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CAPABLE

Cancer Patients Better Life Experience

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

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DEM	Demonstrator, pilot, prototype	**X**
DEC	Websites, patent fillings, videos etc.	
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PU	Public	**X**
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1.Versions History

Version	Date	Author	Comments
1.0	04/11/2020	UPM	First structure
2.0	20/11/2020	UPM	Costs of cancer and market analysis
3.0	30/11/2020	UPM	Integrated inputs from hospitals NKI and ICSM
4.0	05/12/2020	UPM	First complete version
5.0.	11/12/2020	UPM	Version for internal revision

2. Executive Summary

The document shows the activities of market research performed in the second half of the first year of the project. Differently from the initial deliverable: the focus of the market research has been to study the specific costs of kidney and melanoma cancer (presented in chapter 3), and the possible barriers and success criteria to market (chapter 4) to then continue the CAPABLE roadmap to the adoption following the CEHRES method presented in D8.1 (see chapter 5). The document also presents an update of the technology vigilance in chapter 6, which also contains a specific selection of solutions that are relevant competitors of CAPABLE and a study of the existing solution in the 2 hospitals of CAPABLE (ICSM and NKI-NVL). In order to set the basis for the next activities of WP8 the document also presents an updated version of the Consortium IPR strategy (chapter 7) and questionnaire interviews to be launched next year to start exploiting interests from key decision makers (chapter 8).

3. Specific market analysis on kidney and melanoma cancer

The previous deliverable reported the market analysis of the overall cancer market (Chapter 7 of D8.1). This deliverable focuses on the market analysis of the two specific types of cancer managed by CAPABLE, the melanoma and kidney cancer.

In the old continent the prevalence of cancer is quite high, if we consider that Europe is around one tenth of the global population, one in four of all cancers are in these geographical areas.

The following charts show the number of cases in Europe (around 3.9 million cases) and deaths (1.9 million) distributed by the most common cancers.

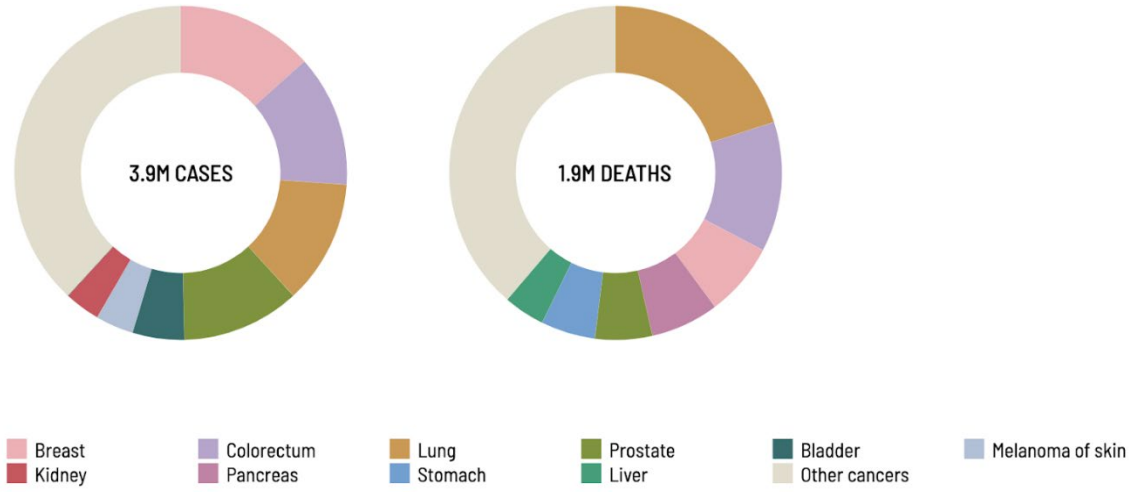

Figure 1: Cases and death of cancer in Europe[1]

In Europe, according to the WHO in 2018[2], the incidence of melanoma signified in 144k (3.4%) new cases, 27k (1.4%) deaths and 494k cases with 5-year prevalence. In the case of kidney cancer, the incidence signified in 136K (3,2%) new cases, 54k (2.8%) deaths and 361k cases with 5-year prevalence.

The next sections describe the costs for both melanoma and kidney cancer, specifically the direct (expenditures made by the health care system) and indirect (productivity loss caused by illness) ones.

3.1. Melanoma Costs[3]

Malignant melanoma (MM) is the most prevalent among the skin cancers. The estimated incidence in Europe is between 4.3 to 19.5 over 100K in men and between 5.5 and 35.4 over 100K in women. If MM is diagnosed at an early stage it can be effectively treated; the ones with a late discovery of the condition have less chance of recovery.

- **Direct costs**: Estimated real direct costs based on the GDP resulted in an average of € 4437 per patient, ranging between € 833 in Bulgaria and € 11901 in

[1] Chart taken from https://canceratlas.cancer.org/the-burden/europe/
[2] https://gco.iarc.fr/today/data/factsheets/populations/908-europe-fact-sheets.pdf
[3] Krensel M, Schäfer I, Augustin M. Cost-of-illness of melanoma in Europe - a modelling approach. J Eur Acad Dermatol Venereol. 2019 Mar;33 Suppl 2:34-45. doi: 10.1111/jdv.15308. PMID: 30811699.

Luxembourg (See table 1). Considering population and prevalence of MM in Europe, national treatment costs were estimated for each country, based on the GDP. Real direct national expenditures varied between approximately € 107 000 in Malta and € 88.0 million in Germany and summed up to € 406.0 million for all included countries which means. When these estimates were based on Health Expenditure (HE), costs per patient were higher with an average amount of € 4521 ranging from € 476 in Romania to € 10 793 in Denmark. National direct costs varied between € 94 000 in Malta and € 95.6 million in Germany.

Table 1: Direct costs of melanoma in Europe (GDP, gross domestic product; HE, health expenditures; p.p., per patient)

Country	Population	Prevalence cases	GDP/capita (€}	Costs p.p. GDP (€)	Total direct costs GDP (€ 1000)	HE share of GDP	HE/capita (€)	Costs p.p. HE (€)	Total costs direct HE (€ 1000)
Austria	8 429 991	1453	37 618	5455	7926	11.8	4439	6220	9038
Belgium	11 128 246	1937	34 822	5050	9781	10.8	3761	5270	10 208
Bulgaria	7 305 888	538	5742	833	448	7.4	425	595	320
Croatia	4 267 558	779	10 302	1494	1164	6.8	701	982	765
Cyprus	1 129 303	60	17 238	2500	150	7.3	1258	1763	106
Czech Republic	10 510 785	1417	15 356	2227	3155	7.7	1182	1657	2348
Denmark	5 591 572	1712	45 239	10 793	18 478	11.2	5067	10 793	18 478
Estonia	1 322 696	187	13 559	1966	368	5.9	800	1121	210
Finland	5 413 971	1286	36 904	5351	6882	9.2	3395	4757	6118
France	65 659 790	10 314	31 784	4609	47 538	11.8	3751	5255	54 205
Germany	80 425 823	17 610	34 296	4973	87 580	11.3	3875	5431	95 632
Greece	11 045 011	633	17 311	2510	1589	9.3	1610	2256	1428
Hungary	9 920 362	1318	9989	1449	1909	7.8	779	1092	1439
Iceland	320 716	52	34 447	4995	260	9.1	3135	4392	228
Ireland	4 586 897	892	38 317	5556	4956	8.1	3104	4349	3879
Italy	59 539 717	10 600	27 096	3929	41 650	9.2	2493	3493	37 027
Latvia	2 034 319	267	10 740	1557	416	6.0	644	903	241
Lithuania	2 987 773	342	11 163	1619	554	6.7	748	1048	358
Luxembourg	530 946	90	82 069	11 901	1071	6.9	5663	7935	714
Malta	419 455	43	17 186	2492	107	9.1	1564	2191	94
Norway	5 018 573	1673	79 047	11 463	19 177	9.0	7114	9969	16 678
Poland	38 063 164	3512	10 231	1484	5210	6.7	685	961	3373
Portugal	10 514 844	1158	16 015	2322	2689	9.5	1521	2132	2469
Romania	20 058 035	1350	6661	966	1304	5.1	340	476	643
Slovakia	5 407 579	871	13 445	1950	1698	7.8	1049	1470	1280
Slovenia	2 057 159	583	17 501	2538	1480	8.8	1540	2158	1258
Spain	46 773 055	5245	22 297	3233	16 958	9.6	2140	2999	15 732
Sweden	9 519 374	3110	44 467	3275	10 186	9.6	4269	3275	10 186
Switzerland	7 996 861	2549	64 727	9386	23 925	11.3	7314	10 249	26 125
The Netherlands	16 754 962	5151	38 506	5584	28 762	12.4	4775	6691	34 464
United Kingdom	63 700 300	14 756	32 329	3970	58 583	9.4	3039	3970	58 583

- **Indirect costs:** annual costs per patient caused by productivity loss due to morbidity ranged between € 126 in Sweden and € 5472 in the United Kingdom (See Table 2). In this cost category, national costs were highest in the United Kingdom (€ 80.7 million) and lowest in Malta (€ 45 230). Costs for all countries amounted for € 217.1 million.

Table 2: Indirect costs of melanoma in Europe

Country	Population	Prevalence cases	GNI costs p.p. morbidity (€)	GNI total costs morbidity (€)	Years of lost productivity	GNI costs per death before	GNI costs p.p. mortality (€)	GNI total costs mortality (€ 1000)
Austria	8 429 991	1453	2227	3 235 303	1365	518 849	39 280	57 073
Belgium	11 128 246	1937	2414	4 676 382	1335	536 432	28 248	54 716
Bulgaria	7 305 888	538	268	143 965	608	47 469	5559	2990
Croatia	4 267 558	779	707	550 474	740	140 571	12 632	9840
Cyprus	1 129 303	60	1421	85 232	108	497 175	41 431	2486
Czech Republic	10 510 785	1417	722	1 022 888	1468	133 383	12 708	18 007
Denmark	5 591 572	1712	692	1 184 704	1065	542 841	29 806	51 027
Estonia	1 322 696	187	674	125 952	238	156 433	12 548	2346
Finland	5 413 971	1286	2245	2 887 575	530	318 357	16 339	21 012
France	65 659 790	10 314	1915	19 746 930	8988	431 964	28 270	291 576
Germany	80 425 823	17 610	2309	40 661 079	10 585	466 338	23 145	407 579
Greece	11 045 011	633	1255	794 587	1175	285 285	41 463	26 246
Hungary	9 920 362	1318	564	743 000	1965	122 764	14 531	19 151
Iceland	320 716	52	1783	92 696	35	209 276	16 098	837
Ireland	4 586 897	892	2388	2 130 131	673	597 767	27 476	24 508
Italy	59 539 717	10 600	1731	18 346 712	8408	366 014	21 581	228 758
Latvia	2 034 319	267	525	140 296	423	137 825	17 034	4548
Lithuania	2 987 773	342	451	154 311	475	107 340	12 554	4294
Luxembourg	530 946	90	2899	260 925	70	539 009	35 934	3234
Malta	419 455	43	1052	45 230	85	224 561	31 334	1347
Norway	5 018 573	1673	3055	5 111 690	1220	553 923	36 421	60 932
Poland	38 063 164	3512	625	2 194 179	6438	157 749	24 210	85 027
Portugal	10 514 844	1158	985	1 141 115	1085	205 902	16 358	19 942
Romania	20 058 035	1350	344	464 772	2933	106 518	17 437	23 541
Slovakia	5 407 579	871	1214	1 057 778	785	289 544	23 935	20 847
Slovenia	2 057 159	583	561	327 345	603	168 238	14 140	8244
Spain	46 773 055	5245	1468	7 700 354	4258	332 834	20 116	105 508
Sweden	9 519 374	3110	126	392 669	2023	453 956	23 793	73 995
Switzerland	7 996 861	2549	3511	8 949 612	1083	740 168	25 843	65 875
The Netherlands	16 754 962	5151	2332	12 009 972	4253	489 841	32 238	166 056
United Kingdom	63 700 300	14 756	5472	80 748 816	9555	379 933	19 723	19 723

- **Total costs:** Combining morbidity and mortality costs, total indirect costs per patient ranged from € 5826 in Bulgaria to € 42 852 in Cyprus. National indirect costs varied between € 930 000 in Iceland and € 448 million in Germany. Indirect costs for all included countries amounted for € 2369 million with mortality costs accounting for 90% of indirect costs. Total COI of MM including direct and indirect costs resulted in € 2775 million to € 2783 million for all included countries which means 1,4% of the overall cancer costs in Europe (199 Billion €, as reported in D8.1).

3.2. Kidney cancer costs

Due to the lower incidence of kidney cancer in Europe, there are no studies on the economic framework of the disease at European level.

In 2006, Lang et al[4], conducted a study on the cost of illness associated with renal cell carcinoma (RCC) in UK, Spain, France and Germany. This study concludes that corresponding estimates of the aggregate annual burden of RCC (€2005) are €541 million (0.27% of the overall cancer costs in Europe), €41.8 million, €171 million, and €1.6 billion, respectively (per-patient costs of €21,792, €10,607, €4781, and €26,397).

Nevertheless, there are studies that have been performed in different countries. In 2018, Cholley et al[5] carried out a study on the economic cost of RCC in France that concludes that the mean cost of illness was estimated at €71,185 ± 52,683 and Outpatient/inpatient treatment and hospitalization represented 76.0% and 19.7% of this cost, respectively.

In the US, according to Chiel et al[6] in 2019, the cumulative costs for the RCC group were $33,685 (2005 US$) [$49,540, in 2017 US$] at 1 year and $110,798 [$162,948] at 5 years. The cost difference between the RCC and the matched control at year 1 was $24,424 [$35,920] in unadjusted analysis and $22,340 [$32,855] in adjusted analysis (adjusting for censoring and controlling for covariates) and was $48,026 [$70,631] and $20,976 [$30,849], respectively, at year 5.

Melanoma and Kidney cancer contribute respectively to the 1,4% and 0,27% of the overall cancer costs in Europe.
Even if marginal both Melanoma and Kidney cancer caused overall costs of 3324 Million € over a total or 199 Billion €. In both cases (and most probably also to other cancer types) the treatment costs are lower in the new EU members (e.g., Romania) and mortality costs are lower in the countries with high domestic product / capita.
From this preliminary analysis it is clear that for the further exploitation of the CAPABLE results it is crucial to understand how much the system will be adaptable to other types of cancer. For this reason, WP8 revised the main exploitable results of CAPABLE in order to understand how much the component are scalable. (See section 7)

[4] Lang, K & Danchenko, Natalya & Gondek, K & Schwartz, Brian & Thompson, D. (2006). "Cost of illness" analysis of renal cell carcinoma. Value in Health. 9. A287. 10.1016/S1098-3015(10)63468-7.
[5] Cholley T, Thiery-Vuillemin A, Limat S, Hugues M, Calcagno F, Mouillet G, Anota A, Nerich V. Economic Burden of Metastatic Clear-Cell Renal Cell Carcinoma for French Patients Treated With Targeted Therapies. Clin Genitourin Cancer. 2019 Feb;17(1):e227-e234. doi: 10.1016/j.clgc.2018.10.016. Epub 2018 Nov 7. PMID: 30502046.
[6] Chien CR, Geynisman DM, Kim B, Xu Y, Shih YT. Economic Burden of Renal Cell Carcinoma-Part I: An Updated Review. Pharmacoeconomics. 2019 Mar;37(3):301-331. DOI: 10.1007/s40273-018-0746-y.

As also discussed in the previous deliverable CAPABLE is a novel digital therapeutic tool that could be added as part of the treatment costs or hospital expenditure. It is a challenge for CAPABLE to have a competitive cost that impact marginally on the costs if compared with the value that the system can generate.

Furthermore, there is a clear tendency that wealthier countries use to spend more on cancer drugs than poorer countries. As reported in the previous deliverable there is a trend that cost of cancer drugs are increasing and improving the overall health outcome. A system as CAPABLE can be a complementary solution if offered together with a specific cancer pharmaceutical therapy.

4. Barriers to market and success criteria

There is a growing demand for eHealth solutions based on Artificial Intelligence but still in Europe only 16% of health care facilities really adopted these types of tools[7]. One of the most critical points for the adoption of AI based systems in health care is lack of a proper Health Technology Assessment, of models for health outcomes and use of a proper cost-effectiveness and cost-utility model. These last are the final results of a complex process in which a novel solution is created, tested and then exploited. Inside this process there are several barriers that need to be known in order to maximise the benefits from a technological solution as CAPABLE.

Those barriers have been identified and actions to mitigate the risks have been defined. Three types of barriers have been considered, as suggested in the systematic research of Schreiweis et al[8]:

- **Individual barriers:** they depend on the actors that are involved in the CAPABLE system, patients, caregivers and health professionals.
- **Environmental and organizational barriers:** these barriers mostly refer to problems related to system deployment in the hospitals.
- **Overall technical barriers:** these situations depend on the solution that has been deployed.

For every identified type of barrier, a list of possible factors has been identified and possible mitigation actions have been proposed.

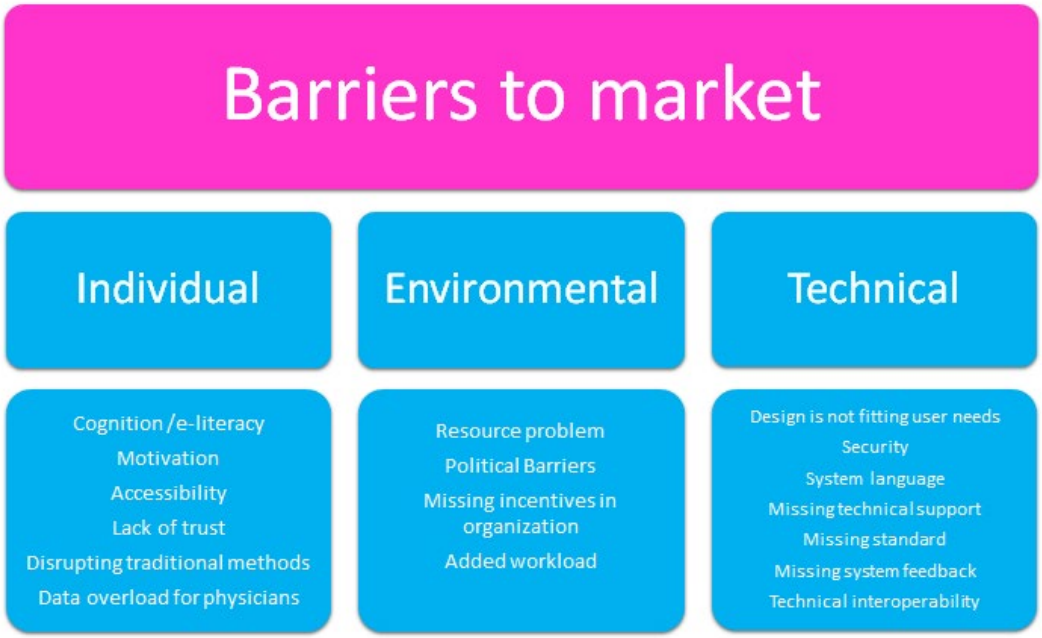

Figure 2: Barriers to market for CAPABLE project

[7] Artificial Intelligence in Healthcare Market by Offering (Hardware, Software, Services), Technology (Machine Learning, NLP, Context-Aware Computing, Computer Vision), End-Use Application, End User, and Geography – Global Forecast to 2025

[8] Schreiweis, B., Pobiruchin, M., Strotbaum, V., Suleder, J., Wiesner, M., & Bergh, B. (2019).
Barriers and Facilitators to the Implementation of eHealth Services: Systematic Literature Analysis. Journal of medical Internet research, 21(11), e14197. https://doi.org/10.2196/14197

Individual barriers

- **Cognition barriers / e-literacy:** this barrier refers to the incapacity of the end users (patients and health professionals) to use the system. This can depend on the incapacity to use the CAPABLE solution and also to be able to learn on how to use the system. The target users are adult with a median age of 58 (CRR) and 65 (MM), ans in some cases participant could have a problem of technology literacy that may jeopardise the adoption of the technology. The system language can also be a problem. Mitigation: set up training activities for the health professional and create a user manual for the end users; provide the system in the spoken language of the user (Italian, Dutch and English); CAPABLE will use a translation framework provided by UPM called Lokalise (https://lokalise.com/) that will manage the translation process of the GUIs for health professionals and patients: rephrasing medical terms in such a way that they are easily comprehensible by patients.
- **Motivation:** this happens when the user has not perceived any value in using the system. Another specific barrier can be that some users can be reluctant to use the system because they prefer a more classical healthcare service based on human-to-human interaction. Mitigation: CAPABLE already adopted user centered design to better craft a system to solve unmet needs of the users. Furthermore, WP2 worked in close collaboration with health professionals and patients and planned periodic assessment of the solution through the WP7 activities. Furthermore, the current pandemic COVID-19 caused for many healthcare system the need to start new and unconventional ways to attend patients using teleconference and ICT systems, thus it's probable that patients become more and more familiar with these modalities.
- **Accessibility:** patients and professionals can have some physical impairments that can be barriers for the use of the system, e.g., tremors and impaired visions. Mitigation: apply principle of usability and accessibility in the system design. Providing realistic exclusion criteria to avoid enrollment of patients with severe physical impairments, who could be frustrated by their incapacity to use the system. The criteria of accessibility of the CAPABLE technology will be assessed in the task 7.1 in which the Consortium will define the study protocol and the inclusion/exclusion criteria (not only clinical). Furthermore CAPABLE also considers the possibility that a caregiver can help the patient to use the system.
- **Lack of trust:** this happens when patients are not feeling that the contents and services have a medical validity because they are not well elaborated or incoherent. The health professionals can also not trust the system because the proposed service is not working well and/or because the managed information is incoherent with the real patient situation. For further commercialization it is crucial that the system demonstrates to be effective and CAPABLE to improve patient outcomes (e.g. QoL, patient satisfaction with the health care service etc.). Mitigation: the system provides contents in the patient's app that are clinically validated. Perform test and revision of the contents. Plan an overall clinical validation as stated in the DoA. The mitigation activities are on track and managed by WP7. Some preliminary results on the feasibility and effectiveness of the system will be available after the execution of the pre pilot at month 30-36. The final results will come at the end of the project, after the completion of the clinical study.
- **Disrupting traditional methods of patient management and increasing patient anxiety:** Many eHealth solutions utilizing AI technology aim to disrupt the traditional management of patients with long term chronic conditions whereby (for example) patients may be currently expected to visit their HCP (Health Care Professional) maybe every month for a regular check-up. eHealth solutions of the future will empower patients to monitor their own disease state on a more continuous basis and identify their risk of further deterioration. Despite recognizing many of the benefits of empowering patients to monitor and manage their disease, there is a lot of concern around misinterpretation of the results and the impact this will have on patient anxiety. To mitigate this concern, it will be essential to ensure that any

new solutions incorporating AI are clinically validated with a high specificity and sensitivity and that patients are educated and trained on the meaning of their results.

- **A work overload for physicians:** Currently physicians spend a vast amount of time interpreting test results and patient medical records. Concern amongst some physicians exists that eHealth solutions used to continually monitor long term chronic diseases may increase physician's workload due to an increased amount of data and test results that will need to be interpreted. CAPABLE must therefore develop eHealth solutions from the perspectives of both the end user (patient) and HCP in mind. Developing a solution that in the end only improves patient outcomes and produces large amounts of patient medical data will find strong resistance from HCPs, if it does not also help them to streamline or reduce their workload. The workload of the Health Care professional will be tracked during the clinical studies in order to estimate the real costs of the implementation of CAPABLE in clinical settings.

Environmental and organizational barriers

The organizational barriers refer to situations at organizational level (in this case hospitals) that can reduce the adoption of a solution such as CAPABLE. These problems can be:

- **Financial resource problem:** when there are not enough resources to adopt the solution in the departments.
- **Political barriers:** it can depend on the political strategy of the decision maker involved in the purchase and deployment of a new e-health system, for example: prioritization of e-health services and lack of readiness to implement novel e-health solutions.
- **Missing incentives in the organization:** this mostly affects the motivation of health professionals that need to have recognized the activities to use a novel e-health service.
- **Added workload:** as mentioned above, a new e-health system generally adds some workload to the healthcare professionals. In order to achieve a complete acceptance of the new e-health system it is important to allocate the human resources for the proper set up of the new digital service. (e.g., time for the training, time for the patient enrolment, time for the daily use of the digital service).

The mitigation of the environmental and organizational barriers will depend on a proper allocation of resources of the medical stakeholders involved in the project. This will help the proper project adoption and validation of the system during the project lifecycle. For the further exploitation the barrier to the market can be overcome by adopting principles of Health Technology Assessment and Value based healthcare to clearly detail the value generated by the system and the required procedures for a proper deployment in real world healthcare systems.

Technical barriers

- Design is not fitting user needs: this happens when the end users (patients and health professionals) find themselves using a system that is not designed according to their expectations and unmet needs. Mitigation: adopt user centred design. Periodically assess the solution with end users (patients and health professionals) as previously commented.
- Security: security issues can happen when users have privacy concerns on the type of information gathered and how it is used. Security can also come from authorities (e.g., ethical committees, security departments etc.) that audit the security of the proposed system. Mitigation: adopt principles of security by design (meaning that security specification starts together with the system design) and create a platform compliant with GDPR.

- Missing technical support: the deployment of a system needs to include the activation of a technical support service in order to solve the user problem and grant the continuation of use of the system. Any errors that stuck the user in the system can generate lack of trust and frustration to the user and can affect the overall system acceptability. Mitigation: design, develop and deploy a technical support infrastructure to provide technical support during the clinical studies that will be performed. WP7 is in process of defining the protocol to provide technical support to the patients and to the health professionals.
- Missing standard: if a digital service is not supporting medical standards it can be a barrier for further medical services in the HIS (Hospital Information System) . Mitigation: CAPABLE project will adopt Health Standard, based on OMOP and FHIR.
- Missing system feedback: a new digital service can be demanding for an end user because it can require performing operations that consume time and request a certain level of attention. From the users' viewpoint it is crucial to receive feedback from the system in order to keep them engaged and reinforce the added value that the system is providing. Mitigation: design the patient app as a system that provides a learning experience, in which the user can learn and not just report data. Provide a system for health professionals that gives full vision of the current health status and clearly shows the possible clinical options according to guidelines. Offer full control and understanding of the Decision Support System embedded in the CAPABLE system.
- **Technical interoperability:** it is a critical issue, as older electronic medical record systems were not designed to work in a network environment. Moreover, regulations pertaining to health information systems are stringent, due to the sensitive nature of medical data. Data in a medical information system comes from different sources including administrative data, health statistics and medical records. As data from different streams will have to be correlated, analysed and processed to generate relevant reports, the data will have to be standardized to make it relevant and usable.

On the other hand, in order to overcome these barriers, it is important to define the success criteria for the project. As done for barriers, three types of success criteria have been identified, again from the systematic research of Schreiweis et al[9]: individual success factors, environmental success factors, and technical success factors.

[9] Schreiweis, B., Pobiruchin, M., Strotbaum, V., Suleder, J., Wiesner, M., & Bergh, B. (2019).
Barriers and Facilitators to the Implementation of eHealth Services: Systematic Literature Analysis. Journal of medical Internet research, 21(11), e14197. https://doi.org/10.2196/14197

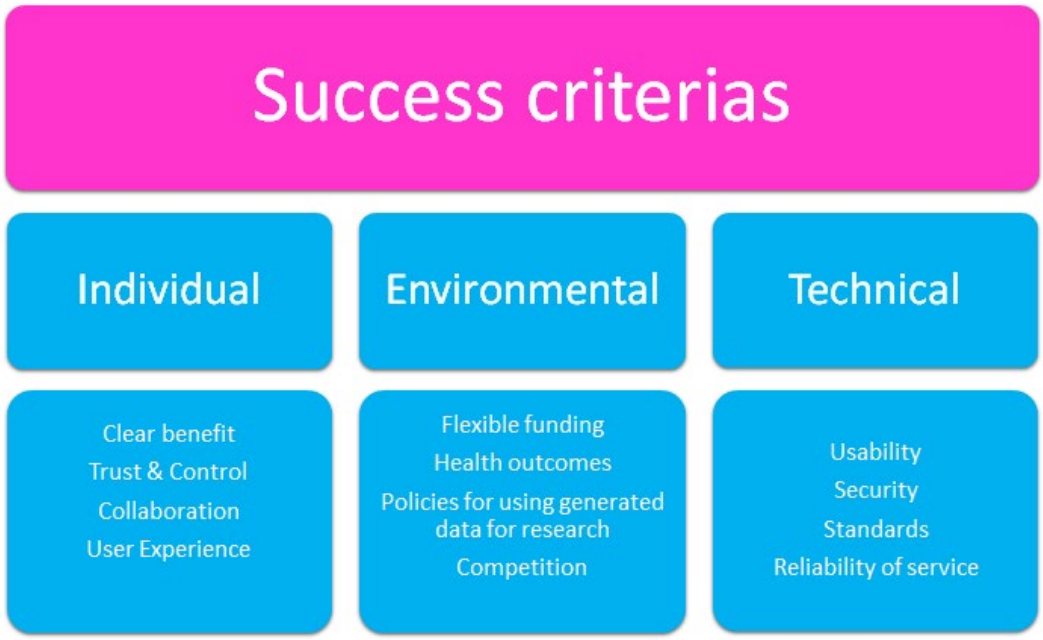

Figure 3: Success criteria for CAPABLE project

Individual success factors

- **Clear benefit:** it refers to generating a feeling of satisfaction with the services that the system offers to users and health organizations. This satisfaction and motivation will be achieved for example thanks to time saving, lower administrative burden, improvement of patient care and quality of life.
- **Trust & Control:** this means that patients and clinicians need to feel that the contents and services have a medical validity. The system has to work well and manage the information in a coherent way according to the situation of users. For further commercialization it is crucial that the system demonstrates to be effective in improving patients' outcomes.
- **Collaboration:** giving users the opportunity to collaborate with the project at different stages gives them a sense of importance. For a successful design of a solution is it crucial to make them part of the development and improvements of the system and services. It should matter to the project that the targeted audience is aware of what it is offered to them. Giving users the opportunity to collaborate with the project can be a win-win situation, because it helps to understand the users and, at the same time, generate the feeling that their opinion about the app they are going to use is being valued.
- **User experience:** any e-health system must provide the best possible user experience in order to keep current users and reach potential users. A good user experience will depend on simple usage, effective results, velocity of the processes, provision of feedback and fast error fixing.

Environmental factors

- **Health outcomes:** this refers to the capability of the system to help, by improving the work system or clinical procedures, the clinical departments to offer a better service that translates into the improvement of the health of patients.
- **Policies for using generated data for research:** The system and the processes carried out will be aligned with the different policies of the relevant health

departments, countries and organizations, following the standards referring to the use of sensitive data and favoring the use of the results for research.
- **Competition:** The system should be sufficiently competitive with the products that already exist in the market and the different tools used by the departments in order to provide added value to the users. To do this, a continuous study of the competition and a continuous improvement of the system must be carried out.

Technical success factors

- **Usability:** the design of the application should meet the needs of the users and it should be ensured that the services are available, efficient and work properly. This success criteria refers to the technical needs that ensure a good user experience must be covered.
- **Standards:** the system must be interoperable to be able to integrate with the standards used in each department such as HL7 and HIS.
- **Security & Privacy:** Privacy refers to the confidentiality of personal information, usually relating to personal data stored on computer systems. Security refers to the protection of computer systems against information, communications, and physical damage. To achieve this, it is necessary to follow the rules and policies established in each place where the system will be used.
- **Reliability of service:** This refers to the stability of communications structures during use. The stability and reliability of eHealth tools, both software and hardware related, are also included.

5. CAPABLE roadmap

As described in the previous deliverable, WP8 proposed to adopt a roadmap for the uptake of e-health solution called CEHRES[10]. In D8.1 a first work on the contextual inquiry has been performed and, in this document, it has been consolidated and extended to the phase value specification. WP8 worked together with WP2 to define the initial interviews of patients and health professionals and used the results to identify unmet needs for the patients and health professionals. In the context of the WP8's work, this result has been used to complete the CEHRES roadmap and refine the contextual inquiry phase and the value specification.

5.1. Contextual inquiry

Thanks to the preliminary interviews performed at the beginning of the project and the periodic support and expertise of clinical partners at NKI and ICSM and patient associations (AIMAC), the consortium identified the following unmet needs for patients (PN) and for clinicians (CN) that have been periodically discussed and revised.

5.1.1. Revised needs

Table 3 describes the revised needs for WP8.

Table 3: Unmet needs for patients and clinicians

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

Need		Description
Patient needs	**PN1**	Cancer treatment causes side effects to the patients. When they are at home in many cases there are not standardized methods to report symptoms. The usual care is to get in contact with the hospital or the clinical center or in case of severe symptoms to directly attend emergency services or specialized units of oncology. A patient at home with specific side effects can manifest worries for the health situation and in some cases do not understand the right level of attention should put on the specific symptoms. The CAPABLE interview with the patient confirms that Patients were interested in using the app for monitoring personal data and symptoms and being able to be remotely followed by the healthcare team.
	PN2	The treatment of cancer requires a multidisciplinary approach of care. Apart from the oncologist, in most centers, other professionals such as nutritionists, psychologists or experts in physical activity are not involved. Therefore, patients in many cases do not receive a complete treatment due to the correlation of those aspects since, for example, a good diet can avoid intestinal problems or physical activity and mental relaxation improve sleep.
	PN3	Better education and support for patients is needed to improve their behaviour regarding the self-management of the disease, adherence to treatment and their quality of life. In many cases, patients are not aware of the things they may be doing wrong or do not know certain habits that are useful for preventing or living with the disease.
	PN4	The opinion of the patients regarding the communication with their healthcare providers is heterogeneous and depends on the clinical center and on their personal experience. For example, from interviews with AIMAC patients, only a half of them is overall satisfied with the communication with the care team, while the other half is not at all or not very satisfied. Therefore, it has been observed that in some centers there is a lack of communication between patients and clinicians or that communication could be better.
Clinician needs	**CN1**	Health care professionals would like to monitor medical and psychosocial parameters, as well as quality of life when patients are at home. It is difficult for clinicians, depending on the center, to follow the patients' progress. In some cases, the clinicians only know about the patient status when the patient comes to the clinical appointments.
	CN2	Clinicians generally need help in decision making and to identify risky and critical situations. Normally this work is done following the recommendations from guidelines. Receiving those recommendations through the decision support system would be very appreciated. In addition, health care professionals would like to receive alerts based on the patient's reported clinical and psychosocial complaints.
	CN3	Today, one of the main challenges for oncologists is to ensure that patients follow the treatments well and that they cope well with the problems presented by the cancer journey. HCPs interviewed mentioned the following needs of patients during their cancer journey, for which often patients ask their help : - Education: information about diagnosis, treatment, symptoms, side-effects (including drug-drug interactions), fitness and exercising, nutrition (including drug-food interactions), energy distribution (fatigue), personal relationships and communication, sex and intimacy, sleep, practical information regarding work, finances and insurances, social activities. - Interventions: such as mindfulness, creative therapy, relaxation and interventions to promote adherence to treatment, to accept reduced QoL/physical disabilities, to promote positive thinking, sleep improvement, to promote lifestyle changes including physical activity. - Psychological support

	CN4	The tools used in the centers need to be interoperable with the centre's own protocols and above all to integrate the HIS. The tools that do not do so pose a greater workload for the clinician, since they must use more than one tool
	CN5	In many centers there is no constant communication between departments. For a correct cancer treatment, it is important that all the clinicians involved in the follow-up of a patient are well organized and that communication between them is as good as possible. Otherwise, these problems are transferred to the patient, who does not receive a good treatment.

5.1.2. Stakeholder analysis revision

From the consolidated needs the table of stakeholders proposed in D8.1 (see Table 4) has been revised and contextualized taking into account the identified needs.

Stakeholder	Impact	Role	Project relation	Unmet needs
Patient	HIGH	End-user	• 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. • A reference point, always available anytime, anywhere in case of special needs arising during treatment.	PN1, PN2, PN3, PN4
Oncologist	HIGH	End-user	• 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.	CN1, CN2, CN3
Nurse	HIGH	User	A new way to improve nursing activities thanks to the improvement in treatment support and management of resources and time.	CN1, CN2, CN3
Nutritionist	MEDIUM	User	New way to follow and support the nutrition and diet of patients without needing frequent appointments and possibilities to continuous evaluation.	CN1, CN2, CN3
Surgery	LOW	User	New way to support decisions and improving communication with clinicians	CN1, CN5
Radiologist	LOW	User	New way to support decisions and improving communication with clinicians.	CN1, CN5
Social Worker	LOW	User	New way to motivate patients and improve their quality of life.	CN5
Psychologist	MEDIUM	User	New way to support mental health and quality of life status of patients without needing frequent appointments and possibilities to continuous evaluation.	CN1, CN5
Caregivers	MEDIUM	User	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.	PN1, PN2, PN3, PN4

Hospital	HIGH	Buyer	• 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.	N/A
Patient Organisations	HIGH	Buyer	A medical solution to obtain better support and measures from patients during treatment.	N/A
Medical Organizations	MEDIUM	Buyer	An opportunity to foster patient self-empowerment, further optimizing the usage of healthcare resources	N/A
Healthcare authorities, agencies and services	MEDIUM	Buyer	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.	N/A
Health IT Businesses	MEDIUM	Buyer	A platform that enables the conception, design and delivery of innovative "plug-in" modules for measuring treatment variables in cancer patients.	N/A
Scientific and research community	MEDIUM	Buyer	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.	N/A
Policy makers	HIGH	Buyer	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.	N/A

Table 4: Stakeholders of CAPABLE

5.1.3. Stakeholder mapping

Stakeholder mapping is the visual representation of the stakeholder analysis. The stakeholders are organized according to the key criteria with which they will affect in the development of CAPABLE project. For this organization, different aspects were taken into consideration as interest, influence, emotional, organisational or role within CAPABLE activities. Considering these aspects, the stakeholders of CAPABLE were organized in 4 groups:

- Stakeholders to manage closely: policy makers, patient organisations, medical Organisations, healthcare authorities and health IT business.
- Stakeholders to keep informed: nurses, nutritionists, psychologists, caregivers, scientific and research community.
- Stakeholders to meet their needs: patients, oncologist and hospitals.
- Stakeholders to keep into account: surgery, radiologists and social workers.

Figure 4 shows the stakeholder map of CAPABLE.

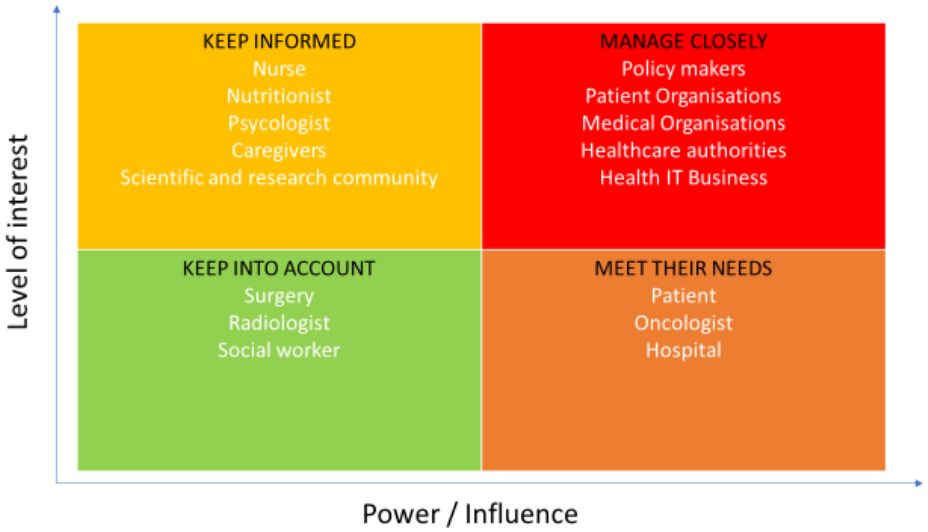

Figure 4: CAPABLE´s stakeholders' map

5.2. Value specification

From the contextual enquiry phase the project elaborated on the issues (needs) to propose specific solutions that generate value for the specific actor. Thanks to this analysis it was possible to define the goals the technology should reach according to stakeholders.

A proper value specification assists in finding out what kind of goals the technology should reach according to stakeholders, and what should be done to reach these goals. Also, the value specification forces the development team to be precise, which helps them to deal with many implementation-related issues like adoption, financing, and use on the short and long term in time.

For the case of CAPABLE two main actors have been considered at this stage: patients and health care professionals. These values (See table 5) have been specified in terms of technical requirement in D2.1.

Table 5: Value proposition of CAPABLE

Value		Description
Patient values	**PV1**	Technology to **monitor the evolution of the disease**. The monitoring of personal data and symptoms through a mobile app makes possible a remote follow-up of patients and allows the healthcare team to know the current patient's situation without waiting for the next appointment.
	PV2	Provision of a **multidisciplinary management of the disease**, involving not only the oncologist, but also other professionals like the nutritionist, the psychologist, and physical activity experts. Thanks to this, the patient can learn different aspects related to their disease and improve each one of them.
	PV3	CAPABLE must represent an opportunity for patients to learn and to improve their behaviour to have a better quality of life. This **learning experience** will be delivered through an app that includes the *capsules* (kind of non-pharmacological interventions to improve the mental wellbeing) and different educational features, which will enable patients to learn a better lifestyle, develop awareness, be able to listen to their body, and to better report symptoms and signs.
	PV4	Provision of a **communication channel between patients and the healthcare team**. As it has been noticed, the patients in some centers feel that the communication is not sufficient. CAPABLE system provides a communication channel through the mobile app that improves this fact, giving the possibility of keeping in touch clinicians and patients.
Clinician values	**CV1**	Possibility of remote motoring. CAPABLE system will provide **remote monitoring** of the progress of the disease including symptoms, side effects and overall quality of life and wellbeing through an application without the need of a visit making the clinicians job.
	CV2	Use **AI** to process this monitoring data and provide a flexible clinical decision support system to identify risky and critical situations (adverse events of therapy, treatment change, referral to another specialist etc.) **following the recommendations from evidence-based guidelines.** Immediate notifications should be displayed when the patient's wellbeing deteriorates and/or if the patient enters acute moderate/severe medical complaints.
	CV3	Provide digital tools to patients to foster adherence and assist to face the daily problems of the cancer journey. The tools must provide features that help clinicians to follow the recommendations and to involve patients during the cancer journey improving the follow up.

	CV4	Deemed necessary by the clinicians for successfully implementing CAPABLE, **integration of CAPABLE and the currently existing electronic health record (EHR) is desirable**. An exchange between the two systems is preferred as the use of two systems (and requiring input of identical data in two different systems) can be seen as redundant. This is for sure a desirable feature for clinicians, however the feasibility of this integration depends on several factors not only related to the clinical management of the patients, but also technical and organizational. It was decided that EHR data will be copied during patient data import in the enrolment phase.
	CV5	Provision of a system that **foster interdepartmental collaborations** to offer integrative services with Supportive Care Team and other specialists (e.g., nutritionists, clinical psychology, social services). CAPABLE will promote the different supportive care options within the centers and will inform the patients of these options available

The values have been used to define the specification of the CAPABLE technology and they will be the first pillar to build the business model of the project, that will be defined at year two of the project (D8.4 Exploitation plan and business models V1, delivery at month 24).

6. Technology vigilance

In the previous deliverable D8.1 a first research on key players and competitors has been performed and in this document it has been consolidated and updated with additional information. To this purpose, it has been performed and updated on the existing solutions in the market, a review of the existing patents, an analysis on the technologies used in the clinical centers of CAPABLE consortium and an analysis of some of the most relevant competitors.

As this task must be periodically reviewed during the project, this information is also available on an online document available in the following URL :

https://docs.google.com/spreadsheets/d/15du7mwLKBI2XYBMOFOMM_GU9YouO59cFggJkX1c8HrY/edit?usp=sharing.

6.1. Update on existing commercial solutions

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. In this section, we update the first research done in D8.1 finding other six products to analyse.

For these products, the overall results found, taking in account different aspects analysed, are:

Features: most of the tools reviewed have some common features, such as patient data visualization, management and analytics, patient support, remote monitoring and handling patient clinical data. Only those systems that have patient-facing tools also collect patient data such as symptoms and few of them physiological and physical activity data.

Technical approach: web-based solutions predominates for the clinician's applications and mobile solutions are usually found for those that involve patients. One of the solutions also includes wearable technology.

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

Target profile: Health care professionals and patients predominate as end-users of the solutions. Half of them provide applications for clinicians and patients integrated in the same system. Only in one case, the caregivers are included as end-users of the patient application.

Type of cancer: The tools analysed are not cancer type specific, they are designed to be used for clinical application in patients with any cancer type.

Stage of the disease: Most solutions are focused only on follow-up and treatment, but one of them is specific only for treatment.

Use of guidelines: Only one of the solutions reported the use of guidelines or clinical pathways related to cancer therapeutics while the rest do not give this information or do not follow them.

FDA and CE mark: Of the 6 analysed tools, none of them have a FDA or CE marked and there is no evidence of the process of obtaining it.

Patents and IPR: The companies analysed don´t provide information about patents or IPR related to their products. Therefore, a search focused on patents related to similar systems or technologies could complement this information that is not provided.

Price: Only one of the tools provides information about the price. In this case, as it is a mobile application available in the app stores is not much significant as most of the companies based their prices 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. In this case, none of the six tools have published information about the studies or research publication in scientific journals or congress.

Annex 10.2 includes the comparative table with the overall information collected from the product available on the market. The table is an update of the one presented in D8.1.

6.2. Patent review

WP8 also performed a patent review of the available registered patents that can be related to the project. Different types of keywords have been used in the web of WIPO IP portal. The keywords are described in the next table.

Keywords
Monitor cancer treatment symptoms
Melanoma cancer
Kidney cancer
Predict toxicity
Computer interpretable guidelines
Symptoms management
Digital intervention cancer mobile

Table 6: Keywords used in WIPO IP portal

The main results for this research are that the majority of the patents related to cancer are in the pharmacological field and describe agents that are useful to reduce symptoms of cancer patients during specific treatment (e.g., chemotherapy or immunotherapy).

A little proportion of these patents are ICT approaches that provide some similar approach of CAPABLE to the problem. The most relevant systems that have been identified are:

1. System to manage symptoms
2. Computer interpretable guidelines
3. Assistive systems for multi therapy delivery

Most of the inventions are generally new (published less than 5 years ago) and many of them apply in the U.S.A. Figures 5 and 6 refer to two patented systems.

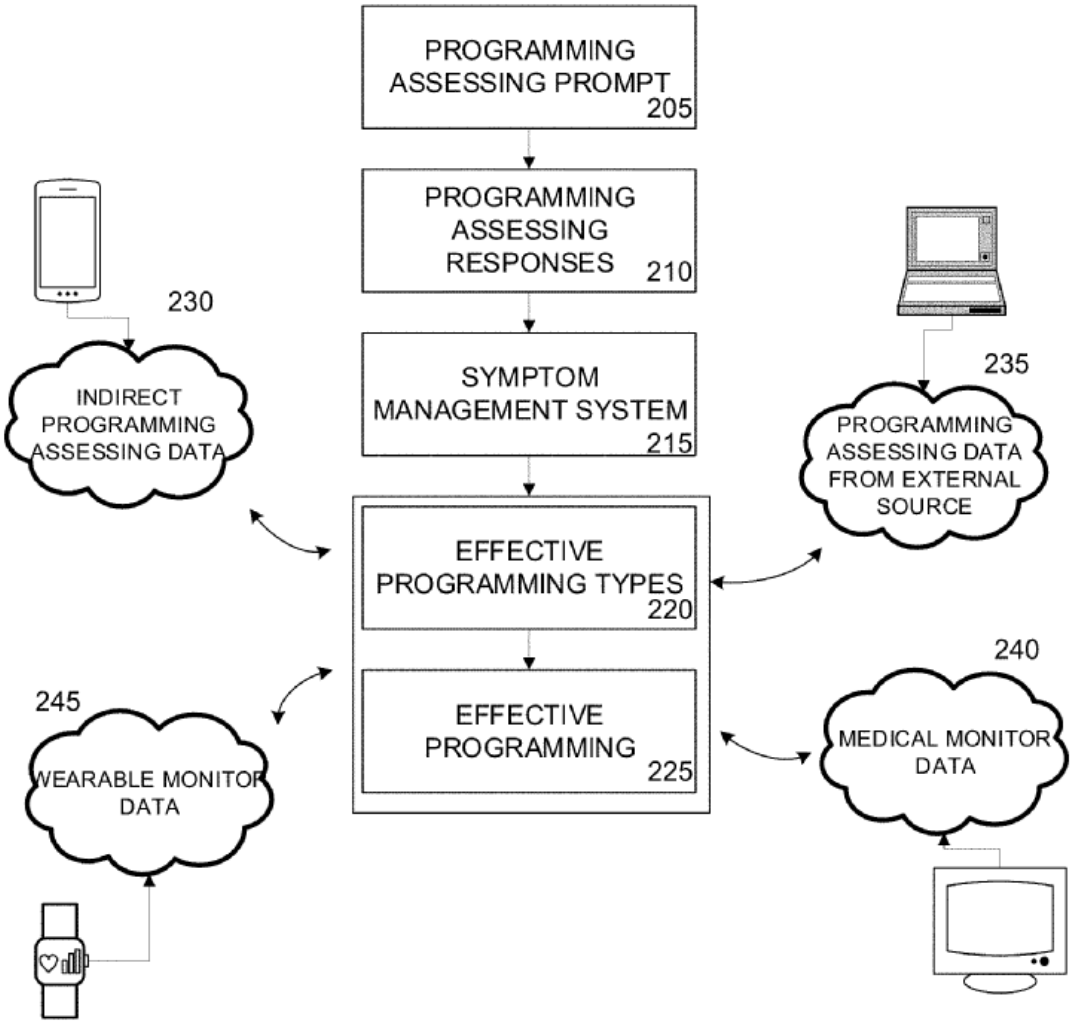

Figure 5: Symptom management system[11]

[11] https://patentscope.wipo.int/search/en/detail.jsf?docId=US215058646&_cid=P10-KIJ44R-83103-1

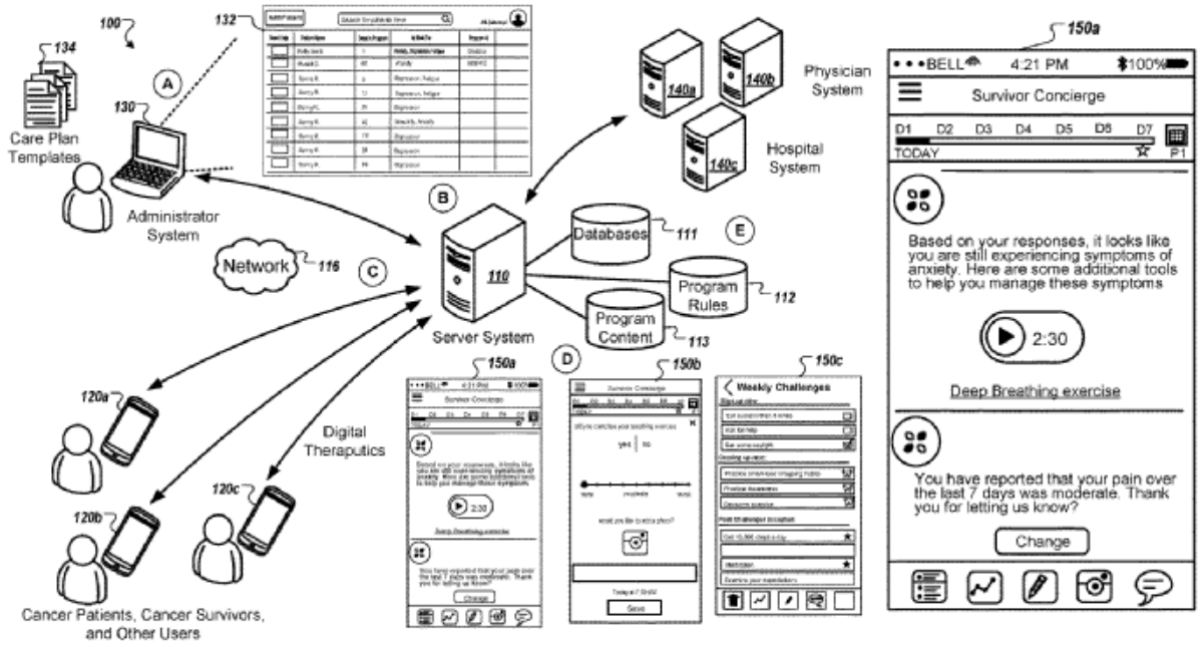

Figure 6: Diagram of Systems and methods for providing dynamic, individualized digital therapeutics for cancer prevention, detection, treatment, and survivorship[12]

WP8 identified possible systems and methods that have been protected with Patent IP. In most of these competitive solutions the patent applies in U.S.A and not in Europe. Courtesy to the solid background of the Consortium it is unlikely to infringe patents because most of the work is based on published results of previous research work (e.g., Computer Interpretable Guidelines, Proforma). Furthermore, the core components that are proposed in CAPABLE differentiate from the existent solutions for being semantic interoperable and based on the implementation of clinical guidelines.

All the details of the selected patents for CAPABLE can be found in the Annex 10.3

6.3. Available technology in the CAPABLE clinical centers

At this stage of the research, WP8 also explored the available digital solutions to manage remotely cancer patients in the two project's hospitals: NKI and ICSM. This study just focuses on solutions to be used remotely by the patients and to not include other technologies used in the clinical practice (e.g., clinical history, clinical report form, PACS technology etc)

6.3.1. Technology available in NKI for Melanoma patients

Currently, patient can access to a hospital web portal[13] in which it is possible to consult appointments, medical records (results of lab tests/scans) and also fill questionnaires. For cancer patients there is a functionality to track the quality of life periodically (using ORC-

[12] https://patentscope.wipo.int/search/es/detail.jsf?docId=US249979440&_cid=P22-KA-GXS1-98028-2
[13] https://www.avl.nl/mijnavl/

QLQ-030). The questionnaire is presented to the patient every 3 months for the first year, every 6 months for the second year, and yearly for the third year and after. The patients receive reminders to fill the questionnaire by email. In the next future it will be possible to see these results directly in the clinical history of the patients.

In the web portal it is also possible to find Information leaflets that are selected by the health care professional depending on the clinical profile of the patients. For the case of the melanoma the following topics are available: Melanoma diagnosis, exams and therapies.

NKI also started to include some digital therapeutic tools that might be competitor of CAPABLE: Kaiku Health and Untire App.

Kaiku Health

Kaiku Health is a platform for digital health interventions. It provides patient-reported outcome monitoring and intelligent symptom tracking. The use of Kaiku Health helps cancer clinics providing optimised care through timely symptom management and improved workflow.

In NKI 17 patients are included in the pilot phase, doctors/nurses and patients provided positive feedback. More details on this solution will be provided in the next chapter.

UnTire app

Untire gives to patients the tools to reduce cancer fatigue (CRF) and get back to living life.

- Easy to use app with videos, tutorials, and daily tips
- Online support community with other CRF peers
- Comprehensive, step-by-step program
- Themes such as Anxiety and Sleep help you better understand fatigue
- Tips and reminders to improve lifestyle
- Exercises for body and mind to increase energy level
- Weekly reports to measure your progress

UnTire app is available in the App Store/Google Play store. Access code is necessary to sign up. Currently, patients can register at the UnTire website for a free access code, which grants access to the app for 1 year. In NKI the physicians and support consultants might recommend the app to patients with CRF. It is not structurally presented to patients as a support tool. More details on this solution will be provided in the next chapter.

6.3.2. Technology available in ICSM for Renal Cell Carcinoma (RCC)

ICSM has a pathology registry developed using RedCap[14] to collect information about demographics, tumour characteristics, line therapies, metastasis, toxicities and other oncological treatments. The data is entered by clinicians and health researchers manually. Clinicians can use HIS to view agenda, manage hospitalizations and outpatient visits, patient can access to part of this information through a dedicated ICSM portal (section "Referti Online") or the dedicated regional portal ("Fascicolo Sanitario Elettronico" on Lombardy region website). ICSM RCC patients do not have access to a platform for digital health

[14] https://www.project-redcap.org/

interventions. They usually receive information leaflets at the beginning of the therapies to inform them about possible adverse events and detailed information on the therapy.

6.4. Case studies

To understand in depth the type of tool that is provided in the market today, some relevant cases that are used for support during the cancer journey have been selected for a more qualitative study. For this, several characteristics of the tools have been analysed:

- Technical characteristics: features of the tool, technical approach, and target users.
- Clinical characteristics: clinical data managed, type of cancer related and the stage of the disease.

The products analysed are the following:

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. It provides patient reported outcome monitoring and intelligent symptom tracking through symptom management and improved workflows. This product is classified as MDD class I medical device.

The kaiku application provides personalized support for patients throughout the different phases of therapy. It reduces uncertainty around symptoms by educating patients on their self-management strategies applying algorithms to triage patients' symptom reports, which helps clinical staff prioritise their daily work. Clinics using Kaiku Health report decreased phone call burden and more efficient patient visits and contacts.

Kaiku Health characteristics are the following:

- Features: Provision of dashboards, reports and imaging examination for clinicians.
- Technical approach: it is available as a mobile app application or web dashboard application.
- Clinical data managed: The solution works with genetic, quality of live, chemotherapy, tissue and immune indicator data.
- Target users: clinicians and patients.
- Type of cancer: It is not specific for a type of cancer but is reported by them for breast, prostate and other urological cancers, lung, colorectal and other GI cancers, hematologic, melanoma and other skin cancers, gynaecological, head and neck cancers
- Stage of the disease: This tool is designed to be used in treatment and follow up phases.

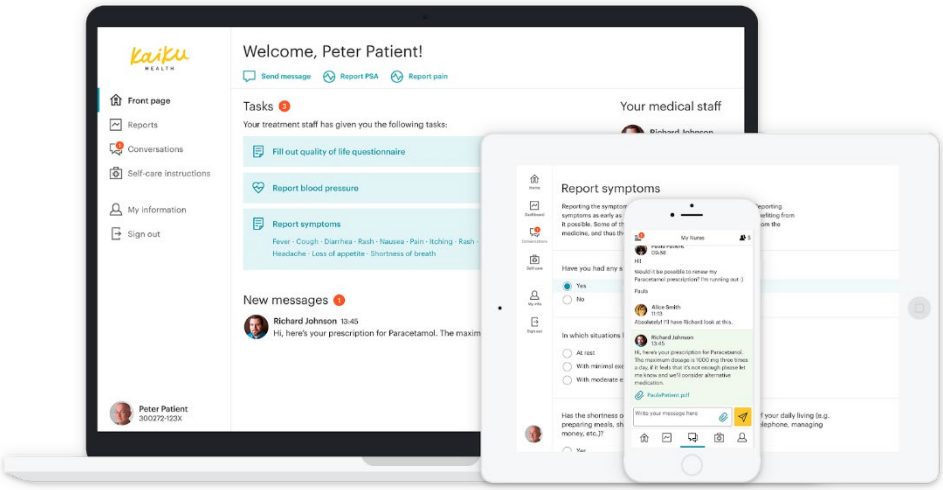

Figure 7: Kaiku Health patient interfaces

Untire

Untire is a digital platform that provides patients with additional support for fatigue beyond cancer through a mobile application that helps healthcare professionals with a better understanding of the patient´s progression towards fatigue.

Untire application helps patients to get more energy physically and mentally providing education about fatigue, ways to relax and worry less, exercises to deal with stress and anxiety, tips for better sleeping, ways to manage their own energy during the day, physical exercises to improve energy and weekly energy measurement. The users of Untire reported that they have more energy and improve their capacity to do more activity after a few weeks of use.

Untire characteristics are the following:

- Features: reports on physical activity, sleeping, etc., overview of historical data and progress, tips and educational content provision.
- Technical approach: provides a mobile application for cancer patients.
- Clinical data managed: It calculates and reduces fatigue managing data related with physical activity, behaviour, anxiety, stress, depression and sleeping.
- Target users: patients.
- Type of cancer: It is not cancer type specific.
- Stage of the disease: the application is designed to be used at any phase of the cancer journey.

Figure 8: Untire application interfaces

Biofourmis

Biofourmis provides a platform that collects and interprets vast amounts of population metadata and compares it to real-time patient physiological signals to provide a clearer picture of chronic patients and their disease trajectory. This real-time picture designed to help clinicians predict and prevent serious medical events. In addition, Biofourmis provides patients with a wearable developed to monitor patients specifically for the platform.

The Gaido system of Biofourmis provides a Prescription Software to continuously monitor and detect early signs of deterioration in oncology patients, pre- and post- treatment. This system enables clinicians to prevent avoidable readmissions and helps spare patients from developing infections, sepsis, dehydration, and other conditions. This reduces length of stay, 30-days rehospitalization and overall healthcare spending while improving quality of life and function in patients with cancer.

Biofourmis characteristics are the following:

- Features: the platform provides an AI-based ecosystem (machine-learning platform) implementing deep neural networks. Also, the features specific for clinical uses are EMR integration, medication delivery, clinical call center, predict and/or detect serious medical events and personalized feedback for patients
- Technical approach: For patients, a wearable and a mobile app are designed, for clinicians, a mobile app and for nurses, a web-based dashboard.
- Clinical data managed: the solution works with population metadata and real-time patient physiological signals.
- Target users: patients, clinicians and nurses.
- Type of cancer: it is specific for patients with solid tumours.
- Stage of the disease: the tool can be used for diagnosis, treatment and follow-up phases.

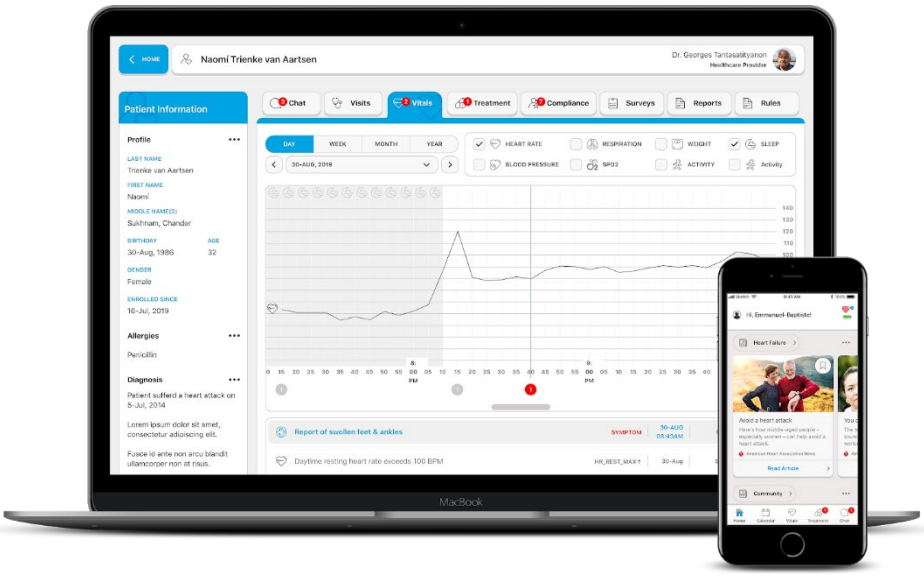

Figure 9: Biofourmis application interfaces

Oleena

Oleena is a platform specialized in digital therapeutics in oncology for patients and their care teams. This platform provides personalized symptom recommendations and symptom reporting thanks to the mobile app and a dedicated interface for the care teams to follow up patient's symptoms and progressions.

The application for patients delivers real-time, personalized recommendations every time a patient reports a symptom and guides and support according to the individual needs. On the other hand, the application for healthcare providers gives them access to automated and adaptive insights on their patient’s symptoms.

Oleena characteristics are the following:

- Features: for patients the application provides symptom management, monitoring the progress of symptoms and activities and helpful resources. For the healthcare providers, the main features are an enrolment interface, symptom triage system and a dashboard with the symptom history of patients.
- Technical approach: it provides a mobile application for patients and web application for healthcare professionals.
- Clinical data managed: the solution works with personal data of patients and symptoms related data.
- Target users: patients and healthcare providers.
- Type of cancer: It is not cancer type specific.
- Stage of the disease: the system is designed to be used at any phase of the cancer journey.

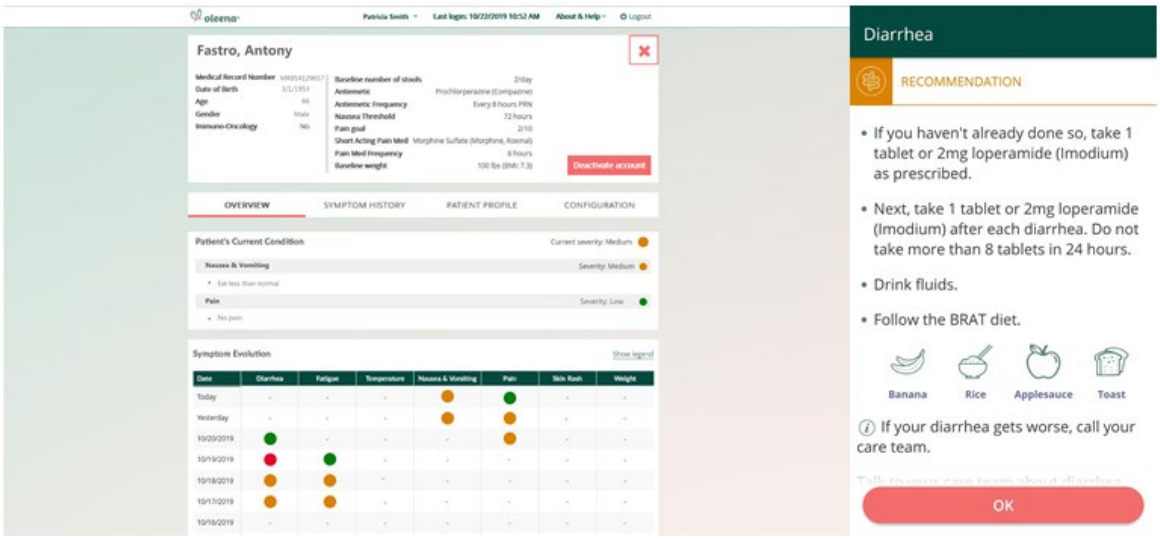

Figure 10: Oleena application interfaces

From the competitor's analysis that has been performed during the first year of the project, the main conclusion is that several needs (presented in 5.1.1) seem to be already covered by market solutions. The vast majority include remote monitoring systems (PN1, CN1) and different methods of intervention and education have been found for patients (PN3, CN3). It has also been seen that one of the most outstanding features of the tools currently used is the patient-clinician communication channel (PN4) and that the more complex systems include a decision support system as a tool for clinicians (CN2).However, interoperable systems with the protocols used in hospitals, or integration of evidence-based guidelines for both patients and doctors, are scarce, as well as tools that allow their use for all roles involved in the cancer journey, which translates into a **lack of integrated care services** able to encompass different health professionals (e.g., psychologist, nutritionists) and also home caregivers, whose needs are often neglected. Therefore, although there is a wide variety of options in the market, as there are still needs to be covered, CAPABLE has the opportunity to provide a more complete (integrated care) system for a greater variety of users.

7.Intellectual Property preliminary inputs

The previous deliverable (D8.1) reported the innovation potentials of the CAPABLE project. A list of innovative elements has been identified and discussed with the consortium (see chapter 8.1 of D8.1). In this document a new update is provided focusing on the following characteristics of the innovative components previously described to:

- Detail the nature and the form of the results / components to be exploited
- Understand the partner position on IPR for the specific component /result
- Understand how the specific module / results can be scalable to other health problem / or other types of cancer

From the updates of the IPR table is is clear that most of the innovation will be the development of the specific component and the conceptual models representing the approach of the solution. It is very clear that it will be possible to scale the results to other types of cancers and in some cases some effort will be required to adapt to the new disease type.

Thanks to these preliminary inputs it will be possible to elaborate a first draft proposal of the IPR strategy for the consortium that will be presented and documented during the second year of the project.

The details of the IPR Matrix are provided in the Annex 10.4

8.Stakeholders questionnaires

CAPABLE has been conceived as a solution to improve the process of cancer treatment when patients are out of the hospital. Considering this initial approach, we consider it relevant to start approaching in the next months the hospital manager and directors of the oncology units that can be potential buyers or external supporters / collaborators of the project.

WP8 prepared a survey to be used to assess the clinical needs and interests and assess the service that has been developed according to the project progresses on the technical and design side.

The questionnaire has the following structure:

1. Assessment of current practice. The section aims to enquire about the presence of any other digital solution for remote follow up of cancer treatments, and about involved professionals;
2. Assessment of volume of services and costs. This part of the interview gathers information about the volume of patients, cost of treatments and budgets for solution to monitors cancer patient at home;
3. Presentation and assessment of the CAPABLE concept. This section presents the CAPABLE concept and then it requires the participants to assess the overall concept, feasibility of the implementation in a hospital, suggested modifications, barriers to the markets, and the founding schema.

This questionnaire will be published online, and different teleconference meetings will be set-up to perform a virtual face to face interview in which also other qualitative aspects of the CAPABLE service will be gathered. The detail of the questionnaire can be found in the Annex 10.1.

9.Conclusions

During this first year of the project WP8 contributed to the design of the CAPABLE services by providing technological intelligence thanks to the market research in digital diagnostics.

In this document, a more specific analysis has been performed on the specific CAPABLE end users (melanoma and kidney cancer patients) and specific information about available technology in the market and in the clinical centers of the project (ICSM and NKI) has been extracted. Furthermore, a more detailed analysis of stakeholders, value and barriers to market has been performed. WP8 adopted the CEHRES methodology that will be used also in the next WP activities to define the business models and IPR strategies (planned for month 24). The activity of research will also continue in the next years with a close liaison with the rest of the WPs in order to:

- Assess the preliminary solution with health professionals, patients (WP7) and understand viability and acceptance of the service;
- Perform specific interviews to hospital managers and experts in innovation in digital health to be able to draw a proposal for further commercialization and exploitation of the CAPABLE project;
- Provide inputs on novel solutions and provide suggestions on possible service improvements (WP2);
- Collaborate with the technical WPs in order to define the best IPR strategy for the exploitation of the technology.

10. Annexes

This chapter contains the annexes that have been commented on in the previous sections.

10.1. Stakeholder questionnaire

10.1.1 CAPABLE-Hospital Manager Questionnaire

[The purpose of these questions is to collect information about the current clinical practice related to cancer patients and the management of the severe symptoms during treatment]

1. In your hospital do you have any service to remotely follow up cancer patients?
   - Yes
   - No
2. If you answered "Yes", please indicate which tele-monitor tool is available in your hospital.

3. If you answered "No", please indicate if a tool for patient's follow-up is used in other hospital services (other than cancer patients service). Indicate the tool name and the service that uses it.

4. What are the professionals involved in the follow-up cancer patient's service?

5. Is there any specialized professional to perform the remote follow up and support service for cancer patients (also by telephone, email, etc.) ?
   - Yes
   - No
6. If you answered "Yes", please indicate the role responsible for this task.

7. Do you have a specific department to manage the care of cancer patients with severe symptoms during treatment?
   - Yes
   - No
8. If you answered "Yes", please indicate the hospital service:
   - Emergency service
   - Oncology service
   - Internal medicine service
   - Other: _____

10.1.2 Cost Assessment

[The purpose of these questions is to collect information about the cost of clinical practice for cancer patients]

1. What is the served volume of attended cancer patients in the hospital
2. Number of patients that have been diagnosed with kidney and melanoma cancer in the last year

   Kidney: _____ Melanoma: _____

3. Cost of radiotherapy cycle _____
4. Cost of chemotherapy cycle _____
5. Cost of immunotherapy cycle _____
6. Unitary cost of appointment in hospital _____
7. Average of appointment duration _____
8. Unitary cost of hospitalization _____
9. Average of hospitalization duration _____
10. Cost of dietary lifestyle intervention (patient / year) _____
11. Cost of exercise lifestyle intervention (patient / year) _____
12. Your hospital has a budget to invest in tele-monitor apps for cancer patients?
    - Yes
    - No
13. If you answered "yes", how does the hospital manage the acquisition of these apps?

10.1.3 Introduction to CAPABLE

CAPABLE is an overall system that combines advanced technologies for data and knowledge management with a sound socio-psychological approach in order to develop a coaching system for improving the quality of life of cancer home patients. The system aims at early detecting and managing cancer-related issues supporting

oncologists to remotely deliver timely recommendations and advice to their patients. Also, the system will be able to self-adapt to a specific patient and to react according to modifications of the patient's dispositions that are to be expected, due to the obvious psychological issues every cancer patient must face.

[The interviewer will also share more information and a quick demo using the latest version of the available prototype]

1. What is your overall opinion of the CAPABLE Concept?

2. Do you see feasible the implementation and adoption of a system like CAPABLE in your hospital?
   - Yes
   - No
3. Which major modifications would be necessary for its adoption?

4. What are the main barriers you identify for the adoption of this system in clinical practice?
   - Integration with Hospital Information System
   - Rejection by healthcare professionals
   - Current use of a similar system
   - Others: _____
5. Who should pay for this system?
   - Oncology service
   - Economic and financial direction of the hospital
   - National Healthcare System
   - Others: _____
6. What is for you, the best funding schema for this system?
   - Fee for number of patients
   - Fee for number of licenses
   - Annuities/monthly payments
   - Others: _____

10.2. Update on existing commercial system

10.2.1. General information

Company	Website	Product	Description	Features	Clinical data
Appli chimio	https://applichimio.com/	Appli chimio	Appli Chimio is a remote monitoring program in your home if you are receiving treatment for your cancer, either chemotherapy or targeted oral therapy. Appli Chimio offers remote home monitoring associated with the coordination of city-hospital caregivers and allows better management of these undesirable effects and better compliance.	sympton evaluation, educational contents, alerts	symptoms
Cureety	https://www.cureety.com/	Cureety	Cureety is a digital platfom that brings benefit from a clear and synthetic view of patients' health status evolution. Manage patients' care throughout their journey: adjust dosage, move forward consultations and paraclinical exams, schedule hospital day care, securely share medical prescriptions, etc.	Patient Reported Outcomes collection, Care management traceability,Shared clinical record, PRO-CTCAE and CTCAE compliant questionnaires, Proprietary therapeutic advise library, Day hospital care planning and scheduling, Monitoring dashboards, synthetic reports, data visualisation	QoL, symptoms, pharma
VivaInk	https://www.vivalnk.com/solutions/chemotherapy-remote-monitoring	AlacrityCare	AlacrityCare is an early-stage digital health company offering new ways to manage the side effects of cancer treatments. Through the use of continuous monitoring solutions, AlacrityCare's data driven software provides real time guidance that enables safer and more personalized interventions than ever before. For patients, our solutions enable better self-management of side effects and peace of mind knowing providers and care givers have real-time visibility into their health conditions	- Remote monitoring and analytics solution to connect providers with patients throughout the treatment journey - Predictive algorithms designed to offer decision support and notifications for personalized, early intervention to avoid costly events	- ECG Rhythm - Body Temperature - Heart Rate - Respiratory Rate
Oleena	https://oleena.com/	Oleena	Oleena is a platform specialized in digital therapeutics in oncology for patients and their care teams. This platform provides personalized symptom recommendations and symptom reporting thanks to the mobile app and a dedicated interface for the care teams to follow up patient's symptoms and progressions. The application for patients delivers real-time, personalized recommendations every time a patient reports a symptom and guides and support according to the individual needs. On the other hand, the application for healthcare providers gives them access to automated and adaptive insights on their patient's symptoms.	for patients the application provides symptom management, monitoring the progress of symptoms and activities and helpful resources. For the healthcare providers, the main features are an enrollment interface, symptom triage system and a dashboard with the symptom history of patients.	Personal data symptoms.

Company	Website	Product	Description	Features	Clinical data
Untire	https://untire.me/	Untire app	Untire is a digital platform that provides patients with additional support for fatigue beyond cancer through a mobile application that helps healthcare professionals with a better understanding of the patient´s progression towards fatigue. Untire application helps patients to get more energy physically and mentally providing education about fatigue, ways to relax and worry less, exercises to deal with stress and anxiety, tips for better sleeping, ways to manage their own energy during the day, physical exercises to improve energy and weekly energy measurement. The users of Untire reported that they have more energy and improve their capacity to do more activity after a few weeks of use.	-reports on physical activity, sleeping, etc.., -overview of historical data and progress - tips and educational content provision	physical activity, behavior, anxiety, stress, depression and sleeping
Chemowave	https://chemowave.com/	chemowave	chemoWave is a health app for cancer patients to track their symptoms, medications, sleep, steps, and other important activities. chemoWave provides people going through cancer with personal insights that enable them to work more effectively with their doctors or care team to better control the side effects and symptoms they experience during cancer.	- Update Overall Condition - Track Symptoms & Mood - See Personalized Insights - Log Activities like Medication, Steps, Sleep: - Use a Quick Log to easily track your cancer journey	symptoms, medications, sleep, steps, and other

10.2.2. Information related to disease and technical approach

Company	Target profile	Type of cancer	Stage of disease	Technical approach	Use of guidelines
Appli chimio	patients, clinicians, caregivers	N/A	follow-up and treatment	mobile app	N/A
Cureety	clinicians	N/A	follow-up and treatment	Web application	Y
VivaInk	patients and healthcare providers	N/A	treatment	Predictive algorithms	N/A
Oleena	patients and healthcare providers	N/A	all	mobile app for patients web app for clinicians	N/A
Untire	patients	N/A	follow-up and treatment	mobile app	N/A
Chemowave	patients	N/A	follow-up and treatment	mobile app	N/A

10.3. Patent Review

ID	Title	Description	International/Local	Publication date	Link

WO2020044124	RELIEVING CHRONIC SYMPTOMS THROUGH TREATMENTS IN A VIRTUAL ENVIRONMENT	The various embodiments disclosed herein includes a virtual environment (VE) system, and method thereof for reducing chronic symptoms in relation to menopause and chronic diseases such as, but not limited to, cancer. The symptoms include, but are not limited to, hot flashes, anxiety, chemo brain, immune system, stress, pain, fatigue, hair loss, nerve and muscle problems such as numbness and tingling, mood changes, and so on.	International	05.03.2020	https://patentscope.wipo.int/search/es/detail.jsf?docId=WO2020044124&_cid=P22-KAGXS1-98028-2
US20190243944	Systems and methods for providing dynamic, individualized digital therapeutics for cancer prevention, detection, treatment, and survivorship	Methods, systems, and apparatus, including computer programs stored on a computer-readable storage medium, for providing dynamic, individualized digital therapeutics for cancer patients and cancer survivors.	USA	08.08.2019	https://patentscope.wipo.int/search/es/detail.jsf?docId=US249979440&_cid=P22-KAGXS1-98028-2
US20130095459	Health monitoring system	A monitoring system for a person includes a processor coupled to one or more wireless nodes; a wearable mobile appliance in communication with the client and one or more wireless nodes; and one or more computer implemented agents with rules executed by the processor, the rules being selected to respond to a client communication relating to a predetermined health condition, each agent communicating with another computer implemented agent, the client or the treatment professional, and upon receiving a communication from the client, the processor selecting one or more computer implemented agents to reply with an instruction on healthy client behavior.	USA	18.04.2013	https://patentscope.wipo.int/search/es/detail.jsf?docId=US77124290&_cid=P22-KAGY2L-01714-9
US20190043501	PATIENT-CENTERED ASSISTIVE SYSTEM FOR MULTI-THERAPY ADHERENCE INTERVENTION AND CARE MANAGEMENT	A patient-centered assistive system for multi-therapy adherence intervention and care management. The intervention may be implemented in the form of a wearable device providing one or more features of medication adherence, voice, data, SMS reminders, alerts, location via SMS, and 911 emergency. Embodiments of the present disclosure may function in combination with an application software accessible	USA	07.02.2019	https://patentscope.wipo.int/search/es/detail.jsf?docId=US236969618&_cid=P22-KAGY49-02205-10

		to multiple clients (users) executable on a remote server to provide patient education, support, social contact, management of daily activities, safety monitoring, symptoms management, adverse events reporting, as well as support for caregivers, and feedback for healthcare providers during the management of patients with multimorbidity. Alternative embodiments implementing monitoring and intervention include using mobile apps or voice-controlled speech interface devices to access cloud control services CAPABLE of processing automated voice recognition-response and natural language understanding-processing to perform functions and fulfil user requests.			
AU2018207068	Medical assistant	A wearable device can present virtual content to the wearer for many applications in a healthcare setting. The wearer may be a patient or a healthcare provider (HCP). Such applications can include, but are not limited to, access, display, and modification of patient medical records and sharing patient medical records among authorized HCPs.	Australia	19.07.2018	https://patentscope.wipo.int/search/es/detail.jsf?docId=AU248469142&_cid=P22-KAGY49-02205-10
WO/2013/088344	(EN) SYSTEM AND METHOD FOR CREATING COMPUTER INTERPRETABLE GUIDELINES USING A KNOWLEDGE ACQUISITION AND MANAGEMENT TOOL	Described herein are systems and methods for transforming clinical guideline documents into computer interpretable guidelines ("CIGs"). One embodiment refers to a method comprising prompting a user, via a graphical user interface ("GUI"), for a plurality of clinical guideline entry steps, receiving, via the GUI, clinical guideline data, prompting the user, via the GUI, for a plurality of formal expression entry steps related to the clinical guideline data, receiving, via the GUI, a formal representation of the clinical guideline data and mapping the formal representation of the clinical data to a CIG.	International	20.06.2013	https://patentscope.wipo.int/search/en/result.jsf?_vid=P10-KIJ2EU-64866
13814508	(EN) Visualization of concurrently executing computer interpretable guidelines	A method for visualizing concurrently executing clinical guidelines executed by a clinical decision support system for a subject includes presenting, on a display, a first guideline window in a graphical user interface, wherein the first	USA	16.08.2011	https://patentscope.wipo.int/search/en/detail.jsf?docId=US82289189&_cid

		guideline window presents information corresponding to a first of the concurrently executing clinical guidelines, and presenting, on the display and concurrently with the first guideline window, a second guideline window in the graphical user interface, wherein the second guideline window presents information corresponding to a second of the concurrently executing clinical guidelines.			=P10-KIJ2FZ-65161-1
US20190043501	PATIENT-CENTERED ASSISTIVE SYSTEM FOR MULTI-THERAPY ADHERENCE INTERVENTION AND CARE MANAGEMENT	A patient-centered assistive system for multi-therapy adherence intervention and care management. The intervention may be implemented in the form of a wearable device providing one or more features of medication adherence, voice, data, SMS reminders, alerts, location via SMS, and 911 emergency. Embodiments of the present disclosure may function in combination with an application software accessible to multiple clients (users) executable on a remote server to provide patient education, support, social contact, management of daily activities, safety monitoring, symptoms management, adverse events reporting, as well as support for caregivers, and feedback for healthcare providers during the management of patients with multimorbidity. Alternative embodiments implementing monitoring and intervention include using mobile apps or voice-controlled speech interface devices to access cloud control services CAPABLE of processing automated voice recognition-response and natural language understanding-processing to perform functions and fulfill user requests.	USA	7.2.2019	https://patentscope.wipo.int/search/es/detail.jsf?docId=US236969618&_cid=P10-KIJ4SY-89277-1
US20180113991	INTERACTIVE APPARATUS AND DEVICES FOR PERSONAL SYMPTOM MANAGEMENT AND THERAPEUTIC TREATMENT SYSTEMS	The present disclosure relates generally to symptom management. More specifically, the disclosure describes a system that pairs biomonitoring mechanisms with a symptom management system. In some aspects, the symptom management system may comprise customized programming that may provide engaging user activities that may directly or indirectly	USA	26.04.2018	https://patentscope.wipo.int/search/es/detail.jsf?docId=US215058646&_cid=P10-KIJ4SA-89125-1

		affect one or more symptoms. In some embodiments, a user may be diagnosed with a disease, infection, or disorder, and the symptom management system may manage and monitor a predefined set of symptoms associated with the diagnosis. In some implementations, individual symptoms may be identified and subsequently monitored and managed separately, such as through the creation and subsequent tracking of a symptom management score.			

10.4. IPR table

This information is available on an online document available in the following URL https://docs.google.com/spreadsheets/d/1rqEX1bpSVL1xvlmwx8hMYZH2LwIarHY-b0NoefjwoeE/edit?usp=sharing.