

# White Paper

Cancer Survivorship - AI for Well-being cluster

#CS\_AIW

**C****A****N****C****E****R**  
**S****U****R****V****I****V****O****R****S****H****I****P** –  
**A****I** **F****O****R**  
**W****E****L****L****-****B****E****I****N****G**



# White Paper

by

## Cancer Survivorship - AI for Well-being cluster

ASCAPE - Ref 875351  
BD4QoL - Ref 875192  
CAPABLE - Ref 875052  
CLARIFY - Ref 860627  
FAITH - Ref 875358  
LIFECHAMPS - Ref 875329  
MENHIR - Ref 823907  
ONCORELIEF - Ref 875392  
PERSIST - Ref 875406  
QUALITOP - Ref 875171  
REBECCA - Ref 965231

May, 2023

Citation: *Callejas, Zoraida; Flynn, Tom (eds.) (2023) White paper of the Cancer Survivorship - AI for Well-being cluster.*

This document is available under CC BY-NC 4.0. For more information, see:  
<https://creativecommons.org/licenses/by-nc/4.0/>.



# Executive Summary

The Cancer Survivorship - AI for Well-being cluster (#CS\_AIW) has brought together 11 EU-funded projects working in artificial intelligence (AI) for healthcare and well-being with the aim of transcending the individual project experiences and stop working in silos. The White Paper presents the #CS\_AIW initiative and our collective shared vision, providing an overview of the participating projects and it reports on the achievements and lessons learned from our collaboration, including both the benefits obtained and the difficulties addressed.

The experience with #CS\_AIW to date has proven that collaboration within the cluster has been extremely beneficial and useful to foster an ethos of cross-fertilization engagement, share best practices, boost cross-sector collaboration, increase the participation of end user communities, and reach a wider audience. The activities organized, which encompass meetings, roundtable discussions, podcasts, a better practices guide, a common data space and the white paper itself, have proven to be an inherited valued initiative to generate, activate and communicate knowledge and innovation in the areas of mental health, well-being, cancer recovery, patient support and participatory research.



# Contents

<b>1. The CS_AIW Cluster initiative</b>	<b>9</b>
1.1 The birth of the CS_AIW Cluster	9
1.2 What issue is the cluster addressing?	9
1.3 Our vision of cancer survivorship and AI for well-being	10
1.4 Our Audience	11
<b>2. Cluster members</b>	<b>13</b>
2.1 Brief presentation of CS_AIW member projects	15
<b>3. Activities of the cluster</b>	<b>27</b>
3.1 Meetings of Minds	27
3.1.1 MoM1 - January 2021	28
3.1.2 MoM2 - May 2021	29
3.1.3 MoM3 and MoM3+ - September 2021	29
3.1.4 MoM4 - February 2022	30
3.1.5 MoM5 - December 2022 and March 2023	32
3.2 Podcast	34
3.3 Better practices guide and common data space	35
3.4 White paper	36
<b>4. Lessons learned from our collaboration</b>	<b>37</b>
4.1 Value and challenges of our collaboration	37
4.1.1 Benefits of participating in CS_AIW	37
4.1.2 Barriers and difficulties encountered in CS_AIW	39
4.2 Addressing technological barriers	40
4.2.1 Hardware and devices	40
4.2.2 Data collection, privacy and interoperability	42
4.2.3 Integration with hospital systems	44
4.2.4 Maintenance and update	45
4.3 Enhancing users' acceptance and compliance	45
4.4 Scientific, legal and ethical barriers	48
<b>5. Future activities</b>	<b>51</b>
<b>6. Conclusions and recommendations</b>	<b>53</b>





# 1

## The CS\_AIW Cluster initiative

### 1.1 The birth of the CS\_AIW Cluster

“Cancer Survivorship – AI for Well-being” (#CS\_AIW) is a cluster of EU-funded projects that FAITH consortium member, TFC Research and Innovation Limited, initiated at the end of 2020 in response to projects working in isolation, and not making use of each other’s knowledge. Individual projects in the cluster were brought together based on common interest regarding cancer survivorship, mental health, quality of life and well-being, depression, and patient support. Within the cluster we are adhering to our motto - “We don’t work in silos”.

CS\_AIW started off as a group of 3 projects (FAITH, MENHIR and ONCORELIEF) working on AI-based solutions for Cancer Care and Cancer Survivors’ well-being, and has since progressed to eleven member projects (see section 2 for a description of the projects). Each of these EU-funded projects have at least two things in common. Firstly, they address the issues of mental health, well-being, depression, and/or patient support in cancer survivors, and secondly, they adopt a participatory research vision.

To date, we organized multiple cluster activities (described in section 3), including the ‘Meeting of Minds’ (MoM) workshops, which transformed from a once-off meeting to bring patient groups and doctors together into a series of events focusing on knowledge and practices exchange between the members, but also including active engagement from end-users and stakeholders. The cluster uses the MoM events as an opportunity to showcase its results, to listen to the relevant parties and stakeholders (e.g., patients and survivors, policymakers) as well as to obtain feedback on the methodology, concepts, and practices that CS\_AIW members are implementing through their solutions.

### 1.2 What issue is the cluster addressing?

Historically, anecdotal evidence has shown that projects working on their own without peer engagement and user feedback arrive at the end of the project lifetime and the results of the project are shelved while research moves on to the next theme.

To address this shortcoming, the Cluster and Meetings of Minds events help to foster an exchange of ideas and a participatory research vision among member projects, allowing for useful comparison between research approaches, end-user engagement strategies, and general knowledge sharing between projects.

In addition to the intra-project knowledge sharing, a key task within the cluster is the engagement with the real end-users or consumers of the Cluster's solutions, which is crucial for gaining market insights and incorporating these important elements, which help improve the solutions' user-centric features, and consequently the solutions' usability and implementation in real-life scenarios. Through this sharing of knowledge between projects and gathering feedback and requirements from our key stakeholders, the cluster contributes to strengthening project offerings by delivering solutions that are based on the collective thought process of all experts across the projects and ensuring that what they deliver is suited to the market's needs.

### 1.3 Our vision of cancer survivorship and AI for well-being

Cancer survivors know the full meaning of team effort, be it with the team of oncologists, radiotherapists, psychologists and caregivers in support of that dreaded journey when cancer is detected, and treatment is necessary. The road to recovery can be long and arduous. Survivors also know the value and importance of mental strength during the treatment process and throughout the entire recovery stage. Through engagement with patients, healthcare providers and researchers, different views are captured, which are used to help verify and validate the ongoing individual project work. This process contributes to ensuring that the technical outputs of the projects are in line with what is needed and will be welcomed by the intended users (i.e., patient and caregivers).

The cluster's MoM events involve several stakeholders, from IT and high-tech experts focusing on Artificial Intelligence, data compliance and privacy professionals, to European Commission policymakers and patient advocacy representatives, which collectively aid our intent to continually improve the framework in line with end user expectations.

As part of the cluster, presently we are also creating a Better Practice Guide (BPG) document which is aimed at defining vocabulary and datasets constructs for a common information space that can lead to the sharing of data and knowledge at semantic level. The task was designed as a steppingstone for a data ecosystem and an application programme interface for the communication of data at semantic level centered around the individual project platforms in the cluster. The development of a data ecosystem that can satisfy technical interoperability within platforms and, at the same time, focus on users' needs and interests throughout the ecosystem data pipeline will require a flexible methodology that can build upon users' knowledge and expectations. This BPG is the initial step along that route. The undertaking will strengthen interest and uptake from a sustainability and eHealth data engagement perspective.

## 1.4 Our Audience

Across the cluster, we aim to boost the adoption of best practices of participatory research in Artificial Intelligence for healthcare and well-being for the benefit of EU citizens. To do this, the readership for this document should include policymakers, international and national funding agencies, researchers, healthcare workers, patient representative organizations and individual EU citizens. Without this audience and readership this exercise has the danger of becoming another asset that sits on the shelf, the very problem that we are attempting to overcome.



# 2

## Cluster members

Presently, the CS\_AIW Cluster has **11 member** projects (Figure 1):

- **ASCAPE** – Artificial intelligence Supporting CANcer Patients across Europe
- **BD4QoL** - Big Data Models and Intelligent tools for Quality of Life monitoring and participatory empowerment of head and neck cancer survivors
- **CAPABLE** - CANcer PATients Better Life Experience
- **CLARIFY** – Cancer Long Survivors Artificial Intelligence Follow Up
- **FAITH** - a Federated Artificial Intelligence solution for moniToring mental Health status after cancer treatment
- **LIFECHAMPS** - A collective intelligence platform to support cancer champions
- **MENHIR** - MEntal health monitoring through interactive conversations
- **ONCORELIEF** - A digital guardian angel enhancing cancer patient's wellbeing and health status improvement following treatment
- **PERSIST** - Patients-centered SurvivorShIp care plan after Cancer treatments based on Big Data and Artificial Intelligence technologies
- **QUALITOP** - Monitoring multidimensional aspects of QUALity of Life after cancer ImmunoTherapy - an Open smart digital Platform for personalized prevention and patient management
- **REBECCA** - REsearch on BrEast Cancer induced chronic conditions supported by Causal Analysis of multi-source data.



Figure 1. #CS\_AIW projects at February 2023

The Cluster brings together **131 partners** from the **26 countries** shown in Figure 2.

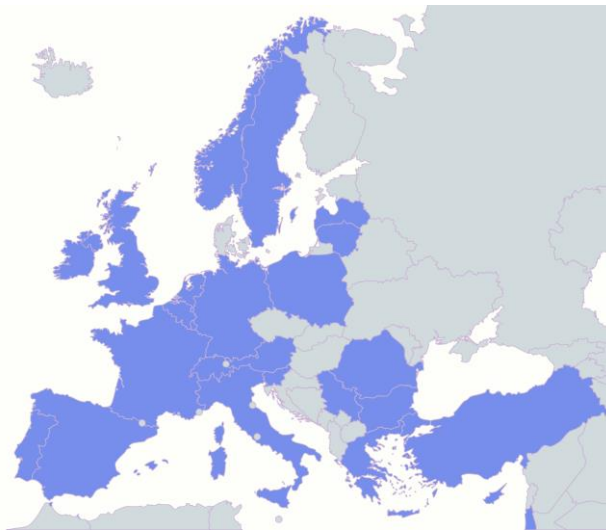


Figure 2. Countries covered by CS\_AIW

## 2.1 Brief presentation of CS\_AIW member projects



### ASCAPE – Artificial intelligence Supporting CANcer Patients across Europe (1st January 2020 - 30th June 2023)

- Gioumpitek Meleti Schediasmos Ylopoiisi Kai Polisi Ergon Pliroforikis Etaireia Periorismenis Efthynis (coordinator)
- ATOS Spain SA
- Siemens SRL
- Netcompany-intrasoft SA
- Panepistimio Patron
- Idryma Technologias Kai Erevnas
- Sphynx Technology Solutions AG
- University of Novi Sad Faculty of Sciences
- Deutsches Forschungszentrum fur Kunstliche Intelligenz GMBH
- Care Across LTD
- Ethniko Kai Kapodistriako Panepistimio Athinon
- Fundacio Clinic per a la Recerca Biomedica
- Orebro Lans Landsting
- Arthur's Legal BV
- Fundación ISYS Internet Salud y Sociedad

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.

ASCAPE' main objective 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 is 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.



## **BD4QoL - Big Data Models and Intelligent tools for Quality of Life monitoring and participatory empowerment of head and neck cancer survivors**

(1st January 2020 - 31st December 2024)

- Università degli studi di Milano (coordinator)
- Universitaetsmedizin Der Johannes Gutenberg-Universitaet Mainz
- Universidad De La Iglesia De Deusto
- Dotsoft Oloklromenes Efarmoges Diadiktioy Kai Vaseon Dedomenon AE
- Fondazione Casa Sollievo Della Sofferenza
- Universidad Politécnica De Madrid
- Multimed Engineers Srl
- University Of Bristol
- Ibm Ireland Limited
- Inetum España S.A.
- Regione Lombardia
- Azienda Sanitaria Locale To3
- Universitetet I Oslo
- Fondazione Irccs Istituto Nazionale Dei Tumori
- Azienda Regionale Per L'innovazione Gli Acquisti S.P.A.
- The University Of Birmingham

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.





## CAPABLE - CAnCER PATiENTS Better Life Experience (1st January 2020 - 31st December 2023)

- Università degli studi di Pavia (coordinator)
- University of Haifa
- Biomeris SRL
- Academisch Medisch Centrum BIJ de Universiteit Van Amsterdam
- IBM Israel - Science and Technology LTD
- UAB Bitsens
- Politechnika Poznanska
- Istituto Clinici Scientifici Maugeri Società per Azioni Società Benefit
- Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoek Ziekenhuis
- Deontics Limited
- Associazione Italiana Malati di Cancro, Parenti e Amici
- Universidad Politécnica de Madrid

After the primary intervention, most of cancer patients are managed at home, facing long-term treatments or sequelae, making the disease comparable to a chronic condition. Despite their benefit, strong therapeutic regimens often cause toxicity, severely impairing quality of life. This may decrease adherence to treatment, thus compromising therapeutic efficacy. Also due to age-related multimorbidity, patients and their caregivers develop emotional, educational and social needs. CAPABLE will develop a cancer patient coaching system with the objective of facing these needs/issues.

The time is right to fully exploit Artificial Intelligence (AI) and Big Data potentialities for cancer care and bring them to patients' home. CAPABLE will rely on predictive models based on both retrospective and prospective data (clinical data, data from unobtrusive environmental and wearable sensors, data from social media and questionnaires). Models will be integrated with existing clinical practice guidelines and made available to oncologists.

Thanks to the mobile coaching system for patients, CAPABLE will allow identifying unexpected needs, and providing patient-specific decision support. This feature, together with the chance of discovering unknown adverse effects of new treatments, makes CAPABLE more than a personalised tool for improving life quality, an advance for the whole research community.

Our team includes complementary partners with experience in data- and knowledge-driven AI, data integration, telemedicine, decision support. In addition, the involved patients' association gives a unique opportunity to access thousands of questionnaires on patients' needs, which will inform the system design. The project addresses EU priorities such as shifting care from hospitals to home to face scarcity of healthcare resources, facilitating patients' re-integration in the society and in the labour market, and ensuring all EU citizens to benefit from an effective, novel cancer care model.



## CLARIFY – Cancer Long Survivors Artificial Intelligence Follow Up

(1st January 2020 - 30th June 2023)

- Servicio Madrileño de Salud
- Universidad Politécnica de Madrid
- Technische Informationsbibliothek (TIB)
- Holos soluções Avançadas em Tecnologias de Informação SA
- National University of Ireland Galway
- University College London
- University College Dublin, National University of Ireland, Dublin
- Accenture Global Solutions Limited
- Grupo Oncológico para el Tratamiento de las Enfermedades Linfoides - GOTEL
- Stelar Security Technology Law Research UG (Haftungsbeschränkt) GMBH
- Grupo Español de Investigación en Cáncer de Pulmón
- Kronohealth SL

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 heterogeneous 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 survivors by risk in order to personalize their follow-up by better assessment of their needs.



**FAITH** - a Federated Artificial Intelligence solution for  
moniTORing mental Health status after cancer treatment  
(1st January 2020 - 30th June 2023)

- South East Technological University (coordinator)
- Euro Care Healthcare Ltd
- Universidad Politecnica De Madrid
- Servicio Madrilenio De Salud
- Uninova-Instituto De Desenvolvimento De Novas Tecnologias-Associacao
- Fundacao D. Anna De Sommer Champalimaud e Dr. Carlos Montez Champalimaud
- Deep Blue SRL
- Suite5 Data Intelligence Solutions Limited
- TFC Research and Innovation Limited

The main aim of FAITH is to apply the latest Artificial Intelligence (AI) and Big Data analytics techniques to better model and predict downward trajectories in depression markers for cancer survivors, 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 that will be brought to the edge (mobile device), thus eliminating the need to transfer large amounts of personal data to the cloud.

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 and Lisbon, with real end users to assess and validate the adoption and usage of the FAITH technologies and platform.



## LIFECHAMPS - A collective intelligence platform to support cancer champions

(1st December 2019 - 31st May 2023)

- Aristotelio Panepistimio Thessalonikis (coordinator)
- Capgemini Portugal SA
- European Cancer Patient Coalition
- EMC Information Systems International Unlimited Company
- Region Stockholm
- Universitat Politècnica de Valencia
- Fundación para la Investigación Del Hospital Universitario La Fe de la Comunidad Valenciana
- University Of Surrey
- Karolinska Institutet
- ADHERA HEALTH SLU
- NETCOMPANY-INTRASOFT SA
- CYBERLENS BV
- MYSPHERA SL
- University of Glasgow
- Nifakos Sokratis
- Massive Dynamic Sweden AB

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 neglect 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).



## MENHIR - MEntal health monitoring through interactive conversations

(1st February 2019 - 31st January 2024)

- Universidad de Granada (coordinator)
- Action Mental Health
- University of Ulster
- Universidad del País Vasco / Euskal Herriko Unibertsitatea
- Intelligent Voice Limited
- Universitaet Ulm
- Università degli studi della Campania Luigi Vanvitelli
- GLOBIT - Globale Informationstechnik GMBH

MENHIR aims at engaging people in the management of self-care and providing a more flexible, immediate and sustained complement to under pressure mental health services. MENHIR chatbot technology provides symptom and mood management, personalised support and motivation, coping strategies, signposting to online resources and complementing the support received by local services. The technology developed will be able to process emotional and mood patterns from different aspects of the voice recorded. This information facilitates rapid intervention and appropriate feedback such as prompts and supportive messages. It will also generate personalized conversations with the users to motivate and engage them at any time and especially in between visits to their local services.

The limitations of previous technology are the high dropout rates due in part to a lack of interactive features and appropriate prompts, difficulties for people with low levels of technological literacy and failure to provide human support. The MENHIR chatbot technology aims to address these difficulties being more usable and intuitive since it simulates everyday human to human conversation. The project will also generate data on how people with anxiety and depression interact with and respond to this technology, and about the benefits it brings to them.

The objectives of MENHIR are to:

- Develop new capabilities and skills for MENHIR participants. As a RISE project, our aim is the sharing of knowledge and ideas across countries, sectors and disciplines. MENHIR will create new opportunities for ICT experts to root technology in a deeper understanding of their prospective users, while psychologists and mental health experts will gain knowledge of the technological tools that can help them improve their clients' wellbeing.
- Establish the strengths, limitations and requirements of mental health chatbots.
- Develop the MENHIR chatbot technology collaborating with people who suffer anxiety and/or mild depression.
- Understand how users engage with chatbot technology and how it may affect their wellbeing over time.


**ONCORELIEF**

## **ONCORELIEF** - A digital guardian angel enhancing cancer patient's wellbeing and health status improvement following treatment

(1st January 2020 - 30th June 2023)

- EXUS Software Ltd (coordinator)
- Maggioli SPA
- Innosystems Symvouleutikes Ypiresies Kai Efarmoges Plioforikis Ypsilis Technologias Monoprosopi Idiotiki Kefalaouchiki Etaireia
- Care Across Ltd
- Ethniko Kentro Erevnas Kai Technologikis Anaptyxis
- Suite5 Data Intelligence Solutions Limited
- Fraunhofer Gesellschaft Zur Forderung Der Angewandten Forschung Ev
- Universitaetsmedizin Der Johannes Gutenberg-Universitaet Mainz
- Mcs Datalabs
- Fciencias.Id - Associacao para a Investigacao e Desenvolvimento de Ciencias
- Time.Lex
- Alma Mater Studiorum - Universita Di Bologna
- Istituto Romagnolo per lo Studio dei Tumori Dino Amadori - IRST SRL

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 skilfully 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 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.



## PERSIST - Patients-centered SurvivorShlp care plan after Cancer treatments based on Big Data and Artificial Intelligence technologies

(1st January 2020 - 29th February 2023)

- Fundacion Centro Tecnoloxico De Telecomunicacions De Galicia (Coordinator)
- Servizo Galego De Saude
- Fundacion Biomedica Galicia Sur
- Dxc Technology Servicios Espana SI
- Isoft Sanidad Sa
- Enterprise Solutions Consultoria Y Aplicaciones
- Emoda Yazilim Ve Danismanlik Sanayiticaret Limited Sirketi
- Univerza V Mariboru
- Haute Ecole Specialisee De Suisse Occidentale
- Latvijas Universitate
- Cyberethics Lab SRLS
- Centre Hospitalier Universitaire de Liege
- Symptoma Gmbh
- Rubynanomed Lda
- National Patients Organisation
- Dh Healthcare Provider Software Spain SLU
- Isoft Sanidad SA

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, PERSIST 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 methodology ranging from the earliest phases of the project throughout its conclusion.



## QUALITOP - Monitoring multidimensional aspects of QUALity of Life after cancer ImmunoTherapy - an Open smart digital Platform for personalized prevention and patient management

(1st January 2020 - 30th June 2024)

- Hospices Civils de Lyon (coordinator)
- Université Lyon 1 Claude Bernard
- Université Lumière Lyon 2
- Centre Hospitalier Regional Universitaire De Besancon
- Instituto Portugues De Oncologia De Lisboa Francisco Gentil Epe
- Consorci Institut D'investigacions Biomediques August Pi I Sunyer
- Hospital Clinic de Barcelona
- Academisch Medisch Centrum Bij De Universiteit Van Amsterdam
- London School of Hygiene and Tropical Medicine Royal Charter
- Scientific Academy for Service Technology Ev
- European Cancer Patient Coalition
- Academisch Ziekenhuis Groningen
- The General Hospital Corporation
- Università della Calabria
- Lyon Ingenierie Projets
- Centre de Lutte Contre le Cancer Leon Berard

"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.





**REBECCA** - REsearch on BrEast Cancer induced chronic conditions supported by Causal Analysis of multi-source data (1st April 2021 - 31st March 2025)

- Aristotelio Panepistimio Thessalonikis (Coordinator)
- Karolinska Institutet
- Helse Stavanger Hf
- Fundació para la Investigació del Hospital Clínic de la Comunitat Valenciana, Fundació Incliva
- Ethniko Kentro Erevnas Kai Technologikis Anaptyxis
- Charokopeio Panepistimio
- Netcompany-Intrasoft Sa
- Eight Bells Ltd
- European Health Management Association
- Time.Lex
- Brostcancerforeningen Amazona I Stockholms Lan
- Region Stockholm

The REBECCA proposal aspires to tap into the potential of Real-world Data (RWD) for supporting ground-breaking clinical research on complex chronic conditions (CCC) as a complement to Randomised Controlled Trials (RCT). REBECCA moves beyond the analysis of Electronic Health Records (EHR), by combining it with detailed monitoring data from multiple wearable, online behaviour and registry data to monitor patients' functional, emotional and Quality of Life trajectories, with high temporal granularity. REBECCA also proposes explainable causal modelling combined with deep learning to account for observed and latent confounders in RWD analysis. The project will focus on the complex array of chronic comorbidities developed during breast cancer recovery, in particular studying the impact of primary and adjuvant cancer treatment on patients' quality of life and assessing the value of detailed patient monitoring as a means for improved patient care, but will also demonstrate the extensibility of REBECCA to other forms of cancer.

To this end, a total of seven studies in Sweden, Norway and Spain will produce new knowledge on clinical management of cancer patients that will shape future guidelines and practices for post-cancer treatments. Best practices resulting from the REBECCA studies will be disseminated to researchers, public health and regulatory bodies throughout Europe to facilitate wider adoption of RWD in clinical research. In addition, the REBECCA platform, capable of detailed monitoring and privacy-preserving federated cross-country data analysis, will provide an infrastructure for continued progress on use of RWD beyond the end of the project. Through these activities, REBECCA aims at the mass adoption of RWD for understanding CCCs and ultimately at establishing RWD as a valuable clinical research and patient management tool.

## 2.2 Common aspects across projects

	ASCAPE	BDAQoL	CAPABLE	CLARIFY	FAITH	LIFECHAMPS	MENHIR	ONCORELIEF	PERSIST	QUALITOP	REBECCA
Focus on cancer	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
Focus on mental health and wellbeing	✓				✓		✓	✓			✓
Wearables	✓	✓	✓		✓	✓		✓	✓		✓
Mobile app	✓	✓	✓				✓		✓		✓
Chatbots		✓		✓			✓				
Repositories and data lakes										✓	✓
Clinician/expert involvement	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Patient/user recruitment through hospitals	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
Patient/user recruitment through organizations / non profits			✓			✓	✓				✓
Co-creation and focus groups	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

# 3

## Activities of the cluster

The activities of the cluster can be categorized into 4 main pillars:

- Meetings of minds (MoM)
- Podcast
- Better practices guide
- Whitepaper
- Common Data Space

### 3.1 Meetings of Minds

Led by the intention to maintain and further well-established and multi-faceted cooperation and adapt it to existing and new challenges.

We don't work in silo – that is the motto of #CS\_AIW. It is quite apt and acts as a forward-looking platform capability for knowledge exchanges and understanding between the engaging projects involved primarily in the cancer survivorship space for ultimately the benefit of patients, medical team and patient care givers.

The Meeting of Minds ('MoM' for short) events are one such pillar activity that are ongoing within the cluster. They are dedicated events primarily held internally within #CS\_AIW on sharing knowledge and different perspectives on key aspects of the individual projects and their development.

The emphasis from the formation of the cluster was that it will be patient/user-centric and collectively, we made it known that we want to know more, to learn and understand better the world of the patient so that more efforts will be applied to bring us closer to the perspective, needs and understanding of the patient recovering from cancer. Through the advancements of modern technology, each project sensibly aims to deliver results that will over time contribute positively to make the world of the patient, medical team and care-givers, better. The MoM events help in that process.

Presently, the 11 participating projects in the #CS\_AIW cluster, set in motion plans for the subsequent year and the MoM events are consistently an integral part of yearly intent. This approach enables high-level segment of MoM events to be preceded by a number of dedicated sessions on specific areas of cooperation of mutual interest and benefit to be realised. An example, being the Business Acumen series of 3 planned MoM events, which presently are ongoing and look at the outcome of project results from a market entry and commercial point of view.

To date five MoM events have taken place, of which one event (i.e., MoM4) was a public event (February, 2022) involving both the European Commission and separately, Patient Associations.

The following sub-sections provide an overview of five MoMs organized by the cluster.

### 3.1.1 MoM1 - January 2021

Established in September 2020, the initial 3 projects in the Cluster (FAITH, MENHIR and ONCORELIEF) collectively decided that the focus of the initial Meeting of Minds event would be on providing a platform for end users as well as members of patient and mental health associations to share their experience and understanding with individual members of #CS\_AIW. The theme of the MoM1 was **'Help us to help you'**. Internal and virtual, it was designed with the intent of capturing bi-directional knowledge and understanding information initially from a patient and carer perspective in order to strengthen the envisaged outcomes of these three important projects related to mental health, patient wellbeing and depression post-cancer.

MoM1 was structured into two areas:

#### Let's listen to the patient experience and story session

Speakers were:

- Mark Kincaid (Action Mental Health, Northern Ireland)
- Thanos Kosmidis (CEO, Careacross, United Kingdom)
- Gerd Murphy (Advanced Nurse Practitioner Psycho-oncology, University Hospital Waterford, Rep. of Ireland)

#### What our projects aim to do

Speakers were:

- MENHIR project: Zoraida Callejas Carrion (Universidad de Granada, Spain)
- ONCORELIEF project: Sotiris Diamantopoulos, (Exus Software Limited, United Kingdom)
- FAITH project: Giuseppe Frau (Deepblue, Italy)

MoM1 was recorded to support the ongoing efforts of the #CS\_AIW members and the main points to emerge from MoM1 were:

1. Family support and continued care is critical, as we learned from Mark Kincaid.
2. Everybody is unique, that's why we need a user-centric approach at the center of everything. Engagement of the end users is pivotal.
3. Thanos Kosmidis expressed the importance of evidence-based knowledge; the issue of anxiety and depression; the lift of the stigma due to the pandemic effect and the general dialogue around mental health. Peculiarity of each person: we come back to the idea that each patient is different and so the solutions must be as well.
4. Gerd Murphy highlighted mental health disorder in Ireland, the medical approach to the discourse, and the importance of multidisciplinary approach in onco-psychology. Gerd also highlighted that if you are medicated, you can develop symptoms from that (and is not a mental health struggle), so the situation is complex.
5. Project presentations: common issue is mental health, with ONCORELIEF is QoL; with MENHIR it is the holistic approach to create a self-supporting mechanism for anxiety and mild depression; FAITH deals with post-cancer patients and the open points on how to provide support. Mark, Thanos and Gerd understood the aims of the individual projects and the need.
6. The underlying issue: we must work together going forward, and see each patient separately as an individual, and find out the best way of supporting them.

### 3.1.2 MoM2 - May 2021

The MoM2 event was aimed at building on from the outcomes of MoM1 with the centrefold of the event aimed at obtaining a better understanding of post-cancer care mental health, specifically from Gerd Murphy, the Advanced Nurse Practitioner Psycho-oncologist. However, MoM2 had to be cancelled and the individual projects moved on from their current stage of requirements gathering to further advance design and development.

### 3.1.3 MoM3 and MoM3+ - September 2021

On 10th September 2021, two internal consecutive virtual events (i.e., MoM3 and MoM3+) were held.

#### MoM3

MoM3 focused on the Business Acumen aspects of projects. The underlying issues of business are often not to the foreground of research projects. The Roundtable MoM3 event was a step in the direction to reverse this trend within the scope of the #CS\_AIW work. LIFECHAMPS, CLARIFY and QUALITOP projects had since joined the cluster and participated in the MoM3 event.

Tom Flynn (TFC Research and Innovation Limited, FAITH), moderated with the five participating project members. In total 9 predefined questions were issued to each participant and completed well in advance. Each project had 2 members at their side of the virtual table, notably the Exploitation Manager and a Clinical /or Technical member of their individual project.

With that information, the moderator was able to conduct the MoM3 session and audience engagement was encouraged. Participants found MoM3 useful and very informative. It was agreed across the cluster that more events focusing on the business aspects of a project would be welcomed and in effect it acted as a springboard for the MoM5 series of events.

### MoM3+

The afternoon of the 10<sup>th</sup> September 2021 was again virtual and internal to the #CS\_AIW projects. It was dedicated to bringing more technical members together and to gain a greater appreciation of each project, such as on key project aspects including clinical trial details, number of users, technology applied, etc. MoM3+ was chaired by Antonis Billis (Aristotle University of Thessaloniki, LIFECHAMPS). In addition to undergoing a mapping exercise, the MoM3+ event activated the need for a definition of common datasets across the engaging projects in the cancer survivorship space. This was seen as very positive by the cluster at large.

Since the initiation of the MoM3+ event, a number cross-project engagements have taken place. Led by Antonis, work is ongoing on the development of a Better Practice Guide on common data sets and dictionaries within the cancer survivorship space.

### 3.1.4 MoM4 - February 2022

MoM4 was held over 2 days on the 23<sup>rd</sup> and 24<sup>th</sup> February 2022. It was our first public event and was held virtually. From the beginning, MoM4 was a patient-orientated event. It was developed around a single key question: "How can new technologies better support patients?". In response, more than 100 stakeholders participated over the two days of the event; the audience included patients, patient associations and advocates, healthcare providers, IT specialists, researchers, and policy makers. Moderated by Tom Flynn (TFC Research and Innovation Limited, FAITH), the two-day MoM4 event really engaged all the participants. In fact, every project in the cluster individually presented their activities, demonstrated work in progress technologies, and received audience feedback. Collectively, the Cluster projects listened and learned from stakeholders' insights. The event helped to strengthen their understanding for a better delivery of what is needed by the patients, clinical professionals, and also their care-givers.

The event enabled the projects involved in #CS\_AIW at the moment (ASCAPE, BD4QOL, CAPABLE, CLARIFY, FAITH, LIFECHAMPS, MENHIR, ONCORELIEF,

PERSIST, REBECCA, QUALITOP) to individually present the projects including demonstrations. Their individual presentations provided insight to the ongoing projects work and included individual Q&A sessions with the audience.

In addition, a roundtable bi-directional discussion with patients, patient associations, and researchers engaged in #CS\_AIW was also held. Moderated by Panos Papachristotu (Academic Primary Health Care Centre) and with the participation of six speakers, each being a cancer/survivor patient, distinguished researcher or patient activist, the discussion outlined important messages regarding the process of co-development in all stages of the research; the need of providing patients with sufficient information in order to ensure their trust in clinical trials; the security of collected data and the importance of making technologies and decision support systems beneficial for patients and not only for clinicians



## MoM4 Highlights

Notable guest speakers, included:

- **Barbara Kerstiens:** Head of Unit "Combating Diseases" - DG Research and Innovation, European Commission.

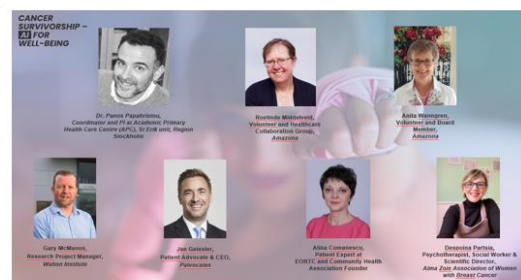
*Dr. Kerstiens presented the ambitious "EU Mission on Cancer", which confirmed that FAITH and the Cluster itself are working in the right direction; putting patients at the centre of innovation, focusing on Quality of Life. Also, the other 3 objectives are: understanding cancer, prevention and early detection, diagnosis and treatment.*

- **Kathi Apostolidis:** Former President - European Cancer Patient Coalition, President - Hellenic Cancer Federation.

*Dr. Apostolidis addressed the audience on how to engage with patients and associations while preparing, executing and evaluating a clinical trial. In her presentation, Dr. Apostolidis explained how best to deliver the research value to the patients.*

- **Gerd Murphy,** Psycho-Oncological Nurse Practitioner - HSE Ireland.

*Dr. Murphy presented the implications of cancer diagnosis from a psychosocial point of view. She shared improvements on how AI can support in key patient areas, such as the importance of awareness and normalization of the distress experience, as well as early detection of poor mental health.*



RoundTable Participants

Figure 3. MoM4 Patient Oriented Round Table

Additionally on the second day (see Figure 3), Barbara Kerstiens from DG Research & Innovation of the European Commission delivered a presentation on patient engagement in European research projects and proposals, outlining the opportunities provided through initiatives such as the European Cancer Patient Digital Center and the Beating Cancer Stakeholder Contact Group.

Gerd Murphy, also a Psycho-Oncology Nurse at the University College Dublin presented on the impact of cancer on patient mental well-being through the psycho-oncology perspective. In her presentation, she identified a range of unmet needs and the desire for very comprehensive undertaking assessment at an individual level, as well as tailored individual interventions to help overcome gaps and improve mental health well-being of cancer patients and survivors.

Kathi Apostolidis, a Board Member of the European Cancer Patient Coalition presented patients' central role in the implementation of clinical research and underlined their role as **active co-creators** rather than just as objects in trials.

The knowledge acquired from the MoM4 was deployed to the relevant projects in the Cluster and the MoM4 report can be accessed at:

[https://www.h2020-faith.eu/resource/cs\\_aiw-cluster-meeting-of-minds-4-report/](https://www.h2020-faith.eu/resource/cs_aiw-cluster-meeting-of-minds-4-report/)

At research and innovation level, notable points were:

- Technology supports clinicians, it doesn't replace them! Clinical decision support systems help to close gaps in care, but alone, they will not improve clinical care.
- The importance of patient and patient organization engagement throughout the entire research and innovation process and not just at requirements and validation phases, cannot be overstated. Involving end-users, be it clinicians or patients or both, throughout the entire cycle for the improvement of cancer patients' quality of life. Health status is a challenge as computer scientists, clinicians and patients have different but complementary approaches. Their understanding is based on experience. Clinical and patients can provide incredible insight along all stages of a project.
- Personalized medicine's tailor-made prevention and treatment strategies are key to fight cancer and improve patients' well-being. In this sense too, patient engagement is essential to ensure that personalized medicine technologies target patients' needs (both physical, but also functional and psychosocial) from a scientific evidence-based approach.
- Psychological, behavioral and social factors may influence the disease process. Therefore, it is essential to take mental health, quality of life and activity data into account to improve cancer patients' well-being.
- Breaking away from relying only on traditional electronic health records and exploiting the volume and variety of new data sources and real-world data can improve our research potential and provide cost-effective and efficient health care.

### 3.1.5 MoM5 - December 2022 and March 2023

Following a number of internal #CS\_AIW meetings on the proposed Business Acumen approach, a series of 3 dedicated events, MoM5, MoM5+ and MoM5++ is up and running. As part of the Business Acumen initiative, engagement is ongoing with a number of Business Angels across Europe and the EIT Health, which is co-funded by the European Commission.



**Series:**

- **MoM5:** Devised to enable Business Angels to present their point of view on what they are looking for. It was held on the 9<sup>th</sup> December 2022 and this was led by the FAITH project.
- **MoM5+:** Looks at the market that the proposed projects will target. This is led by the ASCAPE project and has been held on 29<sup>th</sup> March 2023.
- **MoM5++:** Will be the reverse of MoM5. This time based on predefined questions, each project will pitch to Business Angels and members of EIT Health. Plans for the event is ongoing. However, to keep up the momentum an additional market focus event was included and held on the 19<sup>th</sup> April 2023 and was led by Manuel Ottaviano, UPM, CAPABLE. It focused in Digital Health Technology for cancer: lessons learned. In roundtable manner discussions covered Technology Barriers, User Acceptance and Compliance, Legal and Ethical Barriers as well as Market Acceptance. The event was organised as a virtual and public webinar and we will continue to build momentum in this important area.

**MoM5:**

The MoM5 event was held on the 9<sup>th</sup> December 2022. Virtual and internal, MoM5 involved the cooperation of two Business Angels, Shemas Eivers (Ireland) and Zoltan Szekely (Hungary). Tom Flynn (TFC Research and Innovation Limited – FAITH) moderated, leading to healthy open discussion from the Business Angels on what they are looking for and in tandem, explained in part, how they go about deciding to fund a project/company or not (see screenshot in Figure 4).

Both Shemas and Zoltan were made aware of the #CS\_AIW and the projects that are involved in advance of the MoM5 event.

The screenshot shows a presentation slide with a white background and a blue header bar. On the left side, there is a logo for '#CS\_AIW CANCER SURVIVORSHIP - AI FOR WELL-BEING'. The main title of the slide is 'Business Angel What do they want' in a large, bold, blue font. Below the title, there is a bulleted list of five requirements for business angels. The slide is part of a larger presentation, as indicated by the '33/ 56' page number at the bottom right.

Figure 4. Sample slides on Business Angel perspective

Open discussions and the points of view of the Business Angels with the #CS\_AIW participants were addressed and focused on key business areas including:

- Problem and Solution
- Value Proposition
- Market Opportunity and Risk
- Business Model
- Financial Projects
- Team

#### MoM5+:

The event was held on the 29<sup>th</sup> March 2023. Virtual and internal, MoM5+ involved Manuel Marcelino Pérez (Atos), who provided practical feedback related to uncovering market needs. The session was organised by Ioannis Avramidis (Ubitech, ASCAPE) and moderated by Tom Flynn (TFC Research and Innovation Limited).

It is our aim to continue to build momentum on the Business Acumen aspects of European projects and plan for the final event of the Business Acumen series (MoM5++) later this year.

## 3.2 Podcast

Despite the fact that podcasts have been around more than a decade, this trend has just taken off, and predictions indicate that this is not something that will alter anytime soon. We think the future of podcasting is bright and can accommodate more technology content. So, our cluster wants to stay ahead of the curve and ride this wave. The main objective is to make both the challenges and the digital tool-based solutions connected to cancer care accessible and understandable to a larger audience. This is just one of the ways that things can be speeded up towards the introduction of innovations such as the ones produced in #CS\_AIW in practice! This initiative is led by Ioannis Avramidis (Ubitech, ASCAPE).

To kick things off, we have decided to air the following episodes:

- **Better Practice Guide:** In general, through a Best Practice Guide, experts in a particular field can indirectly promote guidance and best practice recommendations. As we have recognized its power, in this first episode, we plan to discuss with data scientists from the cluster projects and in collaboration with healthcare stakeholders how this guide can be used as a resource for healthcare organizations and individuals seeking to improve their practice and achieve better results. The Better Practice Guide (BPG) is 'bottom up' and is based on the initiative that was devised in the NO-FEAR project, removing standardisation bodies from the process as an alternative practice without incurring high 3<sup>rd</sup> party cost in the process. BPGs are entities in their own right.

- **Uptake of AI solutions in the healthcare sector:** Artificial Intelligence (AI) has the potential to transform healthcare and improve cancer patient support in numerous ways. Overall, digital technologies are important for healthcare and cancer patients to improve cancer care and support patients throughout their cancer journey, from diagnosis to treatment and beyond. AI, for example, is already used for diagnosis, treatment planning, monitoring, and drug development. Just as importantly, it can facilitate patient support: AI-powered chatbots and virtual assistants can provide continuous support for cancer patients, answering their questions and providing personalized advice and guidance.
- **How can we facilitate the introduction of AI in healthcare?** In this episode cluster's experts will discuss some key ways like data infrastructure, AI human resources, privacy and security, regulations, EU culture for innovation that altogether can shape the future of healthcare.
- **Roundtable of experiences.** Cancer patients' experiences are essential to improving cancer care and support. Their feedback can lead to various improvements towards patient-centered care, quality improvement, development of new treatments and supportive care interventions, patients' empowerment and advocacy, and of course the creation of a deeper understanding of the impact of cancer and the needs of patients. Taking all this into account, we will try through this episode to listen to and value patients' experiences, by inviting patient organization representatives to have their say on a more patient-centered care.

### 3.3 Better practices guide and common data space

Presently, we are developing a Better Practice Guide (BPG) document that involves the collaboration of all #CS\_AIW projects and is being coordinated by Antonis Billis (Aristotle University of Thessaloniki, LIFECHAMPS). The BPG is a first step for the establishment of an interoperable component that supports the project platforms involved in the cluster and is delivered in line with the European Commission Directive [COM (2017) 134] for the European Interoperability Framework – Implementation Strategy.

The BPG aim to define vocabulary and datasets constructs for a common information space that can lead to the sharing of data and knowledge at semantic level. The undertaken was designed as a stepping stone for a common data space ecosystem and an application programme interface for the communication of data at semantic level centered around the individual project platforms in the #CS\_AIW cluster.

The development of a data ecosystem that can satisfy technical interoperability within platforms and, at the same time, focus on users' needs and interests throughout the ecosystem data pipeline will require a flexible methodology that can build upon users' knowledge and expectations. This BPG represents an initial step along that route. The

undertaking will strengthen interest and uptake from a sustainability and eHealth data engagement perspective.

### **3.4 White paper**

The present white paper has constituted an effort of all #CS\_AIW members to reflect on the lessons learned not only within their individual projects but also as a result of the collaboration in the cluster. It also documents the process of the creation of the cluster, the activities organized and the values and challenges of our collaboration.

The conclusions reached have been reported in the present document, especially in Section 4. The development of the White Paper has been led by Zoraida Callejas (Universidad de Granada, MENHIR).

We conclude this section with a thought of how remarkable it has been that all work undertaken by the Cluster has been achieved without meeting in person. The cluster began in September 2020. This month, May 2023, we meet in person in Madrid, host UPM/FAITH project, for our monthly #cs\_aiw meeting. Hybrid, many are pleased to meet in person.

## 4

## Lessons learned from our collaboration

As mentioned in section 1, the CS\_AIW cluster was created following the motto *We don't work in silos*, with the idea to exchange knowledge and experiences among different EU-funded projects. In this section, we describe the added value that the cluster is bringing to the participating projects, and also the challenges that we had to overcome in order to sustain a fruitful collaboration.

### 4.1 Value and challenges of our collaboration

#### 4.1.1 Benefits of participating in CS\_AIW

The main added value of our collaboration according to the participating projects has many facets, which have been summarized in figure 5 and include increased collaboration, knowledge sharing, cross-disciplinary innovation, enhanced visibility of project results, and deeper impact on the final user communities.

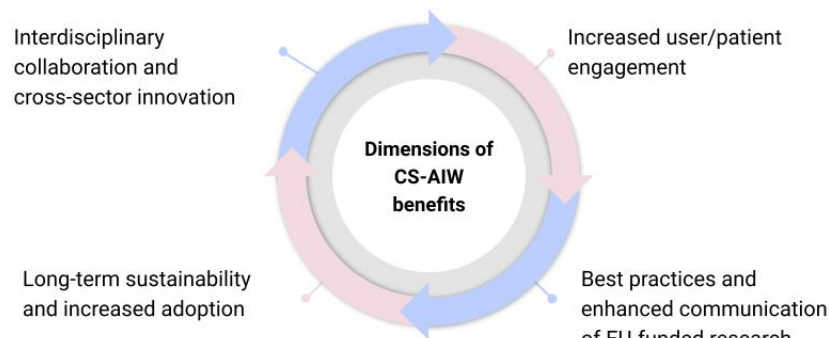


Figure 5. Main dimensions of CS\_AIW benefits

**Interdisciplinary collaboration and cross-sector innovation.** Bringing together experts from different areas with diverging perspectives. Multi and interdisciplinarity are key for EU-funded projects and indeed each consortium in CS\_AIW presents a different combination of background and expertise. The cluster boosts this richness providing a myriad of opportunities to address experts in new areas that were not present in each project in isolation. As such, we bring together diverse perspectives, expertise and experiences, exposing the cluster members to new ideas and ways of thinking around

similar problems, thus leading to research that is more innovative, relevant and impactful.

**Increased user/patient engagement.** Thanks to CS\_AIW, the individual projects have access to a much bigger user community and potential adopters of the solutions being developed, which combined with the fundamental focus on user engagement and co-creation adopted in all projects, allows to:

- Increase user/patient engagement and ensure that a more realistic vision of the user perspectives and needs are considered.
- Increase user/patient trust as they are involved in the whole process.
- Greater diversity in research, which makes the research better adapted to the final users and increases the generalizability of results. It has been particularly useful for projects to listen to patients from other countries and thus complement what they were doing at national level.
- Better communication of results, as involving users can help users to understand how to best communicate results to a wider non-academic community.
- Developing best practices around user/patient involvement in research and development activities.

**Best practices and enhanced communication.** A key aspect of our collaboration is knowledge exchange, not only in the sense of sharing our expertise and background as mentioned above, but also in practical terms related to the multiple lessons learned in a project, for example with respect to the barriers encountered, how solutions were developed, or what could have been done differently. In addition, to exchange different ideas about data has been useful to ensure its accuracy, reliability and to release its full potential while complying with the strict data regulations.

CS\_AIW members are at different stages of their projects, so those who are at an early phase can learn from the experience of more mature projects and avoid risks. These lessons are periodically shared within the cluster and are also documented in this section. Indeed, the collaboration through the cluster has been an inspiration for many of the participating projects that were able to find ideas that could be applied in their different settings.

Collaborating within the cluster facilitates reaching a wider audience and communicating the results in a way that is understandable and relevant to different stakeholders. Additionally, interdisciplinary collaboration leverages the strengths of each project overcoming our limitations to achieve a greater impact and have real-world implications and influence policy and practices.

**Long-term sustainability and increased adoption.** Our interdisciplinary collaboration enhances the opportunities for increased adoption and long-term sustainability in different ways:

- Sharing the data and technological solutions/components being collected and developed, so that we can adopt each other's solutions and achieve more complex systems.

- Developing solutions that are relevant and applicable to society and thus in turn have better chances of increased adoption.
- Share ideas and different approaches to boost exploitation. We have performed dedicated discussion on how to exploit research results, which have been especially useful for non-profit and other members whose market knowledge is more limited.
- Achieving a holistic understanding of the complex topics of the cluster, making it possible for its members to think beyond the duration of their particular projects and generate new project ideas and funding opportunities around the topics of cancer survivorship, quality of life and wellbeing using digital health technologies, including AI and BigData.

#### 4.1.2 Barriers and difficulties encountered in CS\_AIW

Presently, the CS\_AIW cluster comprises 11 projects related to mental health, well-being, depression, and patient support. These are very rich research areas, so the participating projects are focused on specific topics within them and possess different backgrounds and skill sets. The fact that the focus of the participants is not exactly the same brings richness to the cluster, and we consider it as a major benefit, however, it also requires effort from the participants to understand each other, what we do, and how we can benefit from each other. This challenge is being addressed by constant coordination and effective communication.

One of the main benefits of the cluster is to share data. This has been very complex, as we had to comply with the General Data Protection Regulation (GDPR) and ethics approvals, and sharing data across national borders makes the process long and complicated. Issues such as the international use of metadata standards; different approaches to data curation and doubts on how to apply GDPR's regulations on certain situations constitute a challenge when sharing data between different projects.

Another challenge is related to our different timings. CS\_AIW projects have entered the cluster at different moments in the development of their work plans, some were starting, some mid-way and others were almost finishing. This entailed addressing different needs and expectations regarding the participation in the cluster. This has not translated into a barrier for collaboration, as we have been able to share our objectives and accommodate the different needs and sensitivities so that we could all play the role in which we were most comfortable within the cluster.

In relation to the timing, it has also happened that several projects have entered the cluster when it had already been active for a period. This means that the initial projects were acquainted with each other and already had an inertia for the collaboration within CS\_AIW. The fact that we have produced multiple documents, including recordings of our previous events made it easier for the new participants to catch up more easily.

As the cluster progressed, it was also a challenge to **keep up with the advancements** and new developments of the different projects and of the cluster as a whole, which we have been able to promote by means of periodic cluster meetings and a distribution email list. In relation to this, there was the **risk to lose the continuity of the cluster** for several reasons, one is the finalization of particular projects, and the other the fact that project members with a closer relation to the cluster may come and go. Fortunately, we have been able to **adapt to these changes** by establishing a clear communication mechanism and multiple co-organized activities.

## 4.2 Addressing technological barriers

Many different technologies have been addressed in the CS\_AIW projects, figure 6 shows a list of the main dimensions of the barriers encountered, which are described in detail below along with the solutions enacted and lessons learned.

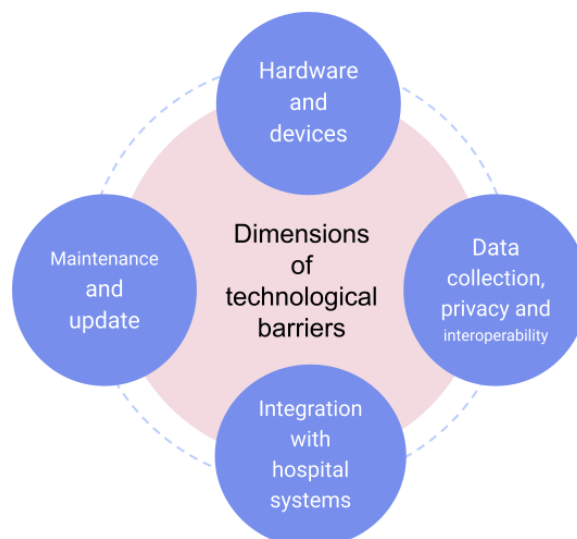



Figure 6. Main dimensions of technological barriers encountered


### 4.2.1 Hardware and devices

 **Smartphone apps.** To implement systems that work in real-world settings, they must be adapted to users' available smartphones. This requires **adapting to a myriad of smartphones' brands and different OS versions** which require specific settings and actions, sometimes to be done manually by end users.

Thus, it requires considerable time and effort to implement and test new features, ensuring that the apps work seamlessly across all devices. As technology and frameworks evolve very fast, simple maintenance can be highly demanding and adapting an app to different smartphones may **require specialized skills**.




Also, it is often **hard to publish in app stores**, especially when continuous location is collected. However, continuous location or other features that may cause problems for stores are important for quantifying daily life and identifying quality of life problems.


 **Solutions:** Wide testing on main smartphones' brands and OS versions and implementation of automatic setup to cope with OS upgrades or new releases of the apps.


Significant effort must be assigned to the specific tasks in the work plan when the developed solution must cope with different versions of the technologies. Frameworks can produce solutions suitable both for Android and iOS (like Flutter) but this also comes with its problems, so it must be carefully considered within the consortium.


It is necessary to consider that some solutions might not be available to all users due to technology constraints. When needed, exclusion of users with non-compliant devices can be considered.

 **Smartwatches.** Several members of the cluster have identified solutions on the market that can be effectively used in clinical trials. However, relevant barriers have been detected:

- Data collected from **commercial devices** are typically not validated and there are no guarantees in most cases.
- **Devices specialized for research** are large, possibly stigmatizing (e.g. screens) and uncomfortable to wear for longer periods. Also, they do not always support good connectivity (e.g., bluetooth) and are very pricey, not suitable for larger studies.
- **Battery life** is typically low when the goal is to collect high-rate data (e.g. accelerometer).
- **Proprietary development kits** do not provide good documentation and offer limited support.

 **Solutions:** There is the possibility to engage with smartwatches vendors. Nevertheless, the experience of our members is that the process of getting in collaboration with a private enterprise for the purpose of accessing a proprietary development framework is not generally easy for everyone, and must be done with plenty of time in the proposal preparation phase.

 **Interaction modalities.** To simulate real life situations, it is many times interesting to consider different interaction modalities, which require tailored processes and solutions, including a combination of devices.

 **Cost.** It is important also to consider the cost of the devices. Usually low cost devices have lower reliability and are more easily breakable. In contrast, better quality devices may be too expensive.

💡 **Solutions:** Try to adapt to real-world technologies already in use by target actors.

## 4.2.2 Data collection, privacy and interoperability

🔧 **Dealing with large volumes of multivariate heterogeneous data from multiple sources** implies working with different protocols for data collection and several standards for data representation, potentially causing data inconsistency and missing data.

The same real-world concepts, e.g., genes, clinical records, can be represented in various formats in existing data sources. The different datasets originating from this variety of data sources thus have different data representation formats, coverages of the domain they represent, and different access methods and permissions. Such properties of the data sources complicate the use of knowledge available in them.

These are the main **semantic interoperability conflicts** identified:

- Structuredness.
- Schematic: different attributes representing patient related concepts, different attributes representing diagnosis related concepts, different identifiers for the same concepts.
- Domain: the data sources cover different aspects of the domain of the concepts (e.g., gene, gene expression, mutation, CNV and CpG), also there exist synonyms (distinct names used to model the same patient-related concepts).
- Representation: different vocabularies for representing patient-related data.
- Language: data sources with data in different languages.
- Granularity: the same concept may be modelled with different levels of detail.

In addition, data collection may be subject to **device restrictions**. It is necessary to investigate ongoing research and establish contacts to understand whether methods/tools may be developed to address and overcome mobile phones restrictions for data export. Also many times it is necessary to **involve end users** to perform simple actions (e.g., open the app periodically) to prevent deactivation.

💡 **Solutions:** It has been key to agree on data **harmonization protocols** and in some cases to define **semantics**, e.g., through cancer ontologies. A main lesson learned is to check in advance data standards and integration potential and allocate the necessary **resources** for such tasks, considering the adequate skills required to perform them successfully.


The resolution of interoperability issues across multiple data sources requires the performance of **pre-processing, curation, and integration tasks**. The process of data integration may include the following steps:


- Pre-processing and curation eliminating redundancies and transforming identifiers into common formats. Entity and predicate recognition and linking can


be conducted over unstructured attributes like short descriptions and comments. Identified entities and predicates can be annotated with controlled vocabulary.

- Semantic annotation. Establishment of equivalences between controlled vocabularies.
- Knowledge integration to describe the correspondences between attributes in the raw data into the concepts, properties, and relations in an unified schema, e.g. with RDF mapping language (RML), RDF vocabularies and OWL ontologies.
- Interlinking the knowledge generated in the projects with other public knowledge graphs, e.g., DBpedia or Wikidata.


For the previously mentioned tasks, **natural language processing techniques** can be of great help, for example to recognize named entities, to discover relationships, map rules or interlink knowledge graphs.

 **Link with patient's health records and data transfer** involves dealing with GDPR and national constraints. In addition, mobile apps are not yet qualified as medical referrals and shall be uploaded by the patient in the health folder.

 **Solutions:** Quality of Life (QoL) questionnaires and scores from mobile apps are exported as pdf files and uploaded in a specific section of the patient health folder by the patient or by the authorized PoC upon patient's consent. We have identified that greater effort is needed from regulatory bodies to facilitate this process.

 **Data privacy and secure data transfer.** A barrier to adoption is that users may fear privacy loss. It is necessary not only to manage the users' expectations but also to make sure that these losses do not happen. This is particularly challenging when transferring wearable data.

It must also be considered that some data types may raise specific challenges. For example, **speech and audio data**. When working with conversational interfaces or analyzing spoken input, a problem arises from the fact that **speech is very difficult to anonymize** without losing important information that may be necessary to process the speech signal (e.g., in CS\_AIW case to detect hints of depression), this undermines the possibilities to share recordings and data collected.

 **Solutions:** Privacy constraints shall be carefully considered when designing a technical solution and research protocols. We have opted for the most privacy-preserving solutions.

To diminish the user's fear of privacy loss, it is important to have **clear privacy statements, informed consent and provide the ability to withdraw** at any point also using the smartphone. Communication with users is fundamental to entrust them and to present the advantages that technology may bring to them.


Standardization of privacy management across mobile OS providers would be needed. The use of a unique set of devices for all research would limit the issues but would not simulate real life unless a standard is agreed by different providers.

With respect to secure transfer of wearable data, it must be managed by a particular project partner that makes it available to the rest of the consortium through a centralized data repository (CDR) based on different access privileges. The data uploaded to the data repository must be previously pseudo anonymised and be devoid of any specific characteristics that allow the connection of a particular piece of information to any present or former patient. The key to allow the linking between the data stored within the CDR and any actual patient resides with the Data Protection Officer (DPO).


CS\_AIW members found it useful to have a wearable manufacturer in the consortium, as it makes it easier to adapt the existing devices to the specific needs of the project.

For the specific case of speech data, we are exploring other possibilities, such as AI techniques. Also, to preserve privacy in speech-enabled interfaces, we have worked on audio processing on-device generating lightweight but yet powerful models that do not require on-cloud resources.

### 4.2.3 Integration with hospital systems

 **Integration with existing hospital systems.** When integrating the technologies developed in hospitals, we have encountered multiple barriers: different languages, different IT systems, varying hospital restrictions and different workflows that make both automatic data collection from electronic health records and transfer of apps to the hospital system difficult.

**Technology complexity.** Our experience shows that there is a big difference between research and product development. Product development is usually focused on simple ready-to-market products, while the results of research projects are based on cutting-edge technologies that involve more complex solutions. The complexity of the systems developed does not only affect the development of the technology itself, but also produces complex bureaucracy (e.g., explaining every module of a sophisticated system in order to be able to deploy it in hospital facilities).

 **Solutions:** Use of open-source tools whenever possible and adherence to standards, data annotation to facilitate interoperability/integration. It is good practice to involve hospital IT and hospital decision makers before starting the experiment and perform accurate cost-effectiveness.

Technology must be implemented locally and only when the system has achieved the necessary qualification, should it be transferred into hospital systems. That is, systems

must demonstrate their usefulness and significant economics and organization impacts to be integrated into clinical routine.

#### 4.2.4 Maintenance and update

**🔧** It is necessary to adapt to fast evolving technologies and keep up with technical innovations and integrate changes quickly and efficiently. This is a very demanding task, especially when the changes must be integrated into hospital systems, which creates costs associated with data maintenance.

**💡 Solutions:** Rely on open and de-facto standard technologies as much as possible, check hospitals' IT standards before developing and implement continuous innovation discovery as part of the technical development.

### 4.3 Enhancing users' acceptance and compliance

Figure 7 shows the main barriers related to user acceptance and compliance, which are described in more detail below.

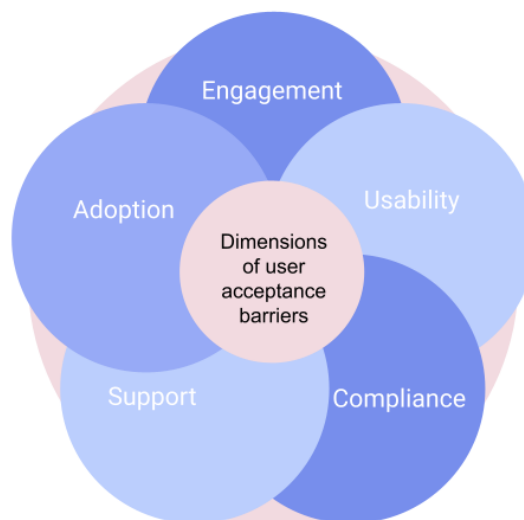



Figure 7. Main dimensions of barriers encountered related to users' acceptance and compliance


**🔧 Engagement.** There exist different barriers to user engagement, depending on the type of user:

- **Patients** need tangible results in order to participate in research. It is harder to recruit patients for observational studies because they do not immediately get something in return for their participation (e.g., guidance, personalized treatment). Also, there are privacy and security concerns: collecting a wide range of data can be another factor of patients not wanting to participate.
- **Clinicians** require that the data and knowledge generated by technology is useful for them, i.e., that they are innovative and more informative than to the ones they usually work with.


 **Solutions:** It is important to carefully describe the overall project aims and the future benefits that can come out from the research effort:

- For patients, the importance of taking part in the study should be underlined and, with equal importance, it should be explained how similar patients will benefit from the data collected in the study. In addition, it is key to be flexible with what real world data (RWD) a patient is willing to provide (e.g., exclude location, exclude web browsing history, etc.).
- For clinicians, provide ways of visualizing the data through dashboards and the generation of intuitive representations and graphics with relevant filtering and search options.


CS\_AIW projects have a strong focus on participatory research. Co-creation facilitates patients' and clinicians' involvement by giving them a voice in the research process, building trust, and promoting understanding of the research topic and its potential outcomes. In the case of clinicians, we found useful to co-design simple metrics and estimates of QoL.


 **Usability.** It is crucial to develop solutions that are easy to use and minimize users' intervention for its correct configuration. In addition, there are other factors that have to do with digital literacy and attitude towards technology.


For clinicians, usability usually entails actionable information. That is, they need a tool to provide timely and insightful answers to their questions in a format that is visual and easy to understand and reliable.

 **Solutions:** It is necessary to anticipate not only the patients' skills and attitudes, but also of other actors such as physicians, informal caregivers, etc. Training activities that show how to interact with the system and obtain the maximum benefit from its use are a very good option, but they must be delivered in effective learning environments tailored to the specific user needs. When designed correctly, these environments can serve as a first validation tool to measure the effectiveness and usability of the services offered.


An important point is to prepare the patient to the readiness level of the technologies delivered in the study which in many cases cannot be comparable with commercial solutions available in the market and explain how different versions will be issued and possible bugs and malfunctioning corrected.

 **Compliance.** We have observed varying degrees of adherence to the procedures established in the projects related to the use of the technical solutions developed. In the worst scenarios, users make a passive use of technology, only in its essential features or even less than expected by the research teams.


 **Solutions:** Recall users by different means (phone, text messages...) promoting the correct use of the technology delivered, while implementing avenues in the apps to make it possible for clinical staff to stay closer to patients.

 **Support.** It is common while the technology is being developed to face moments when the system is not available due to contingencies (e.g., unavailable network connection). A loss of trust may happen in these situations, and also due to bug fixes needed or inexact data reported in the application.


Another important challenge is the time and effort required to monitor alerts and optimize care workflow, e.g., when processing depression cues it is important to be able to detect and act upon cases in which the user may be in danger.

 **Solutions:** To establish realistic workflows for the management of possible malfunctioning and provide asynchronous communication channels (email, recorded messages...) for users to report possible malfunctioning of the system.

Regarding user support on alert situations, we suggest devoting a specific task to deal with these cases. It is important to generate simple and specific alert messages that are understandable and manageable by physicians. To save their time, we have obtained positive outcomes by having a research nurse summarize all collected data related to a specific patient before the physicians acting on the alert.

 **Adoption beyond the project:**

- For patients, it is sometimes complicated to surpass the barrier of going beyond the logic of “I use the technology because the doctor told me to do so”, and the use of the apps is in many cases interrupted after the end of the project.
- For clinicians, the final adoption of the technology after the projects’ finalization is undermined by the fact that many times, they do not get any compensation for their time devoted to the use of the technology (e.g., tracking telemetry data or providing feedback into platforms).


 **Solutions:** To foster patient’s adoption it is necessary to present the benefits generated in terms of knowledge and of clinical application to promote the use of the apps beyond the project phase. We found it was very helpful to carefully pre-validate the technology before delivering it in order to foster the future adoption. Another important aspect is to design the technology in a way that avoids being a constant reminder of the patient’s health problems.

On the other hand, our studies show that discontinued use is not always detrimental, e.g., in the case of mental health, where a plausible objective is that the users at some point do not need the support of the app anymore.


Finally, some CS\_AIW members have designed long-term education programs (as long as 2 years) for patients, their families and caregivers to empower them as actors


in their own care. These programs are based on the scientific-based knowledge acquired during the project, and provide participants with useful skills, validated resources and the opportunity to connect with others that goes beyond the technology developed.

## 4.4 Scientific, legal and ethical barriers

 **Acquiring ethical approvals.** Adding multiple types of data can be very important for the success of observational studies, especially since we are moving away from traditional RCTs towards the use of RWD with causal modeling methods. The challenge is that ethical committees may consider the inclusion of a wide range of very detailed data sources contradicting the data minimization principle. This can extend the time required for processing an ethical application since ethical committees may raise questions on the necessity of collecting specific types of data.

It is necessary to establish privacy preserving protocols and solve potential unclear / unforeseen roles of partners in terms of personal data management.


 **Solutions:** Starting the process of acquiring ethical approval as early as possible is critical to avoid any delays. It is also necessary to define from the beginning data management guidelines and privacy preservation protocols. It is also important to establish formal data processing agreements between project partners discussing the roles (e.g., data processor / data controller) of the entities involved in personal data management.


 **Data quality.** Big Data is characterized by data dimensions, including volume, velocity, variety, veracity, and value:

- Volume denotes that the generation and collection of data are produced at increasingly prominent scales.
- Velocity represents that data is rapidly and timely generated and collected, and refers to difficulties in ingestion of high rate of data inflow with heterogeneous and evolving structures.
- Variety indicates data types, formats, structure, and data generation scale heterogeneity. Data is inconsistent, nor does it follow a specific template or layout; it is captured in diverse forms and sources. These different forms indicate that heterogeneity is a natural property of Big Data, and it is a big challenge to integrate, manage, and analyse such data sources.
- Veracity denotes noise and quality issues in the data. It refers partly to the biases, ambiguities, and noise in data and about understanding the data, as there are integral discrepancies in almost all the data collected. Thus, the necessity to deal with inaccurate and ambiguous data is another facet of Big Data that demands to be tackled to ensure the management and mining of unreliable data. When dealing with wearables as a source of data it is necessary to address missing (e.g., due to lack of Internet connection, battery consumption, etc.), incorrect and incomplete data.




- Value denotes the benefit and usefulness of processing and mining big data. It concerns data quality, including trustworthiness, authenticity, provenance, accountability, and data availability.

 **Solutions:** Carefully devise a **data management plan**, including collection and transfer process from smartphones into repositories. It is important to establish rules for data completeness and coherence that are embedded into the data presentation tools so that experts can verify data quality. The data ecosystem must ensure transparency at all the levels of data management and analytics. Transparent data processing needs to **guarantee traceability** of all the decisions and actions executed by the components of a data ecosystem.


 **Decision making and interpretability.** There exist potential prejudices of some users (e.g. the scientific and medical communities) against the new approaches proposed by the projects and how these have been addressed (e.g. data quality issues, in-silico modeling, transparency of algorithms, control over decision making...). In fact, sometimes having all data and possible conclusions at hand can hinder a correct clinical reasoning.


A related problem is that, provided the innovativeness of the study, physicians need to fully understand the meaning of the many generated parameters (captured data, alerts, chatbot related info, etc.). Developing a clinical decision support system implies **careful assessment of the level of human control or involvement**. Questions such as who is the “human in control” and what are the moments or tools for human intervention? Have to be taken into account as well as the mechanisms and measures to ensure human control or oversight and the measures to enable audit and to remedy issues related to governing AI autonomy.

 **Solutions:** To offer a **realistic account of the limitations** of the results (biases, etc.) and the subsequent level of confidence of the conclusions, limiting the results of computations to the level of interpretative suggestions and leaving the final decision on how to interpret data to physicians.

We also suggest having traditional QoL questionnaires always available and to use intuitive representations and graphs that are easy to process and understand.

The aim must be to **support the patients or complex clinical decision-making processes based on scientific evidence** to improve the efficiency of patient care through a more personalized approach. Human control must be ensured by a strict monitoring of the technical development led by the clinical and legal partner and from an ethics point of view. A **fine-grained human oversight** must be considered and the whole process must be auditable.

 **Restricted collaboration.** A major barrier for integrated care technology happens when hospital departments do not have a **tradition of fluid interaction and collaboration.** This way for example even if the oncology department is involved in a project, many times it is not easy to reach the psychiatry or nutrition department even in the same hospital.

 **Transfer to market and legislation.** A barrier is the lack of knowledge about business models. In addition, sometimes the bureaucracy is so complex (e.g., to be authorized as a medical device) that makes it virtually impossible for SMEs to do it.

# 5

## Future activities

We have set up a **plan for 2023** that comprises the following main activities:

1. Set up a **clinical trial activity group** to cross-fertilize across related projects and engage more with patient groups.
2. Work closer with individual **patient associations**. In February 2022, the MoM4 event was a milestone for the engagement of patients and end user groups with the cluster. We plan to engage with other groups (e.g., QoL .. Doctors, Nurses & Family of Patients). It is understood that Cancer survivorship is the prime focus of clinical experts but QoL is less to their foreground.
3. Further **communicate the cluster and results**:
  - Set up an online webinar on Digital Health Technology for Cancer, where we share lessons learnt, results and implementation barriers.
  - Discuss our co-design experience with patient associations and stakeholders with the European Commission.
  - Create a map of knowledge of the partners for the specific area of cancer. The main aim is to boost potential collaborations as a network of experts and opportunity to draft guidelines, roadmaps and eventually new projects.
4. Building on from the MoM3 event (September 2021) and the completed MoM5 events (December 2022, March 2023), we intend to advance the **business acumen** aspect through engagement with business angels, accelerators, and other relevant actors. Ultimately, and depending on the TRL (Technology Readiness Level), we want to bring project outcomes closer to the market, with a view to help clinical professionals and in particular their patients to obtain a better quality of life.
5. Continue with our **key activities** (see section 3):
  - Meeting of minds. Preparation of a Meeting of Minds 5 (MoM5) on Market Perspective.
  - Podcasts. Preparation and release of new episodes.

- **Better Practice Guide.** Report our conclusions on GDPR, Ethical and Clinical Patient approval, and also how to move further away from the traditional clinical record approach.
6. **General cluster meeting.** We plan to meet in person in the first half of 2023.
  7. **Funding.** We will explore the possibilities for support and funding and plan how to move forward, as many of the project members are finalizing in 2023.

# 6

## Conclusions and recommendations

One of the main lessons learned from CS\_AIW is how to join forces and give visibility not only to our results and innovations, but also to the barriers and challenges. This white paper documents the conclusions reached from our collaboration, thanks to which we have been able to discuss with stakeholders and policy makers, share our results, increase user/patient engagement, and foster interdisciplinary cross-sectorial exchanges. We have also faced difficulties and reported our shared experience on how these can be minimized in the future for other projects.

Among the most relevant experiences for our consortia, is how to address patient associations, involve final users in co-creation and share the possibilities that technology can bring to enhance their lives. As demonstrated in recent studies performed within the cluster, technology is welcome and there are few sceptical users: patients see the benefits that the technology brings. However, as identified in co-creation panels by our projects, false expectations can also be raised on the capabilities of technology and its effects on certain areas, e.g., mental health.

We have provided a detailed overview of the main lessons learned regarding technological barriers, enhancing user acceptance and compliance, and scientific legal and ethical barriers, which we can translate into the following recommendations:

- A strong focus should be placed on participatory research.
- Expectation management is very important. End users should be aware of the expected technology readiness level.
- The time and effort required to monitor data and optimize workflows must not be underestimated.
- It is highly desirable to adapt to real-world technologies in use by target sectors.
- Open-source tools that adhere to standards for data annotation and interoperability should be prioritized.
- It is crucial to work intensively in pre-production settings before transferring to hospital systems.
- Attention is usually not paid with enough advance on data standardization, pre-processing, curation and integration, making sure the necessary expertise and resources are allocated within the project.

- Careful consideration of data privacy constraints and secure data transfer protocols must be complemented with effective communication with users to foster trust.
- Computer scientists and data experts should also be included in the ethical panels, whose members are usually doctors.
- Delays in the authorisation of clinical trials and studies by national regulatory authorities and a general lack of consensus in the interpretation of the General Data Protection Regulation (GDPR) constitute barriers that hamper the collaboration among research projects.
- Addressing the business acumen through dedicated activities with open roundtables helps to make transfer to market more approachable by consortia.



The projects in #CS\_AIW have received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement no.:

ASCAPE - Ref 875351  
BD4QoL - Ref 875192  
CAPABLE - Ref 875052  
CLARIFY - Ref 860627  
FAITH - Ref 875358  
LIFECHAMPS - Ref 875329  
MENHIR - Ref 823907  
ONCORELIEF - Ref 875392  
PERSIST - Ref 875406  
QUALITOP - Ref 875171  
REBECCA - Ref 65231



**UNIVERSIDAD  
DE GRANADA**

The printed copy of this White Paper has been supported by the MENHIR project (ref. 823907) and the University of Granada (Spain)

