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A digital guardian angel app based on a patient-centered AI system to enhancing cancer patient's wellbeing and health status improvement following treatment

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1. Introduction

The burden of cancer

The incidence of cancer has been rising globally reaching 19.3 million new cases and 10.0 million deaths in 2020.[1] One in 5 people worldwide develop cancer during their lifetime, and one in 8 men and one in 11 women die from the disease. Despite the rising cancer incidence, improvements in early detection and treatment have improved cancer survival

the number of cancer survivors is increasing globally, creating the need to improve:

- ❖ **treatment**
- ❖ **wellbeing and quality of life**
- ❖ **and follow-up care**

➢ cancer and its treatment have important physical and psychosocial sequelae[2,3,4,5]**:**

- ❖ Prolonged fatigue
- ❖ cognitive limitations
- ❖ Emotional distress
- ❖ Sleep problems
- ❖ Pain
- ❖ Sexual dysfunction
- ❖ Diverse physical symptoms related with cancer type and its treatment (e.g., hair loss, hand-foot syndrome, peripheral neuropathy)

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How can we help/support cancer patients to improve their quality of life and well-being in the context of digital health?

Healthcare is one of the fastest growing data segments of the digital world.

Healthcare data is increasing at a rate of about 50% per year with **three primary sources** of big data[6,7,8]:

- **providers and payers** (including EMR – electronic medical record- imaging, insurance claims and pharmacy data);
- **omics data** (including genomic, epigenomic, proteomic, and metabolomic data);
- **patients and non-providers** (including data from smart phone and Internet activities, wearable sensors and monitoring tools).

The growth of big data in oncology will provide unprecedented opportunities to explore the biopsychosocial characteristics of cancer and for descriptive observation, hypothesis generation, and prediction for clinical, research and business issues.

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Key questions to be answered by ONCORELIEF project:

❖ What are the main factors or variables underlying the assessment of Quality of Life (QoL) and Well-Being (WB) in cancer patients, after treatment, and how could these be better assessed?

❖ How can we develop efficient and effective assessments of patients' QoL and WB in order to select timely candidates for interventions before these patients increase their side-effect burden, emotional distress, or biobehavioral factors that promote cancer progression?

❖ How should information and education about cancer care be provided to patients since these are the support services most frequently requested by patients?

❖ How should cancer patients be supported (e.g., stress management interventions via internet) in order to improve their physical, mental and social dimensions and therefore extend and improve their QoL and WB?

❖ What can health care institutions and health professionals do to provide high-quality care for the psychological and social effects of cancer, maximizing the health and healthcare of cancer patients?

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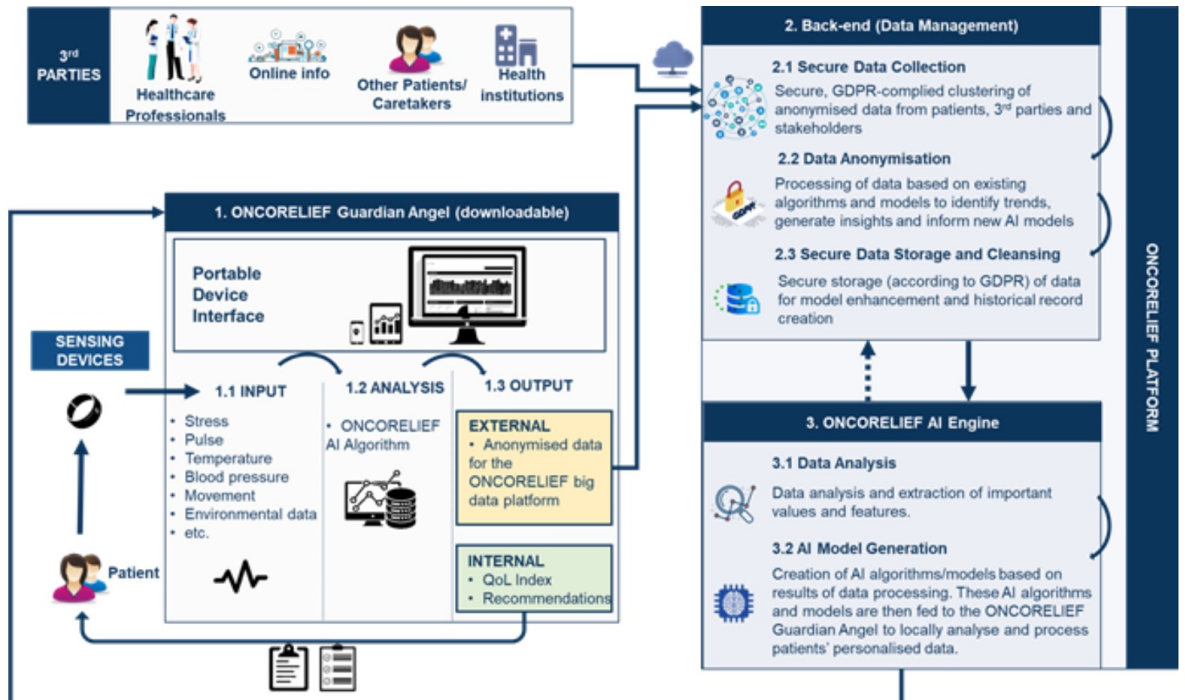| **The ONCORELIEF vision** |
|---|
| **ONCORELIEF is a 36-month action** that will allow the utilization of big datasets in order to develop a user-centred AI system, facilitating the integration of quality of life assessment instruments using PROMs and PREMs, with the objective to **improve:**

❖ **post-treatment health status,**
❖ **wellbeing,**
❖ **and follow-up care of cancer patients**

This will be achieved through **an intuitive smart digital assistant (Guardian Angel),** able to **utilize big data analytics** to provide:

   • personalized support in post-treatment activities and tasks,
   • suggest actions to improve the patients' overall health-status, quality of life and well-being
   • promote an active attitude of self health-care

and ultimately maintain the patient engaged on a wellness journey that will safeguard his/her health over the foreseeable prolonged post-cancer treatment period. |

2. ONCORELIEF PURPOSE

> ➢ ONCORELIEF aims to validate in real-world settings the development of a patient-centered AI system which inputs, analyses and integrates big datasets from the biopsychosocial and environmental dimensions of patients with cancer to improve:
>
> > ➢ post-treatment health status,
> > ➢ increase the wellbeing and QoL,
> > ➢ assist the follow-up care of cancer patients.
>
> ➢ The AI system will generate an ongoing QoL Index to capture the quality of life and WB of cancer patients.
>
> ➢ A smart digital assistant (Guardian Angel) for smartphones will provide personalized support to cancer patients in post-treatment activities and tasks and suggest actions regarding the patients' overall health-status and wellbeing index.

ONCORELIEF HIGH LEVEL VIEW

WB and QOL Index

- ONCORELIEF visualizes current health and well-being and QoL with a personal **ONCORELIEF WB and QoL Index**

- **This index** is a measure of the balance of met and unmet biopsychosocial needs of patients with cancer.

- It is based on the scores of the questionnaires and other assessment tools (e.g.,medical records, wearables) that measure each of the specific needs, and converts all the input data on a 0 to 1000 score.

- Higher Index scores indicate that patients tend to have more met needs than unmet needs.

- Lower index scores indicate the opposite.

- The index is based on patients' critical needs which means that it sllows identify easily unmet needs and propose interventions to help patients overcome this imbalance.

- The ONCORELIEF wellbeing and QoL Index moves up or down in real- time, depending on the balance of met and unmet needs change

- When tracked over time, it will offer a good indicator of how the person's health and wellbeing is evolving.

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Methods

To validate the approach of ONCORELIEF based on Big Data and Artificial Intelligence, 2 pilots will be executed.

- Pilot 1 will include Colorectal Cancer patients (N=300)

- Pilot 2 Acute Myeloid Leukemia patients (n=150)

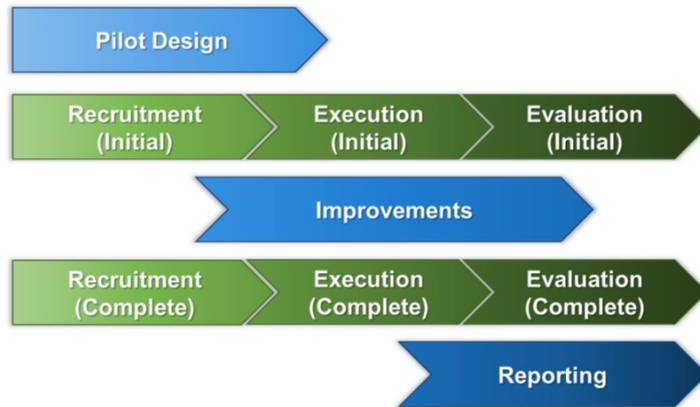**Figure 8: ONCORILIEF Pilot Validation Methodology**

Pilots will benefit from an ==Initial phase==: to evaluate the structure and approach. This phase will target a small number of patients and will last about 1 month, followed by about 2 months of improvements.

The evaluation will lead to specific improvements, based on relevant "**key success factors**" that will have been embedded in the Pilot Design. Example of key success factors may include patient feedback, clinician feedback, recruitment rate, dropout rate, patient engagement, technological readiness, etc. The evaluation will be less focused on the actual Big Data and Artificial Intelligence components.

After making the improvements deemed necessary, the **Complete phase** will begin and will last 12 months.

The Pilots will exhibit patient-centred design characteristics, in recognition of the critical role of patient engagement in the success of the Pilot and the project. Therefore, patient perspectives, preferences and priorities will be evaluated through structured and unstructured interactions during the Requirements Elicitation phase of the project

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- Improved quality of life, symptom management and satisfaction with care/ treatment procedures.

- Better handling of secondary effects and complications like fatigue, cognitive limitations, pain and sexual dysfunction

- Enhanced ability to reduce risk of new medical conditions and improve health status.

- Receive personalized QoL-based care for alleviating symptoms associated with cancer and its treatment

- Receive 'survivorship care' tailored to their specific needs for the transition to the recovering phase of survivorship while dealing with the lingering effects of illness and treatment.

- Improved communication with health-care professionals before, during and after treatment, especially for dealing with symptoms that are not obvious or first-priority but may individually need additional attention

- Enhanced personal confidence driven by the ongoing monitoring that allows them to remain optimistic and improve their outlook on life based on the holistic support system available to them.

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ONCORELIEF ADDED VALUE

PROFESSIONALS AND HEALTH CARE ORGANIZATIONS

- Improved knowledge, availability of data and capabilities for offering personalised, patient-specific support (medical and psychological), on top of any applied treatment method.

- Improved access to patient-specific health and wellbeing status.

- Structured PROMs & PREMs, which can be juxtaposed with patient-specific data, leading to improved understanding of patient outcomes and experiences on an individual or group level

- Access to Real World Data which can constitute the basis for Real World Evidence which is currently the most critical missing piece from the point of care and research perspective.

- Ability to improve the design of clinical trials based on extensive and structured patient input.

- Access to information on patient side-effects that would otherwise be unreported (as evidenced by increasing publications citing gaps in patient-reported vs clinician-reported side-effects, especially in cancer).

- Reduced readmissions and hospitalizations driven by better quality of life, fewer new medical conditions, improved management of overall health and wellbeing

- Enhanced flexibility in patient care as many aspects can be delivered asynchronously and remotely.

The ONCORELIEF project (www.oncorelief.eu) is a H2020 funded project, with a consortium of 13 partners from 8 European countries.

Project consortium

Participant No *	Participant organisation name	Acronym	Country
1 (Coordinator)	EXUS LTD	EXUS	UK
2	MAGGIOLI SPA	MAG	IT
3	INNOSYSTEMS LTD	INNO	GR
4	CARE ACROSS	CARE	UK
5	CENTER FOR RESEARCH AND TECHNOLOGY	CERTH	GR
6	SUITE5 DATA INTELLIGENCE SOLUTIONS LTD	SUITE	CY
7	FRAUNHOFER ITWM	FHG	DE
8	UNIVERSITY MEDICAL CENTER MAINZ	MAINZ	DE
9	MCS DATA LABS	MCS	DE
10	FCIÊNCIAS.ID - ASSOCIAÇÃO PARA A INVESTIGAÇÃO E DESENVOLVIMENTO DE CIÊNCIAS	FC.ID	PT
11	TIME.LEX CVBA/SCRL ADVOCATENKANTOOR	TIMELEX	BE
12	UNIVERSITÀ DI BOLOGNA	UNIBO	IT
13	ISTITUTO SCIENTIFICO ROMAGNOLO PER LO STUDIO E LA CURA DEI TUMORI S.R.L.	IRST	IT

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