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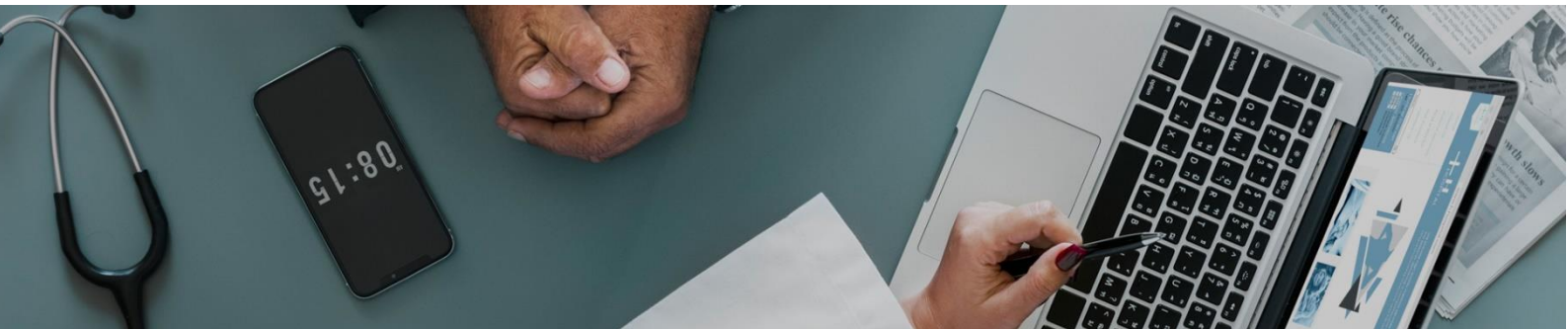
ONCORELIEF NEWSLETTER

THIS ISSUE

About OncoRelief: P.1

Pilots: P.4

Technical News: P.5



ABOUT ONCORELIEF

ONCORELIEF is a 36-month action plan that aims to overcome technical challenges related to the increased importance of health-related quality of life, massive amounts of data from clinical sources, questionnaires, sensor data and rapid advancements in Artificial Intelligence (AI). This is accomplished using a user-friendly application called Guardian Angel (GA) that can use big data analytics to offer support for post-treatment activities and tasks, suggest actions regarding the patients' overall health status, improved quality of life and active health care and keep them engaged on a wellness journey that protects their health over the prolonged post-cancer treatment period.

ABOUT ONCORELIEF

Cancer is increasing globally with 18.1 million new cases and 9.6 million cancer deaths predicted for 2018. Cancer survival has increased despite the rising in cancer cases thanks to advances in detection and treatment. Surgery, chemotherapy, and radiotherapy are examples of common therapies used in the treatment of cancer.

ONCORELIEF is a 36-month action plan that targets to overcome technical challenges related to increased importance of health-related quality of life, large amounts of data from clinical sources, questionnaires, wearable data and rapid advancements in Artificial Intelligence (AI) and Big Data analytics. This is achieved using a user-friendly, intelligent digital assistant called Guardian Angel that can use big data analytics to offer support for post-treatment activities and tasks, suggest actions regarding the patients' overall health status, improved quality of life and active health care and keep them engaged on a wellness journey that protects their health over the prolonged post-cancer treatment period.



The main focus of ONCORELIEF has been placed on two different types of cancer: Acute Myeloid Leukemia (AML), and Colorectal Cancer (CRC). CRC incidence and mortality rates vary around the world. Globally, CRC is the third most commonly diagnosed cancer in males and the second in females. For the past 20 years, colorectal cancer mortality has been decreasing, leading to more survival due to earlier diagnosis and advancements in therapy. On the other hand, AML is considered the most common type of acute leukemia in adults, as it makes up 32% of all adult leukemia cases.

Devices & AI

A large amount of data is collected from a wearable device through the daily use of ONCORELIEF, which is used to monitor the user's health status and post-treatment activities. Methods from artificial intelligence (AI) and machine learning are used to compute and predict a personalized Quality of Life (QoL) index. Also, the the Guardian Angel app is used to provide motivation techniques, like positive affirmations for following the desirable steps, provide personalized suggestions and recommendations based on each patient's data output to improve their health.

Benefits & Impact

The benefits of the ONCORELIEF solution are being evaluated in real-life conditions by performing 2 twelve-month validation studies with 450 patients: one involving Acute Myeloid Leukemia (AML) and one involving Colorectal Cancer (CRC). Since each instance has a unique set of needs, ONCORELIEF aims to be a flexible solution that can be applied in the future and expanded to treat additional cancer types.

The ONCORELIEF system aims to improve the quality of life of cancer patients, as well as facilitate caregivers and clinicians. For patients, ONCORELIEF can be a way to better monitor their health, improve their understanding of their state, better cope with mental distress, depression and anxiety and learn how to improve their post-treatment lives. Better management of each one's own health and a more positive attitude can ultimately improve the social way of living for the patient, and even their employment status.

Clinicians also benefit from a real-time monitoring of the patients, reducing the required number of visits. They also benefit from the clinician-targeted services of ONCORELIEF, which offers monitoring dashboards, an AI engine for data analysis, automatic grouping of patients for improved intervention, etc.



Data Privacy & Security

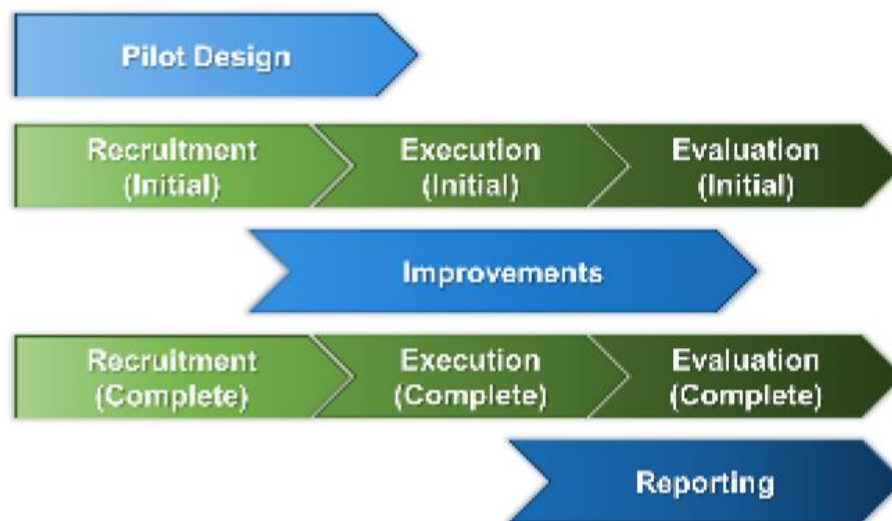
ONCORELIEF collects a number of personal information from the user, including physiological measurements from the wristband, answers to questionnaires, and information from the patient's electronic Case Report Forms (eCRF).

All data collected in ONCORELIEF are stored and protected according to the principles of the General Data Protection Regulation (GDPR), on protection of natural persons with regard to the processing of personal data and on the free movement of such data, so that privacy and security of data can be achieved.

Any person wishing to use ONCORELIEF first signs a consent form informing them about how and why the data are collected and used. All ONCORELIEF users have, at any time, the right to stop using the application and providing their personal information, and to remove their personal information from the ONCORELIEF databases, so that they are no longer available for the needs of the platform.

ONCORELIEF PILOT STUDIES

The purpose of the ONCORELIEF pilot studies is to test the theoretical idea, strategy and implemented tools in practical contexts. While the pilots are in progress, the healthcare experts have the ability to make decisions and communicate with patients in order to reduce their anxiety and stress about technologies. The main goal of the pilots is to test the methodology and the uses of these technologies and not the interventions of the system or the doctors.



There are two pilots; Pilot1, about Colorectal Cancer (CRC) and Pilot2, about (Acute Myeloid Leukemia (AML). The two pilot studies are organized in two countries, Germany and Italy and involve 450 active post-treatment cancer patients. The first results of the pilot studies are encouraging, however there are some issues that are still remaining due to lack of technical skills and knowledge by the users. Additionally, pre-pilot activities have already taken place, focusing on ONCORELIEF technical verifications and on collecting early user feedback and incorporating it into the ONCORELIEF prototypes. Examples of important success variables include feedback from patients and clinicians, recruitment rates, dropout rates, patient engagement, technology readiness, and others.

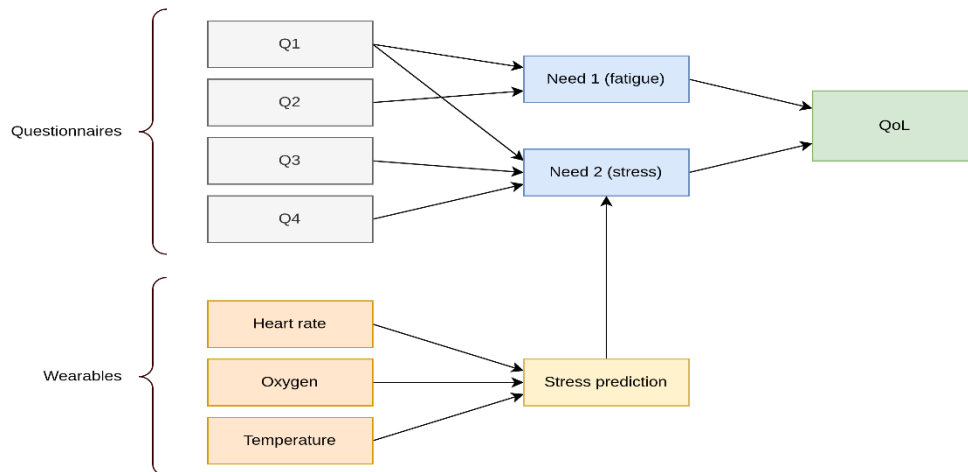
The Initial phase of the pilots focused on a small number of patients and ran for about a month, followed by improvements in the system for around two months. Following this, the complete phase started and will go on for a full year. Since patient engagement is so important to the success of the pilots and the project, the pilots have design elements that are patient-centered. Therefore, during the Requirements Elicitation phase, patient perspectives, preferences, and priorities are assessed through structured and unstructured encounters. The Design is documented for the benefit of these Pilots but also to facilitate the Pilots' evaluation.



ONCORELIEF TECHNICAL NEWS

Quality of Life Index Estimation

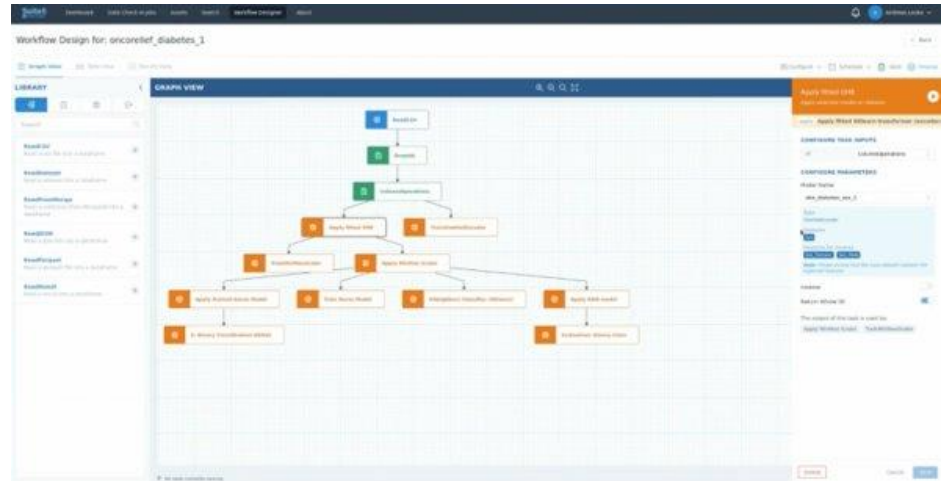
ONCORELIEF visualizes current health and wellbeing using the Quality of Life (QoL) Index, a calculated number from 1 (low) to 1000 (high). It is based on a specific person, cancer type, health literacy and physical symptoms such as pain and overall mental health such as anxiety, depression, positive and emotional distress or negative affect and eventually how they live and work, including social life, exercise, nutrition and sleep. The ONCORELIEF QoL Index moves up or down in real time, depending on how body, symptoms, feelings and lifestyle change. When tracked over time, it can offer a good indicator of how the person's health and wellbeing is evolving.



The ONCORELIEF QoL Index measures the overall health of a person, based on their body physical measurements and symptoms, emotional wellbeing and lifestyle. It is estimated based on an average score of the patients' answers on the questionnaires and wearable data, as it can be seen on the image above. Moreover, input from the wearable device, such as heart rate, oxygen saturation, and activity, is processed through Artificial Intelligence models in order to estimate measures of stress, fatigue and depression, affecting the overall QoL score. Overall, QoL Index is a score and not an age-related measure, so that older people could compare themselves to younger individuals, and also women could compare themselves to men.

AI Engine

ONCORELIEF offers an AI engine to assist clinical researchers in data analysis. The AI Engine allows to design and configure an analytics pipeline for any machine learning or deep learning algorithms. The expected input of the pipeline is defined and may range from batch data stored in storage areas (primarily the ONCORELIEF FHIR server) to real-time data directly sent. The desired output can be provided in two different ways; as a visualization that can be saved by the HCP and as raw data that can be retrieved from another component.



The AI Engine in the ONCORELIEF back-end consist of the Analytics Configurator, the Visualization & Reporting Engine, and the Analytics Execution Service.

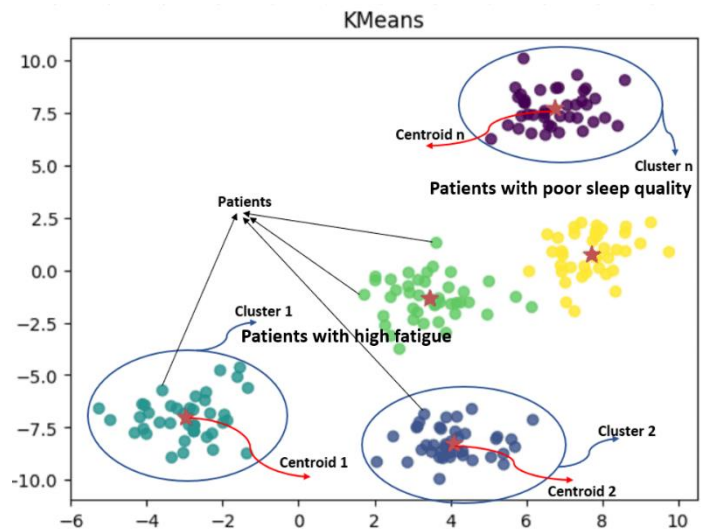
The **Analytics Configurator** works as the interface through which the ONCORELIEF platform can support the value that data analytics can bring to the project through the offerings of machine learning algorithms. It addresses the needs of the project in terms of data processing, from applying machine learning models for health data analytics, to creating visualisations and reports. Data manipulation and analysis functions are provided in the form of easily configurable blocks that can be combined to create a data analysis pipeline.

The **Visualisation & Reporting Engine** gives the ability to visually gain insights from specific health data elements and analytics results. It allows the creation of reports, which may combine various visualisations as well as data samples.

The **Analytics Execution Service** is responsible for executing data analytics tasks based on configuration files generated by the Analytics Configurator, depending on the execution settings that were provided in design time. It can be used to apply machine learning models to specific input data and export the results. The results of each task are saved and can be retrieved later, if necessary.

Patient clustering

In order to provide more personalized recommendations for cancer survivors, but at the same time avoid overloading clinicians with potentially unnecessary information, we borrow the concept of phenotypes to cluster enrolled patients in certain categories, depending on their health, lifestyle, and other observable and measurable conditions. To this end, data captured through the ONCORELIEF questionnaires and through the wearable sensors are processed through feature selection (both supervised and unsupervised ones will be tested) and clustering algorithms (such as k-means) to allow the definition of a number of clusters, with patients within a cluster presenting with similar symptoms, conditions, and characteristics and, thus, requiring similar interventions for their improvement of their quality of life. The number of clusters to be created will be defined in such a way so that the distance between patients of a cluster is small enough to allow similar interventions to be effective, and also the distance between patients of different clusters is large enough to necessitate different interventions. These clusters will be dynamically created as more patients are enrolled in the study and more patient data are captured and processed by ONCORELIEF.



Considering stable clusters, when enough data are captured from a newly enrolled patient, this patient will be assigned to the cluster with the highest similarity. As such, interventions already identified as suitable for this specific cluster of patients, will be provided to the clinician for his/her approval and transmission to the ONCORELIEF mobile app of the patient.

Patient-centric recommendations

The ONCORELIEF method and software framework follows a generic solution concept for providing patients with supportive recommendations. The specific realization of this approach depends on the circumstances of the application scenario, such as the type of information



input that is used for deriving the patient-specific recommendations from, the level of information detail and monitoring that a patient shall receive with the recommendation, or the amount of data acquired about the application of a current recommendation.

In one possible application scenario, the input consists of the patient's disease and reported symptoms. Planning uses a rule-based approach for mapping this input to the indicated recommendations. This model-driven approach thereby draws conclusions by means of existing health expert knowledge. Differently, data-driven approaches use similar former patient cases for deriving suitable recommendations from. The information about a patient case first enters a data analysis with statistical methods like automated classification or AI methods such as artificial neural networks. Such methods identify possible recommendations for the current case by relating them to the empirical value contained in former cases. The health expert then explores the outputs of these different approaches with the supportive recommendation planner. This web application provides decision support functionality, which allows for a goal-oriented selection of the best suited recommendations. Planning may for example comprise a filtering of the recommendation options that were identified by some AI method as generally applicable on the current patient case, continue with their sorting according to the reliability of the AI result and conclude with a selection and possible patient-individual adaptation of the most preferable options.

The recommendations selected by the health expert are then transferred to the mobile application on the patient's smartphone. Recommendations can provide support to patients on different levels. A simple approach is to inform a patient with text messages about what to do or pay attention to. A more advanced option involves structured recommendations that request patients for the documentation of specific data about the application progress and achieved outcome. Such precise information about a patient's health provides highly valuable input for a profound AI-based data analysis in preparation of the next planning step. An extension of the advanced approach features an automated processing of the acquired data by the mobile application itself. For this purpose, recommendations contain additional logical conditions, which encode the expectations of the health expert for their application. The mobile application computes these conditions on the acquired data and provides the patient with suitable feedback about his/her performance. The patient thereby obtains qualified guidance by the health expert even during his/her absence.

Also, in order to maintain the user active and engaged, the ONCORELIEF Guardian Angel application applies motivation techniques from behavioral science, such as positive reinforcement for doing the desirable behavior, use collaborative features from groups and social networks, and provide personalized feedback. As a result, the user is able to get real-time emotional and lifestyle personal feedback and coaching.

EU NEWS

INCISIVE project

Improving cancer diagnosis and prediction with AI and big data

INCISIVE is a research project that aims to develop and validate an AI-based toolbox that enhances the accuracy, sensitivity, interpretability and cost-effectiveness of existing cancer imaging methods.

Additionally, INCISIVE's work is enhanced by the creation of a repository of medical images and an automated machine learning (ML)-based annotation mechanism. These advances will make it possible to donate and share data securely while complying to ethical, legal, and privacy requirements. This will increase access to datasets and allow for the testing of AI-based solutions in the hope that they will eventually be widely used for cancer diagnosis, prediction, and follow-up. INCISIVE uses a variety of data sources, such as biology, imaging, and electronic health records (HER).



The INCISIVE project is currently running under funding by the Horizon 2020 program. For more information, you can visit <https://incisive-project.eu/>.

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