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CAPABLE

Cancer Patients Better Life Experience

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

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1. Versions History

Version	Date	Author	Comments
1.0	12/4/2020	UPM	Table of Contents
2.0	15/5/2020	UPM	First draft version
3.0	8/6/2020	UPM	Contribution in all sections
3.1	15/6/2020	UPM	Version to be revised
3.2	22/6/2020	BIT	Revised version with comments
3.3	22/6/2020	UPM	Candidate final version
3.4	27/6/2020	UPM	Final version

2. Executive Summary

The document presents the preliminary results of the exploitation activities of the CAPABLE project. The activities that will be reported in the document are the following:

- Revision of the challenges for the technologies to improve cancer care
- Approaches to be used to set up a roadmap for the business development of the CAPABLE project (CEHRES Roadmap)
- Analysis of the stakeholders that might directly and indirectly benefit of CAPABLE
- Initial market and competitor analysis
- First draft of the value proposition
- Summarize the conclusion of the work drafting a preliminary SWOT analysis
- Revision of the exploitation opportunities in the project.

3. Problem analysis

Cancer care is a worldwide problem characterized by three main points: i) state-of-the-art clinical medicine, which may include evidence-based and sophisticated therapies targeted to patients' tumor and biological characteristics, ii) an approach to care that is attentive to the spectrum of patients' needs (i.e., physical, psychosocial, functional, spiritual) and iii) the use of systems solutions, both human and machine, that support organizations in achieving their clinical medicine and patient-centered care delivery goals.

In this context, the potential of ICT (Information and Communication Technology) systems to improve care delivery to cancer patients takes special importance trying to overcome the technical, structural, ethical/legal and cultural barriers within the healthcare system[1]. Thus, ICT has the potential to improve cancer care from both the patient's vantage and as part of an overall system-improvement strategy. Figure 1 shows the connections and the potential for ICT to facilitate care delivery.

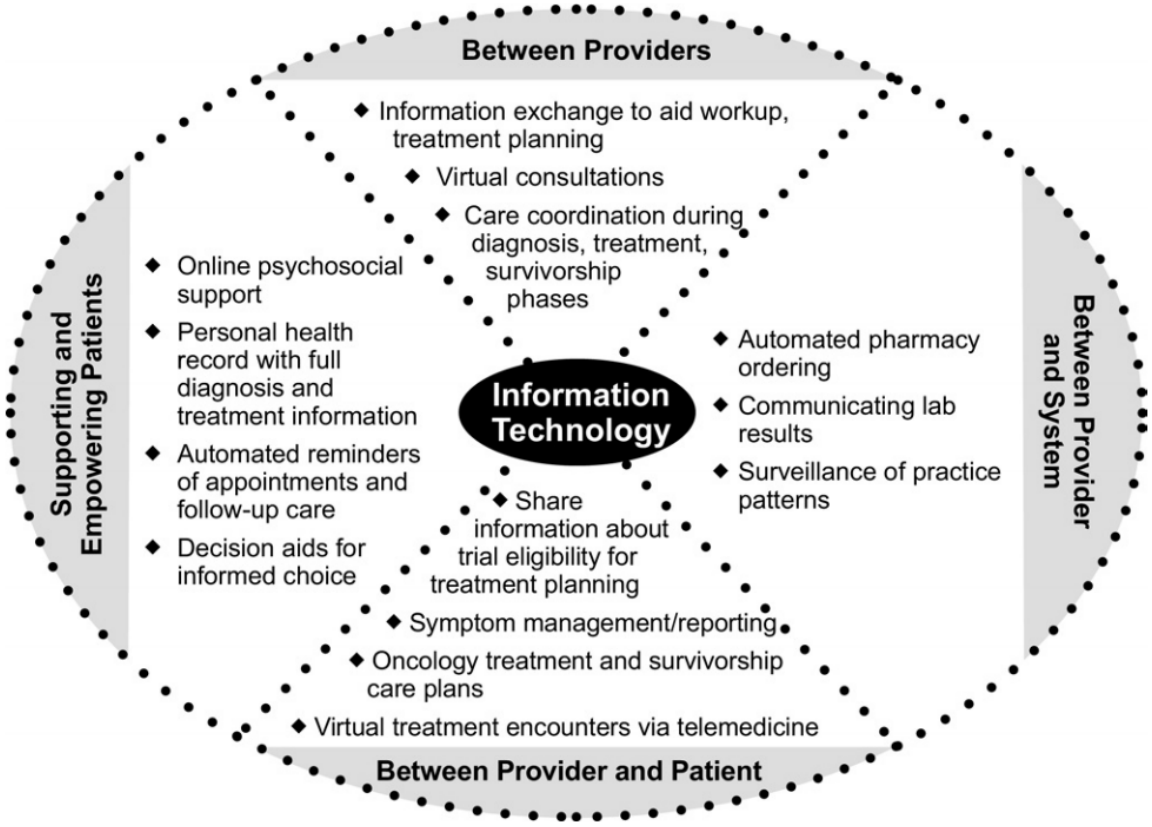

Figure 1: Patient, provider, and system applications of information technology for cancer care[1]

Recent research focuses on how ICT systems can empower patients to become more involved in cancer care. Beyond seeking information, ICT provides resources for social and emotional support of cancer patients and their Caregivers given the anguish and uncertainty that inevitably accompanies a cancer diagnosis, virtual social support groups are a way for patients to find coping strategies and share experiences.

[1] Clauser, S. B., Wagner, E. H., Aiello Bowles, E. J., Tuzzio, L., & Greene, S. M. (2011). Improving Modern Cancer Care Through Information Technology. American Journal of Preventive Medicine, 40(5), S198–S207. doi:10.1016/j.amepre.2011.01.014

Improved cancer management through ICT has received considerable research attention in shared decision-making elaboration, management of symptoms and adherence to the treatment literature. Decision-making aids guide patients (and providers) toward informed choice in situations where different treatments involve compensation based on preferences and values. ICT -enabled decision aids can be individually tailored, highly interactive and scalable, while currently, many treatment decision aids are a generic comparison of treatment options (e.g., mastectomy versus lumpectomy).

Despite the evidence of growing that ICT experimented in the last years, it still has great potential to improve care and results in cancer. There exist persistent challenges to achieve related to information-seeking, including the credibility and trustworthiness of web-based information, and the uneven access to web-based resources among different subpopulations. Also, the concern about security of personal health information is particularly important for cancer patients.

Decision support, continuity of care and care coordination are the main areas where ICT could substantially improve and change the cancer care delivery. Nowadays, computerized decision support systems at the point of care, integrating EHR and adapting guidelines to patients, are one the most treated topics in cancer care that results in proved outcomes in terms of continuity and coordination of care. However, the absence of a widely adopted, technology-driven solution for the trial accrual problem underscores the myriad challenges in this area.

Apart from the technological point of view, there are many obstacles in the healthcare system related to cancer care that must be faced in order to provide high quality care to patients[2]. Some of the identified needs to cover are: i) unrealistic expectations of patients and clinicians with regard to the benefit of certain tests and treatments; ii) inappropriate financial incentives in the health care system; iii) overuse and misuse of medical resources and care that does not align with clinical practice guidelines; iv) insufficient evidence base to facilitate rational clinical and reimbursement decisions; v) legal and regulatory challenges; and vi) lack of consensus on how to assess value in medical care.

It is noticed the importance of ICT in the support of patient centred care of cancer and there is evidence of an enormous progress in the field. Nonetheless, ICT must be more relevant, delivering more than just information to patients, being responsive to the needs of organizations, clinicians and patients, having robust measurements and connecting all stakeholders throughout the systems.

[2] National Cancer Policy Forum; Board on Health Care Services; Institute of Medicine. Delivering Affordable Cancer Care in the 21st Century: Workshop Summary. Washington (DC): National Academies Press (US); 2013 May 20. CURRENT CHALLENGES. Available from: https://www.ncbi.nlm.nih.gov/books/NBK202475/

4. Problem statement

Cancer is a complex disease that requires heavy treatment requirements that severely impair the patient's quality of life. Even if the survival trend is increasing, the overall costs are increasing and there is an urgent need to reduce health care costs and improve the quality of the services from the healthcare systems.

- There is a need to introduce a **new care model** that helps to **understand the real impact of cancer** therapeutics on a patient's life and reduce the occurrence of complications, possible further hospitalizations and additional treatments.
- There is a need to **improve home care** and to leverage on ICT solutions to simplify the collection of PRE and PROMs and foster self-management and remote clinical interventions.
- There is a need to **support the patients and caregivers in the daily difficulties** and life changes required when individuals face the cancer disease.
- There is a need to study the different requisites they can have depending on the individual characteristics (e.g. lifestyle, presence or not of comorbidities, personality, overall mental and physical health, socio-demographic etc) and encompassing all the stages of the cancer disease to offer **adaptative and personalized contents and services**.

CAPABLE proposes to develop an ICT solution to improve the quality of the services of the healthcare providers and impact on the patient quality of life. The mission of WP8 is to guide this project to drive a successful exploitation and the presented work reports the WP8 approach to the exploitation activities and the results of the market analysis that have been conducted in the first 6 months of the project.

5. Methodologies

This section reports the methodologies that WP8 applied to properly conduct the exploitation activities of the project. Two methods are proposed: the CeHRes as an overall project methodology to successfully develop a eHealth systems and a PESTLE analysis approach useful at this stages of the research to inspects factors that influence the market.

5.1. CeHRes roadmap

CeHRes roadmap[3] [4] is a methodology defined by the University of Twente to guide the development, implementation and evaluation of eHealth technologies. This roadmap takes into account the theoretical background of the persuasive design, participatory development, human centred design and business modelling methodologies.

The CeHRes roadmap is composed of 5 main phases: ***contextual inquiry***, ***value specification***, ***design***, ***operationalization*** and ***summative evaluation***. These phases are interconnected through a cycled task (***formative evaluation***) that ensures the activities and results obtained from a phase satisfy with outcomes from the previous phase, the context and the stakeholders' perspective (Figure 2).

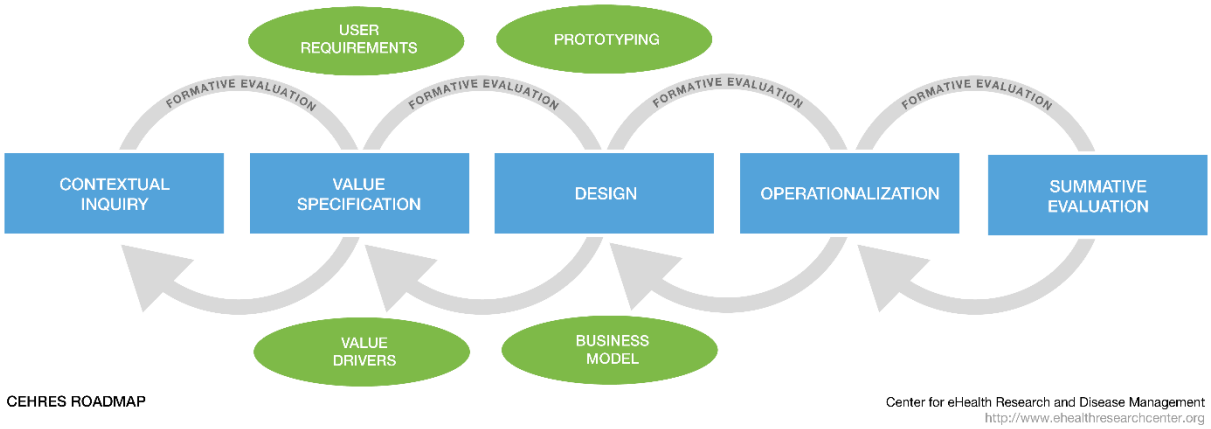

Figure 2: CeHRes roadmap

The ***contextual inquiry*** phase aims to collect and understand information related to the stakeholders and the context where the technology will be implemented. During this phase, workshops, focus groups, personal interviews and field observations tasks are carried out to identify stakeholders' problems, needs and goals that must be covered by the eHealth technology.

We have tackled this phase through periodic meetings with AIMAC partner where information about users' needs and goals have been identified and collected. Moreover, a state of art study about the use of TIC in cancer, patients' unmet needs and healthcare needs was performed. Users and system requirements were obtained from the activities carried out in the WP2. The information gathered through these activities, was integrated and presented in the sections "Problem analysis", "Stakeholder analysis" and "Market analysis" of this deliverable.

[3] Van Gemert-Pijnen, J. E., Nijland, N., van Limburg, M., Ossebaard, H. C., Kelders, S. M., Eysenbach, G., & Seydel, E. R. (2011). A holistic framework to improve the uptake and impact of eHealth technologies. Journal of Medical Internet Research, 13(4): e111

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

The ***value specification*** phase is devoted to identifying and defining the economic, social, medical and behavioural values of the eHealth technology for the key stakeholders. The identified values should be ranked through multicriteria decision-making techniques (e.g. analytic hierarchy/network process). The specified values must be translated into user requirements, functionalities of the design and critical factors for the implementation of the eHealth technology.

A first definition of the value specification is presented in the section "Value proposition" of this report. This definition and the users and system requirements defined in the course of the WP2 tasks will be used to define the system functionalities and first mock-ups.

The ***design*** phase is focused on prototypes development based on the requirements obtained from the previous phase. The cooperative design should be implemented through a co-creation process with users and stakeholders. During this phase mock-ups, storyboards and first prototypes should be created and refined sequentially and iteratively with intended users and validated in real-life environments.

First activities involved in this phase are currently executed in WP6, where Bitsens partner is leading the design and development of initial mock-ups and wireframes.

The ***operationalization*** phase consists of the implementation of activities to introduce, adopt and deploy the eHealth technology in daily practice. During this phase, an operationalization plan is defined taking into account regulations, opinion leaders, triggers, and incentives for using the technology and managing the innovation.

The tasks involved in the WP7 related with the clinical study and the system evaluation will provide information related to the project impact in three levels: 1) on users' behaviour, 2) on hospitals' organization and 3) in clinical results in terms of survival and quality of life of patients. These activities will be part of the operationalization phase for the CAPABLE project.

Finally, ***summative evaluation*** phase covers the impact assessment tasks of the eHealth technology in terms of clinical, organizational, and behavioral. During this phase, the usage of technology and the effects on performance criteria for high-quality healthcare will be measured. Also, the sustainability of the technology will be ensured through continuous evaluation of the factors that influence the impact and acceptance of the technology.

The final evaluation will be conducted as part of the WP7 and WP8, where the results of clinical pilot and evaluation will be combined with the result of the health technology acceptance and the impact on the market.

Summarizing, the activities conducted during this period correspond to the contextual inquiry and value specification phases of the CeHRes roadmap. The results of these phases are included in the first version of this report. Nevertheless, results obtained so far will be continuously reviewed and improved as part of the cycled task of formative evaluation and will be reported in a second version of this deliverable.

5.2. PESTLE analysis tool

The PESTLE analysis[5] [6] is a marketing concept to be used for the strategic analysis of a specific domain. This analysis is recommended for identifying the internal and external factors that influence the adoption or acceptance of a project/product/service. Those

[5] https://pestleanalysis.com/what-is-pestle-analysis/
[6] https://web.archive.org/web/20130717211811/http://hia.com.au/upload/hia/documents/business%20information%20services/sbis_guides/pestle_analysis.pdf

factors are grouped into 6 categories: **P**olitical, **E**conomic, **S**ocio-cultural, **T**echnological, **L**egal and **E**nvironmental.

The ***political*** factors include those actions that can be taken by the government and may influence or affect the business environment and the economy, some of these factors are tax policies and trade tariffs. The ***economic*** factors are related to the economy's performance that directly impacts a business or product and has long term repercussion. Furthermore, they influence the purchasing power of a consumer and change demand/supply models. These factors include inflation rate, interest rates, foreign exchange rates and economic growth patterns, among others. ***Socio-cultural*** factors consider the social environment of the market considering cultural trends, demographics and population analytics. The ***technological*** factors include those that affect the operations of the industry and the market favorably or unfavorably in terms of technology and innovation, such as new products or business processes and new lines of research and development. Consumer laws, safety standards and labour laws are some of the ***legal*** factors that should be considered to identify their effect on the business environment. Finally, ***environmental*** factors are crucial for certain businesses which can be influenced or determined by the surrounding environment, such as tourism or agriculture. These factors include, but are not limited to, climate change, geographical location, global changes in climate, environmental offsets, energy consumption and waste disposal.

The PESTLE analysis can be used for several purposes, such as business planning, marketing strategy, and new product development. This analysis consists of a 2 step process: i) starting with an evaluation of the impact that each factor may have on the business/project; and ii) the planning of a set of actions to minimize any threats and maximise any opportunities.

In the CAPABLE context, the PESTLE analysis is conducted to identify which of these factors affect the solution provided by the project or the healthcare environment where the solution will be exploited. In a second step, we will identify which of these factors are an opportunity or threat and will prepare an action plan to exploit those factors identified as opportunities and reduce the risk of those that are a threat. Subsequently, we will execute the plan and continuously review it to determine if we need to make any change on it or we are still on the right track.

6. Stakeholder analysis

In order to better understand the environment in which the project will be developed, it is necessary to identify and analyse the stakeholders, which will allow knowing the interests of all parties, which may affect or be affected by the project, potential problems that could affect the project, key people for the distribution of information during the implementation phase and groups that should be encouraged to participate in different stages of the project. In the definition phase of the project an initial analysis of the stakeholders was conducted as they are an essential point to consider when defining dissemination and communication plans[7].

During the first 6 months of the project, a desk research, non-systematic collection of material that helps the development team to learn as much as possible about the context, and collection of experts recommendations was done in order to nominate and analyse the most relevant stakeholders of the project. Table 1 shows the list of stakeholders of CAPABLE and how will be the impact and relation of each one within the project.

Stakeholder	Impact	Project relation
Patient	HIGH	• A medical solution to obtain better support with their health trajectory during treatment • A way to actively contribute to the advancement of medical knowledge for improving quality of care in patients treated for cancer, without the need to be burdened with frequent questionnaire administration or other annoying chores • A reference point, always available anytime, anywhere in case of special needs arising during treatment
Oncologist	HIGH	• New way to support decisions, based on new sources of data on cancer patients' treatment (such as symptoms, sensor-based vital signs, behavioral or affective data), available continuously over time • New way to empower and actively support cancer patients in monitoring and managing treatment consequences
Nurse	HIGH	A new way to improve nursing activities thanks to the improvement in treatment support and management of resources and time
Nutritionist	MEDIUM	New way to follow and support the nutrition and diet of patients without needing frequent appointments and possibilities to continuous evaluation
Surgery	LOW	New way to support decisions and improving communication with clinicians
Radiologist	LOW	New way to support decisions and improving communication with clinicians
Psychologist	MEDIUM	New way to support mental health and quality of life status of patients without needing frequent appointments and possibilities to continuous evaluation
Caregivers	MEDIUM	New way to improve the treatment aspects of cancer including quality of life and emotional problems in patients reducing the weight of this fact on caregivers, improving the management of time and resources
Hospital	HIGH	• An opportunity to better integrate existing services involved in the support of cancer patients during treatment, avoiding patients to be referred to the wrong places, wasting their time as well as the time of involved health professionals • An opportunity to foster patient self-empowerment, further optimizing the usage of healthcare resources

[7] CAPABLE Grant agreement, Table 2.3

Patient Organisations	HIGH	A medical solution to obtain better support and measures from patients during treatment
Medical Organizations	MEDIUM	An opportunity to foster patient self-empowerment, further optimizing the usage of healthcare resources
Healthcare authorities, agencies and services	MEDIUM	An effective tool to address the treatment needs of citizens that have been treated for cancer, which, at the same time, maximizes their expected outcomes, reduces referral to wrong health professionals and services, and maximizes health outcomes
Health IT Businesses	MEDIUM	A platform that enables the conception, design and delivery of innovative "plug-in" modules for measuring treatment variables in cancer patients
Scientific and research community	MEDIUM	A way to generate large datasets on health trajectories of patients that are following cancer treatment, that can be used to predict late sequelae and disentangle the causative effects underpinning them.
Policy makers	HIGH	A new source of diverse data and a system that can be integrated in existing Healthcare systems to improve the way health resources are used to care patients treated for cancer

Table 1: Stakeholders of CAPABLE

Of the 15 stakeholders that have been identified, just some of them are directly collaborating with CAPABLE project and participated in different project activities in WP2 and WP7. At the moment patients, oncologists, nurses, hospitals and patient organizations (AIMAC) are directly involved in the project, while others such as surgery, radiologist or psychologist may participate in the future.

7. Market analysis

This section presents the preliminary market analysis that has been performed in the first six months of the project. The section details the overall costs of cancer care and presents the cancer health care journey to detail the different needs at different stages of the disease to then present the analysis of the cancer therapeutic market and a specific segmentation of the digital diagnostic market.

7.1. Economic burden of cancer

At this stage of the CAPABLE research the market analysis focuses on the overall cancer market. Even if the project focuses just on the melanoma and kidney cancer, it is relevant to understand the impact of the global disease.
Cancer is one of the leading cause of death worldwide, in the 2018 the world suffer 9.6 million deaths. The most common cancers are Lung Cancers, Breast with over 2M cases, Colorectal (1.8M), Prostate (1.28M), Skin Cancer (1.04.M)[8]. Kidney cancer is at 12 position with 15K[9] cases. The total cost of cancer in Europe the 2018 was of 199 billion €, with an average of 378€ per capita. There is a clear trend that the health expenditure on cancer increased faster than the increase of incidence of the disease. From 1995 to 2018 the cancer death increased around 20% (from 1.2M to 1.4 cases).
The costs of cancer are high both for the individuals and also for society[10] and the can be structured as follow[11]:
Direct cost of cancer: expenditures made by the health care system. They include the cost the human resources (medical staff), medical device, facilities, pharmacological treatment and vaccines (against human papillomavirus). Inside these costs there is a variable rate of the costs of cancer treatment, the trend is that wealthier countries tend to spend more. The direct costs are increasing over time as the Figure 3 illustrates.

8 https://www.who.int/news-room/fact-sheets/detail/cancer

9 https://www.wcrf.org/dietandcancer/kidney-cancer#:~:text=In%20total%2C%20this%20report%20analyses,15%2C039%20cases%20of%20kidney%20cancer.

10 https://www.cancer.org/cancer/cancer-basics/economic-impact-of-cancer.html

11 Hofmarcher, Thomas, Peter Lindgren, Nils Wilking, y Bengt Jönsson. «The Cost of Cancer in Europe 2018». European Journal of Cancer 129 (abril de 2020): 41-49. https://doi.org/10.1016/j.ejca.2020.01.011.

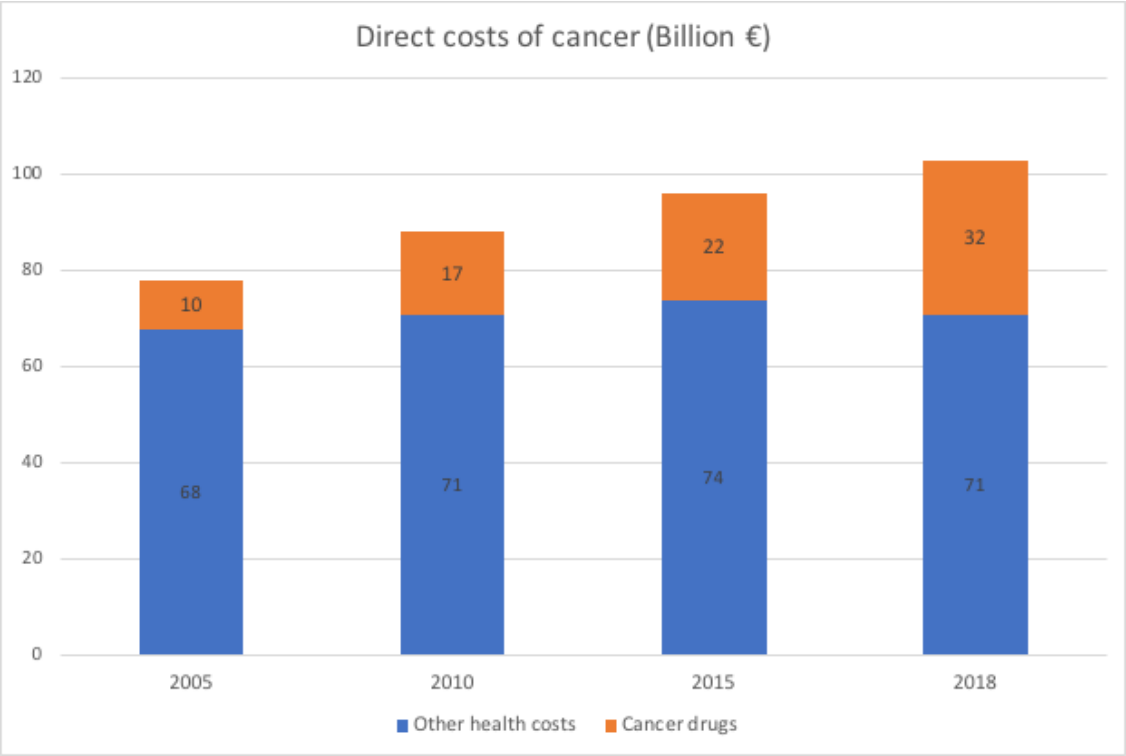

Figure 3: Direct costs of cancer[11]

The other health costs are quite stable over time, meanwhile the cancer drugs costs increased over time.

Indirect costs: there are two types of productivity loss: 1) the premature mortality of people and the earning the could have received continuing working or perceiving a pension if not having cancer 2) The cost associated to temporal or permanent not attendance to work due to the sickness. Figure 4 shows the trends in Europe from 1995 to 2018.

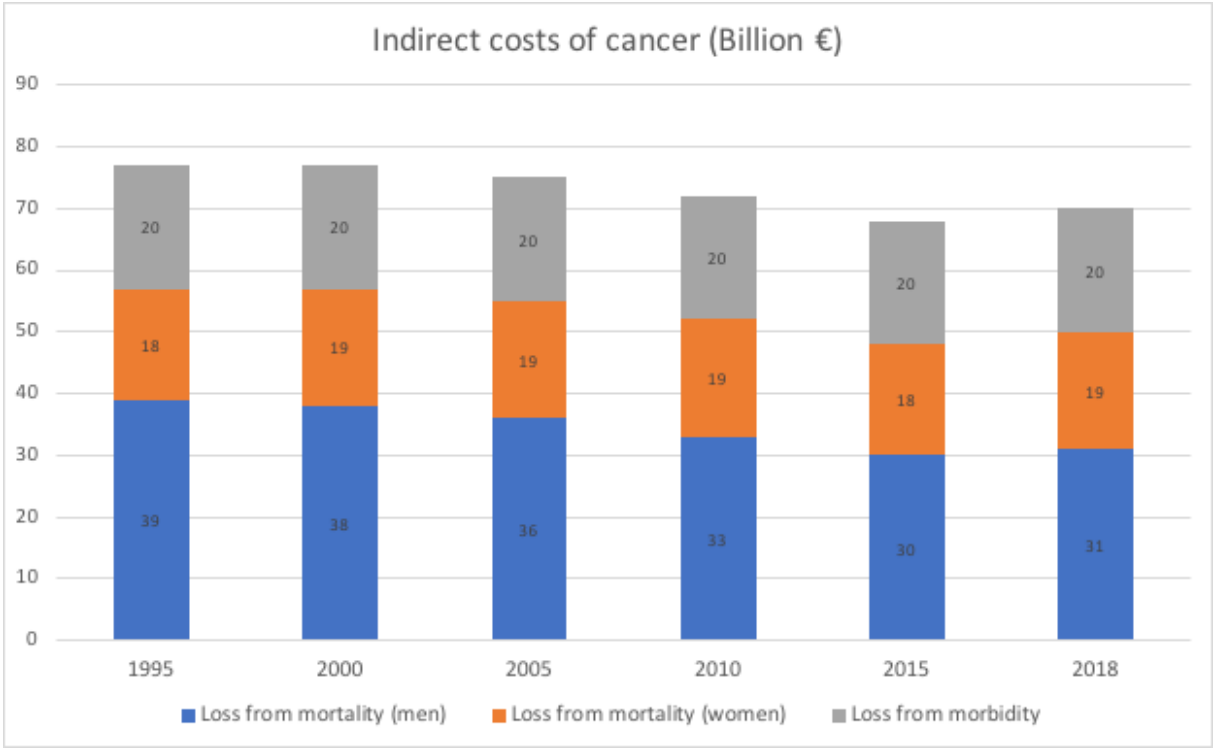

Figure 4: Indirect costs of cancer in Europe[11]

Informal care costs: it includes the time of relatives and friends to support the patient during the course of the disease. These costs are affected by uncertainty because of lack of available data. Out of pocket costs can be care supplies, medication, formal help, second opinion, domestic help, travel expenses. The cancer of a familiar can also impact the care-givers work provoking loss of productivity due to the need to support and help the familiars and relatives. Table 2 presents the cost of cancer per capita in Europe.

Country	**Direct costs (€)**		**Informal care costs (€)**	**Indirect costs (€)**		**Total costs (€)**
	Health expenditure on cancer care	Cancer Drugs		Productivity loss from premature mortality	Productivity loss from morbidity	
Austria	289	108	45	122	32	488
Belgium	284	90	61	123	109	577
Bulgaria	45	31	6	25	7	83
Croatia	61	36	23	49	104	236
Cyprus	103	–	28	46	11	188
Czechia	102	16	18	41	32	193
Denmark	259	89	132	164	126	680
Estonia	73	4	18	46	57	194
Finland	153	60	61	101	28	344
France	278	77	49	106	68	502
Germany	308	92	62	139	53	562
Greece	88	4	29	56	15	188
Hungary	63	40	17	51	9	140
Iceland	197	60	57	126	115	495
Ireland	234	64	37	109	23	404
Italy	**172**	**75**	**85**	**81**	**5**	**343**
Latvia	57	13	17	47	20	142
Lithuania	**70**	**20**	**12**	**40**	**29**	**152**
Luxembourg	363	12	54	150	61	628
Malta	155	–	25	54	4	238
Netherlands	**308**	**62**	**57**	**145**	**81**	**591**
Norway	296	69	68	115	126	605
Poland	**57**	**15**	**15**	**47**	**21**	**140**
Portugal	96	39	36	64	19	215
Romania	36	18	8	31	8	83
Slovakia	79	30	13	47	32	171
Slovenia	113	51	37	80	67	298
Spain	**112**	**61**	**54**	**74**	**20**	**261**
Sweden	187	57	49	82	95	413
Switzerland	511	94	70	202	56	840
United Kingdom	176	49	48	100	22	347
Total in Europe	**195**	**61**	**50**	**94**	**39**	**378**

Table 2: Per capita cost of cancer in Europe[11]

The overall expenditure in cancer in Europe in the 2018 was of 199 Billion €, it comparable to the expenditure of Cardio Vascular disease in the 2015, the amount (210 Billion €) is similarly distributed between costs inside and outside the health care system[12].

7.2. Cancer health care journey

The cancer impacts patients and stakeholders in different ways at the different stages of the health care process:

- **During the diagnostic:** the process includes all the medical procedures to diagnose cancer. Generally, patients are diagnosed because of a specific symptomatology or by chance because of reporting other health problems or participating in screening programs. The challenge in this process is to improve accuracy, reduce the time of diagnostic process and foster the early detection of the disease.
- **During the treatment**: After the diagnostic, the healthcare team proposes specific type of treatments according to the cancer characteristics. The treatments include specific surgeries, radiotherapy, chemotherapy, target therapy, immunotherapy, hormonal therapy and other types of treatment. During this process there are many challenges to be addressed: effectiveness of the therapy, management of side effects, support to patients and caregivers.
- **During the follow up**: at this phase, survivors have to face the return to normal life and manage together with the health professional the risk to have a reoccurrence of cancer.

This classification is not including the screening that could be included as initial stage of this process: it is considered not relevant for this context of research, because CAPABLE is focusing on diagnosed patients and not on at risk population. Patients, health professionals and caregivers have different needs and challenges that have been summarized in Table 3, which presents a preliminary analysis of needs in the three proposed phases.

Actor	Diagnostic	Therapy	Follow-up
Patients	Management of physical symptoms, psychological support (anxiety), health information: understanding disease, understanding treatment options, sleep, Lifestyle changes	Deal with toxicity, changes in the body, psychological support, adherence of the treatments, self-management, immunodepression, nutrition, sleep, changes in ADL (activities of daily life), reduction of QoL, spiritual, Lifestyle changes, autonomy, sexuality, social impact	Occupational functioning, sequelae of treatments, self-management, psychological support, reduction of QoL, sleep, lifestyle changes, social impact
Health professionals	Improve of diagnostic and prognostic tools, patient co-decision aid, tumor boards, empathic and effective patient communication, improve research process (dedicated and understandable analytics resources), generation of new knowledge, high-quality data collection, data integration and standardization	Follow up of the users, reduce treatment toxicity, improve prognostic tool, collaborative decision-making, PREMs/PROMs collection	Early detection of relapse or progression, follow-up and increasing QoL of patients

[12] Wilkins, E., Wilson, L., Wickramasinghe, K., Bhatnagar, P., Leal, J., Luengo-Fernandez, R., Townsend, N. (2017). European Cardiovascular Disease Statistics 2017. Brussels: European Heart Network.

Table 3: Preliminary analysis of needs in the different stages of cancer care

CAPABLE will focus on **the improvement of the therapeutic process using ICT technologies** as enabler of better communication with health care system, remote support for the patients and better remote follow-up to early intervene in case of a worsening of the condition or a side effect of the treatment. The following sections will details the market of the cancer therapeutics and then a specific section of the digital therapeutics will be also reported.

7.3. Cancer therapeutics market

The Worldwide therapeutics market size has been estimated of around 99 Billions $ in the 2018. It is estimated to reach 180 Billion $ by the 2026[13]. The main reason is the increased cancer prevalence that caused a high interest on the pharmaceutical companies to boost the research in this field. The major players in this area are the pharmaceutical companies that collaborate with hospitals to engage them in clinical studies to speed up the validation of new products according to the regulations and to research of new approaches for cancer therapeutics. Among this players there are: Amgen Inc, AstraZeneca PLC, Bayer AG, Bristol-Meyer Squibb Company, F. Hoffmann-La Roche Ltd, Johnson & Johnson. There is an increase competition between the players. Over the past years, 57 new oncology therapeutics have been launched in the market as shown in Figure 5 [14].

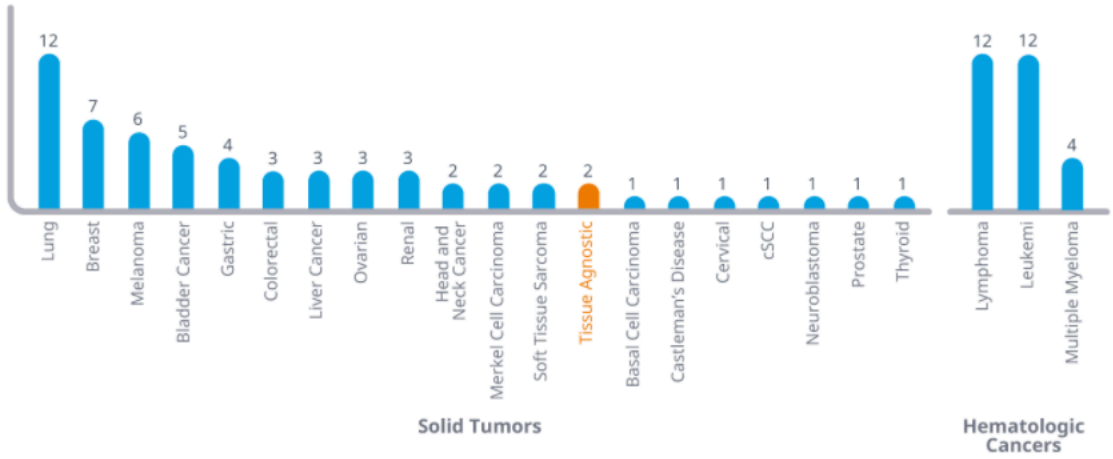

Figure 5: Pharmacological trends in oncology (2019)[14]

Cencer treatments are in continuous transformation, for instance recently immunotherapies has been introduced. The last trends in the market are targeted therapies, just in the 2018 849 molecules have been proposed, with an increase of 77% since 2008. Figure 6 shows the trend of experimentation (Phase II) of treatments.

[13] https://www.mordorintelligence.com/industry-reports/european-cancer-therapies-market-industry
[14] https://www.iqvia.com/insights/the-iqvia-institute/reports/global-oncology-trends-2019

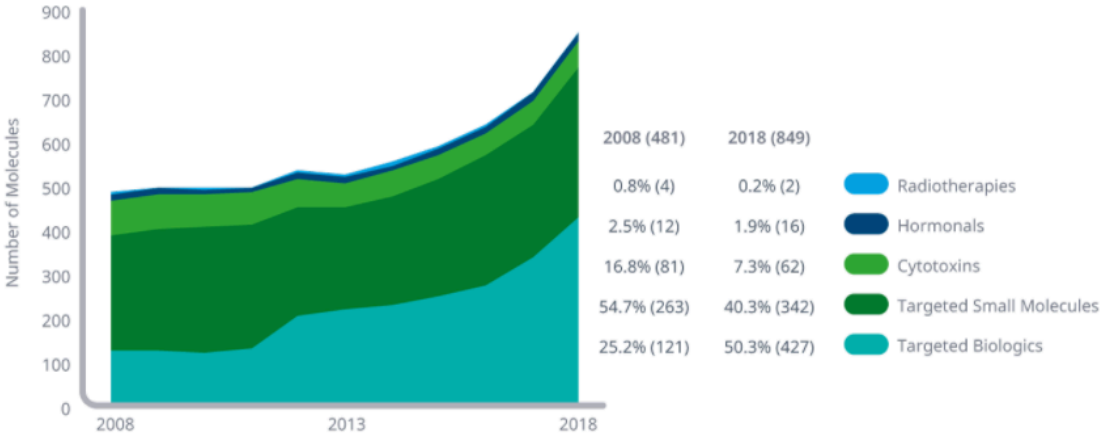

Figure 6: Evolution of the therapeutics techniques over time[14]

7.4. Digital therapeutics market

The demand of digital therapeutics is increasing because the high penetration of smartphones and tablets in the society, to reduce health care costs (reduction of visits, hospitalizations, improvement of the quality of life of the users etc). The trend demonstrated a high growth of opportunities in the market. In fact, Allied Market research published a report about the digital therapeutics reporting that the overall market generated 2.24 $ worldwide. The estimation is to reach 9.64 Billion $ with a Compound Annual Grow Rate (CAGR) of 19,9%. The key players worldwide are Proteus Digital Health, Inc, 2MORROW, Omada Health, Voluntis, Welldoc, Fitbit, Medtronic, Pear therapeutics, Resmed and Livongo Health[15]. The highest contribution in the market share is in North America.
The digital therapeutics are delivered through mobiles apps with functionalities that can offer guidance to a specific user, they work in conjunction with a drug regimen (as in the cancer case), promote behavior change (improvement of adherence or changes in the lifestyle), connect with medical devices (e.g. insulin pump) or consumer electronics (e.g. Fitbit). The digital therapeutics solution can support the different phases of the patient care journey described in the previous section, included the prevention one[16]. Digital therapeutics are disruptive because they address unmet needs that traditional care and treatments cannot cover. This represent an opportunity for the companies that provide therapies. Also, the FDA (Food and Drug Administration) recognized this opportunity and proposed a Software Precertification (Pre-Cert) Pilot Program in August 2017 to inform the development of a future regulatory model of software-based medical devices (SaMD). For pharmaceutical and med-tech companies the digital therapeutics can be an asset for the core business: it provide the opportunity to differentiate with low capital investment (compared to the one required to release a new pharmacological treatment) and to extend the product life cycle, the follow up of the patients and fill the gaps of the healthcare needs. The level of disruption had also to face uncertainties and challenges that Deloitte presented in a report[16] (Figure 7).

[15] https://www.globenewswire.com/news-release/2020/02/25/1990165/0/en/Digital-Therapeutics-Market-to-Reach-9-64-Bn-Globally-by-2026-Allied-Market-Research.html
[16] https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-digital-therapeutics.pdf

Product	Market	Channels	Pricing	Regulations
Uncertainties and challenges				
• Product definition is unclear to the market • Challenge to prove validity until paired with clinical evidence • First to market, best consumer experience, and largest user base are critical	• Patient learning curve may be a challenge as patients adjust to the new user experience • Global-scale commercialization strategies of digital therapeutics are unclear	• Physician and health care provider adoption hurdles exist • Health insurance companies may be able to sponsor access or usage of digital therapeutics	• Pricing and reimbursement are uncertain due to the nascent state of market • Pricing is expected to diverge from traditional apps and medical treatments	• Regulatory pathway is at the FDA's discretion • Analytics and big-data applications face same regulatory path as biomarkers
Anticipated level of disruption				
• Novel product expected to differentiate treatments and provide competitive advantage	• Market is expected to grow significantly, competing with existing life sciences revenues • Initially expected to be small relative to existing markets	• Channels for prescription treatments are expected to be similar • Channels for preventative care are novel for the life sciences industry	• Significantly lower pricing has the potential to disrupt existing pricing strategies	• Approvals will follow novel and unprecedented regulatory pathways

Figure 7: Deloitte analysis of challenges and disruptions for digital therapeutics for pharma industry[16]

The digital therapeutics market is segmented according the type of disease: diabetes, obesity, cardiovascular disease, neurological disease, respiratory disease are the most common available solutions. The diabetes had the highest revenue in digital therapeutics. At the moment it was not possible to segment the cancer digital diagnostic sector and to quantify the market size[17]. More qualitative information will be reported in the competitor analysis.

7.5. Key players & competitor analysis

The key players and competitors are identified and analyzed as part of the market analysis. The analysis was performed separately: 1) identifying similar academic and research projects and 2) identifying same solutions currently available in the market.

Research projects financed in the same call of the CAPABLE project have been compared and analyzed through a comparative matrix. The list of projects, their information and metrics to perform the comparison have been extracted from the public repository of the Community Research and Development Information Service (CORDIS) website. This is the European Commission's primary source of results from the projects funded by the EU's framework programs for research and innovation.

To perform this comparison a matrix was created where the following metrics are included:

- Project description
- Project start and end dates
- EU budget in euros
- Project related to cancer (type of cancer)
- Stage of disease (screening, diagnosis, prognosis, treatment, follow-up)
- Use of guidelines
- Technical approach for patients follow-up (mobile app, wearable, web app)

In the same way, the available technologies in the market environment were collected. The search strategy followed are composed of 3 phases: 1) reviewing for known companies

[17] https://www.alliedmarketresearch.com/digital-therapeutics-market

(e.g. Leuko, Medtronic), 2) searching commercial tools using the google search engine and the keywords "platform patients follow-up" + "cancer" and 3) further market exploration of commercial tools search by big companies like Samsung, General Electric, LG and others.

The information gathered from the technologies have been compared and analyzed in a comparative matrix based on the following extracted features:

- Company information (name and website)
- Product
- Description/Features
- Technical approach (mobile app, wearable, web app, Artificial Intelligence, etc.)
- Clinical data
- Target profile (end-users)
- Type of cancer
- Stage of disease (screening, diagnosis, prognosis, treatment, follow-up)
- Use of guidelines
- FDA or CE mark
- Patents or IPR
- Price of the solution
- Product based on previous research/clinical studies

Results of both analyses are summarized in the following sections.

7.5.1. Academic & research

A total of 9 research projects (including CAPABLE) were funded in the same call (SC1-DTH-01-2019 - Big data and Artificial Intelligence for monitoring health status and quality of life after the cancer treatment) of the CAPABLE project. All the projects are focused on solutions for the management and treatment of cancer patients, however, they focus on different types of cancer (in cases where the type of cancer is reported) and none focuses on solutions for patients with kidney cancer or melanoma, which differentiates the CAPABLE project from the others. In general, most projects offer solutions for the treatment stage and only half of the projects focus on the follow-up stage.

The average duration of the projects is 3 years, therefore most of them would finish before CAPABLE and therefore they may have a finished product in advance. However, the funding received is approximately € 5M (median = € 4,992,945), which is below the almost € 6M financed for the CAPABLE project.

According to the information provided by the projects summary, only two of them implement clinical guidelines, same as CAPABLE project. Moreover, the technical approach followed by all projects is the use of Artificial Intelligence and Big Data analytics techniques, only 3 projects implement the users' intervention through mobile apps and one project proposes the use of wearables.

Similar to CAPABLE, only one of the projects (Qualitop) is focused on the identification and prediction of the occurrence of adverse events related to immunotherapy treatment.

Analyzing the information provided at the start of these projects, there is the possibility that the solutions developed and implemented in the future will be marketed and become potential competitors of the CAPABLE solution.

Therefore, the results of these projects must be followed in order to provide a solution in the CAPABLE project that will differentiate itself and be a competitive product for new solutions on the market, especially the solution obtained by the Qualitop project.

Annex 1 includes the comparative table with the detailed information of all financed projects.

7.5.2. Market solutions

As mentioned above, a search of products currently available on the market has been carried out, identifying similar solutions to the one that will be implemented in the CAPABLE project. It should be noted that most of the companies whose products were identified as potential competitors, do not publicly provide all the information needed, and it is necessary to contact the supplier to obtain it. For this reason, we consider that the analysis carried out so far is a first result that should be continuously improved during the course of the project; identifying also new companies or products that are launched on the market during the time of project development.

Once analyzed the market products similar to the CAPABLE solution, the overall results found, taking into account the different aspects analyzed, are:

Features: most of the tools reviewed in this research have some common features, such as patient data visualization, management and analytics, patient support, appointments management and handling patient clinical data. Only those systems that have patient-facing tools also collect patient data such as symptoms, PROs measures and few of them physiological data through wearables.

Technical approach: web-based technologies predominate, although there are also full software solutions with no exclusively web-technologies but also local functioning. Mobile solutions are usually found for those tools that are also interacting with patients. Only in one solution, wearable technology is used.

Clinical data: different clinical data is involved depending on the tool goal. The most common that have been identified are imaging, physical activity, genetic and clinical tests. Solutions focused on the patients' follow-up also manage physiological data, QoL information and measure of PROs.

Target profile: healthcare professionals are the end-user of most of the tools, but when it comes to a comprehensive system, patients are also provided with an application. Only in one case, the caregivers are included as end-users of the patient application.

Type of cancer: most of the tools are not focused on specific cancers, but for any type of cancer's follow-up. Some tools are specific for a type of cancer, e.g. lung cancer, pancreatic cancer, breast cancer, glioblastoma and oesophageal cancer.

Stage of disease: Most solutions are focused only on follow-up and treatment, but some of them are also focused on diagnosis. Only one solution includes all the disease phases from screening to follow-up.

Use of guidelines: More than half of the solutions follow the clinical guidelines or pathways, while the rest do not give this information or do not follow them.

FDA and CE mark: Of the 13 analyzed tools, only 3 have a FDA or CE marked or are in the process of obtaining it.

Patents or IPR: Most of the companies analyzed don't provide information about patents or IPR related to their tools. Therefore, a search focused on patents related to similar systems or technologies could complement this information that is not provided.

Price: Of the 13 analyzed tools, only 1 provide information related to price and provide different pricing based on the range of patients that will be treated each month.

Previous research/clinical studies: Most of the available systems in the market don't specify if their solutions are based on previous research or validated in clinical studies. Only 4 of the identified tools have published information about the study's ethics approval or research publications in scientific journals or congress related to the technologies implemented.

Annex 2 includes the comparative table with the overall information collected from the product available on the market.

In order to expand the available information of commercialized products and focusing on identifying the current market for mobile solutions for cancer patients, we also extracted information from the result obtained in the research on smartphone apps for cancer in the digital health marketplace[18]. A total of 123 mobile apps was analyzed in this study, where only the 20% includes the monitoring of side effects during the treatment and only 3% of the applications provide validated content by healthcare professionals. Moreover, most of the analyzed applications are implemented for individual use, and they are not part of a comprehensive system where the patient can have continuous communication and follow-up by the healthcare providers.

In this sense, a strength of the CAPABLE solution will be to constitute a complete system, where not only patients will have access to a solution to handle their disease and side effects during treatment, but also healthcare professionals will be provided with a tool to manage their patients' data and have support in the decision making process based on guidelines during the follow-up. Moreover, the system will be evaluated and validated by a clinical study in a real clinical environment.

[18] Charbonneau, D. H., Hightower, S., Katz, A., Zhang, K., Abrams, J., Senft, N., … Thompson, H. S. (2020). Smartphone apps for cancer: A content analysis of the digital health marketplace. DIGITAL HEALTH. https://doi.org/10.1177/2055207620905413

8. Value proposition

At this stage of the project the value proposition is based on the innovation potential of the concept. CAPABLE targets the digital therapeutics market to offer a solution for the patients to:

- Early management of side effects
- Foster medication adherence and self-management of light and mild symptoms
- Promote of the overall wellbeing during the cancer health care journey
- Easily collect PREM and PROM information, physiological data from wearable sensors, information about habits and overall physiological wellbeing.
- Empower professionals with a Decision Support System that integrates guidelines, disease progression models and data from the patient app and wearable devices.

Currently the consortium has three key activities:

- Engage patients and patient association to co-design the CAPABLE system and extract using NPL techniques information from the AIMAC forum
- Definition of the requirements of the overall solution
- Development of a first version of the prototype focusing on two specific use cases:
  - Management of one specific side effect
  - Propose activities to foster overall wellbeing of the person.

8.1. Innovation potentials in CAPABLE

WP8 revised with the consortium the innovation potential of the technology that will be developed in the project. The overall CAPABLE system contains the following innovative elements described in Table 4.

CAPABLE Component	Partners	Main innovation
CIG-based DSS: I. KB of CIGs (modelled guidelines) - DEONTICS II. PROforma Engine - DEONTICS III. Multimorbidity Controller (GoCom) - UoH CIG = Computer Interpretable Guidelines	DEON, UoH	In CAPABLE DEON will (i) extend the PROforma decision model to support the use of both goal-based argumentation and probabilistic updating in decision-making; (ii) provide support for guideline modelers to integrate prediction algorithms into PROforma tasks; (iii) implement mixed models that can use logical and probabilistic techniques separately or in combination as required; (iv) enhance the Alium development platform to support the PROforma extensions to develop cancer decision support and smart pathway services. In CAPABLE will extend the Multimorbidity Controller with additional behavioural patterns in the CIG representation to support important functionality that is not yet addressed: temporality of recommendations, patient preferences, priorities of guideline goals, adverse events and linking to external knowledge bases (e.g., AEOLUS) and different mitigation modes, including delaying actions and modulating drug doses.
Predictive models (risk prediction and disease progression)	IBM	CAPABLE will explore the application of causal inference to address potential confounders and use them to improve the accuracy of the data driven analysis, towards better identification of factors that lead to disease progression and relapse. In CAPABLE we will also extend the LPM (Learning Process Model) approach by utilizing the CIG's action sequencing in order to propose decision support that considers not only the recommended actions but also their correct sequencing.

		By analysing the patients' records, the following can be obtained: 1) Personalized treatment recommendation a) Predict the patient outcome on each of the possible treatment options 2) Comparative Effectiveness of drugs a) Discover sub populations that may benefit from a switch to a particular treatment 3) Interpretation and evidence a) Provide characterization of patients with similar predicted response b) Characterization of each discovered sub population c) Descriptively visualizing the distribution over certain patient parameters: (stretch) Visualizing the features most discriminating of that sub population vs the entire cohort
Natural Language Processing algorithm	IBM	AIMAC provides data from its forum, which are analyzed through NLP techniques to extract patients' needs. The results of this process will produce an input to drive the development of additional functionalities of CAPABLE system. Extracting this type of information from social media data is the main innovation of this process
Virtual Coaching system	PUT	By combining monitoring and coaching functions, CAPABLE will be able to provide constant feedback to the patient and physician based on patient's state and actions. In this way patients will be in the "center of care", even during longer periods between encounters, and physicians will have valid and current information thus they will be able to react to any changes in a timely manner. We will further extend the data processed by the Coaching System by including sensor readings and outcomes from prediction models. This will facilitate a better integration of the Coaching System with new AI tools for guideline enactment (implemented within the clinicians' DSS), so psycho-behavioural interventions are synchronized with prescribed treatment. Moreover, the availability of additional information will allow us for further customization of interventions given patient preferences and environmental factors. Finally, in cooperation with domain experts (clinicians and representatives of patient associations) we will develop a repository of interventions (including those intended to improve the mental and social wellbeing) specific for selected types of cancer that are based on actual patients' needs and expectations.
Care provider (Clinicians) dashboard	BIT	The web system will use data provided from mobile application by artificial intelligence–oriented algorithms in order to evolve into efficient clinical DSSs.
Patients & caregivers mobile app	BIT	The patient app will act as a unique access point for the patients to interventions and information, including educational resources (e.g., booklets published by AIMAC), available in the CAPABLE system. Moreover, it will offer mechanisms for personalized, quick and precise search for relevant information and knownledge. To our best knowledge, no apps use standards to integrate collected data with those in the hospital EHRs, nor allows a dynamic configuration based on the patient's status change over time, which are core features of CAPABLE.

Ontology-based knowledge-data mapper	UoH	Within the CAPABLE project we will use the OHDSI OMOP information model and we will produce queries accordingly. In addition, we will introduce additional, advanced temporal operators to deal with data that will be collected over time and will need to be abstracted in order to feed the predictive models.
Case Manager	UNIPV	An ontology will also be developed to organize the events that will trigger the activation and the interactions of the different Knowledge Sources of CAPABLE, mediated by the case manager. Events need to be classified in terms of suitable features so that the Knowledge Sources may easily tell the ones they are interested in and subscribe with the Case Manager (for example, an event belonging to the Treatment class in the ontology - e.g. a drug prescription - could trigger the Knowledge source "Prediction Models of Adverse Effects").

Table 4: Innovation potential of the CAPABLE components

8.2. PESTLE Analysis

This section presents the PESTLE analysis of the project based on the analysis and research done on the context in which CAPABLE will be integrated.

Political:
As a project funded by the EU, the political environment will be marked by the EU Health Policy[19]. In Europe each country holds the responsibility for organising the health services and care but the EU serves to control and complement the national policies. CAPABLE will have to face the different policies in each country of the consortium partners. In general EU policies aim to protect and improve the health of EU citizens, support the modernisation of health infrastructure and improve the efficiency of Europe's health systems.

Economic:
Europe is one of the major economic blocks and many of the economic leading world countries form part of the UE, generating free trade and movement block with a single currency. The healthcare market in Europe is expected to grow from around $2080 billion in 2016 to around $2125 billion in 2020[20]. Digital therapeutics tools represent a unique opportunity to increase the improve the quality of the health care system, and better empower citizens to manage disease o foster healthy lifestyle. The current COVID-19 pandemic highlighted the need to accelerate the provision of these types of technologies. CAPABLE will compete in the digital therapeutics markets.

Social:
Every year, 3.5 million people in the EU are diagnosed with cancer, and 1.3 million people die from cancer each year[21]. Cancer is the second leading cause of mortality in EU countries

[19] https://ec.europa.eu/health/policies/overview_en#:~:text=EU%20countries%20hold%20primary%20responsibility,the%20health%20of%20EU%20citizens
[20] https://www.businesswire.com/news/home/20180111005681/en/Europe-Healthcare-Market-Report-2017-Forecasts-2020#:~:text=The%20European%20healthcare%20market%20is,economic%20conditions%20in%20many%20countries.
[21] https://www.businesswire.com/news/home/20180111005681/en/Europe-Healthcare-Market-Report-2017-Forecasts-2020#:~:text=The%20European%20healthcare%20market%20is,economic%20conditions%20in%20many%20countries.

after cardiovascular diseases, accounting for 26% of all deaths in 2013. More than 1,3 million people died of cancer in 2013 across all EU Member States[22].
In this context, it's worth noting that the population is increasingly approaching medical devices and health applications. Users of technology are every day more numerous and see these products as a real option of treatment.

Technological:
Nowadays, digital engagement is a key factor in the delivery of cancer care[23]. Thanks to web and mobile technologies large groups of patients can engage with each other and share information. Healthcare systems and professionals are working in the adaptation and development of incorporating new technologies to improve the quality of medical care. In addition, consumer devices and sensors (wearables) have provided a new, growing dimension of digital engagement and another layer of patient-generated health data to foster better care and research. Finally, electronic health records are the new standard for cancer care delivery allowing to measure quality in real time and follow guidelines with precision.

Environmental:
Nowadays, the EU and the entire world's developed countries have enormous environmental challenges[24]. Air pollution is one of the biggest environmental problems causing an important risk to public health and specially in the EU, most of the member countries fail to meet air quality standards. Other notable environmental challenges facing the EU are climate change, stratospheric ozone depletion, loss of biodiversity, major accidents, acidification, deterioration of habitats and water pollution, forest degradation, and chemical risk. By the way, these facts should not affect the development of the CAPABLE project

Legal:
The CAPABLE solution must follow the directives of the EU for non-invasive medical devices of Class I (directive 93/42/EEC) and (98/79/EC)
Regarding the use of new software tools for decision support that might be qualified as medical devices, we will refer to the following directives:

- EN ISO 14155-2 (2004) "Clinical investigation of medical devices for human subject. Clinical investigation plan" defining the procedures to prepare the plans devoted to the evaluation of medical devices.
- EN ISO 14971 (2007) – "Application of Risk management to medical devices" addressing risk identification, assessment and acceptability in the use of medical devices.

To operate to worldwide market there is reference certification from FDA of Software as a Medical device. (SaMD).

8.3. SWOT Analysis

This section presents the SWOT analysis of CAPABLE project based on internal consultations and analysis and a research done on the context in which CAPABLE will be integrated.

Strengths:

[22] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12154-Europe-s-Beating-Cancer-Plan/public-consultation
[23] Fisch, M. J., Chung, A. E., & Accordino, M. K. (2016). Using Technology to Improve Cancer Care: Social Media, Wearables, and Electronic Health Records. American Society of Clinical Oncology Educational Book, (36), 200–208. doi:10.1200/edbk_156682

[24] https://www.howandwhat.net/pestel-analysis-european-union-eu/

- CAPABLE will provide access to clinical guidelines, especially when multiple conditions coexist. This requires harmonization of different guidelines for addressing multimorbidity.
- CAPABLE will be focused both on clinicians and patients giving clinicians a decision support system and customizable follow-up of patients and allowing patients to better face side effects.
- Provision of wide patient support, from compliance to treatment to emotional issues.
- Interoperability provided by CAPABLE will allow merging measurements from patients and caregivers with those available in the Electronic Health Records of the treating institutions

Weaknesses:
At this phase it is difficult to identify weaknesses of the CAPABLE solution. We identified some risks that we are properly managing

- The possible lack of acceptability as the system is not tested by end-users. WP2 is adopting User Centred Design approaches and AIMAC is collaborating in the design. Very soon the project will start the test of the prototype with end users.
- Complexity of the system. The complexity of the system can generate some problems in its development and make it difficult to implement in health systems. Specific task forces has been created to define requirements and the overall technical solution.
- Not ready to commercialize. At the moment it is difficult to predict what would be the readiness at the end of the project.
- The lack of certification of CAPABLE could be a problem for the adoption of the system by the institutions. WP8 will start in the next period activities to support CAPABLE certification.

Opportunities:

- Penetration of smartphone technologies in the society
- A way to improve patients' and caregivers' quality of life and self-management through personalized coaching functionalities
- Increased interest on adoption of tele-monitoring system for healthcare, as the adoption of new information and communication technologies is growing in the society and COVID-19 accelerates this need.
- Limiting the increasing costs of cancer care. Interest from stakeholders in cost-effective solutions to improve the quality of the service and the quality of life of the patients

Threats:

- Despite the fact that the digital therapeutics market is in continuous growth, there are big competitors with established brands that cover a lot of the market. This keeps the level of competition very high and makes it difficult for new products and enterprises to position themselves in the market successfully.

9. Conclusions and future works

This first deliverable shares the progress of the exploitation activities performed in WP8. The main results of this work are the following:

- Adoption of the CeHRes ehealth roadmap for the harmonization of the activities of design, development and validation of the CAPABLE system with the activities of business development and strategies of exploitation.
- Preliminary market analysis, identification the costs of the problem, market size, involved stakeholders.
- Preliminary definitions of the value proposition, revision of the innovation potential of the CAPABLE components, SWAT and PESTEL analysis.

The activities to be performed in the next semester will be:

- Collaborate with the other WPs to consolidate the CAPABLE solution, consolidate the value proposition and set up a roadmap for the exploitation and business development.
- Continue the market surveillance focusing on the two types of cancer addressed in CAPABLE project (melanoma and kidney) to identify new existing solutions, new technological trends and opportunities and specific unmet needs from clinical and patient perspective.
- Draft a proposal of the Intellectual Property Policy for the project.
- Explore the guidelines for certification to harmonize current technical development with future potential certification.
- Gather qualitative and quantitative information from relevant stakeholders performing interviews, surveys and exploiting other previous research activities that could help to refine the CAPABLE services.

10. Annexes

10.1. Annex 1

Comparative matrix of academic & research projects

Call for proposal: H2020-SC1-DTH-2019
Topic: SC1-DTH-01-2019 - Big data and Artificial Intelligence for monitoring health status and quality of life after the cancer treatment

10.1.1. General Information

Acronym	Name	Description	Start-End Date	EU Budget (€)
PERSIST	Patients-centered SurvivorShIp care plan after Cancer treatments based on Big Data and Artificial Intelligence technologies	PERSIST aims at developing an **open and interoperable ecosystem to improve the care of cancer survivors**. The key results to be achieved by partners are: increased self-efficacy and satisfaction with care as well as reduced psychological stress for a better management of the consequences of the cancer treatment and the disease, resulting in an improvement in health and wellbeing and a faster integration into the labour market, where applicable, compared to usual care (KR1); **increased effectiveness in cancer treatment and follow-up** by providing prediction models from Big Data that will support decision-making and contribute to optimal treatment decisions with positive consequences in the QoL and the health status of survivors (KR2); and improved information and evidence to advance the efficacy of management, intervention and prevention policies/strategies in order to timely treat side effects and, if possible, avoid secondary diseases and fatal events. The long-term result will be to reduce the socio-economic burden related to cancer survivors' care (KR3). The ecosystem proposed consists of a Big Data platform to be built on top of an open infrastructure from one of the partners and a mHealth application for patients. **The main building blocks to be developed are a multimodal sensing network running on a smart phone that will collect relevant data regarding the wellbeing of the patient**; predictive models from anonymised health data from thousands of breast and colorectal patients; and modules essential for the development of a decision support system, which will employ the predictive models mentioned. Furthermore, PREDICT will contribute to establish evidence on the use of liquid biopsy techniques to the follow-up of cancer patients treated with curative purposes. **A pilot study involving 160 patients and 32 health care professionals** will be decisive to establish a co-creation	01/01/2020 - 28/02/2023	5 065 106.25

Acronym	Name	Description	Start-End Date	EU Budget (€)
		methodology ranging from the earlies phases of the project throughout its conclusion.		
LifeChamps	A Collective Intelligence Platform to Support Cancer Champions	The steady increase in life expectancy, mean age and cancer survivorship across the developed countries together with evidence from cancer and geriatrics care research bring forward the urgent need to deal with the "age issue" as a key component of global cancer care strategies. In 2012, an estimated 6.7 million new cases of cancer were diagnosed in adults aged 65 years and older, representing 47.5% of the total number of new cancer cases worldwide while 8% of the world population in that time was aged 65 years and older. On the other side, increasing age and comorbidities are often associated with a discriminant lower use of aggressive cancer therapies, as well as a higher neglection for their preferences in health-related quality of life (HRQOL) care support. To address the above, LifeChamps **delivers a novel, context-aware and large-scale analytics framework capable of delivering multi-dimensional Quality of Life (QOL) support to all the different cancer life champions during and after their treatments.** LifeChamps is **providing support to middle aged and older (pre-frail and frail) cancer patients, as well as their caregivers and healthcare professionals, with an integrated Big Data-driven solution capable to improve their QOL via a timely and more accurate clinical decision support at the point of care**. Its **Artificial Intelligence (AI) and analytics engine, running both at the cloud and at the mobile edge**, can determine accurately which factors affect the oncological patients' QOL the most, during and after their treatment. Furthermore, complemented by a health recommender system LifeChamps offers personalized healthcare services (i.e., symptom monitoring, treatment and rehabilitation) to these patients and their caregivers. The LifeChamps platform will be validated in four multi-national pilot use case scenarios aimed at demonstrating its applicability and validity for all the requirements of the SC1-DTH01-2019 Call (prediction, care, advice).	01/12/2019 - 30/11/2022	4 999 915
QUALITOP	Monitoring multidimensional aspects of QUAlity of Life after cancer ImmunoTherapy - an Open smart digital Platform for personalized prevention and patient management	Better monitoring of cancer immunotherapy patients Cancer immunotherapy has helped to significantly advance cancer treatment. However, there remain two main challenges that hinder the path to better health and quality of life for cancer patients after starting immunotherapy. There is a need for **predictive markers for immunotherapy-related adverse events** as well as information on such patients beyond randomised controlled trials. To address these problems, the EU-funded QUALITOP project aims **to develop a European immunotherapy-specific open smart digital platform**. The platform will help **identify the determinants of patients' health status, define patient profiles in a real-world context, and provide real-time recommendations**. The project	01/01/2020 - 31/12/2023	5 196 772.50

Acronym	Name	Description	Start-End Date	EU Budget (€)
		will thus enable **better monitoring of the health and quality of life of cancer patients who are undergoing immunotherapy**. Objective "**Cancer immunotherapy** brought about significant progress in cancer treatment. It resulted in high efficacy in some cancers; e.g., **up to 60% objective response rate in melanoma** and 80% complete response rate in acute lymphoblastic leukaemia. Nevertheless, two main challenges still impede improving cancer patients' health status and quality of life (QoL) after immunotherapy initiation: 1) a crucial need for "predictive markers" of occurrence of **immunotherapy-related adverse events (IR-AEs)** to predict and improve patients' health status and promote their QoL; and, 2) the lack of knowledge on patients after start of immunotherapy outside randomised controlled trials. To reach these goals, significantly more diversified sources of data are required. Project QUALITOP aims at **developing a European immunotherapy-specific open Smart Digital Platform and using big data analysis, artificial intelligence, and simulation modelling approaches**. This will enable collecting and aggregating efficiently **real-world data** to monitor health status and QoL of cancer patients given immunotherapy. Through causal inference analyses, QUALITOP will **identify the determinants of health status regarding IR-AEs** and **define patient profiles in a real-world context**. For this, heterogeneous data sources (big data), both retrospective and prospective --collected for QUALITOP from clinical centres in four EU countries—will integrate lifestyle, genetic, and psychosocial determinants of QoL. Using **machine learning approaches**, QUALITOP will **provide ""real-time"" recommendations stemming from patient profiles and feedbacks via the Smart Digital Platform**. Furthermore, an increased visibility on patients' behaviour, a better IR-AEs prediction, and an improvement of care coordination will help analysing through simulation modelling approaches the gain in cost-effectiveness. **Guidelines will be issued over the short and long-term**.		
ASCAPE	Artificial intelligence Supporting CAncer Patients across Europe	Smart interventions to support cancer patients Cancer is a serious illness. Recent technological advances in Big Data, artificial intelligence (AI) and machine learning can help improve the quality of life of patients. The EU-funded ASCAPE project will **create an open AI infrastructure for health stakeholders such as hospitals**. **New knowledge produced by this process will be sent back to the open AI infrastructure to be shared among everyone while the medical data will still remain private**. The **services to be designed and deployed** by the project will **include intelligent interventions for physiological and psychological support, improved patient and family**	01/01/2020 - 31/12/2022	4 999 991.25

Acronym	Name	Description	Start-End Date	EU Budget (€)
		counselling and guidance, early diagnosis and forecasts of ill health, identification of disease trajectories and relapse, as well as improved health literacy. Objective The latest cancer statistics highlight encouraging advances in decreasing cancer-related mortality. However, given that one in two people will be diagnosed with cancer in their lifetime, and due to the growing and ageing population, the absolute number of people living with cancer is set to keep increasing substantially in the near future. The main objective of ASCAPE is to take advantage of the recent ICT advances in **Big Data, Artificial Intelligence and Machine Learning to support cancer patients' quality of life and health status**. To achieve its objective, ASCAPE will **create an open AI infrastructure that will enable health stakeholders (hospitals, research institutions, companies, etc.) to deploy and execute its AI algorithms locally on their private data**. Any **new knowledge** produced by this process **will be sent back to the open AI infrastructure**. This way **the knowledge will be shared among everyone while the medical data will still remain private**. The services to be designed, piloted and deployed inside this project will include intelligent interventions for physiological and psychological support, improved patient and family counselling and guidance, early diagnosis and forecasts of ill-health, identification of disease trajectories and relapse, improved health literacy etc. ASCAPE will **focus the training of the AI in two types of cancer, breast and prostate**. This way, it will achieve sufficient coverage across genders as well as age groups, hence facilitating its ongoing improvements and applicability towards any type of cancer in the future. The ASCAPE project will be developed in 36 months by a competitive consortium of 15 partners from 7 countries, which corresponds to a well-balanced structure, involving big companies, SMEs, research centres and universities. Despite the great diversity of entities within the proposal, ASCAPE partners bring state-of-the-art complementary skills ensuring the ability of the consortium to develop the proposed solutions.		
FAITH	a Federated Artificial Intelligence solution for moniToring mental Health status after cancer treatment	AI analytics for mental health monitoring in cancer patients. The main goal of the EU-funded FAITH project is to develop a better model for mental health monitoring during disease and treatment for cancer patients to improve their quality of life and aftercare, applying the latest advances in AI and Big Data analytical techniques. The concept of the project is based on federated machine learning, which builds machine learning systems without direct access to	01/01/2020 - 31/12/2022	4 831 233.75

Acronym	Name	Description	Start-End Date	EU Budget (€)
		personal treatment data. Individual patient devices will run their own personalised AI models, and a global AI model will aggregate the individual model learnings. The **AI model will analyse depression markers predicting negative trends to enable timely intervention**. The project consortium has trial sites in several European countries to assess and validate the adoption and usage of this new analytical platform. Objective The main aim of FAITH is to **apply the latest Artificial Intelligence (AI) and Big Data analytics techniques to better model and predict disease/treatment trajectories of cancer patients**, with the goal of **improving their quality of life and aftercare**. To protect privacy of the individual, but still gain insights that are beneficial to the broader population, FAITH will be **applying the concept of federated machine learning, which makes it possible to build machine learning systems without direct access to personal treatment data that will be used for training in machine learning**. **Devices private to the patient will run their own personalised AI models**, via the project's 'AI Angel' application, **while a global AI model aggregates the individual model learnings** (rather than the traditional approach of a central repository of holding all private patient data). FAITH's **'AI Angel' will remotely analyse depression markers, predicting negative trends in their disease trajectory, giving their healthcare providers advanced warnings to allow for timely intervention**. These markers are treated under several distinct categories: Activity, Outlook, Sleep, and Appetite, in accordance with the **3M strategy for population health: Monitor–Measure–Manage**. Central to the vision of the FAITH project is to measure population health deeply, it is necessary to monitor individuals on a continuous basis to cast a wide enough net over a user's health data. A key strength of FAITH is the involvement of eminent cancer hospitals and specialists in the consortium to provide relevant applicable cancer care related use cases that can effectively leverage a big data framework using computational intelligence approaches and methodologies that can be used for long term cancer care health risk and symptom minimisation for patients. FAITH has trial sites in Madrid, Waterford, and Lisbon, with real end users to assess and validate the adoption and usage of the FAITH technologies and platform.		
BD4QoL	Big Data Models and Intelligent tools for Quality of Life monitoring and participatory	Helping head and neck cancer survivors get back to normal life The number of treatment options available for head and neck cancer (HNC) has increased in the last decade thanks to advanced technologies. While current post-treatment care plans focus on functional and health conditions, there are	01/01/2020 - 31/12/2024	4 985 975

Acronym	Name	Description	Start-End Date	EU Budget (€)
	empowerment of head and neck cancer survivors	socioeconomic determinants of quality of life that also need to be addressed. The EU-funded BD4QoL project aims to **improve HNC survivors' quality of life by developing a person-centred monitoring and follow-up plan**. It will **use artificial intelligence and Big Data collected from mobile devices, in combination with multi-source clinical and socioeconomic data and patients' reported outcomes**. Analysis of the **quality of life indicators collected over time will facilitate early detection of risks, prevent long-term effects of treatment, and inform patients and caregivers for personalised interventions**. Objective **Head and neck cancer** can take away a patient's "right to feel human," and its impact on physical appearance, physical functioning, psychological status and general quality of life (QoL) can be devastating. Over the past several decades, the number of patients who survive head and neck cancer (HNC) has increased; this makes lifelong surveillance critical. HNC imposes an extremely high socioeconomic burden on patients during and after cancer compared to other tumors, including costs from treatment-induced morbidities, loss of workforce participation and short-term disability. Current survivorship care plans mostly focus on functional and health conditions of treated patients, whereas socioeconomic determinants of quality of life are often neglected due to difficult data collection. The widespread technologies for social communication and unobtrusive personal monitoring embedded in smartphones and object we commonly use and in our living environments have the potential to unobtrusively collect wealth of indicators of individual QoL. BD4QoL objective is **to improve HNC survivor's Quality of Life through person-centred monitoring and follow-up plan by contribution of artificial intelligence and big data unobtrusively collected from commonly used mobile devices, in combination with multi-source clinical, -omic, socioeconomic data and patients reported outcomes**, to profile HNC survivors for pBD4QoL objective is to improve HNC survivor's Quality of Life through person-centred monitoring and follow-up plan by contribution of artificial intelligence and big data unobtrusively collected from commonly used mobile devices, in combination with multi-source clinical, -omic, socioeconomic data and patients reported outcomes, to profile HNC survivors for personalized monitoring and support. The analysis of QoL indicators collected over time will allow to early detect risks, prevent long-term effects of treatment and inform patients and caregivers for personalized interventions.		

Acronym	Name	Description	Start-End Date	EU Budget (€)
CLARIFY	Cancer Long Survivors Artificial Intelligence Follow Up	Data analysis to improve quality of life for cancer survivors The number of cancer survivors has increased in recent years due to advances in diagnoses and treatment. Ensuring post-treatment quality of life of survivors remains a challenge. The EU-funded CLARIFY project will **identify the risk factors for deterioration in a patient at the end of oncological treatment**. Specifically, it will collect data about survivors from breast, lung and lymphoma cancer (the most prevalent types) from hospitals in Spain. **Using big data and artificial intelligence techniques, it will integrate all data with relevant publicly available biomedical information, as well as information from wearable devices used after the treatment**. The data will be analysed **to predict patient-specific risk of developing secondary effects and toxicities from their cancer treatments**. Objective There were 17 million new cases of cancer diagnosed worldwide in 2018. Survival rates of cancer patients were rather poor until recent decades, when diagnostic techniques have been improved and novel therapeutic options have been developed. It is estimated that more than 50% of adult patients diagnosed with cancer live at least 5 years in the US and Europe. This situation leads to a new challenge: to increase the cancer patients' post-treatment quality of life and well-being. This proposal aims at identifying cancer survivors from three prevalent types of cancer, including breast, lung and lymphomas. The patient data will be collected from different Spanish hospitals and the selection will be based on ongoing health and supportive care needs of the particular patient types. We will **determine the personalised factors that predict poor health status after specific oncological treatments**. For this aim, **Big Data and Artificial Intelligence techniques will be used to integrate all available patient´s information with publicly available relevant biomedical databases as well as information from wearable devices used after the treatment**. To predict patient-specific risk of developing secondary effects and toxicities of their cancer treatments, we will **build novel models based on statistical relational learning and explainable AI techniques on top of the integrated knowledge graphs**. The models will utilise background knowledge of the associated cancer biology and thus will help clinicians to make evidence-based post-treatment decisions in a way that is not possible at all with any existing approach. In summary, CLARIFY proposes to integrate and analyse large volumes of heterogenous multivariate data **to facilitate early discovery of risk factors that may deteriorate a patient condition after the end of oncological treatment**. This will effectively help **to stratify cancer**	01/01/2020 - 31/12/2022	4 841 962.50

Acronym	Name	Description	Start-End Date	EU Budget (€)
		survivors by risk in order to personalize their follow-up by better assessment of their needs.		
ONCORELIEF	A digital guardian angel enhancing cancer patient's wellbeing and health status improvement following treatment.	New AI interface to help cancer survivors Advances in early diagnosis and cancer therapy have greatly improved chances of cancer survival. A big challenge is to ensure survivors have the best possible quality of life. The EU-funded ONCORELIEF project is bringing together the latest technological advances and occupational psychology/health sciences. It is **developing a user-centred artificial intelligence (AI) system to create an intuitive smart digital assistant called Guardian Angel**. Not only will **it provide personalised support in post-treatment activities and tasks**, it will also **suggest actions regarding the patients' overall health-status, improved wellbeing and active healthcare**. Ultimately, the Guardian Angel will help the cancer survivor remain engaged on a wellness journey that will safeguard his/her health during the post-cancer treatment period. Objective The burden of cancer is rising globally and is estimated to have reached 18.1 million new cases and 9.6 million cancer deaths in 2018. Despite the rising cancer incidence, improvements in early detection and therapeutic treatment have improved cancer survival. As a consequence, the number of cancer survivors is increasing globally, creating the need to improve not only treatment but also wellness and follow-up care. Cancer treatment often involves combined modalities such as surgery, chemotherapy, and radiotherapy. In the past decades, more effective and targeted therapeutic modalities and less destructive cancer treatments have been developed such as immunotherapy and drug-targeted therapy. Even so, cancer and its treatment have important physical and psychosocial sequelae. ONCORELIEF is a 36-month action that will leverage the above 6 drivers in order to skillfully and methodologically overcome technical challenges, by introducing new approaches that will allow the **utilization of big datasets in order to develop a user-centered AI System to facilitate the integration of QoL assessment instruments through the use of PROMs and PREMs in order to improve post-treatment health status, increase the wellbeing, and follow-up care of cancer patients**. This will be achieved through an **intuitive smart digital assistant** (Guardian Angel), able **to provide personalized support in post-treatment activities and tasks, suggest actions regarding the patients' overall health-status, improved wellbeing and active health-care and ultimately maintain him/her engaged on a wellness journey that will safeguard his/her health over the foreseeable prolonged post-cancer treatment period**. To achieve	01/01/2020 - 31/12/2022	4 872 250

Acronym	Name	Description	Start-End Date	EU Budget (€)
		this, ONCORELIEF builds on the combined knowhow of its interdisciplinary industry-driven consortium that brings together state-of-the-art technological skills, design thinking methodology and occupational psychology/health sciences.		

10.1.2. Information related to disease and technical approach

Acronym	Related to cancer (Y/N)	Stage of disease (screening, diagnosis, prognosis, treatment, follow-up)	Use of guidelines (Y/N)	Technical approach for patient's follow-up (mobile app, wearable, web app)
PERSIST	Y (breast and colorectal patients)	• Treatment	N/A	• Smart phone app
LifeChamps	Y	• Treatment • Follow-up	N/A	• Big Data-driven • Artificial Intelligence (AI) • Analytics engine • Cloud • Mobile app

Acronym	Related to cancer (Y/N)	Stage of disease (screening, diagnosis, prognosis, treatment, follow-up)	Use of guidelines (Y/N)	Technical approach for patient's follow-up (mobile app, wearable, web app)
QUALITOP	Y	• Treatment (immunotherapy)	Y	• Big data analysis • Artificial intelligence (Machine Learning) • Simulation modelling approaches
ASCAPE	Y	• Diagnosis • Prognosis • Treatment	N/A	• Big Data • Artificial Intelligence and Machine Learning • Intelligent interventions
FAITH	Y (breast cancer)	• Treatment	N/A	• AI and Big Data analytical techniques • Federated machine learning
BD4QoL	Y (head and neck cancer)	• Treatment	Y	• Artificial intelligence and big data unobtrusively collected from commonly used mobile devices
CLARIFY	Y	• Follow-up	N/A	• Big Data and Artificial Intelligence techniques • Wearable devices
ONCORELIEF	Y	• Follow-up	N/A	• Artificial intelligence • Intuitive smart digital assistant

10.2. Annex 2

Comparative matrix of solutions available on the market

10.2.1. General Information

Company	Website	Product	Description	Features	Clinical Data
Leuko	https://leuko.io/	PointCheck™	PointCheck™; the first noninvasive device for the screening of severe neutropenia. By imaging the blood flowing through the capillaries in the finger, PointCheck™ is able to determine if white cell levels are dangerously low, completely noninvasively without having to extract any blood	• - A simple finger-based blood test - Identify elevated risk of infection	• White blood cell levels
Kaiku Health	https://kaikuhealth.com/	Kaiku Health	Kaiku Health is a digital health intervention platform for cancer clinics. Digital symptom management is shown to improve patients' overall survival and quality of life.	• Dashboards, reports, imaging examination	• Genetic data • QoL data • Chemotherapy • Tissue • Immune indicator
VieCure	https://viecure.com/	VCurePrecision platform	VCurePrecision™ is the only **Artificial Intelligence platform that helps oncologists generate patient-specific treatment plans** in real time and at point-of-care using a state-of-the-art clinical inference engine. The platform is a comprehensive, intelligent EMR which includes medical and treatment history, progress notes, prescribing, medication administration record, scheduling, and pharmacy. It also has a mobile patient app to enhance patient engagement, treatment plan adherence, side-effect monitoring, and communication between the patient and the oncology care team.	• Dashboards, follow-up visits and scheduling appointments, intelligent EMR which includes medical and treatment history, progress notes, prescribing, medication administration record, scheduling, and pharmacy	• Physical and laboratory • Medication tracking • Lifestyle considerations (diet, exercise) • Counseling and encouragement (psychosocial, spiritual, financial, lifestyle) • Longer-term side effects
VieCure	https://viecure.com/	Patient Engagement App	Our app empowers patients with important details for current treatment and ongoing survivorship/wellness needs, including medication	• Dashboards • Follow-up visits and scheduling appointments	• Physical and laboratory • Medication tracking

Company	Website	Product	Description	Features	Clinical Data
			tracking, lifestyle considerations (diet, exercise), counseling and encouragement (psychosocial, spiritual, financial, lifestyle), longer-term side effects, how to monitor and report toxicities so they get resolved, follow-up visits and scheduling appointments.	• Intelligent EMR which includes medical and treatment history, progress notes, prescribing, medication administration record, scheduling and pharmacy	• Lifestyle considerations (diet, exercise) • Counseling and encouragement (psychosocial, spiritual, financial, lifestyle) • Longer-term side effects
RiAtlas	https://www.riatlas.it/	OncoSmart	OncoSmart is the first "clinically validated" digital application (Software as Medical Device) for patient with cancer, through the Oncology Care Pathway. AI-based and IoT tools for actively remote monitoring: - Automatic classification of patient health status - Analytical visualization of personal data, correlated with clinical data - Alerting & Insights for early detection of clinical risks	• Compliant with GDPR • Compliant with HL7/FHIR protocol • Use of standard taxonomies (e.g. International Classification of Functioning, Disability and Health (ICF)) • Dashboards • Symptom and disease classification • Alerting, profiling and self-monitoring	• Patient activity • Heart rate (HR)
OncoLens	https://www.oncolens.com/	Survivorship Care Planning (SCP)	Cancer patients deserve an individualized survivorship care plan that includes guidelines for monitoring and maintaining optimal health after moving beyond their cancer treatment. The solution enables care team members to eliminate time-consuming, manual processes associated with collecting required data, identifying patients, tracking down proper signatures and delivery to patients.	• Simplify Tumor Board management • Facilitate survivorship care planning • Automate accreditation and quality reporting through an intelligent workflow engine	• Tissue
Syapse	https://www.syapse.com/	Syapse	Syapse integrates, standardizes, and normalizes clinical and genomic data in a centralized platform that can be utilized by healthcare providers, researchers, executives, and others to advance the practice of precision medicine.	• Data visualization, centralization and data management.	• Clinical • Pathology • Radiology • Genomic

Company	Website	Product	Description	Features	Clinical Data
			By connecting with electronic health records (EHRs), data warehouses, registries, and other sources, Syapse is able to extract complex clinical data such as diagnosis and staging, pathology and radiology reports, treatment and outcomes, demographics, and more. Syapse also captures genomic and other molecular test results as structured data through direct integration with molecular diagnostics labs. Additionally, Syapse applies a data quality improvement framework that uses a combination of manual abstraction by highly trained medical data professionals and machine learning to create a comprehensive patient record.	• Connection with electronic health records (EHRs), data warehouses and registries	• Treatment • Laboratory results
ARIEL Precision Medicine	https://www.arielmedicine.com/	Ariel	Ariel delivers precision medicine solutions for the diagnosis, monitoring and treatment of complex chronic diseases and disorders. Integrate complex genetics into clinical decision-making, empowering doctors and patients to prevent, mitigate or even reverse disease progression. A comprehensive interpretation of the genetic data is provided in the context of each patient's current symptoms, biomarkers and health history. Precision medicine can help you navigate your health conditions by: **Recommending screenings before you have symptoms.** Precision medicine can screen for genetic susceptibility before you experience symptoms. **Personalizing your treatment. Precision medicine allows your healthcare team to personalize your treatment.** In some cases, targeted therapies may be available to you.	• Integrates a patient's symptoms and genetics with complicated medical information using systems modeling, machine learning and other advanced reporting technology. • Personalized guide to patient management.	• Genetic data • QoL data

Company	Website	Product	Description	Features	Clinical Data
Medtronic	https://www.medtronic.com/covidien/en-us/products/interventional-lung-solutions/lunggps-patient-management-platform.html	LungGPS™ Patient Management Platform	The LungGPS™ patient management platform is a disease-state data management system designed to streamline the management of lung nodule patients, from identification through diagnosis, treatment, and long-term survivorship. **Nodule Management Software** This disease-state management platform: - Identifies patient reports with incidental nodules through use of advanced artificial intelligence tools - Reviews patient information against applicable clinical guidelines - Enrolls patients into a management protocol with automated notifications, reminders, and status updates - Reports program metrics and key performance measures	• Dashboards • Web-based patient and data management • Workflow • Guideline compliance • Reporting	• Image • Clinical tests • Nodule state
General Electric	https://www.gehealthcare.com/products/navify-tumor-board	NAVIFY® Tumor Board	Monitoring and treatment management. NAVIFY® Tumor Board is a cloud-based workflow product that securely integrates and displays relevant aggregated data into a single, holistic patient dashboard for oncology care teams to review, align and decide on the optimal treatment for the patient.	• Dashboards • Medical image viewing • Review the latest guidelines • Record patient diagnostic and treatment paths	• Imaging • Other relevant data from patient • Guidelines
Umotif	https://www.umotif.com/	OurBrainBank	It is a free app that patients or caregivers use to track symptoms, share data with clinicians, and donate data to medical research.	• Analyze the data to gain insights • Provide improved patient support • Speed up trial recruitment • Support the first Patient Reported Outcome (PRO) measure in GBM, incorporating the patient	• Patient-reported data (symptoms, mood, activities and treatments)

Company	Website	Product	Description	Features	Clinical Data
				experience alongside traditional objective measures	
Living With	https://www.livingwith.health/	Living With Oesophageal Cancer	Living With Oesophageal Cancer can help overcome these challenges by supporting patients with a personalised, reliable and accurate source of information to guide them through their care pathway – all in an easy to digest format which they can access in the comfort of their own home. It allows healthcare professionals to monitor patient progress, provide them with relevant information attached to upcoming appointments and improve care.	• Patients can connect to their clinic via a free connected app • Monitor their symptoms remotely • Send and receive messages directly to patients • Provide relevant information to their pathway stage • Review PROM's including the HNA (Holistic Needs Assessments) assessment • Remote tracking of measures including weight	• Patient symptoms • Messages between patient and clinician • Pathway stage information • PROMs • Patient measures including weight
biofourmis	https://www.biofourmis.com/	Biovitals Sentinel® Painfocus™ Gaido™	Prescription Software to continuously monitor and detect early signs of deterioration in oncology patients, pre- and post- treatment Gaido enables you to prevent avoidable readmissions and helps spare your patients from developing infections, sepsis, dehydration and other conditions Reduce Length of stay, 30-days rehospitalization and overall healthcare spending while improving quality of life and function in patients with cancer.	• AI-based ecosystem (machine-learning platform) • Deep neural networks • EMR integration • Medication delivery • Clinical call center • Predict and/or detect serious medical events • Personalized feedback for patients	• Population metadata • Real-time patient physiological signals

10.2.2. Information related to disease and technical approach

Company	Target profile (end-users)	Type of cancer	Stage of disease (screening, diagnosis, prognosis, treatment, follow-up)	Technical approach (mobile app, wearable, web app)	Use of guidelines (Y, N, N/A)
Leuko	• Patients	• Chemotherapy patients • Immunosuppressed patients	• Treatment	• AI algorithms	Y
Kaiku Health	• Clinicians	• Breast • Prostate and other urological cancers • Lung • Colorectal and other GI cancers • Hematologic • Melanoma and other skin cancers • Gynecological • Head and neck cancers	• Treatment • Follow-up	• Mobile app • Web dashboard	Y
VieCure	• Clinicians	N/A	• Treatment • Follow-up	• Artificial Intelligence • Codified clinical rules and pathways • Telehealth • Smartphone technology • EMR	Y
VieCure	• Patients	N/A	• Treatment • Follow-up	• Artificial Intelligence • Codified clinical rules and pathways • Telehealth • Smartphone technology • EMR	Y
RiAtlas	• Clinicians • Patients	• Breast • Prostate cancer • General cancers	• Treatment • Follow-up	• Digital health record • Wearable and mobile app for patients • AI-based tools	N

Company	Target profile (end-users)	Type of cancer	Stage of disease (screening, diagnosis, prognosis, treatment, follow-up)	Technical approach (mobile app, wearable, web app)	Use of guidelines (Y, N, N/A)
				• Web portal for health professional • Measurements of blood pressure, EC	
OncoLens	• Clinicians (oncol-ogists)	N/A	• Diagnosis • Treatment	• Rules-based workflow • Web app • Mobile app	Y
Syapse	• Clinicians • Healthcare pro-viders • Researchers • Executives	N/A	• Follow-up	• Machine learning • Full software	N/A
ARIEL Preci-sion Medicine	• Clinicians • Patients	• Pancreatic cancer	• Screening • Diagnosis • Treatment • Follow-up	• Full software	N/A
Medtronic	• Clinicians	• Lung cancer	• Diagnosis • Treatment • Follow-up	• Imaging technologies • Web-based dashboard	Y
General Elec-tric	• Clinicians	N/A	• Diagnosis • Treatment • Follow-up	• Cloud-based workflow	Y
Umotif	• Patients • Caregivers	• Glioblastoma	• Treatment • Follow-up	• Smartphone or tablet app	N/A
Living With	• Patients	• Oesophageal cancer	• Treatment • Follow-up	• Smartphone app • Dashboard web-app	Y

Company	Target profile (end-users)	Type of cancer	Stage of disease (screening, diagnosis, prognosis, treatment, follow-up)	Technical approach (mobile app, wearable, web app)	Use of guidelines (Y, N, N/A)
biofourmis	• Patients • Clinicians • Nurse	• Solid tumors	• Diagnosis • Treatment • Follow-up	• Wearable • Medical-grade biosensor with a high patient adherence rate • Patients mobile app • Clinicians mobile app • Web-based nurse dashboard	N/A

10.2.3. Commercial Information

Company	FDA or CE Mark	Patents / IPR	Price	Based on previous research/clinical studies
Leuko	This is an investigational device. It is not for sale. The claims made on this website have not been evaluated by the FDA or the CE Mark authorities.	N/A	N/A	https://doi.org/10.1002/ajh.25516 https://doi.org/10.1038/s41598-018-23591-0 https://doi.org/10.1109/EMBC.2015.7320119
Kaiku Health	Kaiku Health is CE-marked as MDD class I medical device	N/A	N/A	https://doi.org/10.1007/s00432-018-02835-6 https://doi.org/10.4137/CMENT.S40219
VieCure	https://viecure.com/certifications	N/A	N/A	N/A
VieCure	https://viecure.com/certifications	N/A	N/A	N/A
RiAtlas	N/A	AI-based proprietary tools, supported by machine learning and predictive models, are constructed on "validated" clinical dataset, and protected by an IPR **(patent submitted, Nr. 102019000007139)**. International Classification of Functioning, Disability and Health (ICF)	N/A	N/A
OncoLens	N/A	N/A	N/A	N/A
Syapse	N/A	N/A	N/A	N/A

Company	FDA or CE Mark	Patents / IPR	Price	Based on previous research/clinical studies
ARIEL Precision Medicine	N/A	N/A	N/A	N/A
Medtronic	N/A	™*Third party brands are trademarks of their respective owners. DynaCAD™** is a registered trademark of Koninklijke Philips N.V. All other brands are trademarks of a Medtronic company.	The LungGPS™ patient management platform is **only available for sale in the United States**.	N/A
General Electric	N/A	N/A	N/A	N/A
Umotif	N/A	N/A	Non-profit	The OurBrainBank Study received ethics approval from the New England IRB #120170332 (US) and the University of Leeds (UK). OurBrainBank launched in the US in 2018.
Living With	N/A	N/A	https://www.livingwith.health/pricing/	N/A
biofourmis	FDA Pre-submission Also obtained regulatory approval in countries outside the U.S.	N/A	N/A	https://doi.org/10.1109/EMBC.2019.8856482 https://doi.org/10.1159/000501433