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. 8.7
Exploitation plan and business models – V3

Due Date: [31/1/2024]
Submitted On: [27/03/2024]

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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.

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Versions History

Version	Date	Author	Comments
1.0	15th November 2023	UPM	Table of Content
2.0	20th December 2023	Consortium	Individual exploitation interests integrated
3.0	23rd January 2024	UPM	Section 1 and section 2 completed
4.0	2nd February 2024	UPM	First draft of roadmap to commercialization
5.0	23rd February 2024	UPM	First completed version
6.0	15th March 2024	UPM	Revised version

1.Executive Summary

This deliverable presents the innovation and management activities of the last 13 months of the CAPABLE project. The document describes the innovation management activities that supported the revision of the core value drivers of the CAPABLE solution and of the individual results. The individual exploitation plan of each partner is presented, and the feedback received from external stakeholders are presented. Then the document reviews the CAPABLE opportunities, a market an analysis update is presented, and a SWOT analysis is proposed to describe the core aspects of this research.
Finally, the document presents the roadmap to the commercialization that consists of a set of activities that would be the driver for the commercialization activities of the CAPABLE solution. Finally, the document presents the conclusion and lesson learned.

2.Innovation management activities

The section presents the activities that have been carried out during the last 13th month of project life. During this period the CAPABLE technology has been finalized, tested and deployed in the two consortium's hospitals (NKI and ICSM): a total of 3 clinical centers had the opportunity to use the solution according to specific clinical protocols that have been defined by WP7. In this context the role of WP8 has been to monitor the whole process of deployment and execution of the clinical study and collect qualitative and quantitative information on the acquired experience.
Following the adopted CEHERES[1] methodology, described in the previous deliverables (D8.1) WP8 has been involved in the depicted phases (see figure 1) as follows:

- Operationalization: WP8 contributed to the design of the protocols to be adopted by the clinical center to assess the overall solutions from end users perspective, its managers, hospital managers and other relevant stakeholders that have been involved during the process of development, deployment and test of the CAPABLE technology.
- Summative evaluation: all the acquired data has been used to perform specific studies on clinical outcomes and user experience (in WP7) has been used together with qualitative information from Consortium partners and key stakeholders that shared their own perspective and experience on CAPABLE. All this information has been used to perform an overall Health Technology Assessment that has been reported in D8.8.

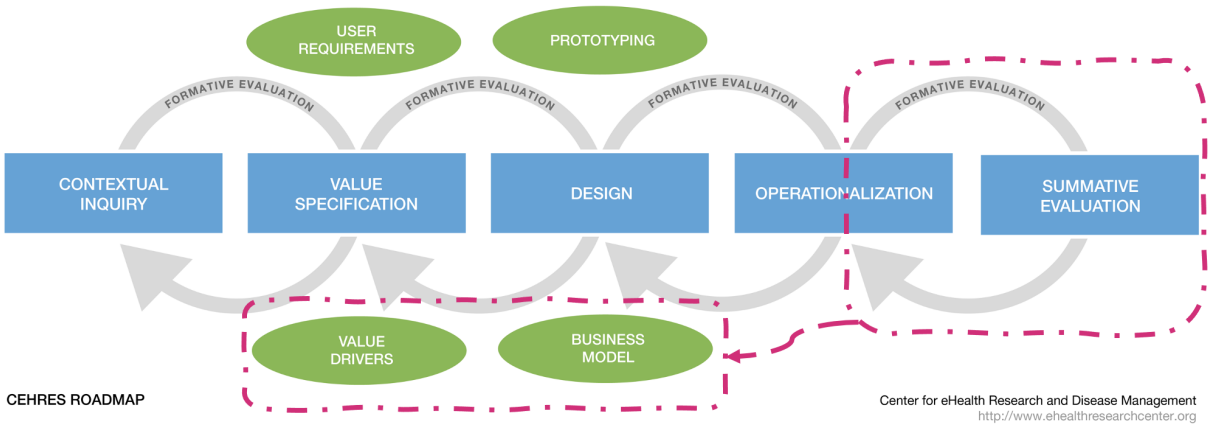

Figure 1: Phases of the CEHERES methods (in red the ones of the reported period)

The acquired information has been used to refine the value drivers of the business model proposed for CAPABLE and extend them, to a wider exploitation strategy that would not only cover commercialization aspects but also other actions to maximize the uptake and dissemination of the results in the society. This will be detailed in section 4.

The next section will present all the qualitative information that has been collected by key stakeholders, internal and external from the CAPABLE project.

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

Individual exploitation plans

This section provides updates on the individual exploitation plan of every partner. To better know the specific results of each partner it is recommended to check deliverable D8.6 that presents the project's results and the IPR policy.

Università Degli Studi Di Pavia (UNIPV)

UNIPV aims to leverage the outcomes of the CAPABLE project by implementing a comprehensive strategy to enhance research and education across various interconnected domains. The initial phase involves harnessing individual achievements, such as the versatile software tool "Case Manager," designed as a universal service. This tool will be repurposed in other e-health initiatives to orchestrate clinical services. The strategy includes analyzing how to adapt the Case Manager in other clinical contexts that require the coordination of different clinical processes and data flows.
Another facet of the exploitation plan of UNIPV is to promote the overall CAPABLE telemonitoring system to collect Patient-Reported Experience Measures (PREM) and Patient-Reported Outcome Measures (PROM) for use in research studies. A first attempt (unfortunately not funded) has been done by participating in a fund call from a pharmaceutical company (AstraZeneca) to perform a follow up study with breast cancer in ICSM.
Additionally, efforts will focus on advancing clinical guidelines modeling and developing a Clinical Decision Support System. Future for the CAPABLE results include seeking national or European research funds to conduct a multicenter study with a larger patient cohort, demonstrating the clinical benefits of the telemonitoring solution and exploring novel sensors for remote follow-up of cancer patients under treatment.
Presently, CAPABLE features an ancillary app suggesting optimal walking paths based on air pollution data from sensors in Pavia. The intention is to integrate this functionality, along with others, into a unified application and extend its reach to additional geographical areas.
Furthermore, UNIPV has integrated the research outcomes into various academic courses, spanning undergraduate, Master, and Doctorate programs in Computer Informatics and Bioengineering. The university also plans to incorporate DEONTICS results into educational scenarios, simulating diverse clinical workflows for medical students. The objective is to leverage the knowledge acquired from the CAPABLE project to develop advanced AI courses focused on knowledge modeling and representation, accessible to both computer science and medical students. Additionally, the knowledge generated will continue to be disseminated through participation in conferences and the publication of scientific papers.

University of Haifa (UoH)

The University of Haifa (UoH) has produced a significant outcome known as the Knowledge Data Ontology Mapper ("New-KDOM"). This autonomous component is capable of defining clinical abstractions and querying them based on raw data, assuming that the raw data is stored in a repository adhering to the HL7 FHIR standard. New-KDOM introduces novel mapping classes and operators supporting hierarchical and temporal mappings, accommodating operations with a degree of uncertainty. Modelers can articulate abstractions by specifying mapping instances through an XML KDOM Editor, and the runtime component of KDOM generates and

executes FHIR queries. KDOM can seamlessly process requests from a generic system component to obtain an abstraction and return results as FHIR resources, including Observation, Medication Request, and Communication.
UoH intends to explore the broader application of KDOM beyond the CAPABLE Decision Support System (DSS) within clinical settings, leveraging the network of hospitals across Europe and Israel. This exploration will actively involve young researchers who are interested in contributing to the commercialization of their components, such as New-KDOM and GoCom.
Furthermore, the knowledge generated during the CAPABLE project will be strategically utilized in several ways: (a) disseminating and sharing novel methods developed, (b) constructing a portfolio outlining future research ideas building upon existing CAPABLE research, and (c) delivering presentations and incorporating this knowledge into educational courses. This multifaceted approach ensures the effective dissemination and application of the valuable insights gained throughout the CAPABLE project.

Biomeris Srl

BIOMERIS specializes in the implementation and customization of software solutions designed to integrate, explore, and analyze heterogeneous patient data sources. As a partner in the CAPABLE project, BIOMERIS plans to capitalize on specific outcomes, particularly the CAPABLE data platform, which will be made publicly accessible within the OMOP community. This strategic move aims to enhance the visibility of BIOMERIS services and expertise within the broader healthcare community. The plan of the company is to adapt the result to the OMOP community and to publish this new contribution before the OHDSI symposium that will be held in June 2024[2] .
Simultaneously, BIOMERIS is committed to supporting the ongoing exploitation of the overall CAPABLE system. The project has been a unique opportunity to put in practice health standards in a clinical domain and new knowledge has been acquired in terms of technical security measures and privacy issues at legal, regulatory, organizational and technical levels.
BIOMERIS led the process of optimization of the system for demonstration purposes: it led together with UNIPV the deployment of the demo version of CAPABLE. Furthermore, in case of a research or commercial opportunity BIOMERIS would be able to provide support for the deployment and maintenance of the system, ensuring its continued functionality and effectiveness.
Beyond these technical aspects, BIOMERIS expresses its readiness to actively promote and disseminate the CAPABLE solution to the network of hospitals it serves for data management activities. By leveraging its established relationships within the healthcare sector, BIOMERIS aims to facilitate the adoption and recognition of the CAPABLE solution among relevant stakeholders.
In summary, BIOMERIS is strategically positioning itself to not only benefit from the individual results of the CAPABLE project but also to actively contribute to the system's ongoing success, industrialization, and widespread adoption within the healthcare community.

Academisch Medisch Centrum Bij De Universiteit Van Amsterdam (AMC)

[2] https://www.ohdsi-europe.org/index.php/symposium/

The Academic Medical Center (AMC) is strategically leveraging the results of the CAPABLE project to enhance knowledge across various technological domains. These areas of focus include:

- Guideline Modeling: Strengthening expertise in creating and implementing clinical guidelines. The AMC worked closely with NKI and the guideline modeling team to develop computer-interpretable guidelines that fit with the existing information systems and workflow at both NKI and in Italy. The lessons learned from this experience will help make future guideline implementation projects more robust in an international context.
- FAIRification Approaches and Methods: Enhancing knowledge in making data Findable, Accessible, Interoperable, and Reusable (FAIR). The AMC captained the efforts to FAIRify the results of CAPABLE. This will help not only to make the results of CAPABLE more findable, accessible, interoperable, and reusable, but also the knowledge of *how* to do this can be re-used by other projects.
- Healthcare Interoperability and Customization: With a special emphasis on standards such as OMOP (Observational Medical Outcomes Partnership) and FHIR (Fast Healthcare Interoperability Resources). Based on lessons learned in CAPABLE, we are establishing an approach to more sustainable mapping across information standards (such as OMOP and FHIR) and terminologies (including SNOMED CT, RxNorm, ATC).
- Medical Device Certification: Developing proficiency in the certification processes for medical devices. The AMC led the process of meeting the regulatory requirements in the Netherlands related to the MDR. Together with the legal experts at UniPV, we are documenting what we've learned so it can be used by our partners and by other projects. As one of the first Horizon projects under the new MDR, we have already been approached for advice and reassurance by others who are writing proposals for new Horizon projects.
- Modeling Clinical Needs and Patient User Experience: Understanding and incorporating the requirements of clinical settings and user experiences into modeling efforts. The AMC was directly involved in assessing clinician and patient information needs and translating these to feature requests in the clinician dashboard and patient app, particularly with respect to symptom reporting. The generalizable findings are reported in scientific publications.

As illustrated by the examples above, this acquired knowledge will be strategically applied in various business contexts:

- Academic: Integrating these assets into medical informatics training courses at both Bachelor and Master levels.
- Research: Utilizing this knowledge in other projects related to the implementation and customization of specific healthcare information standards.
- Consultancy: Collaborating with companies and hospitals to support the implementation of interoperable solutions in healthcare.
- Policy Making: Engaging in discussions with research funding organizations and government bodies to contribute to the development of policies that advocate for the actual implementation of FAIR approaches and a more robust approach to interoperability.

In addition to these business contexts, AMC is committed to supporting the promotion and dissemination of the overall CAPABLE system. This outreach will leverage the local network of stakeholders in digital health, participating in events such as matchmaking sessions and digital health technology conferences.

IBM Israel - Science and Technology Ltd

IBM has contributed to the CAPABLE project in the form of predictive models and tools for risk prediction and disease progression, using Machine Learning approaches. IBM outlines three strategic actions aligned with its company roadmap to exploit these results:

- Enhancing IBM Platform for Accelerated Discovery: IBM plans to augment its platform for accelerated discovery, which is based on IBM hybrid cloud, AI, and quantum computing. The insights gained from the CAPABLE project's predictive models and tools have been integrated into this platform, reinforcing its capabilities for efficient and advanced discovery processes.
- Contribution to Open Source: IBM is committed to contributing to the open-source community, particularly in the field of biomedical sciences. This includes active participation in the BiomedSciAI[3] organization and contributing to projects such as FuseMedML[4]. FuseMedML is an open-source Python-based framework designed to facilitate collaboration and accelerate discoveries in Fused Medical data through advanced Machine Learning technologies. IBM's contributions will focus on deep learning applications in medical imaging and digital pathology using the PyTorch framework.
- Participation in AI Competitions and Challenges: IBM plans to engage in AI competitions, such as BMMR2[5] in breast cancer and KiTS 2021[6] in kidney cancer. Additionally, the company aims to organize challenges, such as the Knight challenge in kidney cancer. This active involvement in competitions and challenges serves to showcase IBM's expertise and foster innovation in the AI community.

Thanks to the CAPABLE research and other similar initiatives, IBM was able to consolidate open AI projects to build predictive models in healthcare, specifically for cancer research. The code to create models like CAPABLE predictive models has been open sourced.

The AI models defined in the CAPABLE project could be adapted to be used with Watsonx tools[7] and the benefits would be:

- Model can be generalized and extended to other cancer types.
- Open: Watsonx is based on the best open technologies available, providing model variety to cover enterprise use cases and compliance requirements.
- Trusted: Watsonx is transparent, responsible, and governed. IBM’s models are trained on trusted datasets, eliminating legal, regulatory, ethical and inaccuracy concerns.

[3] https://github.com/BiomedSciAI
[4] https://github.com/BiomedSciAI/fuse-med-ml
[5] https://wiki.cancerimagingarchive.net/pages/viewpage.action?pageId=89096426
[6] https://kits-challenge.org/kits21/
[7] https://www.ibm.com/watsonx

- Targeted: Watsonx is designed for enterprise and targeted at business domains; Watsonx is designed for business use cases that unlock new value.
- Empowering: Watsonx lets you go beyond just being an AI user and become an AI value creator, allowing you to train, fine-tune and deploy, and govern the data and AI models you bring to the platform and own completely the value they create.

The overall CAPABLE system would be strategic for IBM research if used to validate a specific cancer treatment (e.g. monitoring side effects) to collect data that would be used to create models for drug discovery.

Bitsens Jsc

Bitsens aims to capitalize the technical results achieved in the development of WP6 interfaces by introducing a novel product in the wellness sector focused on symptom reporting. This application will function independently, without direct connection to specific healthcare professionals, refraining from offering clinical decisions or recommendations. Its primary purpose will be for self-management and tracking, following a conventional B2C model—a domain where Bitsens possesses both expertise and a proven track record. This strategic move aligns seamlessly with the company's evolutionary trajectory.
WeatherMind[8] helps you understand the impact of weather on your health. With personalized weather forecasts, self-assessments, and journaling, our app helps you take control of your well-being.

Figure 2: WeatherMind screenshots

The app has the following key features:

- Accurate weather forecasts tailored to the user's location.
- Mood tracking and symptom reporting for a holistic mental health overview.

[8] https://apps.apple.com/lt/app/weathermind-health-forecast/id6448552322

- Comprehensive self-assessment tests for various weather-health correlations.
- Journaling to prioritize concerns, needs, and activities for better decision-making.
- Breathing exercises to manage stress and anxiety with calming background sounds.
- Educational materials to understand the connection between weather and the user's health condition.
- In-depth statistics to track your weather-health dependencies.

Simultaneously, Bitsens is committed to facilitating the exploitation of the comprehensive CAPABLE system. This commitment is contingent upon the establishment of an appropriate legal and operational framework by the consortium, or a subset thereof, wherein each partner takes responsibility for their respective components. Participating in the CAPABLE system's exploitation provides an avenue for Bitsens to enter the healthcare market with a B2B solution, representing a significant advancement for the company. Recognizing the more ambitious nature of the B2B model, Bitsens is prepared to secure the necessary resources for effective market penetration. The current plan is to prepare and submit an EIC Accelerator grant proposal for a market take-up of the CAPABLE application as a whole. This will entail signing agreements with relevant consortium partners.

Politechnika Poznanska (PUT)

PUT intends to capitalize on both the specific (Virtual Coach module) and the overall outcomes (Overall Capable System) of the project in various strategic ways:

- Specific Results Utilization: The Virtual Coach (VC) component, formal models of patient-oriented clinical guidelines, rules, and workflows represented in PROforma, along with tools for simulating patients and machine learning methods and models for predicting behavior change interventions will serve as foundational elements. These tools, methods, and models will be harnessed to stimulate further research in knowledge- and data-driven patient decision support and coaching. VC, complemented by an additional visualization layer (a dedicated patient-oriented front end), will function as a testbed and demonstrator for novel coaching strategies and methods. This approach facilitates the showcasing of results and fosters collaboration with clinical and scientific partners across diverse fields and specialties. Currently, there is an ongoing process of revising the results and adapting them to open knowledge representations (e.g., BPM+ Health for guidelines, workflows, and rules) in order to facilitate their use by the research community. Moreover, some of the results (e.g., simulation tools described in published papers) have been made already available as open source and the remaining ones (e.g., the source code of VC) will be published soon using appropriate open licenses.
- Overall System Exploitation: The comprehensive CAPABLE system, exemplifying a modern decision-support environment rooted in advanced technology like wearables and clinical evidence-based knowledge representation and reasoning, represents a key overall result. PUT aims to promote the reuse of the system in alternative contexts, such as neurology

or elderly care, and explore opportunities for system extensions and limited real-life testing in collaboration with clinical partners like medical universities, hospitals, and clinics. Through connections with the Polish Telemedicine and e-Health Society[9], PUT will find ways to disseminate and promote the CAPABLE research and discuss aspects related to its implementation in the clinical practice.

- Knowledge and Experience Sharing: Knowledge and experiences gained during the development of these results will be disseminated through various channels. PUT has already incorporated this knowledge into courses offered to undergraduate, graduate students, and doctoral students including "Medical Informatics" and "AI in Biomedical Informatics." Dissemination will extend to professional associations and societies, such as the Polish Telemedicine and e-Health Society and the Polish Society of AI in Medicine, through meetings, seminars, and other similar events. Results will also be presented at scientific conferences, seminars, and workshops. Participation in other local and EU projects and initiatives will provide a platform for sharing insights from the project. Moreover, PUT will look for opportunities to present the results to med-tech and pharma companies to find a possible venue for collaboration.
- Deployment in Healthcare Settings: PUT will explore opportunities for deploying the CAPABLE system or selected components in collaborating hospitals in Poznan, with a focus on providing care to cancer patients. This aligns with the practical application of the developed technologies in real healthcare settings.

Istituti Clinici Scientifici Maugeri (ICSM)

ICSM's approach to exploiting the CAPABLE project involves advancing and refining the overall CAPABLE solution, with a specific emphasis on enhancing telemonitoring services for cancer patients. The strategy encompasses active participation and collaboration with the CAPABLE contribution and contribution to specify, test, and validate new novel services resulting from CAPABLE. Key elements include defining service specifications, conducting rigorous tests, and validating the functionality with a focus on real-world applicability. The partner would be available to continue using the system in a research environment and strengthen the clinical evidence to consolidate the uptake of telehealth solutions such the CAPABLE system.

Stichting Het Nederlands Kanker Instituut-Antoni Van Leeuwenhoek Ziekenhuis (NKI)

The NKI is keen on advancing research in telemonitoring services for cancer patients. The CAPABLE experience and other initiatives (currently the hospital is testing in another research study the KAIKU commercial health platform) are used to consolidate digital service in the oncology unit and improve PREM and PROM of the served patients. The next activities would focus on finding other resources and grants to continue the validation of digital health technology for oncology. NKI envisions contributing to the broader adoption and understanding of digital solutions in the healthcare landscape in the Netherlands.

[9] https://www.telemedycyna.org/

Deontics Limited (DEON)

Deontics sees commercialization of results as key to the involvement in the CAPABLE project. It pursues two general approaches to deployment of the clinical AI system based on Computer Interpretable Guidelines:

- Backend only, where Deontics provides a clinical AI engine hosted in the cloud and accessed via APIs which can be used to integrate the engine into all kinds of systems (the approach taken in CAPABLE);
- Full system, where Deontics provides a web-based UI and integration functionality alongside the engine.

The CAPABLE solution is an excellent example of the former type of deployment where Deontics can provide the back-end AI and decision support engine. Deontics sees that the overall telehealth system has several commercial opportunities:

- An opportunity to raise the profile of the Deontics system through demonstrations and deployments of the full-scale system in prestigious healthcare organizations.
- An opportunity to work commercially with CAPABLE partners who can provide front-end, user-facing and system integration skills. (e.g. collaborating with Bitsens).
- A sales opportunity through the direct commercialisation of CAPABLE. Deontics can offer dissemination to a network of stakeholders who may be interested in features of the full system. For example, stakeholders who wish to improve recruitment of patients to clinical trials. This is seen in part as impacted by difficulties in managing participant wellbeing and side-effects, aspects in which CAPABLE can bring expertise.

Associazione Italiana Malati Di Cancro, Parenti E Amici (AIMAC)

AIMAC expresses a keen interest in advancing patient empowerment through the implementation of digital solutions in healthcare. The CAPABLE solution holds particular appeal for AIMAC as it has the potential to enhance cancer patients' quality of life during treatments. AIMAC envisions actively supporting the promotion of the CAPABLE solution across FAVO (Federazione italiana delleAssociazioni di Volontariato in Oncologia) and Aimac's 50 Info Points within major Italian hospitals.
The potential adoption of the CAPABLE solution aligns with AIMAC's commitment to advancing social studies aimed at identifying barriers and gaps in the implementation of digital solutions in healthcare. Leveraging AIMAC's extensive network, CAPABLE will be introduced and linked to Italian scientific societies, Universities, Cancer Centers,vAssociations of patients. Furthermore, AIMAC envisions supporting the development of a patient app that operates independently of the oncology department. This app aims to facilitate self-management and counseling for patients. This parallel initiative reflects AIMAC's commitment to providing comprehensive support for patients beyond the clinical setting. Overall, AIMAC's involvement is instrumental in not only promoting the CAPABLE solution within healthcare institutions, but also in contributing to broader initiatives addressing digital tools and patient empowerment in the healthcare landscape.

Universidad Politécnica De Madrid (UPM)

Thanks to the CAPABLE contributions UPM deepen the experience in the design and assessment of personalized health solutions in the field of oncology. These

results will be exploited with publication in scientific journals and participation in international conferences. UPM is committed to sharing this knowledge across various educational levels, including Master's, Bachelor's, and PhD courses in bioengineering and human factors with technology. The exploitation and business activities led by UPM represent a relevant opportunity to position the institution as catalyst of innovation and promoter of novel solutions in the market.
The partner will support the dissemination, and exploitation of the overall Capable system, completing the activities of WP8 and specially UPM will be actively involved in finding new opportunities leveraging on the large network of contacts in the healthcare sectors, the participation in the EIT health program and other European Initiatives (e.g., IHI), task forces and joint actions. UPM is also interested to leverage on the CAPABLE results to strengthen the European network of research around cancer, UPM is fully supporting the cluster of projects called "Cancer Survivorship Artificial Intelligence for Wellbeing" and working in close collaboration with patient associations as AIMAC, the Spanish GEPAC, to further explore user needs and technology gaps and find opportunities to capitalize the CAPABLE results. UPM supported the creation of a demo environment for CAPABLE to give the opportunity to the Consortium to continue testing and evaluating the solution and allow dissemination to hospitals and other key stakeholders.

Stakeholder activities

During the last year of the project WP8 also carried out activities to collect qualitative information and feedback about the CAPABLE approach and possible opportunities of commercialization or exploitation. The following type of stakeholder have been interviewed:

- Hospital managers: they would be ideally potential customers of the overall solution of CAPABLE and they would offer a good perspective on how telehealth technologies could be adopted in the hospitals.
- Managers of MedTech companies: they would provide information on strategies to operate in healthcare sectors. MedTech could be key partners for the exploitation of CAPABLE.

The interviewed guide has been adapted to the specific group and consider the following points:

- Current context of digital technologies in the market / hospital
- Presentation of CAPABLE
- Feedback on CAPABLE solution
- Discussion on the uptake of CAPABLE

Current context

In the hospital of Pavia San Matteo there are multidisciplinary teams called case managers that provide remote support to the patient, but they are not using an IT service of telehealth, this is done by phone.
In some units there is a lack of digital technology, and this generates a barrier for the adoption of digital solutions.
The cardiology units are the most advanced in terms of remote services for patients. In most of the hospitals it is present a service to monitor arrhythmia using monitoring technology (e.g. holter devices).

In Italy there are two factors that are opening the opportuning to solution like CAPABLE to remotely follow-up patients:

- The pandemic experience: the COVID-19 crisis has accelerated the adoption and integration of telemedicine into healthcare systems around the world. Several key factors contribute to the enhanced readiness of telemedicine: increased acceptance and awareness and increasing understanding of the benefits of telehealth services.
- Regulatory changes: many countries have adapted their healthcare regulations to facilitate the use of telemedicine. Regulatory barriers that previously hindered widespread implementation have been eased, allowing healthcare providers to offer telehealth services more easily. In Italy the minister of health published the guidelines for telemedicine the past November 2022 to specific context of use and opportunity of the telehealth services[10].

All the interviewed stakeholders acknowledged that one key aspect of the uptake of Telehealth system is the consolidation of a reimbursement schema.
A recent study from Robin van Kessel et al analyzes different reimbursement schemes of European countries plus Israel[11].

Table 1: Summary of reimbursement strategy in Europe and Israel

Country	**Type of reimbursement**
Belgium	Reimbursement of digital health solutions does not focus on reimbursing the solution itself. Rather, the Belgian reimbursement system covers a particular health care trajectory holistically and digital health solutions may be deployed by the practitioner as part of the health care process
France	Reimbursement of digital health solutions can occur through the centralized pathway of medical devices. Connected medical devices have recently been added to the scope of the French National Authority for Health's directory of products that qualify for reimbursement within the statutory health insurance
Germany	Digital health apps specifically can be reimbursed under the statutory health insurance if they are approved by the Federal Institute for Drugs and Medical Devices and listed in the national digital health directory.
Italy	Digital health solutions can be reimbursed under the national health system, although the reimbursement procedures of digital health apps and pricing protocols have been not already established. All regions in Italy adopted tariffs for telehealth and matching reimbursement procedures for all modes of service delivery (digitally supported or in person)

[10] https://www.salute.gov.it/imgs/C_17_pubblicazioni_2129_allegato.pdf
[11] Van Kessel, R. et al. Digital Health Reimbursement Strategies of 8 European Countries and Israel: Scoping Review and Policy Mapping. JMIR Mhealth Uhealth 11, e49003 (2023).

The Netherlands	The Dutch Healthcare Authority has published guidance documents to help health professionals in the Netherlands distinguish between clinical medical apps and assistive health apps. This distinction is important in the Dutch health care context to determine whether a digital health solution has to be reimbursed under individual health insurance companies (in the case of use in primary care, home, or community settings) or whether they can be reimbursed by the basic health insurance package[12]
Poland	it is limited, in fact a reimbursement pathway within the National Health Fund for digitally delivered health services was created as part of an emergency COVID-19 pandemic policy. The scope of digital health in Poland is currently limited to tools of digital consultation between health care professionals and patients, consultations between health care professionals, as well as the e-prescription system.
Sweden	Each region is responsible for the price-setting of digital health care services and the corresponding copayments for patients.
United Kingdom	NICE provides recommendations on a value-based pricing for a digital health app. However, pricing negotiations occur individually with the 42 integrated care boards.
Spain	The Telemedicine service is part of the digital health strategy[13] of the national health system, but it still lacks specific legislation to regulate, standardize and provide a reimbursement schema. Now the most relevant commercial initiatives are supported by insurances and the private hospital networks.

Feedback on CAPABLE system

The system has been presented and discussed with the stakeholders. The overall feedback of the solution was positive, and some critical aspects have been identified:

- Integration with the Hospital infrastructure: a system like CAPABLE would require a seamless integration with the EHR of the hospitals, but not in all the cases this would be feasible because of no technical reasons (access to the infrastructure, lack of authorizations, restricted policy for external products). This is a big barrier, and it requires a lot of efforts to achieve the integrations. Big players such as Philips, Medtronic, Dedalus that provide several services to hospitals can provide the access to integration platforms that would facilitate the integration with EHR and to the clinical processes of the hospital. This will be a booster for the integration of novel solutions led by SMEs and startups that want to operate in the healthcare sector.

[12] https://www.government.nl/topics/ehealth/government-encouraging-use-of-ehealth
[13] https://www.sanidad.gob.es/areas/saludDigital/doc/Estrategia_de_Salud_Digital_del_SNS.pdf

- Deployment of the product: in general, this would depend on the hospital needs and policies on IT infrastructure. Most of the hospitals use an intranet and internal cloud solutions. Few hospitals adopted cloud solutions and if adopted they are not connected to the Hospital Information System or Electronic Health Records.
- Allocation of appropriate resources of the health care system: hospitals have a problem of resource management and reimbursements of the offered service. Implanting a telemedicine service requires the allocation of specific personnel to maintain and to operate with the system. The provider of the solution should consider the eventuality to provide a scalable service to cover the operations that the hospitals would be unable to do. Medtronic for instance provides a telehealth solution called Get Ready used to empower patients during the pre-surgery phase and they provide a service center to remotely manage the patients and reduce the operation with the system, in a way that clinicians only intervene when necessary.
- Business Models: according to the discussion with MedTech stakeholders the business model would depend on the country and on the context of funding and purchase: with a reimbursement schema a telehealth product would be purchasable using a subscription model, and in case of applying to punctual available funds (e.g. coming from EU recovery Funds, R&D funds) this would request a more tailored business model and adjusted to available resources. Another possible option is the model pay for use, giving the possibility to have free access and eventually use the solution in the clinical practice.

CS_AIW activities

During the past 13 months WP8 joined the activities of the CS-AIW cluster that unites 11 EU-funded initiatives focused on harnessing Artificial Intelligence (AI) for healthcare and well-being, specific for cancer. Together, these projects aim to synergize their efforts, pooling experiences, and insights to maximize collective impact. Established in October 2020, the cluster endeavors to amplify the outcomes of each project for the broader benefit of society. Different activities have been organized and the 3 following are very linked to WP8:

- Discussion on research limitation, barriers to the implementation and lesson learned: CAPABLE project organized a set of events to discuss all these aspects.
- Production of a white paper of recommendations[14].
- Comparative study on project's research and achievements using the SWOT analysis approach: these activities (lead by UPM) contributed to the generation of knowledge and commonalities among the projects of the cluster.

The cluster met on a monthly basis, the CAPABLE consortium led activities related to barriers and lessons learned with the aim to share the knowledge acquired from all the projects and give visibility to the challenges faced by every research project. As results of this activities a set of seminars have been organized and they can be summarized as follow:

- Webinar with title "*Lesson Learnt on Digital Health Technologies related to Cancer*" the 19th March 2023 where the discussion points were related to patient experience and technical barriers of ICT technologies, the health professionals' experience on the usage of the clinical decision support

[14] https://www.cs-aiw.eu/assets/reports/CS_AIW_whitepaper.pdf

systems, medical Device Regulation from the perspective of a EU funded project and market acceptance of the results of EU funded projects

- Discussion during the physical Meeting in Madrid (11th and 12th May 2024 in UPM facilities), where initial discussions on barriers for the uptake of technology in healthcare and the death valley of research projects has been discussed.
- SWOT presentations (2 events): UPM led the continuation of the discussion on barriers for the uptake and proposed the online session to deeply discuss the experience from the clusters' project. 7 SWOT analysis from cluster's projects have been presented and discussed, to find commonalities and differences. The projects that participated to these activities were: CAPABLE; FAITH (GA 875358), LIFECHAMPS (GA 875329), BD4QoL (GA 875192), ASCAPE (GA 875351), ONCORELIEF (GA 875392), REBECCA (GA 965231). Quantitative and qualitative research activities are now ongoing.

The collaboration with the CS_AIW will continue also beyond the project and the following activities are planned for the 2024:

- Direct engagement with the European Commission: representation delegation to meet EC to present our collective work and support them at policy level. Currently the partners are working on an update on the white paper to present issues and recommendations for next EU R&D&I activities.
- Workshops on results, uptakes, and opportunities: the cluster will continue the monthly meeting and activities oriented to integrate best practices and share knowledge.
- Dissemination activities: the cluster will continue with activities to disseminate the results of the single projects (included CAPABLE) and to make visible the joint activities to the public audience (through podcasts), researcher (with scientific papers) and other stakeholders (meetings and white papers).

The cluster activities will also be an opportunity to consolidate relationships with key stakeholders for the CAPABLE projects as hospitals, bioengineers, patients' associations and companies (specially SMEs) that would be interested to start joint exploitation initiatives and research activities leveraged on previous project results.

3.The CAPABLE opportunity

Market review and updates

WP8 provided an extensive market in the previous deliverable D8.1 and D8.2. From these activities the CAPABLE consortium produced a live repository of competitors and companies active in the field of digital therapeutics in oncology. This live document has been presented in D8.4 (see section 3), updated and periodically revised. The link is available here:

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

In the context of this final deliverable WP8 shows how the market has changed in the last 2 years.
The COVID-19 pandemic sped up the marked preparedness for the overall digital therapeutics market, increasing the number of solutions of telemedicine, teleconsultations in all the health areas, especially the ones related to mental health and chronic disease (cardiology and endocrinology are the areas that mostly fulfill the market).
In oncology four factors are driving the use of digital technologies:

- The complexity of the cancer journey that involves different stakeholders in different phases (diagnostic, treatments, follow up, palliative care, end of life, survivorships).
- The opportunities of the telehealth services to provide remote consultations, monitoring and follow up.
- Personalized medicine: is an approach to cancer treatment that tailor medical decisions, interventions, and therapies to individual characteristics of each patient and their tumor based on genetic profile. It is possible to target a specific therapy and optimal approaches for immunotherapy.
- Integrated medicine: digital health is also an opportunity to integrate the care processes of different health specialists that are required as complementary support for the patients (psychologist, nutritionists, physiatrist and other specifics specialists that depend on the type of cancer and on the treatment).

With the advent of technology and innumerable companies entering the digital health space, it is important to understand the significance of proven clinical efficacy of digital health solutions and to differentiate digital therapeutics from other digital health or wellness solutions.

Specific solutions for MELANOMA
One of the most promising concepts is an AI based method used to monitor using images the skin of the patients. This approach has been used by different companies (SMEs and industries) to create digital services to better assess the risks, the diagnostics, or the treatment response. Two relevant solutions can be mentioned:

- Derm assist[15] from Google is a CE Marked device (type 1). This solution is not intended to be used in clinical practice but as an initial pre-diagnostic test that patients can perform using their mobile.

[15] https://health.google/consumers/dermassist/

- Skinive[16]: a Dutch start-up that provided a solution for patients and health professionals to detect different types of skin lesions (also pre-cancer and skin cancer disorders) with a sensitivity of 94,7%.

Specific solutions for Renal Cell Carcinoma

No specific solution has been identified, the screened solutions belong to the market of apps for patients, such as Kidney Cancer Manager that help patients to manage therapy and visits and access to basic education and information and additionally can be connected to the health professional that uses the Point of Care solution from Kaplan[17]. Another relevant solution is an ongoing study in the US on a Smart-Phone App for Patients with Advanced Renal Cell Carcinoma Undergoing Combination Immunotherapy sponsored by Pfizer[18].

Remote symptom reports and management

Most of the monitored solutions allow symptom reporting and remote patient monitoring and specific notifications are sent to care providers.
Untire[19] app provides support to patients to fatigue side effects and offers a comprehensive lifestyle intervention to improve mental health, nutrition and physical activity habits. Kaiku health[20] (already reported in D8.4 as relevant competitor) represent one of the most comprehensive solution available in Europe and currently is making a partnership with Electa[21] a MedTech that provide devices for radiotherapy, radio surgery and other solutions, They have a specific portfolio of services and products in the field of oncology and integrate the Kaiku technology to add value to the therapy and improve the follow up of patients. Another solution is the German Cankado pro-react-onco[22] (class I MD) that provides a telehealth solution to monitor evolution of cancer and a app that provides a daily support to patients, allowing symptom reporting, behavioral advices and AI driven decision support and Incident prediction to assess the evolution of the disease of the patients. This solution has different Pharma companies as partners (Roche, Pfizer, Novartis, MSD).

General telemedicine and teleconsultation

The market also provides general solutions for telemedicine and teleconsultations that have been used to support patients during oncology. A very famous American brand is Huma[23] that provides services of teleconsultation, remote follow up, gathering of vital signs. This solution is widely used in the USA and UK, (in the UK it is part of the NHS digital toolkit). Another interesting solution is Ticuro[24] (from Italy), a general telehealth solution used to monitor different typologies of patients, offering a service of teleconference, remote monitoring of physiological signals (using IoT technology) and supporting the execution of care plans defined by the specialists.

Integrated Care

[16] https://skinive.com/
[17] https://atpointofcare.com/
[18] https://clinicaltrials.gov/study/NCT05579847
[19] https://tiredofcancerapp.com/
[20] https://kaikuhealth.com/
[21] https://www.elekta.com/products/oncology-informatics/elekta-one/
[22] https://partners.cankado.com/germanys-first-diga-for-breast-cancer-patients/
[23] https://www.huma.com/
[24] https://www.reply.com/ticuro-reply/it/

Attune[25] is a digital intervention to promote mental health in patients during the treatments. It helps to shift negative self-talk, deal with stress, to relax and to improve sleep habits. It also provides a clinical dashboard to show to the professionals the progress of the patients.

SWOT analysis

SWOT analysis is a strategic planning tool used to identify and understand the Strengths, Weaknesses, Opportunities, and Threats related to the project. The SWOT has been defined and refined during the project using the following methods:

- Stakeholder revision and discussion: the SWOT has been periodically discussed during the Consortium meeting and presented in the CS_AIW meetings. Some feedback has been gathered and used to refine the next version of the diagram.
- Research and Data Collection: Gathering relevant data and information from various sources such as market research, and the results from the final evaluation of the CAPABLE technology (WP7).
- Interviews and Surveys: Conducting interviews or surveys with key stakeholders, as manager of MedTech, Hospital managers, IT managers, researchers.

After identifying the various factors, prioritizing and ranking they have been ranked based on their significance and impact on the specific dimension. The following sections describe the results of this analysis.

Strengths

The clinical studies demonstrate that the CAPABLE system is adaptable to other types of CANCER. In fact, ICSM partners were able to test the system with patients affected by cancer different from melanoma and renal cell carcinoma, the target initially planned in the project. The solution demonstrated to be interoperable and the NKI hospital was able to make the system interoperable with the Electronic Health Record. Specifically, it was possible to simplify the process of enrollment and get information on treatment and type of cancer. The system differentiates from market solutions to support the implementation of clinical guidelines using a specific engine provided by the company DEONTICS. The result of the final clinical study shows a successful deployment of the system generated in the Italian clinical centers, an improvement of the quality of life of the patients (3 points of the scale QLQ-C30) and high usability and acceptance has been reported both from patients and health professionals. (More details on the results can be found in D7.8 and D7.10).

Weakness

According to the Description of Action document and according to the results, the CAPABLE system was able to achieve a TRL6 (System/process prototype demonstration in an operational environment) that represents excellent R&D results but still far from being a commercial product. 3 key issues have been identified and need to be addressed in the exploitation activities:

[25] https://attunerx.com/

- Simplification of the deployment of the technology: the CAPABLE technology required complex hospital procedures and high computational resources has been allocated to integrate the solution. 8 Virtual Machines have been installed and configured in every hospital, making the procedure expensive and complex to maintain. Under the technical viewpoint the solution was manageable but required an intense use of resources to maintain the system.
- Operationalization of the technical support: the WP7 results shows how different implementation of the CAPABLE solution would lead to different types of results. The key factor is the allocation of technical resources to support the health professionals and patients that tested the system. The commercialization of the CAPABLE system would require stronger procedures of technical support and not be possible to delegate this responsibility to the hospital facilities because in some healthcare contexts this is not feasible. The technical support should be considered as a service integrated in the CAPABEL solution.
- Certification: to become a digital product CAPABLE needs to get the CE certification and must be registered as class IIa of Medical Devices. This would require extra resources and effort to document, audit and improve the final solution. Finally, a more systematic clinical study must be performed (e.g. randomized controlled trial) to increase the level of evidence of the impact of the system in the health care and to the patients.

Opportunities

During the project the market changed and currently it is ready for solutions like CAPABLE. The previous section of this document shows that in the last 2 years the European market started having different commercial products operating in the field of digital therapeutics for cancer. On the political side Europe start also putting a lot of efforts to fight the cancer pandemic and a strategic plan called Beating Cancer Plan[26] has been created and supporting with a financial resource of up to €250 million for cancer-related project, and support wider digital investments, such as relating to electronic data, cybersecurity, and digital skills from which the health sector will benefit. On the consumer's side the experience of the SARS-CoV-2 pandemic obliged the healthcare systems to set up telehealth services (mostly of teleconsultation, counseling, and support) and this increased the acceptance of the digital solutions to provide health services.

Threads

Nowadays the digital health market is more mature, and the competitors appeared in Finland, France, Italy, UK, Germany and started operating across the whole Europe. MedTechs and Pharmas companies are strengthening partnerships with SMEs to position themselves in this market and attach digital telehealth solutions to other health care services (e.g. surgery devices, pharmacological treatments) and have presence in this relatively new and now mature market of digital therapeutics in oncology. Another critical aspect is the fact we are in a legal transition period in which changes for Medical Device and AI services. The Many manufacturers and associations had pointed out the impossibility to obtain an MDR certificate of conformity at the end of the transitional period initially provided for,

[26] https://health.ec.europa.eu/system/files/2022-02/eu_cancer-plan_en_0.pdf

regarding the insufficient evaluation capacity of the notified bodies. From the CAPABLE experience we had to submit the documentation to 2 different notified bodies, manage the two different feedback and allocate many resources to manage the numerous required iterations with the regulatory bodies. Another key barrier that needs to be considered in the context of digital healthcare solutions is the change management: hospital workflows, organizational rules are difficult to change and adapt to new models of care management. In the oncology domain still there are many challenges to foster integrated care services and intra departmental collaboration to offer a holistic approach on the cancer treatment, reimbursements schemas are available but not fully implemented and adopted by the hospitals. Furthermore, under the organizational side there is still a lack of qualified operators specialized in the management of telehealth systems and tele counseling. The last thread is related to the nature of the EU funded projects, for the case of Research and Innovation Actions that are unique opportunities to build and test novel solutions but at the end of the project there is this transition period between end of the project and product realization that is the Death Valley[27]. This period is characterized by the lack of specific funds, difficulties to set up an appropriate team that will create and exploit the product, difficulties in engaging the key stakeholders, managing the costs of scaling up the technology and adopting the right business strategy.

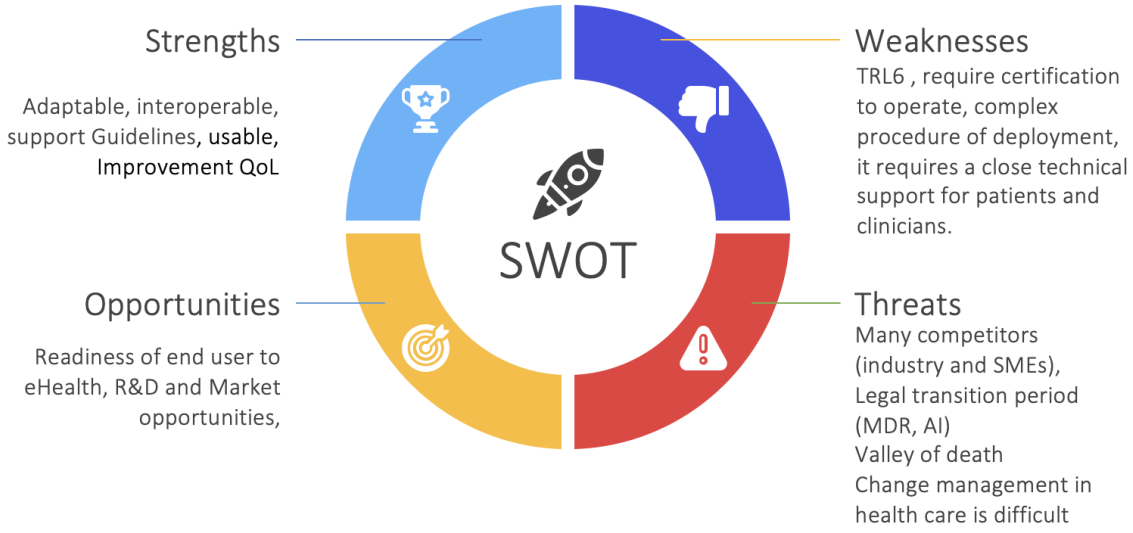

Figure 3: SWOT analysis of the CAPABLE solution.

[27] Saheed A. Gbadegeshin et al. Overcoming the Valley of Death: A New Model for High Technology Startups, Sustainable Futures, Volume 4, 2022, 100077, ISSN 2666-1888

4.Roadmap to commercialization

The CAPABLE roadmap to commercialization is based on short and middle term plan to set up the precondition for a proper exploitation of the results. In this chapter the focus will be related to the commercialization of the overall project's results, the CAPABLE system intended as a telehealth solution to support and monitor patients during the treatment phase. The following subchapter present a list of activities (A) that need to be completed to be ready for the commercialization activities.

A1: Simplification of the system

According to the pilot experience the technology demonstrated to work properly but it required a complex deployment since every software artifact has been deployed in a dedicated virtual server, generating high costs of deployment for the hospitals. In the last months the project WP8 remarked on the need to optimize the deployment procedures to reduce costs. This process has already started, and the main result is the deployment of the CAPABLE solution in one web-based hosting environment provided by UPM (and only 2 components were not deployed in this server).

At the same time the integration of a commercial wearable sensor Asus demonstrated to be perceived as a high value for the patients but generated in some cases technical malfunctioning (battery and synchronization with the app problems and in some cases skin reactions). It is recommended to re-evaluate the choose of a more stable wearable sensor with a seamless integration and better ergonomics for the patients.

CAPABLE projects provided the patients that joined the clinical study with an Android device. Part of the patients reported feedback to desire having the app in their own device and to avoid managing 2 devices (the personal and the study smartphone). The commercial solution of CAPABLE should be an installable app compatible with the patient's devices. This will also reduce the cost of deployment giving the possibility to avoid the cost of a Smartphone and leveraging on the one owned by the patients. This strategy is widely applied also by the competitors. Currently the patient app is available in android and new versions for IOS (and optionally Windows Mobile) need to be developed.

A2: Availability of the demo

The CAPABLE technology is a solution that is deployable in hospital infrastructure, and it is now available on the Web. This generated a limitation to make visible the technology and to provide an opportunity to interested stakeholders to evaluate the technology. WP8 supported the creation of an online demo, and this initiative was also an opportunity for the technical partners to contribute to the A1 (activity lead by BIOMERIS and UNIPV). UPM provided just one service machine that had been used to deploy 6 of the 8 services. The process has been successfully completed and WP9 boosted the activity by publishing in the project's webpage[28] the information related to the demo. This new available service has been used to

[28] https://capable-project.eu/demo/

start the activities of dissemination and presentation of the solution to key stakeholders (hospitals, Medtech, SMEs etc).

A3: Partnerships with ICSM and NKI hospitals

The consortium verified the possibility to continue the collaboration with the current hospitals and to continue the usage of the system. ICSM accepted the challenge and is internally verifying how to allocate the clinical resources. NKI granted the availability to further collaborate on the testing of the CAPABLE solution and this would require resources to set up appropriate support to clinicians and patients. Furthermore, some fundings are required to cover the costs of the technology deployments, patients devices and software maintenance.

A4: Possible extension pilot in new hospital

The consortium analyzed a possible scenario to run a new pilot in a new hospital, to understand resources and required effort to deploy an improved and refined version of the system. The technical partner estimated activities for training, deployment, personalization (if required) and maintenance of the system. To simplify logistics one scenario could be to deploy the solution without the use of the wearable sensors that would reduce maintenance activities (according to the WP7 reports the Smartwatch produced a significant number of technical issues) and deployment costs (the purchase of the device).

A5: Business model refinements

WP8 provided an initial business model in D8.5. This business model has been improved considering the following:

- Pricing and fee have been updated according to increase of costs of human resources and technology.
- Channel: it is important to consider MedTech, Pharma and IT companies that can include the CAPABLE solution as part of their portfolio of services. This is very in line with the market trends as also explained in the previous section.
- Reimbursement strategies: countries are implementing reimbursement policies of telehealth systems, and this would be a very important opportunity. The price of digital health solutions is mainly determined through discussions between national or regional committees and digital health solution manufacturers, in the absence of value-based pricing mechanisms. Financing digital health solutions outside of traditional reimbursement schemes has occurred through healthcare innovation or digital health-specific financing schemes. This reimbursement strategy would be the key for the update in the public national health systems of Europe.

A6: Stakeholder engagements and partnerships

The following table provides a list of stakeholders that should be part of the CAPABLE ecosystem to successfully commercialize the solution and foster initiative for the technology maturity.

Table 2: Key stakeholders for CAPABLE

Stakeholder	**Interest**
Hospital managers / head of clinical units	They are the potential buyers of the solution. They would be interested to include CAPABLE in the portfolio of digital service to implement a strategy of hospital digitalization, increase the presence and coverage of the health services in the area. They would use funds coming from reimbursements of telemedicine systems, incentives from the National Health System for digitalization, research funds, private funds from pharma or CROs.
Health professionals	They are potential end users of the CAPABLE solution. Health professionals should be oncologists, nurses that would like to benefit from the CAPABLE dashboard to follow up patients, consult clinical guidelines and see the evolution of the patients.
Cancer patients	Patients during treatment would be the target users. They would access the system under the proposal of the oncologists that follow the disease course. They would receive (as in the clinical CAPABLE study) specific devices (dedicated Android app and Asus Smartwatch) and in the envisioned commercial product they would use the personal devices (app and smartwatch). Optionally the hospital would be able to provide in some cases a dedicated phone and wearable sensor.
Patient associations	The patient associations would be an optimal channel for the dissemination and promotion of the CAPABLE solution, to increase awareness to cancer patients and show novel approaches of remote care management. Patients' association could press policy makers to increase access to digital services for patients support and counseling.
Pharma companies	Pharma companies are a potential partner and investor of the CAPABLE technology. They could be interested to include the solution to their portfolio to add value to a specific pharmacological treatment to use CAPABLE to monitor side effects of specific pharmacological therapies. As mentioned in the previous section they are a group of competitors that operate in partnerships with pharma companies.
Medtech	Medtech companies that operate as service or product providers in the medical sector could be interested in partnership with a telehealth solution as CAPABLE to provide continuity of care in out-hospital settings.
Policy makers in the field of healthcare	According to national and European digital health strategies, policymakers may be interested in promoting

	policies that encourage investment in telehealth research and development. Policy makers could also establish clear reimbursement policies specially for Telehealth services, expand reimbursement coverage and promote value based care models to incentivize the use of Telehealth solutions to improve clinical outcomes and reduce costs.
Research and academic centers	Research and academic centers would be interested to adopt a solution like CAPABLE to continue research in digital health and consolidate evidence of clinical effectiveness of telehealth systems like CAPABLE. Furthermore, more specific research would be fostered in the field of Human Computer Interaction, digital interventions, clinical engineering and in general digital health.
Medical scientific societies	They have a significant role in the aspect of promoting digital health technology, advocate specific reimbursement strategies and promote activities of education and training to foster the uptake of digital technologies and reduce the cultural resistance to the change.
Regulatory bodies	The regulatory bodies will play a key role in setting rules, guidelines, and support services to grant data privacy, quality of data, cybersecurity and the interoperability of IT systems as well as IP rights. Regulatory issues (product classification as medical device) and financing are also key for the development of digital health.

A7: IPR Managements

D8.6 describes the Intellectual Property Management of the project. The potential joint exploitation of the overall CAPABLE system has been defined, recognizing the ownership to the technical team who developed the solution, and granting the access at level of the service to the other partners that contributed to the design, validation, and test of the systems. The infringement procedures have been set in place and this will be the starting point for the discussion on possible joint venture actions or start up initiatives. During the conversations with the partners for the individual exploitation initiatives the SME companies declared their interest in a possible collaboration for the commercialization of the system, but this would require additional funds to increase the TRL level of the solution.

A8: Set up of support service for CAPABLE

One relevant result of the final CAPABLE pilot was the fact that there was a significant gap of the performance of the CAPABLE system between the Dutch and Italian study. One of the most important reasons was the fact that CAPABLE demonstrated to require a certain level of technical support that the Italian hospitals were able to provide thank to the collaboration with a bio-engineering

unit of the hospital (linked to the UNIPV partner) meanwhile NKI did not allocated any technical resources and used the research staff of the CAPABLE project (no technical team). This difference generated differences in the type of technical support for the patient and health professional. Next pilot study must take into account this crucial aspect of support and the CAPABLE promoters are required to set up a support service available for the hospital with the capability to offer a prompt technical response and solution to the end-users' problems. To cover this significant requirement, it is recommended to:

- Consolidate a protocol of technical support.
- Allocate human technical resources during the pilot study.
- Also consider the role of on-site support that could be at hospital and eventually at a patient's home.

This service would add additional costs to the deployment of the CAPABLE solution, but it is mandatory in order to provide a professional and high-quality service.

A9: Certification and qualification of the system

During the CAPABLE project the Medical Device Regulation started being active and this required setting up different activities to follow the new legislation. This was not a planned effort but generated a deep knowledge and experience in the consortium. UNIPV, NKI, ICSM and AMC worked to analyze, document and prepare all the documentation to present CAPABLE as class IIa MDR. This authorization was required also for systems to be tested in clinical research. These activities will be a strong starting point for the certification and qualification of the CAPABLE solution as an MDR product. The documentation was submitted to national Dutch and Italian authorities and in the next future EUDAMED will be the central authority. The introduction of EUDAMED under the MDR has experienced a delay, with the revised launch anticipated in the second quarter of 2024. From the fourth quarter of 2024 onwards, obligatory utilization of the database will commence for actor registration, clinical investigations, performance studies, vigilance, and post-market surveillance. Mandatory adoption for unique device identifier (UDI)/device registration is scheduled to begin in the second quarter of 2026. Another mandatory task would also be to get the CE mark of the CAPABLE product. Three essential steps need to be performed:

- Implement a Quality Management System (QMS).
- Certify the company with ISO 13485 to ensure the proper management of quality devices.
- Clinical trials are compulsory in Europe under the MDR for high-risk and innovative medical devices. Nonetheless, the devices must possess clinical evidence demonstrating their safety and efficacy for the claims on their labeling. The requirement depends on the type of existing clinical evidence. Clinical data should offer adequate evidence to prove at least conformity with the applicable General Safety and Performance Requirements (GSPR).

A10: Access to funds and investments

The previous activities for the commercialization roadmap required some funds that are crucial for the further technology maturity (from TRL6 to TRL7 and then 8), validation, certification, and qualification. Furthermore, additional resources would be required for the set-up of the business entity that would be responsible to provide the CAPABLE service.

- Public-Private Partnerships (PPPs): Collaborating with private sector partners can unlock additional funding opportunities for telehealth initiatives. PPPs often leverage both public and private resources to support innovative projects in healthcare delivery and technology adoption. THE IHI initiative represents an opportunity to join health research and innovation between the EU and Europe's life science industries. UPM is leading a project called IMPROVE[29] which goal is to create a framework for the integration of Patient Generated Health Data to foster the uptake basing on Value Based Healthcare. This multidisciplinary collaboration includes 10 use cases, one specific to oncology in which a solution like CAPABLE could fit. Furthermore, new incoming IHI calls could be an opportunity to create new joint collaboration between research institutions and the Healthcare industry.
- EU4 Health: the specific EU programme dedicated to health has a specific priority in the field of cancer called Beating the Cancer plan that has two specific areas in which the CAPABLE solution could be proposed: Diagnosis and Treatment and Quality of life of cancer patients and survivors. New research initiatives could be launched and use CAPABLE as the starting point of new approaches and studies. Different granted related to the topic has been planned in the last quarter of 2024[30]
- EIT Health is a pan-European consortium of leading healthcare companies, research institutions, and universities. It is part of the European Institute of Innovation and Technology (EIT), an EU body created to foster innovation and entrepreneurship across Europe. This institution fosters the formation of young businessmen and the scaling up of new products and companies that want to operate in the field of healthcare. UPM is a partner of this network and could be part of any initiative launched by the consortium.
- COST[31] is an intergovernmental programme funding interdisciplinary research networks between researchers and innovators in a wide range of topics. Cost also included research initiatives in the field of cancer.
- European Innovation Council[32]: the EIC Accelerator would help SME companies to reach TRL8 ('Grant Only' schema) or TRL9 ('Grant First' schema).
- National funds: CAPABLE partners would be also able to look at national funds from public or private institutions. Funds would be to foster the uptake of digital health technologies, increase clinical evidence of prior research.
- Investment venture capitals: spanning from digital health platforms and wearable devices to AI-driven diagnostics and telemedicine, the EU health tech landscape is brimming with inventive ideas. This surge of progress has been propelled in part by an increasing number of investors dedicated specifically to health tech and life science ventures.
- Corporate investors, including healthcare companies, technology firms, and telecommunications providers, and Banks are increasingly investing in telehealth solutions to capitalize on the growing demand for digital health services. Companies like Philips, Siemens Healthineers, and Deutsche Telekom, BBVA are examples of major players investing in telehealth initiatives across Europe.

[29] https://cordis.europa.eu/project/id/101132847
[30] https://hadea.ec.europa.eu/programmes/eu4health/calls-and-contracts/tentative-calendar_en
[31] https://www.cost.eu/
[32] https://eic.ec.europa.eu/

5.Lesson learned and conclusions

The CAPABLE project was a unique opportunity to collaborate with a multidisciplinary Consortium to contribute to one of the most challenging health issues of modern society, cancer. The Research and innovation activities have been carried out following the CEHRES roadmap that thanks to its iteration produced formative processes that make possible the definition and identification of business opportunities in the field of digital health, specifically the digital therapeutics. This work has been carried out with a close collaboration with the consortium with three level of interactivity:

- Definition and consolidation of the value of the results. The open collaboration between WP8 and the other WPs fosters the overall understanding of the technical solution and the feedback from the end users gathered during the WP7 activities helped to create a refined version of the value of the CAPABLE solution.
- Understanding and alignment of individual and consortium strategies. The periodic workshops, discussions and meetings generated individual strategies in which every partner would take profit of their own results and also would be interested to start joint initiatives and collaboration for the exploitation of the overall CAPABLE solution.
- Definition of a strategic roadmap for the exploitation of the CAPABLE results, based on individual and collaboration of the consortium. These results would be the initial guide and reference for the post project exploitation activities.

During these 49 months of research the market landscape demonstrates to increase awareness and interest in the field of digital health technologies in the field of the treatment of oncology. New SMEs and products have been launched and big stakeholders from Pharmas and Medtechs started partnerships with the new operators.
The findings from the clinical validation indicates that symptom monitoring tools improve Quality of Life for cancer patients, and possibly could also increase adherence to cancer medications and giving insights into patient experience. The overall results of the project can be considered positive, but some aspects of the research activity can be considered as key factors for the success and need to be further researched and developed in the next years.

- Reimbursement strategies need to be further implemented and standardized across European countries.
- Lack of solutions and approaches for integration of novel digital tools in clinical practice: a good solution for the uptake could be integration of this tool in one seamless Graphical User Interface with EHR and other tools (e.j. PACS) that provide specific health information.
- Barriers for the implementation in the clinical practice: it is crucial to find new policies of incentives for the uptake and experimentation of new digital technologies in the clinical centers.
- Consolidate and standardize the practice of co-design activities from patients and health professionals, leveraging on reference centers, living labs, patient association, and medical societies to access to a broader range of end users.
- Consolidate in the design process the early discussions with regulators and end-users and making agile refinements in early stages of product development.

Finally, it is important to highlight that the CAPABLE research was an experience that engaged more than 250 patients and health professionals and other stakeholders and contributed to the generation of a culture of digitalization and improvement of the health care system following a participative approach.