based on the modelling of the side effects of the different cancer therapies and on the clinical guidelines. It also provides functionalities to share and get the experience from other similar patients.
The app also contains digital interventions to foster health habits and mental wellbeing of the users.

5.1.5 "Market" – Target market

The mHealth app market is projected to reach 230 billion dollars worldwide. Apps for the self-management of cancer represents a very little portion of this market (less than 0.5%). Around 93% of the apps are free, the rest of the apps cost between 3€ to 25€. This trend is also confirmed by the penetration of the Smartphone devices in the world, by the fact that new generations use to look for specific apps for health.
Since the project is supported by the Italian cancer patients association AIMAC the first target market will be in Italy, targeting young adults with specific interest in mobile technology. However, note that AIMAC is linked to the European Cancer Patient Coalition (ECPC), thus facilitating the access to other markets.
Additionally, the Project aims to find supporters of the initiative, other patient's organisation, the national health system. The idea is to use these resources to promote research on cancer patient user experience.

5.1.6 "Market" – Early Adopters

The early adopters will be selected from the network contact of AIMAC association. According to the first performed analysis the early adopter can be young adults with a recent cancer diagnosis with specific interests on technology gadgets.

5.1.7 "Market" – Competitors

A detailed analysis of the competitors has been performed. The analysis considers apps linked to specific initiatives or patient's communities. These apps demonstrated to have higher adoption because the providers are a trusted source of information and in some cases, they also provide access to a cancer community. Similarly, the CAPABLE app wants to adopt the same strategy and not release just an app in the Apple Store but a service that has a societal challenge: study the cancer experience and create a community to be used to establish a communication between academia, industry and society about the problems cancer patients are facing in their daily life. The role of the Foundation and the liaison with the AIMAC patient's association will be the key for the success.

A market analysis has been performed and it is available to the following URL:

https://docs.google.com/spreadsheets/d/1VYHjDmdCFmrRZ4vHB5WFUMDH15IQKvVvt_rYRhjeZFw/edit#gid=1832075390

This analysis considers the following metrics:

- Name of the app
- Short description of the app
- Patient community. If the app offers functionality to access to a network of patient.
- If the app provides one of the following functionalities
    - Symptom report.
    - Medication management
    - Feedback on symptoms
    - Lifestyle intervention - physical activity
    - Lifestyle intervention - psychosocial support
    - Lifestyle - sleep
    - Lifestyle - dietary habits
    - Education on Cancer
- Use of wearable devices, trackers etc.
- If the app offers a specific service for caregivers
- Business model of the app
- Link of the app

The analysis concludes that the apps that have link to patient community in general are not supporting many functionalities to foster the self-management. Many of the apps linked to a community are in general free and the business is based on donations from users and stakeholder interested to maintain the community.

5.1.8 Go to Market – Use model

The users will download the app from the app stores (Apple and Android). The app will be visible through the patient's association page. The app will implement a freemium model, some functionalities will be unlocked if the user donates at least 1€. At the same time the Foundation will launch other campaigns to relevant stakeholders to get donations or funding to study the cancer experience in patients empowered by digital tools.

5.1.9 Go to Market – Timing

The app will be available 6 months after the end of the project. When the app will be ready for the clinical study (beginning of 2023) the team will work to create the stand-alone version for this business case.

5.2 Exploitation roadmap

5.2.1 Actions

The following table shares the list of actions to commercialize the KER3. The table also proposes an initial candidate that can be the responsible of the task. The assignation has been done considering the skills, knowledge and contribution shared in the CAPABLE project. This proposal will be refined in the next period.

Table 14: proposed action for the exploitation of KER3

Task	Start	End	Initial candidate
Agreement of collaboration in the foundation	1	6	UPM
Agreed business strategy and business model	1	8	UPM
Pilot with Beta tester users	6	15	BITSENS
Creation of foundation and agreement of level of participation of the partners	1	10	UNIPV

Fund raising campaign	11	15	AIMAC
Participation in research programs	1	10	UNIPV, UPM
First research contract to perform a medical study and certify the system	1	15	UNIPV, UPM
Deployment of the CAPABLE service	1	6	BIOMERIS
App maintenance	1	6	BITSENS
Legal support for the digital app	1	6	UNIPV, UPM
Strategic plan of the foundation for the sustainability	1	12	UPM
IPR management, transfer of licence to the Foundation	1	6	UPM
Marketing activities	1	24	BITSENS
Strategic liaison with relevant stakeholders.	1	24	AIMAC

5.2.2 Roles

The idea would be to set up a Foundation with this initial structure that is under discussion:

- AIMAC: President
- UPM: Operation management / scientific advisor
- UNIPV: Scientific advisor
- BITSENT: app provider
- BIOMERIS: backend provider

The rest of the partners could be external collaborators. The following diagram shows the initial organizational map of the business case:

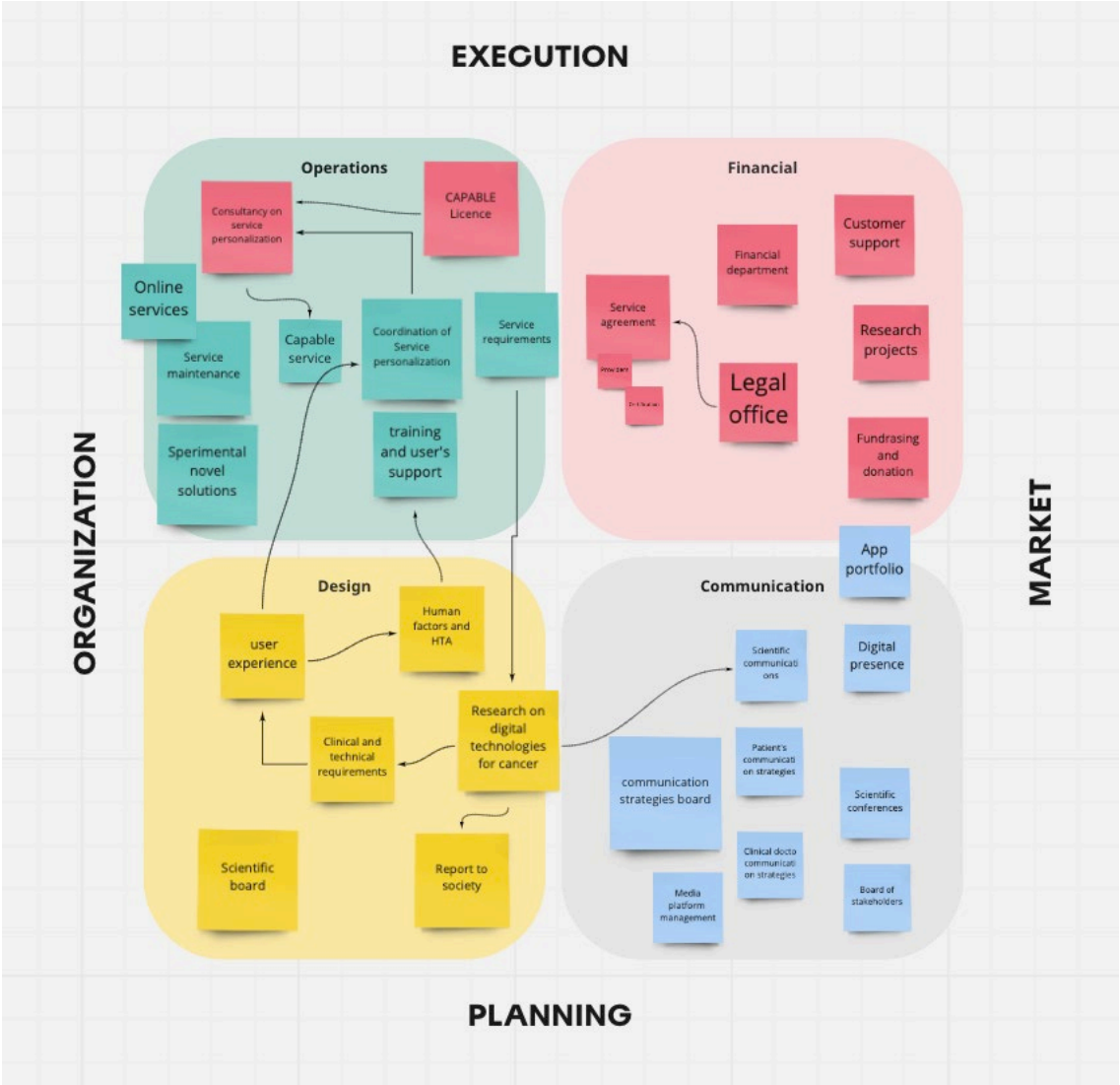

Figure 3: Organizational map for the commercialization of KER3

5.2.3 Milestones

WP8 proposes the following milestones to be achieved after the project to achieve the commercialization of the KER3.

Table 15: milestones for the exploitation of KER3

Milestone	Months after the project	Means of verification
M1: service available	6	Service is available in the cloud
M2: agreements and Foundation creation	10	existing of a legal entity, signed contracts
M3: Beta tests finished	15	Platform has at least 100 users
M4: funded project	15	Gran agreement
M5 fund raising	15	raised 20000€

M6: Final business plan	15	Document of business plan
M7: Marketing and sales activities are ready	15	Assistance to 2 conferences. Service portfolio, Web Page

5.2.4 Financials Costs

The following table breakdowns the estimated costs for the exploitation plan. This is an initial estimation that will be iteratively refined and detailed in the next deliverables of WP8.

Table 16 costs for the exploitation of KER3 (€)

Type of costs	**Description**	**Total**	**Year 1**	**Year 2**	**Source of funding**
Foundation	taxes, legal and admin consultancy	40000	40000	0	Supported by partners, proportional to shareholder
Deployment and maintenance of Capable service	Hosting and developers	90000	60000	30000	R&D funded project
CAPABLE App personalization	Collaboration with UPM, UNIPV, UoH, PUT, AMC	120000	80000	40000	R&D funded project
Capable App integration in the forum	Integration with the forum and possibility to cluster by user's profile	40000	20000	20000	R&D funded project
Marketing for the campaign	Digital media advertising	4000	3000	1000	supported by partners
Company webpage	Cost to set up a web page	10000	10000	0	Supported by partners
Marketing activities	Digital marketing, participation to conferences, events etc	30000	15000	15000	Supported by partners
Certification documents and taxes	taxes, legal consultancy	16000	8000	8000	R&D funded project
	Total	**350000**	236000	114000	

5.2.5 Revenues

The following table describes an estimation of revenues:

Table 17: initial estimation of revenues for KER3

Type of income	**Description**	**Year 1**	**Year 2**	**Year 3**

R&D project	Project to collect PREM and PROM of cancer patients		250000	0
Start-up seed funding	Funding to accelerate the Foundations activities	50000		
Fund raising	Crow funding	20000		5000
Donations	Donations from user to use the app and donations from stakeholders		25000	60000

5.2.6 Other sources of coverage

Other sources: since most of the costs are for the technology adaptation, we can ask the partner to support actions or to find resources from research project at national and European level.

5.2.7 Impact in 3-year time

Impact related to the EU call of Capable (SC1-DTH-01-2019):

- Better and faster means of high-quality response to prevent or timely address development of new medical conditions and/or improve the quality of life; (KPI: number of early reported side effects).
- Better knowledge for improved patient counselling as well as to improve follow-up of patients; (KPI: improved knowledge of patients on cancer management).
- Novel information on health maintenance, onset, and course of medical conditions with a view to optimise prevention and treatment; (KPI: number of downloaded apps and current number of patients using CAPABLE).

Other societal impacts:

- Job created: 1 new Foundation with 1 employer fully dedicated.
- Turnover of 200K€/year.

5.3 Risk assessment

A systematic risk analysis has been performed considering different factors related to partnerships, technology, market, legal and financial. At this state the situation is between action and control, in which there are two crucial activities that are managed by the Consortium:

- A possible misalignment on the overall exploitation strategy. The initial proposal is to set up a foundation, that may limit other commercial opportunities to the partners.
- The difficulties to get donations form patients and relevant stakeholders. This will require to set up a proper strategy and mission of the Foundation and the role of the app to be used as source of statistics on needs, feedback on the overall cancer journey.

There are other critical risks that are related to the post project phase (related to the difficulties to get donations) that at this stage can be mitigated refining the value proposition to be sure to attract the interest of patients and stakeholders.

The following metric have been used to classify the risk:

- Description of the risk
- Criticality, the degree of criticality of the risk related to the final achievement of this Key Exploitable Result rated from 1 to 10 (1 low- 10 high)
- Probability of risk happening, rated rate from 1 to 10 (1 low - 10 high)
- The potential intervention to mitigate the risk
- Estimated Feasibility/Success of Intervention, rated from 1 to 10 (1 low- 10 high)

- Conclusion according to the 3 estimated values (criticality, probability, and success of intervention) the risk is then classified as control, action, no action, or warning.

The following tables show the risks related to different aspects, the team, and the technology

Table 18: risks related to the partnerships

	Risk Description	Criticality	Probability of risk happening	Risk Grade	Potential intervention	Feasibility/Success of Intervention	Conclusion
1	Not all the partners are committed to exploit their component for the Overall CAPABLE system	*8*	*6*	**48**	Meeting to clarify the position of every partner. Signed document of commitment for the exploitation	*6*	**Control.**
2	Difficulties to agreed joint exploitation participation	*8*	*8*	**64**	Agreed before the exploitation activities the participation of every partner	*6*	**Action!**
3	Misalignment of the exploitation strategy between partners	*4*	*4*	**16**	Agree the strategy before the starting of the joint exploitation	*9*	**Control.**

Table 19: risks related to technology

	Risk Description	Criticality	Probability of risk happening	Risk Grade	Potential intervention	Feasibility/Success of Intervention	Conclusion
4	Low adherence and usability of the system	*7*	*7*	**49**	during the course of the project we are going to	*9*	**Control.**

					make UX studies		
5	Difficulties in implementing the patient association recommendation	*5*	*5*	**25**	Provide an initial assessment and estimation of the required efforts	*4*	**No Action'**
6	Technology becomes obsolete	*6*	*7*	**42**	periodic updates of the technology. Increase market vigilance to discover new technological trends	*4*	**No Action'**

Table 20: risks related to the market

#	Risks Description	Criticality	Probability	Risk Grade	Potential intervention	Success of Intervention	Conclusion
7	Difficulties to get donation by the patients	*8*	*10*	**80**	increase marketing activities and distribution channel	*3*	**Warning**
8	Big player entering in Europe as competitor	*6*	*7*	**42**	Differentiate CAPABLE service from the big player service	*6*	**Control**
9	Too much investment to set up the service	*7*	*7*	**49**	early estimation and periodic revision of the workplan	*6*	**Control**

Table 21: risks related to the IPR and legal issues

#	Risk Description	Criticality	Probability	Risk Grade	Potential intervention	Success of Intervent	Conclusion

						ion	
10	Conflict of IPR	*2*	*3*	**6**	IPR is managed in the project. Every partner will have clear idea of ownerships	*8*	**No Action**
11	A competitor copy the CAPABLE service	*5*	*7*	**35**	Register trademark, copy-right the software . Patent is not possible	*8*	**No Action**
12	Legal problem to operate in the health care sector (certifications , quality of service)	*4*	*6*	**24**	Early consultancy to reduce legal and bureaucratic barrier to operate in healthcare sector.	*8*	**No Action**

Table 22: financial and management risk factors

#	Risk Description	Criticality	Probability	Risk Grade	Potential intervention	Success of Intervention	Conclusion
13	Marketing and distribution fails due to a weak strategy	*7*	*9*	**63**	Revise the strategy	*6*	**Action!**
14	Marketing and distribution fails due to a lack of resources	*7*	*10*	**70**	a.) Adapt strategy to low-cost activities b.) Dedicate staff more specifically	*2*	**Warning**

Table 23: regulatory risks

#	Risk Description	Criticality	Probability	Risk Grade	Potential intervention	Success of Intervention	Conclusion

15	Product encounters difficulties in the CE process for Medical Device	*6*	*6*	**36**	Starting on MDR requirements earlier than originally planned to ensure that the product is ready to start the certification process shortly after the end of the project	*9*	**Control**

5.4 Use options

The idea is to make a joint exploitation by creating a Foundation with the mission to study the uptake of digital technologies during the cancer journey. The Foundation will be responsible to engage stakeholder to report patient's needs, patient reported outcomes, and perceived quality of care. The Foundation will offer to the community of patients an app based on Capable and the link to a patient community. The Foundation will be sustained by the donations of patients and stakeholders, and by research grants.

6.Conclusions and future works

This deliverable presented the results of the exploitation activities of the first two years of the project. At this stage the most challenging and complex business scenario have been presented focusing on the joint exploitation of the results and a direct use as exploitation route. This has been an opportunity to start sharing among the consortium initial potential joint exploitations. KER1 and KER3 has been worked together with the Horizon Result booster, KER2 is still at germinal phase and needs to be further discussed and analysed to assess the viability of the exploitation.
The activities foreseen for the next period will focus on the following actions:

- Refinement of the KERs, possible consolidation of the direct route of exploitation or definition of business case for indirect use.
- Definition of the individual exploitation plan of every partner, including in this strategy the possible commitment with some of the KERs presented in this document or in new ones.
- Focus on other routes of exploitation different from the commercialization.
- Surveys to main stakeholders that might be attracted by the CAPABLE results including hospital managers, companies (MedTech, pharma) and researchers.

The presented work has been performed in collaboration with the CAPABLE consortium that joined the periodic WP8 meetings, and the workshops from Horizon Results Booster, which has been a unique opportunity to align the vision of the partners toward the exploitation activities.