

## Application Details

---

**Call Name:** CaixaResearch Health 2022

**Application Number:** HR22-00080

**Proposal Title:** Development, implementation and clinical trial of an eHealth ecosystem of psychosocial care and symptom management for cancer survivors.

**Proposal Description:** Expansion and implementation and clinical trial of an eHealth ecosystem to leverage psychosocial care to cancer patients effectively and efficiently in comparison to treatment as usual

**Proposal Acronym:** Care4Survivors

**Project Leader:** Cristian Ochoa

**Host Organization:** Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)

**Faculty or Research Center:** Institut Català d'Oncologia (ICO)

## Classification of the Application

---

**Select the Thematic Area of your proposal**

Enabling Technologies

**Is the proposal about Amyotrophic Lateral Sclerosis (ALS)?**

No

**If the proposal is about Enabling Technologies, please select to which of the other 4 Thematic Area is related to**

Oncology

**Classify your proposal**

Clinical

**Select the type of your proposal**

Research Consortium

**Does your proposal include Civil Society Organizations?**

Proposal with Civil Society Organisation(s)

**Information for "la Caixa" Foundation**

**Are you or any member of your group applying to any other "la Caixa" Foundation call (research, innovation projects and fellowships)?**

Yes

**Please indicate the application code (such as HR20-00001, CI18-00001...) for each of the proposals where you or a member of your group applied**

**Application Code**

HR22-00501

**Do you or any member of your group have an ongoing project with "la Caixa" Foundation (research, innovation projects and fellowships)?**

No

**Select the discipline that best classifies your proposal**

Diagnostic tools, therapies and public health

**Keywords****Main Keywords**

F04.096.628.808.500 - Psycho-Oncology;H01.671.293.239 - Digital Technology;H02.249 - Evidence-Based Practice

**Other Important Keywords**

E02.183 - Clinical Protocols;F01.470.315 - Psychological Distress;E01.370.872 - Symptom Assessment;F01.058.683 - Posttraumatic Growth, Psychological;L01.399.500 - Health Information Management

## Proposal Information

---

### Scientific Abstract

---

Cancer diagnosis and its treatments cause a massive psychosocial impact. Several interventions have already proved to be effective in reducing patients' emotional distress and improving their quality of life (QoL). However, their access is confronted with poor early detection of needs, long waiting lists, mobility, and economic restrictions. Most of these obstacles can be overcome through the digitalisation of health services, which has the potential to generate a breakthrough in care standards.

In 2019, leaders of this consortium developed an innovative eHealth ecosystem to foster healthy experiences in cancer, integrating a four-stepped psychosocial program focused on breast cancer (BC). Care4Survivors is the evolution of that ecosystem to reach a broader cancer population. The study will be developed in the first year after diagnosis of lung cancer (LC) or colorectal cancer (CRCA), which are the second and third most frequent in both men and women and the first and second causes of death in Europe. Besides tailoring the platform to LC and CRCA, the new ecosystem will incorporate a gradual symptom management module with patient-reported signs and remote monitoring through wearables.

The present project will conduct 2 multi-country (Spain and Portugal) and randomised trials to compare the effectiveness and cost-utility of the Care4Survivors ecosystem with the usual psychosocial care and symptom monitoring for LC and CRCA. The assessment of both interventions will cover implementation and performance indicators (e.g., needs detected, satisfaction), psychosocial outcomes (e.g., stress, QoL) and symptom management (quantity and time to be treated).

Also, a comparative economic analysis will be conducted with emphasis on costs reductions for the health system, return-to-work time, medication use and adherence. We expect the eHealth platform to be as effective as the usual care regarding health outcomes but to be more economical while improving patient experience.

### Lay Summary

---

Being diagnosed with cancer is usually a turning point in a person's life. Although educational, emotional, and social interventions have proved to support patients, limited resources are often available to reach all of them, and especially at the time they need such attention. This project will join Spanish and Portuguese centres with great expertise in cancer care and health research to provide a digital ecosystem that covers the psychological, social and health needs of patients with lung or colorectal cancer. The intervention will be applied in the first year after the diagnosis, and its effectiveness will be compared with usual care in terms of its capacity to improve relevant psychosocial indicators (i.e., distress, quality of life) and to monitor and manage symptoms more effectively. Moreover, an economic analysis between interventions will also be performed to estimate the cost of each intervention and its advantages in terms of the number of gained years lived in full health.

## SCIENTIFIC EXCELLENCE AND IMPACT

---

### Project Quality

---

#### State of the Art

---

To be diagnosed with cancer is a life-threatening event, around half of patients experience significant emotional and psychosocial necessities often unrecognised[1]. Actually, distress has been proposed as the sixth vital sign along with temperature, blood pressure, pulse, respiratory rate and pain[2]. To manage all these symptoms appropriately is crucial to preserve quality of life (QoL) in cancer patients[3]. In fact, substantial symptom burden is a major contributor of poor QoL in LC [4] and in CRCA survivors[5] and, if not managed adequately, they may have a massive impact on patients' functionality, treatment compliance and use of healthcare resources apart from QoL[3].

Yet, the inclusion of distress as a vital sign pushes the boundaries of comprehensive cancer treatments beyond symptom management. Indeed, one of the most recent and complete meta-analyses on the effects of psychosocial interventions has proven their efficacy on distress and QoL in cancer survivors[6]. But even when this evidence is well-established, access to these services is far from universal given poor early detection strategies, shortage of health professionals in national health systems, mobility restrictions and long waiting times for interventions[7].

Among the actions proposed to efficiently implement psychosocial attention and adequate symptom management are to deliver them progressively and responsively, to restructure their contents and to regulate their intensity according to patients needs[8]. Another possibility is to make use of Information and Communication Technologies (ICT). Indeed, web and mobile platforms for screening, monitoring, or managing physical and psychosocial symptoms have the capacity to overcome most of the mentioned limitations[9]. Similarly, remote monitoring via wearable technologies enables collecting health-related measures in real time, offering a complete picture of patients' health while making clinic visits dispensable. Electronic patient reported outcomes (ePRO) obtained through these devices have shown to extend survival and to reduce overall costs compared to traditional alternatives[10,11]. Specifically, the use of wearables improved sleep quality in BC patients[12] and physical activity and capacity[13] in CRCA survivors[14]. Those measures have been related to less fatigue, pain and improved QoL in patients with LC[15]. Regardless all these results and the ability of most persons to use these devices—also the elderly[16]—, ICT resources still lack solid comparative evidence in terms of their psychosocial and health impact[10,17].

The presented project will use ICT to provide an eHealth platform based on the successful BC platform (see Preliminary data\*) developed by this consortium, adapted for patients with LC and CRCA. This platform will be a digital companion for cancer survivors by delivering psychosocial attention to address their needs and by monitoring and addressing those symptoms expected to have an impact on key health indicators. The current intervention for BC consists of four stepped levels of psychosocial care

which starts with a screening and monitoring module and becomes more specific according to patients' needs (psychoeducational campus, support community and psycho-oncological group treatment through videoconference). The symptom monitoring, which will include digital wearables, follows the same structure by providing further attention depending on symptom severity and urgency. For a graphical representation of the whole stepped program please see Figure 1.

Care4Survivors advances towards a holistic understanding of cancer using patient-reported experience and outcome measures (PREMs and PROMs) and remote physiological records. Analysing the relation between self-reported and physiological experience during the cancer journey and their predictive ability is an added value of this project, which will employ flexible and diverse information to follow-up the patients' journey.

### **Preliminary data**

---

There is substantial evidence reporting good clinical results for the use of screening and monitoring systems, and online psychosocial treatments in cancer. However, no studies have been found in the literature integrating these services. Similarly, no publication has been found exploring the effectiveness of stepped interventions adapted to survivors' complexity, performing the whole program online, or estimating their cost-effectiveness. This is an important gap that the current health crisis derived from COVID-19 has turned into a pressing need, especially considering the increase in cancer prevalence and survival, and the great difficulties to deliver in-presence psychosocial care. The technological integration of these resources is proposed as a solution to enhance service coverage and improve efficiency, since recent reviews have suggested these systems to be cost-effective and acceptable for both service funders and users[18,19].

The most important landmark feeding into Care4Survivors is ONCOMMUN (<https://oncommun.eu/>), a project funded by the European Institute of Innovation and Technology (EIT) that developed in 2019-2020 a pilot version of the eHealth ecosystem environment for BC patients, which has now provided care to more than 750 users. According to the data collected from the implementation of such pilot BC platform, acceptance, use and attrition rates reached 57.62%, 74.60% and 15.34%, respectively. In addition, up to 76.19% of users reported being satisfied with the platform and 75.95% informed that it was easy to use. Among an initial sample of 189 participants that were first recruited and therefore have been further analysed, up to 150 health symptoms and 293 psychosocial needs were detected during the first year, which could be responsively managed by the eHealth system in an average time of 2.05 days for the former and 5.91 days for the later, leading 94.33% of users to remain in the preventive steps (Level 1 to Level 3). Finally, baseline levels of participants in the study suggested that 46.32% of patients experience significant distress after their diagnosis, which clearly justifies the development and delivery of intervention programs. These results have been sent for publication and are currently under review. Also, our team has proven that the on-line positive psychotherapy which is delivered in the 4th intervention level (Figure 1) is as effective as other well-established approaches[20], and that it performs equally in face-to-face and online formats[21]. Finally, preliminary cost-effectiveness analyses reported to the EIT suggested that the eHealth ecosystem has the potential to reduce usual care costs by 25%, by promoting savings particularly in transportation, infrastructure and disability leaves items.

In conclusion, we propose herein the refinement and appraisal of an innovative eHealth ecosystem to integrate digital health follow-up with online stepped psychosocial care and symptom management, with the objective of providing services to a broader cancer population. The lessons learned in the last three years will serve as valuable feedback to scale the solution to LC and CRCA in Spanish and Portuguese hospitals. Thus, this project pursues a critical advance towards an integrated model of cancer care that will adapt to the specific psychosocial and health needs of each survivor. Such feature, acquired through the cross-fertilisation between technology and healthcare, has the potential to become a turning point in the delivery of patient-centred interventions to the society. It is worth highlighting that IDIBELL-ICO was the leader of ONCOMMUN, IPOC was a clinical partner in the consortium, and FUOC's PI was the scientific manager. This record of joint successful collaboration strengthens the capacity of the consortium to fulfil the challenges faced by this project, which will also take advantage of many resources and materials already translated to both Spanish and Portuguese.

## Project aims and objectives

---

The main objective of the present project is to implement and assess an online stepped ecosystem for psychosocial and symptom screening, monitoring, management and care (Care4Survivors) in Spain and Portugal, using an eHealth platform developed to offer early detection and tailored treatment to LC and CRCA survivors. The delivery of this cutting-edge solution pursues to generate a positive impact on participants' health, proving to be not only effective but also efficient in time and budget commitments. Moreover, the samples selected will enhance its future scalability by allowing the collection of data of heterogeneous oncological populations, while covering the current need for online technologies in healthcare.

In order to reach these overall objectives, the effectiveness and costs of the eHealth platform will be compared to current psychosocial and symptom management standards in the participating healthcare institutions through two noninferiority randomised trials. Specifically, the objectives pursued are:

- To register the number of emotional distress cases and the time needed to deliver psychosocial care to them.
- For the eHealth solution, to analyse the percentage of resolved cases within the preventive steps (from level 1 to 3).
- To register the number of symptoms detected, and the time needed to provide management.
- For the eHealth solution, to analyse the percentage of resolved cases within the level 1 (automatic symptom advice).
- To promote changes in survivors' levels of distress, post-traumatic stress (PTS) and growth (PTG), as well as QoL.
- To register physiological variables relevant to record emotional arousal, stress, and activity levels in cancer patients
- To improve the acquisition of cancer-related health knowledge among survivors through educational resources. These are available in the digital solution in (2nd level) and will be provided to the usual care group through a website.
- To evaluate the effectiveness and cost-effectiveness of introducing the eHealth ecosystem strategy in LC and CRCA patients compared to the usual psychosocial care from the social perspective for the two countries independently and in combination.
- To achieve high levels of use, usability, acceptability and satisfaction of the platform

The eHealth platform is expected to show similar effectiveness levels to those of usual care for the psychosocial outcomes measured. However, it is foreseen to be faster in detecting clinical cases and more responsive, as well as to reach higher cost-effectiveness.

## Expected results

---



1. The creation of eHealth environments to improve access of LC and CRCA patients to psychosocial support and symptom management.
2. To facilitate the detection of symptoms and psychosocial clinical cases and to decrease the waiting-time to receive attention by 25% compared to the current average 15 days of the usual care.
3. Survivors in the eHealth arm will obtain similar results in distress, stress, growth, and QoL than those receiving usual care. Improvements will be found in 50% of participants, who will mostly (>75%) remain in preventive intervention steps.
4. Monitoring of clinical symptoms is a crucial part of the oncological follow-up of patients with CRCA/LC, which is currently conducted in face-to-face settings, consuming staff resources and patients' time. The introduction of wearables will allow remote symptom management, decreasing by 15% nursing follow-up time.
5. The eHealth solution will improve health knowledge by 20% compared to usual care, increasing their self-care practices.
6. To increase savings in public health, achieving better cost-effectiveness per QALY by 15%. The digital system will improve adherence to key medication, additionally decreasing by 20% the need for psychotropic drugs, and by 25% the number of return-to-work days after diagnosis.
7. The platform will reach high usability and satisfaction among more than 70% of its users; with acceptance and use rates over 50% and 65% respectively, and an attrition of 25%.

## Scientific approach and workplan

---

### Methodology and scientific approach

---

**Experimental design:** We propose two noninferiority randomised trials testing two experimental conditions: 1) eHealth, 2) usual psychosocial care. Assessments will be conducted at recruitment (T0), 4 months (T1), 8 months (T2) and 12 months from T0 (T3). Two separate trials have been devised given participants' characteristics, intervention contents and comparators are specific to each diagnosis. All practices will adhere to Responsible Research and Innovation (RRI) principles.

**Participants:** Participants will be recruited through the LC and CRCA units of the Institut d'Investigació Biomèdica de Bellvitge - Institut Català d'Oncologia (IDIBELL-ICO, IDIBELL is the institute managing ICO's research), the Instituto de Investigación Sanitaria del Hospital Universitario La Paz (IdiPAZ), and the Instituto Português de Oncologia de Coimbra (IPOC). Individuals accepting to participate will undergo assessments to check the following inclusion criteria: 1) being  $\geq 18$  years; 2) first episode of LC or CRCA (determining their inclusion in one trial or the other) in the previous 6 weeks; and 3) access to internet and user-level experience. In turn, the exclusion criteria are: 1) current major depressive episode, 2) risk

of self-harm, 3) active psychotic symptoms, 4) substance abuse and 5) expected life expectancy under 6 months. Exclusion criteria 1 to 4 will be assessed with the MINI International Neuropsychiatric Interview. Patients not meeting eligibility criteria but experiencing substantial distress will be referred to the Psycho-oncology Unit of participating hospitals. Sample sizes were estimated with R software, setting a non-inferiority margin of 5 points in the Hospital Anxiety and Depression Scale [22], with power at 80% and one-tailed  $\alpha$  of 2.5%. A dropout rate of 25% was assumed. It was anticipated that 152 participants were necessary in each trial ( $n = 76$  per arm). Therefore, considering both diagnoses, 304 participants will be recruited. Due to the capacity of each centre, 50% of the sample will be collected at IDIBELL-ICO, 30% at IdIPAZ and 20% at IPOC.

**Variables and instruments:** The primary outcomes are the number of detected symptoms; the waiting time until intervention; and emotional distress, PTS, PTG and QoL. Secondary variables are related to cost-effectiveness, health knowledge and eHealth literacy, adherence, satisfaction with the intervention and usability. The specific instruments are:

- 1) Sociodemographic, clinical, and economic data. Obtained from health and digital records.
- 2) Health symptoms. Edmonton Symptom Assessment Scale (ESAS) [23].
- 3) Emotional state thermometer. 0-10 Visual-Analogue Scale (VAS).
- 4) Emotional distress. Hospital Anxiety and Depression Scale (HADS) [24].
- 5) PTS. Post-traumatic Checklist-5 (PCL-5) [25].
- 6) PTG. Post-traumatic Growth Inventory (PTGI) [26].
- 7) QoL. European Quality of Life Scale (EQ-5D-3L) [27].
- 8) Treatment adherence. Adherence to Refills and Medications Scale (ARMS) [28].
- 9) Health knowledge. Ad-hoc questionnaires after educational videos and articles.
- 10) Physiological measures. Sleep hours and quality, heart rate and HRV, steps, oxygen saturation and energy expenditure.
- 11) Platform usability. System Usability Scale (SUS) [29].
- 12) Satisfaction with the intervention. 0-10 VAS.
- 13) eHealth Literacy. eHealth Literacy Questionnaire (eHLQ) [30].

Measures 3), 10) and 11) will only be collected in the eHealth arm since these are linked to the system (see Interventions section below). For a detailed assessment schedule see Table 1.

**Procedure and data acquisition:**

#### 1. Development of LC and CRCA environments:

This design phase will be fed by results of the previous BC system and by two focus groups with professionals and survivors in each country, one for LC and one for CRCA. These will entail 6-12 participants (gender-balanced) each and will be transcribed and analysed according to Thematic Analysis. Before the focus groups, literature on eHealth interventions for LC and CRCA will be systematically reviewed to find topics relevant to discuss with participants. The knowledge generated by the aforementioned tasks will be integrated by a working group composed by at least one patient and one professional from each diagnosis, the project coordinator, a representative of the technological provider, a gender equality and a health literacy expert from the Fundació per a la Universitat Oberta de Catalunya (FUOC), an expert in health lexicology from Universitat Pompeu Fabra (UPF), and a

representative of the Federació Catalana d'Entitats Contra el Càncer (FECEC) to strengthen the views of end users. This working group will also consider the gender perspective in its composition and decisions.

The solutions for both cancers will share a set of structural items (e.g., psychosocial instruments), to which diagnosis-specific resources will be added building upon the working group decisions (e.g., symptoms available in LC must be different to those in CRCA). A preliminary Portuguese BC platform was also created in 2019 and the time for development at IPOC is expected to be reduced.

2. Clinical trials implementation: Survivors diagnosed with LC or CRCA will be invited to participate by their medical team. If interested, they will meet with our group at their hospital, the study will be described and informed consent signed in case of acceptance. In the eHealth arm, participants will receive a smartwatch to register physiological activity and those lacking equipment (i.e., smartphone or tablet) will be offered a device.

Interventions:

1) eHealth intervention: This group will access the Care4Survivors Basics (1st level) for their diagnosis, the base platform for screening and monitoring from which both the psychosocial and symptom management programs start. See Figure 1 for a graphical representation.

The psychosocial program features three additional levels: an educational campus (step 2), a peer-support community (step 3), and online group psychotherapy (step 4). To decide on movements to higher levels of care, the emotional state thermometer is administered weekly. If score >5, users are asked to complete the HADS. Then, if HADS > 9, they are scaled up. Participants remain in each step for at least 2 weeks, allowing adequate access to its featured services. In the symptom management program, when severe symptoms are identified in the Care4Survivors Basics, nursing staff contact patients to provide health education (2nd level) and scale them to medical staff if symptoms are not solved in 1-2 weeks (depending on severity; 3rd level).

2) Usual psychosocial care: This group will receive standard psychosocial care in participating centres, led by a mental health professional. In Europe, different management programs are offered across regions. Therefore, clinical partners have agreed in advance that 12 monthly individual, 60-minute sessions of emotional support and psychoeducation adapted to each cancer group are representative of their practices. This program will be delivered together with the usual symptom management in these institutions (i.e., follow-up visits and nursing calls).

A shared protocol will be developed for both interventions, in agreement between partners, which will be disseminated in the recruiting institutions before the trials' start to ensure consistency.

Data collection and analysis: Two databases will be created at each recruiting centre for each trial. The first one will associate participants' identifiable personal data (e.g., names) with an alphanumeric code, and will be saved in an encrypted external hard drive stored and key-protected within the office of the institution's PI. The second database will record all data to be analysed making use of these alphanumeric codes and will be stored in a secure collaborative cloud compliant with the European General Data Protection Regulation (GDPR; EC/2016/679). Data will be gathered using REDCap

(Research Electronic Data Capture), which is also GDPR-compliant. REDcap supports blind randomisation, which will be employed in both trials, stratified by centre and cancer stage. Data will be monthly downloaded from REDCap, coded in both databases, and these backed up in a second encrypted external hard drive. Every 3 months one researcher at each clinical centre will conduct a data integrity check.

Descriptive results will be provided at baseline and between-group differences assessed with Student's t-test and chi-squared tests. Implementation and performance variables will be analysed, with Multilevel linear models (MLM) used to compare both groups in variables 2 and 4-8 (see Table 1). Effect sizes (Hedges' g) will be reported, and non-inferiority tested. Finally, for cost-effectiveness analyses, a Markov model will be developed to simulate two hypothetical cohorts of patients with LC and CRCA as they transition across exclusive health states with a time horizon of 6 and 12 months. A health utility value will be assigned to each health state to measure the QoL. The analyses will be performed under the social perspective. Analyses will be conducted using R and SPSS, separate results will be generated for each diagnosis and the effect of moderators will be analysed, including gender, digital health literacy and clinical site.

## **Work plan and timeline**

---

WP1-Coordination and management: Led by the Steering Committee (PL and PIs) and informed by an Advisory Board. Annual reports will be written. In-person/online meetings will be alternated every 3mo. Risk mitigation plans will be applied and ethics supervised.

WP2-Development of the LC and CRCA environments: To define the new environments, knowledge will be collected through literature reviews (registered and sent for publication in an open access journal) and focus groups, then merged with the BC study results by the project's working group and presented in a report

WP3- Physiological data monitoring integration. WP3 will start with a literature review (published in an open access journal) of psycho-physiological markers of arousal, stress, and activity employed in oncology. Then, decisions of the specific markers to use will be integrated into the Care4Survivors ecosystem (WP2)

WP4-Care4Survivors Portuguese: All new texts will be translated and culturally adapted by IPOC, and then integrated with those from the pilot BC version into the final Portuguese ecosystem

WP5-Clinical trials implementation: Both trials will be registered and disseminated at hospitals, and a final version of the protocols agreed. Recruitment and T0 assessments will start and continue until T3 completion. An engagement report will be written to allow mitigation plans and therapies will be supervised and assessed with standardised tools

WP6-Data management and analysis: A data management plan will be produced. Databases will be updated and backed up monthly and checked for integrity every 3mo. Analyses will cover baseline data as well as longitudinal and cost-effectiveness data

WP7-Dissemination to the society: A dissemination plan will be devised. The study will be presented in, at least, 10 public actions, 10 scientific conferences and 4 journal articles. A webpage and social network accounts will be created, and guidelines shared with policymakers

Please see Figure. 2 (Pert Chart)

## Proposal task Gantt Chart

#	Work Package	Name	Description	Responsible	Start Date	End Date	Status
---	--------------	------	-------------	-------------	------------	----------	--------

1	1	Scientific coordination	Via the Steering Committee, coordinated by the activity leader, Dr. Cristian Ochoa, with input from the Advisory Board.	Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)	01/09/2022	31/12/2025	Completed
2	1	Administration, communication, and reporting	Cloud management, email management and further systems will be used for communication and coordination. Annual reports will be written and sent to the funding institution (D6, D10, and D12; months 12, 24, and 36).	Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)	01/09/2022	31/12/2025	Completed
3	1	Consortium meetings	Organisation of face-to-face consortium every 3 months and interspersed with network-wide videoconferences.	Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)	01/09/2022	31/12/2025	Completed
4	1	Risk management and mitigation	A monitoring process will be applied through a traffic lights system. Mitigation plans will be discussed to apply the best solution available.	Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)	01/09/2022	31/12/2025	Completed
5	1	Clinical Ethics compliance	The PI at each institution will safeguard the compliance of the protocols.	Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)	01/09/2022	31/12/2025	Completed
6	1	Development of the digital ecosystem	The gender-balanced working group devised for this project will analyse the information collected in the previous tasks to conform a list of recommendations (D1, month 6) to be implemented by the technological provider in the design and development of the LC and CRCA platforms (M3, month 9).	Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)	01/09/2022	01/06/2023	Completed

7	1	Cost-effectiveness modelling, analysis and reporting	Development of Markov models for LC and CRCA for the two countries independently and in combination, and cost-effectiveness analyses supplemented by sensitivity analyses to assess the effect of uncertainty concerning the various model input parameters on estimated cost-effectiveness of the optimal strategy identified for each country. These results will be reported in a cost-effectiveness report (D14, month 36).	Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)	01/09/2024	31/12/2025	Completed
8	2	Evidence updates and conceptualisation	A systematic review will be registered (M1, month 3) for each of the interest cancer patients (LC and CRCA) and sent for publication in open access journals (D7, month12).	Fundación para la Investigación Biomédica del Hospital Universitario La Paz	01/09/2022	01/09/2023	Completed
9	2	User needs analysis	User needs analysis for developing a seamless, secure, and consistent ecosystem. Focus groups will be conducted at IDIBELL-ICO and IPOC to gather information on potential additions and changes in both cancer environments.	Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)	01/09/2022	01/03/2023	Completed
10	3	Analysis of psycho-physiological markers	Analysis of psycho-physiological markers of arousal, stress and activity. A literature review will be registered (M2, month 3) and sent for publication in an open access journal (D8, month 12).	Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)	01/09/2022	01/09/2023	Completed
11	3	Integration of psycho-physiological markers	Integration of psycho-physiological markers into the Care4Survivors LC and CRCA ecosystems in Spain (ICO-IDIBELL and HULP-IdiPAZ) and Portugal (IPOC).	Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)	01/01/2023	30/06/2023	Completed

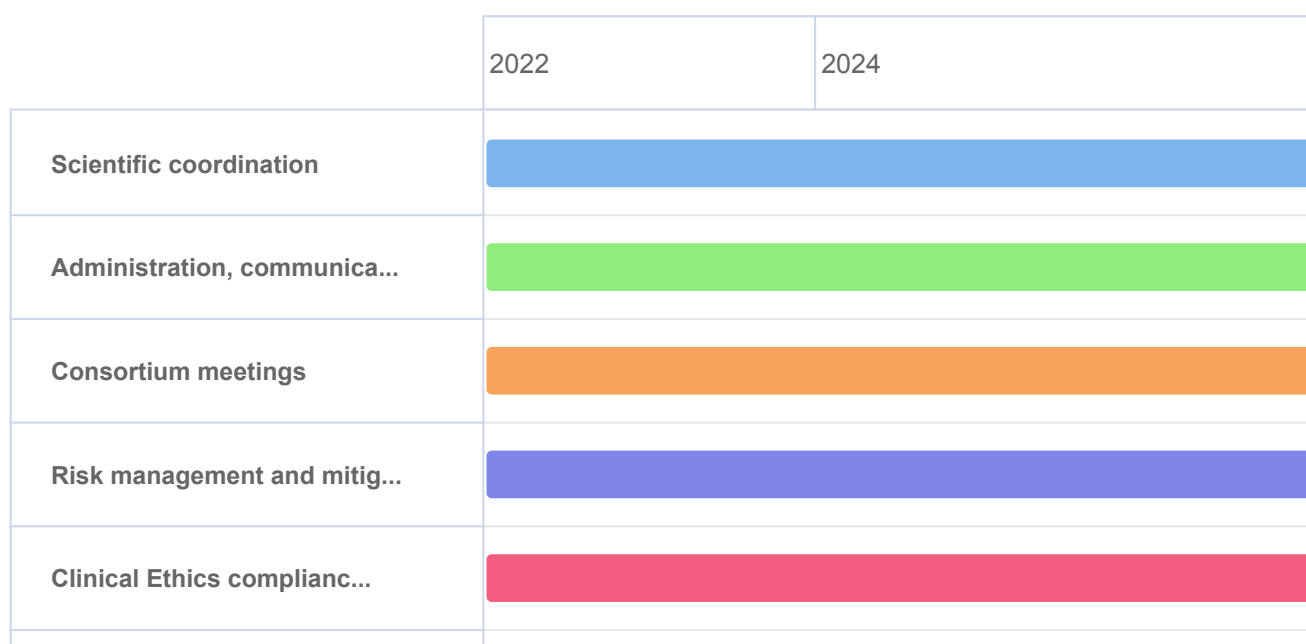


12	4	Translation Package	All new texts needed to conform the LC and CRCA environments will be translated by IPOC (D4, month 9).	Instituto Português de Oncologia de Coimbra Francisco Gentil, EPE	01/01/2023	01/07/2023	Completed
13	4	Adaptation of materials and cultural review	The texts translated will undergo a cultural review by IPOC members to ensure their applicability in their region, giving particular relevance to the educational materials in the Campus.	Instituto Português de Oncologia de Coimbra Francisco Gentil, EPE	01/01/2023	01/07/2023	Completed
14	4	Development of the Portuguese ecosystem	Outputs from the previous tasks will be merged to lead to the final version of the Portuguese ecosystem (M4, month 12).	Instituto Português de Oncologia de Coimbra Francisco Gentil, EPE	01/01/2023	01/10/2023	Completed
15	5	Clinical trials preparation	Clinical trials preparation and registration of the final version of the protocols in an open repository (D5, month 9). Online workshops will be conducted in each centre to internally disseminate to professional teams.	Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)	01/03/2023	01/09/2023	Completed
16	5	Recruitment	Recruitment will start at the three clinical centres (ICO-IDIBELL, HULP-IdiPAZ and IPOC) at month 13 (M5) and will remain open for 9 months. After 5 months recruiting, an engagement a unified report will be written by IDIBELL-ICO (D9, month 17).	Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)	01/09/2023	01/06/2024	Completed



17	5	Psychot herapy supervi sion	The group psychotherapy at the 4t level of the eHealth arm and the psychological support from the usual care arm will be supervised and a random selection of sessions assessed with standardised tools to estimate treatment integrity at all clinical centres	Institut d'Investiga ció Biomèdica de Bellvitge (IDIBELL)	01/ 09/ 20 23	31/ 10/ 20 25	Co mp let ed
18	5	Baseline and follow-up assessments	T0 assessments in the two trials will be followed-up in month 21, and T3 in month 33 (M6).	Institut d'Investiga ció Biomèdica de Bellvitge (IDIBELL)	01/ 09/ 20 23	31/ 10/ 20 25	Co mp let ed
19	6	Data manage ment and curation	A data analysis plan (DAP) will be written (D2, month 6). Databases will be created and updated periodically, undergoing also integrity checks.	Universitat Oberta de Catalunya (UOC)	01/ 09/ 20 22	31/ 12/ 20 25	Co mp let ed
20	6	Psychosocial and health data analysis and reporting	Analyses will be firstly performed on complete baseline data and described in a report (D11, month 27), and then on longitudinal data, whose results will also be reported (D13, month 36), always according with the DAP.	Universitat Oberta de Catalunya (UOC)	01/ 07/ 20 23	31/ 12/ 20 25	Co mp let ed

Gantt Diagram of the proposal





## Study limitations and contingency plan

Risk assessments will be conducted at consortium meetings every 3 months. The following risks will be reported to the WP coordinator to for their management:

- Unsatisfactory collaboration: Most partners feature a successful track record together, which ensures their cooperation. Also, the creation of a steering committee (SC) will ensure the face-to-face and virtual meetings to prevent and anticipate this problem, seeking the collaboration of other consortium members to mitigate it.
- Slow recruitment: The PI at each recruiting centre will organise a meeting with professionals to solve potential doubts and queries. Closer support will be offered to elder patients to facilitate their participation.
- Difficulties in understanding or using Care4Survivors: A health literacy expert will be part of the development team to prevent this risk. A Welcome program will be conducted with all to make sure they can use the platform effectively.
- Difficulties maintaining the participants engagement: Participants will be followed up by professionals hired by the project to solve technical difficulties and to identify engagement problems to solve proactively.
- Failure to disseminate results effectively: The network of scientists', practitioners', and specially survivors' associations (FECEC) offered by the consortium mitigates this risk. If one action fails to reach enough stakeholders, all members will seek a future replacing or reinforcing activity.

## Impact

---

### Scientific and social relevance

---

The cost of cancer treatment and the associated long sick-leaves represents 85 billion EUR in Europe. To date, research has proved the positive effects on health of screening and monitoring systems and online psychosocial interventions, but these services have not been integrated in cancer settings yet. This timely proposal will test an all-encompassing digital environment to improve distress and QoL in oncological patients, while increasing their safety through remote symptom monitoring. In addition, we present a thorough analysis in terms of cost-effectivity, which will be a valuable addition to implementation science.

Health education needs and emotional distress typically occur in the main psychosocial transitions of the cancer journey (e.g., treatment, return-to-work, relapses). Thus, an innovative online system focused on such transitions will allow earlier and adjusted educational and psychosocial interventions, which are crucial for ensuring treatment adherence, distress reduction, and enhancement of QoL. The results obtained by the running BC digital ecosystem suggest that these objectives may be fulfilled. Building upon these firsts findings and adding all the improvements described herein, a refined version of the

system will be launched and adapted to meet the concrete needs of LC/CRCA survivors.

The recruitment of participants in LC/CRCA, which are the second and third most frequent cancers both in woman and man, is anticipated to provide valuable input on the differential performance of the solution among clinically diverse users. The advantage of this approach is to facilitate the development of adaptive interventions that deploy treatment strategies based on specific symptoms. At the same time, the multi-country nature (Spain and Portugal) of the project will advance towards its implementation in diverse geographical areas and health systems, enriching the program's resources and contributing to its flexibility. With this scope, we will produce results representative of real-world environments, and prepare the digital ecosystem for further scalability into other cancer diagnoses, leveraging services that have been even more demanded during the recent pandemic.

This proposal is based on the following specific impacts:

1st: To improve access to high-quality health education and psychosocial cancer care

1. To reduce the lapse between the detection of health education and psychosocial needs and their management by 25%

2nd: To implement the first effectiveness assessment of an integrated psychosocial eHealth environment for patients with LC and CRCA.

2. To decrease emotional distress and PTS, and to increase PTG and QoL, in more than 50% of LC and CARC survivors

3. To solve 80% of cases at psychosocial risk through preventive interventions

4. To expand health knowledge and self-care practices among 60% of users. In addition, more than 80% of users are expected to be satisfied with the platform

5. To attain high levels of usability among survivors, with the platform being rated as highly usable by more than 60% of users

3rd: To develop the first evidence-based assessment of an integrated and stepped symptom-management eHealth environment for patients with LC and CRCA

6. Key advances on the study of symptom monitoring by directly including hybrid methods (self-reports and psychophysiological) ICT in the daily oncological care

4th: To conduct the first noninferiority trial of an eHealth system providing results of its economic and ecological impact

7. To reduce the expenses associated to usual care by 25%, achieving better cost-utility per QALY through the eHealth platform by a minimum of 15%

8. To foster adherence to oncological medication in 70% of survivors, reducing participants required psychotropic medication by 20%

9. To reduce the sick-leave days by up to 25% once the primary cancer treatment ends

5th: Increasing savings in public health by indicating and describing the most cost-effective strategy

### **Ethical, social, legal and environmental project implications**

---

The current project involves the participation of humans, who will be informed on their rights before their decision on joining the study: voluntary participation; no compensation beyond the possible beneficial effects of interventions and no consequences if they refuse to participate. Given the non-physical nature of interventions no harm is anticipated, but any adverse event will be reported. All procedures are in line with the Helsinki Declaration of 1975 (2008 revision). The informed consent will be signed before data collection, giving a copy to participants with an information sheet.

The consortium is committed to the principles of respect for participants and their autonomy; maximising benefits and minimising risks for them and ensuring that they are treated fairly. The partner in charge of data analysis (FUOC) have submitted a preliminary version of the project to the Ethics Committee to collect valuable feedback for the final study protocol. Each partner will obtain ethics approval following relevant regional, national and international research laws. Since sensitive personal information will be collected and processed, methods to securely collect, store, access and share data will be devised, allowing traceability and meeting the latest version of the European GDPR (EC/2016/679).

The digital ecosystem will be designed to be as inclusive as possible for users. Gender and ethnic neutral language will be employed, and user-friendliness will be an important goal to be pursued. Also, devices will be lent whenever not owned by participants. The six environmental objectives of the EU Taxonomy Regulation will be respected, especially through circular economy (e.g., trying to re-use of devices) and keeping the carbon footprint at its minimum (e.g., mixing face-to-face and online activities). A gender perspective will be taken into account in the analysis as well as integrated in educational materials, dissemination activities and the research teams.

---

### **Dissemination, social engagement and knowledge transfer**

---

According to a patient-centred strategy, this study seeks to impact four different agents, building a map of stakeholders in southern Europe. Results will be disseminated through at least 4 high-impact articles, 10 national and international scientific conferences, and 10 outreach actions for survivors and the general public. To pursue these goals, the dissemination strategy has been incorporated as a separate WP to efficiently involve all relevant actors, which will comply with the Research results management and open access policy of "la Caixa Foundation". In addition, synergies will also be fostered in order to leverage the knowledge and tools developed to relevant users. The foreseen activities are outlined below:

- 1) For cancer survivors: Videos, leaflets, posters, and open informative sessions will be primarily hosted by the FECEC and the participating hospitals, as well as by collaborators such as the Josep Carreras Foundation.
- 2) For health professionals and researchers: The strategy for professionals will be implemented through scientific societies, including the Sociedad Española de Oncología Médica (SEOM) and the Sociedade Portuguesa de Oncologia (SPO), releasing mailing campaigns, performing presentations in their periodical conferences, and meetings with their working groups. The project will also be disseminated through IDIBELL's External Seminars programme and at industry events.
- 3) For society and mass media: The multi-channel approach will include face-to-face (e.g., talks, presentations, workshops) and social media actions (e.g., website posts, press releases, social networks) to maximise the project's impact, always within the framework of RRI. Citizen engagement will be pursued through the participation in activities such as "Pessics de Ciència" (Pinches of science), "Recerca i Salut: som a prop teu" (Research and health: we are close to you), the Science Week, Barcelona Science Festival, Pint of Science, or the European Researchers' Night.
- 4) For industry: The long-term survival of the ecosystem in the Spanish health system is guaranteed, as it is a strategic action supported by ICO and long-term contracts have been signed with the main providers. However, its scalability will depend on the interest it may arise in potential funders, both public and private.
- 5) For policymakers: The ecosystem will be presented to other healthcare institutions and meetings will be held with policymakers and business representatives.

## References

---

1. 

**Title:** Awareness and barriers to use of cancer support and information resources by HMO patients with breast, prostate, or colon cancer: patient and provider perspectives  
**Author(s):** Eakin EG, Strycker LA  
**Journal:** Psychooncology  
**Publication date:** 2001-03-01  
**DOI:** 10.1002/pon.500
2. 

**Title:** Psychiatric and psychosocial implications in cancer care: the agenda of psycho-oncology  
**Author(s):** Luigi Grassi  
**Journal:** Epidemiol Psychiatr Sci.  
**Publication date:** 2020-01-09  
**DOI:** DOI: 10.1017/S2045796019000829
6. 

**Title:** Effects of psycho-oncologic interventions on emotional distress and quality of life in adult patients with cancer: systematic review and meta-analysis.  
**Author(s):** Faller H, Schuler M, Richard M, Heckl U, Weis J, Küffner R  
**Journal:** Journal of clinical oncology : official journal of the American Society of Clinical Oncology  
**Publication date:** 2013-02-20  
**DOI:** 10.1200/JCO.2011.40.8922
7. 

**Title:** Psychosocial oncology care resources in Europe: a study under the European Partnership for Action Against Cancer (EPAAC).  
**Author(s):** Travado L, Reis JC, Watson M, Borràs J  
**Journal:** Psycho-oncology  
**Publication date:** 2017-04-01  
**DOI:** 10.1002/pon.4044
8. 

**Title:** Cost-Utility of Stepped Care Targeting Psychological Distress in Patients With Head and Neck or Lung Cancer.  
**Author(s):** Jansen F, Krebber AM, Coupé VM, Cuijpers P, de Bree R, Becker-Commissaris A, Smit EF, van Straten A, Eeckhout GM, Beekman AT, Leemans CR, Verdonck-de Leeuw IM  
**Journal:** Journal of clinical oncology : official journal of the American Society of Clinical Oncology  
**Publication date:** 2017-01-20  
**DOI:** 10.1200/JCO.2016.68.8739

9. **Title:** Review of electronic patient-reported outcomes systems used in cancer clinical care.  
**Author(s):** Jensen RE, Snyder CF, Abernethy AP, Basch E, Potosky AL, Roberts AC, Loeffler DR, Reeve BB  
**Journal:** Journal of oncology practice  
**Publication date:** 2014-07-01  
**DOI:** 10.1200/JOP.2013.001067
10. **Title:** Remote Oncology Care: Review of Current Technology and Future Directions  
**Author(s):** McGregor BA, Vidal GA, Shah SA, Mitchell JD, Hendifar AE  
**Journal:** Cureus  
**Publication date:** 2020-08-31  
**DOI:** 10.7759/cureus.10156
11. **Title:** What is the value of the routine use of patient-reported outcome measures toward improvement of patient outcomes, processes of care, and health service outcomes in cancer care? A systematic review of controlled trials.  
**Author(s):** Kotronoulas G, Kearney N, Maguire R, Harrow A, Di Domenico D, Croy S, MacGillivray S  
**Journal:** Journal of clinical oncology : official journal of the American Society of Clinical Oncology  
**Publication date:** 2014-05-10  
**DOI:** 10.1200/JCO.2013.53.5948
12. **Title:** Tangled in the breast cancer web: an evaluation of the usage of web-based information resources by breast cancer patients.  
**Author(s):** Nguyen SK, Ingledew PA  
**Journal:** Journal of cancer education : the official journal of the American Association for Cancer Education  
**Publication date:** 2013-12-01  
**DOI:** 10.1007/s13187-013-0509-6
13. **Title:** Efficacy of Mobile Health Care Application and Wearable Device in Improvement of Physical Performance in Colorectal Cancer Patients Undergoing Chemotherapy.  
**Author(s):** Cheong IY, An SY, Cha WC, Rha MY, Kim ST, Chang DK, Hwang JH  
**Journal:** Clinical colorectal cancer  
**Publication date:** 2018-06-01  
**DOI:** 10.1016/j.clcc.2018.02.002



- Title:** A randomized controlled trial of WATAAP to promote physical activity in colorectal and endometrial cancer survivors.
14. **Author(s):** Maxwell-Smith C, Hince D, Cohen PA, Bulsara MK, Boyle T, Platell C, Tan P, Levitt M, Salama P, Tan J, Salfinger S, Makin G, Mohan GRKA, Jiménez-Castuera R, Hardcastle SJ
- Journal:** Psycho-oncology
- Publication date:** 2019-07-01
- DOI:** 10.1002/pon.5090
- Title:** Performance status and activity level of lung cancer patients using wearable devices as passive monitoring: A scoping review
15. **Author(s):** Ponce Aix S, Crama L, Núñez-Benjumea FJ, Sánchez S, Cervera-Torres S, López M
- Journal:** Journal of Clinical Oncology
- Publication date:** 2021-05-28
- DOI:** 10.1200/JCO.2021.39.15\_suppl.e21141
- Title:** Trends and Effectiveness of ICT Interventions for the Elderly to Reduce Loneliness: A Systematic Review.
16. **Author(s):** Choi HK, Lee SH
- Journal:** Healthcare (Basel, Switzerland)
- Publication date:** 2021-03-07
- DOI:** 10.3390/healthcare9030293
- Title:** Digital health interventions to help living with cancer: A systematic review of participants' engagement and psychosocial effects.
17. **Author(s):** Escriva Boulley G, Leroy T, Bernetière C, Paquenseguy F, Desfriches-Doria O, Préau M
- Journal:** Psycho-oncology
- Publication date:** 2018-12-01
- DOI:** 10.1002/pon.4867
- Title:** Economic evaluations of psychosocial interventions in cancer: a systematic review.
18. **Author(s):** Dieng M, Cust AE, Kasparian NA, Mann GJ, Morton RL
- Journal:** Psycho-oncology
- Publication date:** 2016-12-01
- DOI:** 10.1002/pon.4075

19. **Title:** Interventions for enhancing return to work in individuals with a common mental illness: systematic review and meta-analysis of randomized controlled trials.  
**Author(s):** Nigatu YT, Liu Y, Uppal M, McKinney S, Rao S, Gillis K, Wang J  
**Journal:** Psychological medicine  
**Publication date:** 2016-12-01  
**DOI:** 10.1017/S0033291716002269
20. **Title:** Stress Management or Post-traumatic Growth Facilitation to Diminish Distress in Cancer Survivors? A Randomized Controlled Trial  
**Author(s):** Ochoa-Arnedo C, Casellas-Grau A, Lleras M, Medina JC, Vives J  
**Journal:** International Journal of Clinical and Health Psychology  
**Publication date:** 2017-01-01  
**DOI:** 10.1016/j.ijchp.2016.09.002
21. **Title:** Video conference vs face-to-face group psychotherapy for distressed cancer survivors: A randomized controlled trial.  
**Author(s):** Lleras de Frutos M, Medina JC, Vives J, Casellas-Grau A, Marzo JL, Borràs JM, Ochoa-Arnedo C  
**Journal:** Psycho-oncology  
**Publication date:** 2020-07-03  
**DOI:** 10.1002/pon.5457
22. **Title:** Critical consideration of assessment methods for clinically significant changes of mental distress after psycho-oncological interventions.  
**Author(s):** Vaganian L, Bussmann S, Gerlach AL, Kusch M, Labouvie H, Cwik JC  
**Journal:** International journal of methods in psychiatric research  
**Publication date:** 2020-06-01  
**DOI:** 10.1002/mpr.1821
23. **Title:** The Edmonton Symptom Assessment System (ESAS): a simple method for the assessment of palliative care patients  
**Author(s):** Bruera E, Kuehn N, Miller MJ, Selmser P, Macmillan K.  
**Journal:** Journal of Palliative Care  
**Publication date:** 1991-06-01  
**DOI:** <https://doi.org/10.1177/082585979100700202>

24. **Title:** The hospital anxiety and depression scale.  
**Author(s):** Zigmond AS, Snaith RP  
**Journal:** Acta psychiatrica Scandinavica  
**Publication date:** 1983-06-01  
**DOI:** 10.1111/j.1600-0447.1983.tb09716.x
25. **Title:** The Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5): Development and Initial Psychometric Evaluation.  
**Author(s):** Blevins CA, Weathers FW, Davis MT, Witte TK, Domino JL  
**Journal:** Journal of traumatic stress  
**Publication date:** 2015-12-01  
**DOI:** 10.1002/jts.22059
26. **Title:** The Posttraumatic Growth Inventory: measuring the positive legacy of trauma.  
**Author(s):** Tedeschi RG, Calhoun LG  
**Journal:** Journal of traumatic stress  
**Publication date:** 1996-07-01  
**DOI:** 10.1007/BF02103658
27. **Title:** EQ-5D-3L User Guide  
**Author(s):** EuroQol Research Foundation  
**Journal:** EQ-5D User Guides  
**Publication date:** 2018-12-01  
**DOI:** <https://euroqol.org/publications/user-guides/>
28. **Title:** Development and evaluation of the Adherence to Refills and Medications Scale (ARMS) among low-literacy patients with chronic disease.  
**Author(s):** Kripalani S, Risser J, Gatti ME, Jacobson TA  
**Journal:** Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research  
**Publication date:** 2009-01-01  
**DOI:** 10.1111/j.1524-4733.2008.00400.x

29. **Title:** SUS-A quick and dirty usability scale  
**Author(s):** Brooke J.  
**Journal:** Usability Evaluation in Industry  
**Publication date:** 1996-06-11  
**DOI:** <https://www.taylorfrancis.com/books/e/9780429157011/chapters/10.1201/9781498710411-35>
30. **Title:** A Multidimensional Tool Based on the eHealth Literacy Framework: Development and Initial Validity Testing of the eHealth Literacy Questionnaire (eHLQ)  
**Author(s):** Kayser L, Karnoe A, Furstrand D, Batterham R, Christensen KB, Elsworth G, Osborne RH  
**Journal:** J Med Internet Res.  
**Publication date:** 2018-02-12  
**DOI:** doi: 10.2196/jmir.8371.

## PROJECT TEAM

If a member of the project that has accepted your invitation does not appear in the corresponding Project Team section, please press "Save draft" to refresh the information.

## Members of the Project

Organization	Country	Full Name	Role
Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)	Spain	Cristian Ochoa	Project Leader
Universitat Oberta de Catalunya (UOC)	Spain	Juan Carlos Medina	Principal Investigator
Instituto Português de Oncologia de Coimbra Francisco Gentil, EPE	Portugal	Piedade Leão	Principal Investigator
Universitat Pompeu Fabra (UPF)	Spain	Rosa Estopa	Principal Investigator
Fundación para la Investigación Biomédica del Hospital Universitario La Paz	Spain	Ángela Palao	Principal Investigator
Federació Catalana d'Entitats contra el Càncer-Junts contra el Càncer (FECEC)	Spain	Ramón Maria Miralles	Civil Society Organisation Contact

## Justification of collaboration within the Research Consortium

This project represents a critical step forward in the development of a personalised digital solution to provide psychosocial care in cancer. A preliminary version of the platform has recently been created with the support of European innovation funding. Such original work represents the valuable seed that this study aims to refine, grow and scale to a broader oncological population. Given the complexity of this venture, which must face structural changes to adapt to the wide differences between cancer diagnoses, the consortium has retained the leaders behind the seminal project in Spain and Portugal, while it has incorporated new determining stakeholders to secure the necessary know-how and increase its workforce to conduct the planned activities, including the RCT.

The consortium is integrated by five RPOs and one CSO. IDIBELL-ICO features a balanced combination of research and healthcare expertise, which offers attention to around 20,000 new users per year due to its high level of specialisation (it provides coverage to 60% of cancer patients in Catalonia). In turn, IdiPAZ is one of the largest healthcare providers in the Spanish capital, Madrid, with a certified

oncological unit treating almost 3,000 new cases each year. Like IDIBELL-ICO, IPOC is a research and health institution focused almost exclusively on Cancer, being indeed the principal care provider in central Portugal assisting approximately 1,500 new oncological cases per year. Moving to non-clinical partners, UOC is a leading international online university, which currently ranks the fifth largest in Spain. It employs more than 400 researchers and features three transdisciplinary innovation hubs, including the e-health Centre. Similarly, UPF is another top university which boasts excellent research figures. Indeed, it is the first Spanish university in percentage of papers published in the most influential journals. Finally, FECEC offers a network of 15 civil entities that impulse educational, emotional and social support actions in North-Eastern Spain. Indeed, with 115,000 members in total, it is one of the largest organisations of its kind, with the 5,000 individuals receiving psychological support from FECEC each year being a representative example.

The rich combination of research, healthcare, and civil engagement expertise offered by the consortium partners will lead to the design of the definitive version of the e-health ecosystem featured in this project, improving its contents and user experience. Indeed, the area in which the platform has performed worst in the pilot study is usability. The strategic know-how provided by UOC, UPF and FECEC is expected to leave this limitation behind. In turn, the recruiting centres will secure the number of participants needed in the RCT for each cancer diagnosis. Finally, throughout the study, the network of researchers, practitioners and survivors who have teamed up in this proposal will cooperate to leverage results to a wide audience of external stakeholders, implementing a strategy designed in advance to impact the whole contemporary European society.

To fulfil all these tasks, a detailed coordination strategy has been devised to foster synergies between partners. A Steering Committee will be created, participated by the PI at each centre and led by the PL, who will meet every 3 months (combining face-to-face and online means) to supervise the project's activity; to appraise the work conducted in scientific, clinical, communicative, and ethical terms; and to anticipate the next steps until the following meeting. A hired project manager (i.e., a post-doctoral researcher) at IDIBELL-ICO will ensure the smooth collaboration among all participants to meet the objectives of the study. Finally, an Advisory Board will be conformed with experts in oncology, psychosocial care, and ethics to independently audit the performance of the consortium and to provide support to its actions.

## Project Leader

---

**Full Name:** Cristian Ochoa

**Research experience** 7-12 years  
**since completion of PhD:**

## Project Leader and PL's Team. Relevance in relation with the proposal

---

The research team leading this proposal is a consolidated group officially recognized by the Catalan Government as "Research in cancer health services" (Ref. 2017SGR00735; PI: Josep Maria Borràs, PhD. Head of the Cancer Control Unit), which belongs to IDIBELL-ICO, and has a trajectory of intense research. The "Psycho-oncology and eHealth" research team within the group drives this specific proposal under the direction of Dr. Cristian Ochoa (PL), the Head of IDIBELL-ICO's eHealth Unit and one of the most prominent international young researchers in this field. Dr. Ochoa-Arnedo (PhD) is a Clinical Psychologist expert in psycho-oncology and associate professor at UB. He is also main investigator and leader of five national and one European projects in psycho-oncology related to eHealth (see specific section above). As the leader of "ONCOMMUN" (EIT Health proposal), he has generated valuable data on psychoeducational care to cancer patient's through digital resources and his complete profile place him in an excellence position to lead this ambitious project.

The PL's team also counts on:

- Aida Flix Valle, psycho-oncologist and researcher (PhD student with competitive public funding) and is leading the multicentre clinical trial for the BC ecosystem
- Dr. Maria Serra-Blasco (PhD) is an experienced researcher in the field of mental health with practice managing multicentre projects.
- Laura Ciria Suárez, a psychologist, researcher, and currently e-learning manager of IConnecta't
- Dr Melinda González (PhD) is an oncological nurse and a psycho-oncologist

The rest of ICO team is also highly multidisciplinary and include health psychologists with expertise in psycho-oncology (Arnau Souto and Darío Fernández), a clinical psychologist (Dr María Lleras, PhD), advance practice nurses specialized in oncological research (Dr Ana Rodríguez, PhD and Isabel Brao), a psychiatrist who has a long trajectory collaborating with the psycho-oncology service (Dr Rosa Hernández, MD, PhD) and a computer scientist (Cristina Benedi). Dr Mireia Díaz (PhD), is a research associate with background in Statistical Sciences and Techniques with a long experience in simulation models and economic evaluations of cancer prevention programs. The team also counts with specialized physicians that will collaborate in the knowledge-based phase period to collect patients' necessities and in the recruitment, phase helping to disseminate the program and offering it to patients. Thus, Ernest Nadal (PhD, Head of Lung Unit), Jesús González (MD, PhD. Palliative medical specialist), Ramón Salazar (MD, Head of the Medical Oncology Department) and Cristina Santos (MD, oncologist) who also have experience in similar digital health projects, will join the project. The group's productivity has increased exponentially, achieving up to 18 national and international competitive projects.

---

## **Research Experience PL**

From	To	Position	Organization
01/01/2008	26/02/2013	PhD Medicine Program	University of Barcelona
01/07/2013	01/12/2020	Assistant Professor	University of Barcelona
01/01/2014	01/12/2020	Head of Psychooncology and eHealth research group	IDIBELL research foundation
01/01/2018	01/12/2020	Head of eHealth Clinical and Research Program IConnecta't	Catalan Institute of Oncology and IDIBELL research Foundation
05/07/2021	08/11/2021	Permanent Associate Professor	University of Barcelona

Number at the Publication section	DOI	Statement describing significance
1	10.1080/17439760.2020.1765005	For the first time, a study shows and confirm, with a highly rigorous design of a randomized control trial, how this novel approach to reduce distress (positive psychotherapy) has better results than the traditional standard.
2	10.1002/pon.5457	Historical milestone in psychology and psychooncology with special importance in covid pandemia. The first randomized clinical trial in cancer that shows that a group psychological treatment, carried out by multi-videoconference, has equivalent positive results to the same face-to-face treatment.



3	10.1002/pon.5194	The most recent and comprehensive systematic review of the use and impact of internet in cancer. It analyses 2 very different ways of using the Internet for health: 1) the spontaneous use and 2) the use guided by professionals. An essential article in eHealth associated with cancer.
4	10.1002/pon.4753	Well-designed empirical study with a relevant sample of cancer patients. According to an innovative methodology, it clearly shows how the psychological state in cancer influences the use of internet to face the process of assimilating the disease.
5	10.1016/j.ijchp.2016.09.002	Well-designed empirical study with a relevant sample of cancer patients. According to an innovative methodology, it clearly shows how the psychological state in cancer influences the use of internet to face the process of assimilating the disease.

#### **Major significant research outputs and other merits**

PL's competitive research grants as PI:

- > 2022-2024. Early and stepped psychosocial treatment of a digital health ecosystem for patients with advanced lung cancer: a randomized controlled trial. AECC Strategic Projects. 149,999 EUR
  - > 2019: Oncommunities: Online cancer support communities. HORIZON 2020 - European Institute of Innovation and Technology. Participated by a consortium of 10 European institutions with high excellence in research in Spain, Germany, Portugal and Poland. 498,963 EUR.
  - > 2020: Oncommunities. HORIZON 2020. A new reapplication of the first study. Amount: 372,865 EUR.
  - > 2016-2019: Online vs in-person group psychosocial treatment in breast cancer survivors: A multicentre randomized controlled trial, efficacy, costs and predictors (PI15/01278). Spanish Ministry of Health. 69,575 EUR.
  - 5. 2021-2022: Development of an eHealth Platform adapted to patients with Chronic lymphocytic leukemia. AstraZeneca. 60,500 EUR.
- Dr Ochoa-Arnedo has given up to 35 national and international presentations including 12 invited talks.

Awards:

- EIT Health with the Francisco del Pozo Award as the best educational program of 2020
- Avedis Donabedian Foundation award in the category of Best Digital Health Solution to IConnecta't.
- HINTT in patient safety category (2020, Portugal)
- Investir em Saúde (2020, Portugal).

More details on scientific publications, projects and relevant impact on media can be consulted on our open website (<https://www.psicooncologiaonline.com/en/>).

## Principal Investigators of the Research Performing Organization

**Please select the number of Research Performing Organizations in your proposal**

4

## Principal Investigator of the Research Performing Organization 1

**Please select the PI that this section describes**

Ángela Palao

**Research experience since completion of PhD**

7-12 years

**Principal Investigator and PI's Team. Relevance in relation with the proposal.**

The "Psychiatry and Mental Health" research group, led by Dr Ángela Palao Tarrero (MD, PhD) – Principal Investigator and Coordinator of the Psycho-Oncology Program –, is a well-established team in the Instituto de Investigación Hospital Universitario La Paz- HULP-IdiPAZ. It is interested in the effectiveness of different psychological interventions for people physically and/or emotionally distressed. This interest in clinical research is growing and has helped the group to become notably experienced in the performance of clinical trials. So far, these trials have included people with severe mental illnesses (e.g., psychosis, bipolar disorder) but also people with physical conditions, such as multiple sclerosis, chronic pain, or cancer. In addition, one of the group's major research fields is eHealth. The team have developed three online mindfulness-based interventions with target populations that range from non-clinical to people with psychosis. The main solution is a mindfulness course delivered via a smartphone app ("REM Coming home"). Results are very promising in terms of anxiety reduction, and mindfulness and self-compassion increase among healthcare students. In addition, they have also developed an online course on the edX platform with the Universidad Autonoma de Madrid on Introduction to emotional regulation based on Mindfulness, which has currently over 30,000 participants. At IdiPAZ, psychiatrists (Beatriz Rodríguez Vega, MD, PhD., Psychiatrist and Head of the Psychotherapy Unit), health psychologists (Cristina Rocamora, MsC.), clinical psychologists (Dr Marta Torrijos, PhD), oncologists (Jaime Feliu, MD, PhD.; Javier de Castro, MD, PhD.) and other practitioners encourage their patients to download these apps and to participate in the eHealth programs offered in the hospital. In turn, several group members are part of a European research consortium RESPOND (Improving the Preparedness of Health Systems to Reduce Mental Health and Psychosocial Concerns resulting from the COVID-19 Pandemic), funded by the Horizon 2020 program (H2020-SC1-PHE-CORONAVIRUS-2020). This project, led by the WHO, implements emotional self-care for health professionals through two programs developed by the WHO through a digital application.

Finally, the team's PI of this project, Dr Ángela Palao, is a senior researcher and advisor for the "Humanising Medicine" plan funded by the Madrilenian Health Department. Similarly, the "Experimental Therapies and Biomarkers in Cancer" Group is another consolidated research team at HULP-IdiPAZ. Its director, Dr Javier de Castro (MD, PhD, Medical oncologist, and Head of the Lung Cancer Unit), is the president of the Association for the Research in Women's Lung Cancer (ICAPEM, Spanish acronym), and he has also joined this consortium.

## Research Experience

From	To	Position	Institution
01/01/2007	01/01/2009	PhD Student	Autonomous University of Madrid
01/01/2009	22/11/2021	Posy-doctoral Reseracher	"Hospital La Paz Institute for Health Research" (IdiPAZ)
01/01/2017	22/11/2021	Adjunct Professor of Psychiatry	Autonomous University of Madrid

Number at the Publication section	DOI	Statement describing significance
6	10.1002/pon.1800	This randomised controlled trial explores the effectiveness of narrative therapy plus escitalopram versus TAU plus escitalopram in a sample of people with cancer and depression
7	10.1002/pon.2036	This paper presents a grounded theory qualitative analysis that compares the narratives of participants who received either narrative therapy or TAU
8	10.5209/PSIC.59171	The work explores whether a stoic coping attitude is a risk or a protective factor in a sample of people with cancer
9	<a href="https://doi.org/10.1007/s12671-019-01157-z">https://doi.org/10.1007/s12671-019-01157-z</a>	This is a theoretical work that proposes to include elements of mindfulness and self-compassion in the healthcare for people with chronic pain
10	10.1186/s12888-019-2206-4	This clinical trial explores the feasibility and the tolerability of a mindfulness-based social cognition training program (SocialMIND) for people with psychosis developed by the authors

#### PI's major significant research outputs and other merits

1. Clinical trials funded by public grants. Apart from RESPOND project, the HULP-IdiPAZ team has been awarded three major grants from the Spanish Carlos III Health Institute to fund three clinical trials: "Bi-Mind" (mindfulness-based cognitive therapy for people with bipolar disorder), "AGES-Mind" (mindfulness-based social cognition training for people with psychosis) and "SURVIVE" (randomised controlled trial for people with suicidal behaviour).
2. Industrial and intellectual property of eHealth interventions. The group has developed different online interventions to promote mental health and well-being across different populations. Particularly, two smartphone apps ("REM Coming Home", "Staying calm in the OR"), one web-app ([www.socialmindtraining.com](http://www.socialmindtraining.com)) and one Massive Open Online Course (<https://www.edx.org/course/introduccion-a-la-regulacion-emocional-basada-en-m>) have been developed since 2015.
3. Pre-doctoral positions supported by public and private grants. Since 2015, the Group has achieved up to four positions for pre-doctoral researchers. Three of them were financially supported by the European Regional Development Funds, and another one by "La Caixa" Foundation.
4. Financial viability of eHealth interventions. The development and technical maintenance of applications developed by HULP-IdiPAZ is granted through agreements with the Health and Psychotherapy Institute, with La Paz University Hospital, and with the Lung Cancer Patients' Association.

## Principal Investigator of the Research Performing Organization 2

---

**Please select the PI that this section describes**

Piedade Leão

**Research experience since completion of PhD**

N/A

**Principal Investigator and PI's Team. Relevance in relation with the proposal.**

---

The IPOC (Instituto Português De Oncologia De Coimbra) is a reference institution in the provision of healthcare to cancer patients in central Portugal. The hospital is fully accredited since 2005 by CHKS - Healthcare Accreditation and Quality Unit, one of the most prestigious international organizations in the area of quality in health. Such acknowledgement has been renewed in 2010, 2014 and 2017. Similarly, since 2011, IPOC is also accredited by the Organization OEI - European Cancer Institutes, having been re-accredited in 2017.

With a strong background in clinical research, especially reinforced in the last years, the IPOC has established several protocols with other prestigious international entities. In this regard, the collaboration presented here will further boost Portuguese research in oncological and psychosocial areas, promoting patients' quality of life.

Building upon the existing synergies with IDIBELL-ICO through the Oncommunités projects targeting patients with breast cancer, IPOC is totally committed to scale up digital care to patients with other oncological diagnoses, namely lung cancer and colorectal cancer; this new partnership will fuel an innovative and multidisciplinary strong interaction between different professionals in Spain and Portugal.

The teams count with the leadership of Piedade Leão, MA, Clinical Psychologist and Head of the Psychological Unit; she has great interest in palliative care and the processes of psychological adaptation to chronic illness of patients and their families; she also has been working with the IConnecta's team in the last years; she is also the leader of the Psychosocial Team of IPOC that results from a partnership between IPOC and Fundación "la Caixa". Other member of the team is Lourdes Barradas, MD, Head of the Lung Cancer Unit and director of the Pulmonology Service of the hospital; she has a long experience in the diagnosis and treatment of cancer patients, namely lung cancer patients. Isabel Domingues, MD, is an oncologist that works in Oncology Service of the hospital and she has great interest in lung and colorectal cancer patients. Helena Domingues is a high specialized oncology nurse; she works daily with lung and colorectal cancer patients and their families; she also integrated the teams that have been working in the IConnecta Project. Gisela Almeida is also a high specialized oncology nurse that works daily with lung and colorectal cancer patients; she has great interest in the research area and is involved in several research projects.

The team is highly motivated and committed to this project. All the members have advanced training and several years of experience with cancer patients. Specially, the professionals involved will be:

- Lourdes Barradas, MD. Pulmonologist and Head of the Lung Cancer Unit
- Isabel Domingues, MD. Medical oncologist
- Helena Faustino, MsC. Advanced practice nurse
- Gisela Almeida, MsC. Advanced practice nurse

---

## Research Experience

From	To	Position	Institution
01/01/2007	23/11/2021	Coordinator of Psychology Department	Instituto Português de Oncologia de Coimbra (IPOC)
01/01/2012	23/11/2021	Teacher in the Master "Palliative care"	Faculdade de Medicina da Universidade de Coimbra
01/01/2019	24/11/2021	Director of Psychosocial Team	Instituto Português de Oncologia de Coimbra in a partnership with Fundación "la Caixa"
01/01/2019	24/11/2021	Researcher at Oncommunities Project, responsible for the psychological area	Instituto Português de Oncologia (IPOC) in a partnership with Instituto Catalán de Oncologia (ICO)

Number at the Publication section	DOI	Statement describing significance
11	9789897511362	Reference book in the psycho-oncology field

### PI's major significant research outputs and other merits

> European Research and innovation grant (partners of ICO-IDIBELL, which leads also this proposal): Oncommunities: Online cancer support communities. HORIZON 2020 - European Institute of Innovation and Technology. Participated by a consortium of 10 European institutions with high excellence in research in Spain, Germany, Portugal and Poland. Duration: 01/01/2019 - 31/12/2019. Principal Investigator: C. Ochoa.

> European Research and innovation grant (partners of ICO-IDIBELL, which leads also this proposal): Oncommunities: Online cancer support communities. HORIZON 2020 - European Institute of Innovation and Technology. Participated by a consortium of 13 European institutions with high excellence in research in Spain, Germany, Portugal and Poland. Duration: 01/01/2020 - 31/12/2020. Principal Investigator: C. Ochoa.

> 2020 Investir em Saúde Prize, with the Project Oncommunities. This award is an initiative of the Jornal de Negócios, Janssen Company, Associação Portuguesa dos Administradores Hospitalares and the Accenture (Knowledge Partner), that recognizes good practices in health in Portugal.

> 2020 HINNT Award to the best solution for patient safety in Portugal, for Oncommunities Project.

> 2019, winner of Professor Luís António Martins Raposo Prize with the Project Oncosexologia – Vivências da sexualidade em mulheres com doença oncológica.

### Principal Investigator of the Research Performing Organization 3

---

**Please select the PI that this section describes**

Juan Carlos Medina

---

**Research experience since completion of PhD**

<7 years

---

**Principal Investigator and PI's Team. Relevance in relation with the proposal.**

PSiNET (Psychology, Health, and Internet) is a research group of FUOC's eHealth Centre, an innovative hub focused on the development of technological solutions to enhance digital health quality. The main interest of PSiNET is the study of health promotion and the improvement of people's QoL through ICTs. The group has an applied scope, providing professionals, researchers, and the society with a psychological view on the use of ICTs in health environments. Established in 2002 and consolidated by the Catalan Government in 2017 (2017SGR239), the group's research focuses on the use of digital tools for knowledge acquisition and healthcare. Currently, PSiNET embraces the study of ICTs in different populations and contexts, and the activity of its members involves the analysis of personal factors, the appraisal of intervention programs, the creation of conceptual models, and the improvement of research methodologies.

Dr. Joan C. Medina (PhD.), FUOC's Principal Investigator, is an emerging researcher who has participated in numerous multicentre RCTs. His latest projects are all embedded in eHealth areas and have raised over EUR 5 million. His tasks in these studies have included the leadership of research designs, methodologies and statistical analyses, experience that will be integrated in the project through his coordination of data management and analysis. In turn, Dr. Eulàlia Hernández i Encuentra, PhD., PSiNET's leader, features a vast experience in eHealth innovation and research through the use of both quantitative and qualitative methods. Her expertise will be a key asset for the appraisal and improvement of the Care4Survivors ecosystem presented herein, as well as for the measurement of its effects on health indicators. Another group member is Dr. Mercè Boixadós i Anglès, PhD., who will contribute to the methodological design part, as well as to data analysis. In the last years, her main aim has been to study the psychological aspects connected with the use of ICT in relation to people's health and QoL. In turn, Dr. Adrián Montesano (PhD.), Professor at FUOC, has an extensive expertise in clinical psychology and psychotherapy research projects. He has conducted various psychotherapy-centred RCTs and developed virtual reality clinical applications. Consequently, he will support the refinement of the design and methodology, trials implementation and data analysis. Finally, Dr. Rocio Pina Ríos, PhD., lecturer at FUOC and also member of PSiNET, will aim to integrate gender perspective and legal psychology into the project. She has conducted several studies in gender violence and, as a psychologist, she has advised different entities on gender policies (e.g., developing equity protocols, gender violence prevention in the workplace).

---

**Research Experience**



From	To	Position	Institution
01/01/2016	10/12/2018	PhD Student	Barcelona University
01/01/2019	21/06/2019	Post-doctoral Researcher	Barcelona University
25/06/2019	31/12/2019	Post-doctoral Reseracher	Bellvitge Biomedical Research Institute (IDIBELL)
07/01/2020	22/11/2021	Lecturer and researcher	Foundation for the Open University of Catalonia

Number at the Publication section	DOI	Statement describing significance
2	10.1002/pon.5457	Randomised controlled trial to test the efficacy of the online psychological intervention that will be offered within the stepped program presented by this proposal
12	10.1136/ bmjopen-2020-041548	Protocol of the multicentre randomised controlled trial of the breast cancer environment from the eHealth intervention proposed in this project
13	10.2147/JPR.S221227	Appraisal of the effects of an eHealth intervention using quantitative and qualitative methods
14	10.1007/s00520-020-05335-x	Study of how breast cancer patients evaluate and make use of online resources to manage their disease
15	10.1371/journal.pone.0208245	One-year results of a randomised controlled trial, performing analyses similar to the ones proposed in this project

#### PI's major significant research outputs and other merits

---

1. Recent participation in six research projects on eHealth:

- Mental health promotion and intervention in occupational settings, funded by the European Commission.
- Recovering life wellbeing through pain self-management techniques involving ICTs, funded by the European Commission.
- Online cancer support communities (Oncommunities), funded by the European Institute of Innovation and Technology.
- Online psychosocial cancer screening, monitoring and stepped treatment in cancer survivors: A randomized controlled trial, funded by the Carlos III Institute.
- Psychotherapy for youths with moderate depression: can virtual reality improve its efficacy?, funded by the Spanish Ministry of Science, Innovation and Universities.
- Development and effectiveness of a mHealth intervention in the improvement of Health Literacy and self-management of the pluripathological patient with heart failure: a randomised controlled trial, funded by the Research and Innovation Institute of Cádiz.

2. Coordination of the Health Literacy, Empowerment and Health Participation area of the eHealth Center, Fundació per a la Universitat Oberta de Catalunya.

3. Statistical leadership in two international research networks: Research Group in Clinical and Health Psychology Interventions (led by the Universitat de Barcelona), and Research Group on Meditation and Buddhism (coordinated by the University of East London).

4. Membership of the Scientific and Advisory Committees of international conferences.

## Principal Investigator of the Research Performing Organization 4

---

### Please select the PI that this section describes

---

Rosa Estopa

### Research experience since completion of PhD

---

>20 years

### Principal Investigator and PI's Team. Relevance in relation with the proposal.

---

The IULATERM research group (Lexicon and Technology), founded by M. Teresa Cabré in 1994, conducts research in the following research lines: terminology, neology, specialised lexicography, specialised discourse, linguistic variation and lexical change, lexicology (morphology, semantics and lexical syntax), language technologies, computational linguistics, corpus linguistics, change management and language diversity. In the health field, the expertise of the IULATERM has focused on:

1. Medical terminology.
2. Health communication.
3. Medical Specialised Text.
4. Applied terminological applications, such as dictionaries or app-webs.
5. Automatic retrieval of information, such as terminology extractors of medical terminology.

• Every 2 years, we organize "HEALTHCOM, COMUNICACIÓN, LENGUAJE Y SALUD" [HEALTHCOM, COMMUNICATION, LANGUAGE AND HEALTH], a research event focalized in communication with patients.

Moreover, our latest research in this field has led to 3 books on Medical Terminology and Health Communication between 2019 and 2020, in addition to 2 app-webs: "COMJUNTOS", and "Primer diccionario de medicina para niños" [First medicine dictionary for children]. These scientific outputs must be added to the articles provided below.

The researchers participating in this project are:

- Rosa Estopà, PhD. Senior Lecturer at the Department of Translation and Language Sciences of the UPF.
- Laia Vidal, PhD. Researcher at the Applied Linguistics Institute of the UPF.

Rosa Estopà has a long experience in medical communication. She started with her doctoral thesis dedicated to the construction of an automatic extractor of medical terminology. In recent years, she has studied the understanding of health information for patients. This line of research has led to the development of a protocol of good practices, which considers essential to compose texts cognitively and linguistically enriched so that patients can assimilate information about their illness. Estopà teaches classes at the Faculty of Medicine (UPF) in the subject of Doctor-Patient Communication and supervises several PhD students related to this field. In particular, she is directing with Cristian Ochoa Laia Vidal's thesis. Vidal is finishing her dissertation on the intelligibility of health discourses in the virtual community that integrates the third level of care in the digital ecosystem of this proposal. Preliminary results, which will be valuable for this proposal, prove that by controlling the terminology in the elaboration of community texts addressed to patients, they understand much better the information about their disease. In addition, Vidal has developed terminological infographics that foster assimilation of health knowledge.

## Research Experience

---

From	To	Position	Institution
01/01/1999	01/01/2004	PhD Student	Pompeu Fabra University
01/01/2001	01/01/2005	Coordinator of PhD Program of Applied Linguistics	Pompeu Fabra University, Institute of Applied linguistics
01/01/2004	01/01/2008	Head of Neology Observatory	Pompeu Fabra University, Institute of Applied linguistics
01/01/2004	01/01/2009	Lecturer	Pompeu Fabra University, Institute of Applied linguistics
01/01/1994	22/11/2021	Researcher of IULATERM	Pompeu Fabra University, Institute of Applied linguistics
01/01/2004	22/11/2021	Coordinator	NEOROC, Red de Observatorios del Español peninsular
01/01/2004	22/11/2021	Coordinator	Online Terminology Master (Universitat Pompeu Fabra)
01/01/2006	22/11/2021	Coordinator	NEOXOC, Xarxa d'Observatoris del Català
01/01/2009	22/11/2021	Senior Lecturer	Universitat Pompeu Fabra

Number at the Publication section	DOI	Statement describing significance
16	10.5209/clac.70574	Study of the understanding of medical reports with standard readability tools
17	10.1088/1367-2630/ab023e	Results of a comprehension survey with real medical reports and cognitively and linguistically enriched medical reports
18		Proposal of an innovative methodology for the creation of terminological dictionaries for the non-specialist
19	10.1075/nlp.2.04cab	A pioneering, comprehensive, contrastive review of terminology detection systems
20	10.1075/term.7.2.06est	A theoretical study that raises the importance of terminological units in specialised texts.

#### PI's major significant research outputs and other merits

1. Principal Investigator in 6 recent research projects on health language and communication:
  - Evolution of scientific knowledge in medicine: the lexical and semantic change (TERMMED, FFI2017-88100-P). Spanish Ministry of Science, Innovation and Universities. 2018-2020
  - TOGETHER. Overcoming socio-educational barriers and promoting health literacy. La Caixa Foundation. RECERCAIXA2015. 2015-2018
  - The words of medicine at school: AP-WEB. Girona Official Association of Medical Doctors. 2018-2020
  - Playing with the words of science (2012ACDS00050). Department of Economy and Knowledge, Catalan Government. 2012-2013
  - Playing to define science II (FCT-12-4488). Spanish Foundation for Science and Technology. 2012-2013
  - Playing to define science (FCT-11-2501). Spanish Foundation for Science and Technology. 2011-2012

Participation as researcher in 23 research projects on terminology in competitive calls

2. Supervisor of 7 PhD Theses on Health Terminology in the last 5 years
3. Recipient of several awards on innovation, research and social transference, the latest being:

Awards:

- To the best app for patients, in eHealth Awards 2018, for COMjunts, the app that guides medical communication. Awarded by the association of researchers in eHealth AIES, and communication agency COMSALUD. Madrid, 28/11/2018.
- To university social awareness projects for Paraules a les sales d'espera de pediatria [Words in pediatric waiting rooms], given by Social Committee of the UPF, 18/7/2019.

## Civil Society Organizations

---

**Please select the number of Civil Society Organizations in your proposal**

1

### Civil Society Organization 1

---

**Please select the CSO that this section describes**

Ramón Maria Miralles

**Civil Society Organizations**

---

Federació Catalana d'Entitats Contra el Càncer (FECEC) is a federation representing up to 15 CSOs located in Catalonia, which offers support to cancer survivors and their families, trains professionals and volunteers, and transfers knowledge to the general public. The strategic position of FECEC, a renowned entity in North-Eastern Spain, represents a valuable asset for the project at several levels. Its expertise in the experience of living with cancer, both from the patient and professional experience, will influence the structure and contents of the digital solutions developed. Also, relevant will be its role as a central actor in the dissemination, making the results available for survivors and their families. These activities will be coordinated and aligned with RPOs' activity through the involvement of FECEC in the Steering Committee. The personnel involved in the proposal will be Ramon M. Miralles, the institution's president, and Clara Rosàs, its general manager.

## Publications

---

1. **Title:** Stress Management or Post-traumatic Growth Facilitation to Diminish Distress in Cancer Survivors? A Randomized Controlled Trial  
**Author(s):** Ochoa-Arnedo C.  
**Journal:** The Journal of Positive Psychology  
**Publication date:** 2020-01-01  
**DOI:** 10.1080/17439760.2020.1765005
2. **Title:** Video conference vs face-to-face group psychotherapy for distressed cancer survivors: A randomized controlled trial.  
**Author(s):** Lleras de Frutos M, Medina JC, Vives J, Casellas-Grau A, Marzo JL, Borràs JM, Ochoa-Arnedo C  
**Journal:** Psycho-oncology  
**Publication date:** 2020-07-03  
**DOI:** 10.1002/pon.5457
3. **Title:** A systematic and comprehensive review of internet use in cancer patients: Psychological factors.  
**Author(s):** Lleras de Frutos M, Casellas-Grau A, Sumalla EC, de Gracia M, Borràs JM, Ochoa-Arnedo C  
**Journal:** Psycho-oncology  
**Publication date:** 2020-01-01  
**DOI:** 10.1002/pon.5194

4. **Title:** The role of posttraumatic stress and posttraumatic growth on online information use in breast cancer survivors  
**Author(s):** Casellas-Grau A.  
**Journal:** Psychooncology  
**Publication date:** 2018-08-01  
**DOI:** 10.1002/pon.4753
5. **Title:** Positive psychotherapy for distressed cancer survivors: Posttraumatic growth facilitation reduces posttraumatic stress.  
**Author(s):** Ochoa C, Casellas-Grau A, Vives J, Font A, Borràs JM  
**Journal:** International journal of clinical and health psychology : IJCHP  
**Publication date:** 2017-01-01  
**DOI:** 10.1016/j.ijchp.2016.09.002
6. **Title:** Combined therapy versus usual care for the treatment of depression in oncologic patients: a randomized controlled trial.  
**Author(s):** Rodríguez Vega B, Palao A, Torres G, Hospital A, Benito G, Pérez E, Dieguez M, Castelo B, Bayón C  
**Journal:** Psycho-oncology  
**Publication date:** 2011-09-01  
**DOI:** 10.1002/pon.1800
7. **Title:** Differences in depressed oncologic patients' narratives after receiving two different therapeutic interventions for depression: a qualitative study.  
**Author(s):** Rodríguez Vega B, Orgaz Barnier P, Bayón C, Palao A, Torres G, Hospital A, Benito G, Dieguez M, Fernández Liria A  
**Journal:** Psycho-oncology  
**Publication date:** 2012-12-01  
**DOI:** 10.1002/pon.2036
8. **Title:** Estoicismo frente al cáncer: riesgo o protección  
**Author(s):** Castelo, B., Palao, Á., Carmona-Bayonas, A., Jiménez Fonseca, P., Jara, C., Ayala de la Peña, F., ... & Calderón Garrido, C  
**Journal:** Revista de Psicooncología  
**Publication date:** 2018-03-23  
**DOI:** 10.5209/PSIC.59171



9. **Title:** Compassion in the Treatment for Chronic Pain: an Ethical Imperative with Neurobiological Effects  
**Author(s):** Tarrero ÁP, Zarcero MT, Muñoz-Sanjose A, González CR, Vidal-Villegas MP, Mediavilla R & Rodríguez-Vega B  
**Journal:** Mindfulness  
**Publication date:** 2019-10-01  
**DOI:** <https://doi.org/10.1007/s12671-019-01157-z>
10. **Title:** Mindfulness-based social cognition training (SocialMIND) versus psychoeducational multicomponent intervention for people with a first episode of psychosis: a study protocol for a randomised controlled trial.  
**Author(s):** Mediavilla R, Muñoz-Sanjose A, Rodriguez-Vega B, Bayon C, Palao A, Lahera G, Sanchez-Castro P, Roman E, Cebolla S, de Diego A, Pastor JM, Bravo-Ortiz MF  
**Journal:** BMC psychiatry  
**Publication date:** 2019-07-29  
**DOI:** 10.1186/s12888-019-2206-4
11. **Title:** Cuidados Paliativos em Oncologia  
**Author(s):** Leão, P. & Albuquerque, E.  
**Journal:** Temas Fundamentais em Psico-Oncologia.  
**Publication date:** 2015-01-01  
**DOI:** 9789897511362
12. **Title:** E-health ecosystem with integrated and stepped psychosocial services for breast cancer survivors: study protocol of a multicentre randomised controlled trial.  
**Author(s):** Ochoa-Arnedo C, Medina JC, Flix-Valle A, Anastasiadou D  
**Journal:** BMJ open  
**Publication date:** 2021-03-08  
**DOI:** 10.1136/bmjopen-2020-041548
13. **Title:** Effects and Experiences of Families Following a Web-Based Psychosocial Intervention for Children with Functional Abdominal Pain and Their Parents: A Mixed-Methods Pilot Randomized Controlled Trial.  
**Author(s):** Nieto R, Boixadós M, Ruiz G, Hernández E, Huguet A  
**Journal:** Journal of pain research  
**Publication date:** 2019  
**DOI:** 10.2147/JPR.S221227

14. **Title:** An exploratory study in breast cancer of factors involved in the use and communication with health professionals of Internet information.  
**Author(s):** Ochoa-Arnedo C, Flix-Valle A, Casellas-Grau A, Casanovas-Aljaro N, Herrero O, Sumalla EC, de Frutos ML, Sirgo A, Rodríguez A, Campos G, Valverde Y, Travier N, Medina JC  
**Journal:** Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer  
**Publication date:** 2020-10-01  
**DOI:** 10.1007/s00520-020-05335-x
15. **Title:** One-year follow-up of a randomized trial with a dilemma-focused intervention for depression: Exploring an alternative to problem-oriented strategies.  
**Author(s):** Feixas G, Paz C, García-Grau E, Montesano A, Medina JC, Bados A, Trujillo A, Ortiz E, Compañ V, Salla M, Aguilera M, Guasch V, Codina J, Winter DA  
**Journal:** PloS one  
**Publication date:** 2018  
**DOI:** 10.1371/journal.pone.0208245
16. **Title:** Escalas de legibilidad aplicadas a informes médicos: límites de un análisis cuantitativo formal  
**Author(s):** Porras-Garzón, J; Estopà, R  
**Journal:** Círculo de Lingüística Aplicada a la Comunicación  
**Publication date:** 2020-07-09  
**DOI:** 10.5209/clac.70574
17. **Title:** Diagnóstico del nivel de comprensión de los informes médicos dirigidos a pacientes y familias afectadas por una enfermedad rara  
**Author(s):** Domènech, O; Estopà, R  
**Journal:** e-AESLA  
**Publication date:** 2019-06-15  
**DOI:** 10.1088/1367-2630/ab023e
18. **Title:** Build to deconstruct and re-construct: Collaborative development of a school science dictionary  
**Author(s):** Estopà R.  
**Journal:**  
**Publication date:** 2014-01-01  
**DOI:**

19. **Title:** Automatic term detection: a review of current systems  
**Author(s):** Cabré, M. T.; Estopà, R.; Vivaldi, J.  
**Journal:** Recent Advances in Computational Terminology  
**Publication date:** 2001-06-15  
**DOI:** 10.1075/nlp.2.04cab
20. **Title:** Les unités de signification spécialisées: élargissant l'objet du travail en terminologie  
**Author(s):** Estopà, R  
**Journal:** Terminology  
**Publication date:** 2001-01-01  
**DOI:** 10.1075/term.7.2.06est

## BUDGET

---

**Personnel:** 550,538.68

**Personnel Comments:** NA NA NA 1 post-doctoral researcher will be hired full-time at IDIBELL-ICO for project management. 1 research assistant for data analysis (last 2yr) and another (last 9 mo) to carry out the cost-effectivity analysis. For patient monitoring, a research assistant will be hired part-time (20h/week). For the same tasks, 2 research assistants will be hired part-time at HULP-IdiPAZ and at IPOC and 1 at UPF. A communication technician will be hired 5h/week at FECEC.

**Travel:** 54,200.00

**Travel Comments:** Costs related to a) coordination and training activities, b) assistance to national and international congresses and conferences for the dissemination of results, and for IDIBELL-ICO only, c) meetings of the Advisory Board and d) attending to the final event of project closure.

**Equipment:** 17,800.00

**Equipment Comments:** 5 computers will be purchased to monitor, code and analyse data. 24 tablets will be purchased for monitoring and dissemination actions as well as to provide them to patients with no devices.

**Consumables:** 39,058.80

**Consumables Comments:** 6 security external hard drives (2 at each recruiting institution) will be purchased to securely store and back up data from participants. 152 validated smartwatches will be purchased to carry out the remote symptom monitoring. At FECEC, printings and copies for dissemination and citizen engagement are also budgeted.

**Publications:** 25,700.00

**Publications Comments:** The costs to translate/language review and publish at least 4 high-impact articles in open-access journals are considered, increasing the budget in this section to allow 2-3 additional publications to further disseminate the project's results.

**Dissemination and social engagement activities:** 16,600.00

**Dissemination and social engagement activities** 35 dissemination actions are expected to reach all stakeholders relevant for the project in Spain and Portugal, while communication support services are budgeted for FECEC. In health partner's centres at least 6 dissemination activities will be done (2 massive opened presentations /2 massive open dissemination conferences /2 workshops with health professionals).

**Other Direct Costs:** 44,250.00

**Other Direct Costs** Expenses related to the translation of the platform contents, the purchase of secure collaborative cloud and online survey system accounts, the obtention of psychometric instruments' copyrights for digital use, and the creation of new educational resources.

**Indirect Costs: maximum** 74,814.74  
**10% of Direct Costs:**

**Indirect Costs** 10% Indirect costs associated with the implementation of the project.  
**Comments:**

**Subcontracting Audits:** 12,000.00

**Subcontracting Audits** External consultancy services will be hired to conduct an independent audit of the project expenses at the three major project members (ICO-IDIBELL, HULP-IdiPAZ and IPOC), which will also audit FUOC, UPF and FECEC.

**Other Subcontracting:** 163,000.00

**Other Subcontracting** Costs associated to the ecosystem development and maintenance, the recording and editing of 50 educational videos, and support for the technology transfer model.

**Total Requested:** 997,962.22

## DECLARATIONS

---

**The Host Organization is a Non-profit Research Organization**

Yes

**The PL must be linked, either by statute, work contract or other type of collaboration, within the framework of this Project, to the Host Organization when applying for the grant. The PL may also be legally linked to private foundations or non-profit organizations through which the research activities of the Host Organization are carried out or managed, in accordance with the current legislation.**

Yes

**The results of the project are not subject to rights, of any nature, held by for-profit organizations.**

Yes

**I obtained my doctoral degree before the date shown below (taking as a reference the date which appears on the doctoral degree).**

Yes

**This proposal complies with ethical principles (including the highest standards of research integrity – as set out, for instance, in the European Code of Conduct for Research Integrity – and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct).**

Yes

**This proposal follows the internal rules of the organization regarding ethics requirements and will require approval of the corresponding ethics committees before signature of the grant agreement (if selected); no research activities will be performed until such approval.**

Yes

**The information contained in this proposal is correct and complete.**

Yes

**The proposal complies with the Rules of Participation for the Health Research Call.**

Yes

**I have read and understood the Rules of Participation of the Health Research Call.**

---

---

Yes

**FIGURE 1.** Stepped pyramidal eHealth ecosystem intervention for patients providing **A)** psychosocial care and **B)** symptom management





**FIGURE 2.** Pert chart including project activities (organized by work-packages, **WP**) considering the contribution of each Partner Organization. **WP leaders** are included in the orange band along with the **WP title**, and other partners contribution are included in the yellow band below.



\*LC=Lung Cancer / CRCA=Colorectal Cancer

**TABLE 1.** Administration schedule for each measure.

Measures	T0	Treatment	T1	T2	T3
1. Sociodemographic, clinical, and economic data	X				X
2. Health symptoms	X		X	X	X
3. Emotional state thermometer*		X			
4. Emotional distress	X		X	X	X
5. Post-traumatic stress	X		X	X	X
6. Post-traumatic growth	X		X	X	X
7. Quality of life	X		X	X	X
8. Treatment adherence	X		X	X	X
9. Health knowledge		X			
10. Physiological measures*		X			
11. Usability*			X		
12. Satisfaction			X		
13. eHealth Literacy Questionnaire	X				X

\*Only completed by survivors in the e-health arm.