	Quality of Life in Oncology: measuring what matters for cancer patients and survivors in Europe	
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EUonQoL

Quality of Life in Oncology: measuring what matters for cancer patients and survivors in Europe

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Table of contents

Executive Summary

The aim of this deliverable is to describe the main digital tools, namely the web platform and the web app that are being developed in the context of the EUonQoL project for the collection, storage and analysis of the data coming from the questionnaires of the EUonQoL kit.

In the contemporary era, digital systems play a pivotal role in the collection, preservation, and analysis of data, ushering in a transformative paradigm in information management. The significance of these systems lies in their ability to efficiently gather vast amounts of data from diverse sources, ensuring a comprehensive and dynamic understanding of various phenomena. Digital platforms not only facilitate the storage of immense datasets but also offer sophisticated tools for their systematic preservation, mitigating the risk of loss or deterioration. Moreover, the advent of advanced analytics and machine learning algorithms within these systems empowers researchers and decision-makers to derive valuable insights from the data, uncovering patterns, trends, and correlations that might otherwise remain elusive. The integration of digital systems in data management not only enhances the speed and accuracy of information processing but also fosters innovation and discovery across a spectrum of fields, underlining their indispensable role in the modern landscape of knowledge acquisition and utilization.

This highly technical delivery lies at the intersection of several other WPs of the EUonQoL project, namely WP2, WP4, WP5 and WP7

The intended audience for this Deliverable is made by the European Commission and by the Beneficiaries.
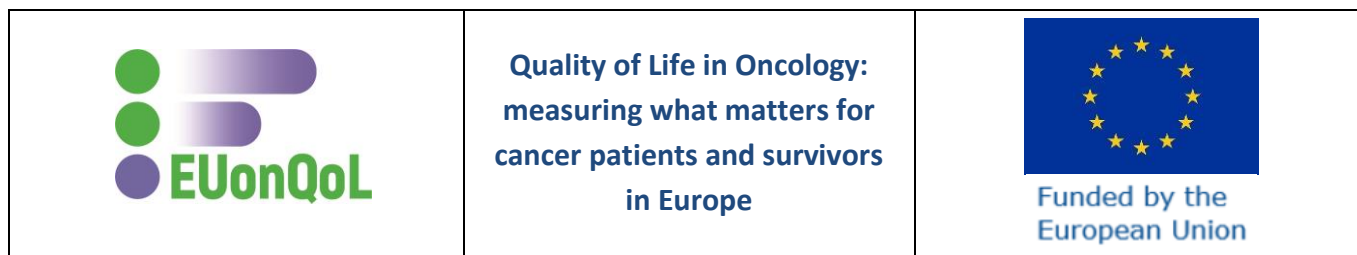
1. The EUonQoL project

The EUonQoL consortium has been established to develop, validate, and disseminate the European Oncology Quality of Life toolkit (EUonQoL-Kit), a unified tool for the assessment of QoL among European cancer patients. The EUonQoL project aims to review existing QoL scales and to develop new metrics by harnessing the strengths and overcoming the limitations of previous tools. The EUonQoL-Kit will be a new digital system for QoL self-assessment by patients and their caregivers, available in the languages of the 27 EU countries and developed from the patient's perspective. The overall project is based on participatory research principles, through the involvement of a representative panel of patients and public members throughout all project phases.

The EUonQoL-Kit and the data that it will collect will be used in future efforts by, for example, health policy makers, within (EU) cancer policy initiatives, or within cancer research projects - in order to evaluate QoL outcomes on an EU health policy level. A strength of the toolkit is that it will be unified, so it can be applied in all EU countries. This allows for the collection of country-comparative data. When comparing results between countries, it is important to take certain country-level determinants into account that may potentially explain differences in QoL outcomes between countries. The EUonQoL project consists of 11 work packages in total, of which this current report is written in the context of work package 6. The EUonQoL-Kit will allow country comparisons of QoL data among EU member states, as well as the identification of patient characteristics associated with better or worse QoL outcomes. It is intended that member states use these comparisons to inform improvement of their health care systems. This requires that key actors in EU member states not only know how their country results compare with other countries, but also why comparisons are more or less favourable for their country. The work package leader of WP6 is DIGICORE (www.digicore.eu) an international Consortium established in year 2021 for the digitalization of RWE studies. In this project DIGICORE has involved as Affiliated Entities two associate members, namely Istituto Nazionale Tumori IRCCS "G. Pascale" in Napoli, Italy and Istituto Nazionale Tumori IRCCS "Regina Elena" in Rome, Italy, together with partner Region Hovedstaden in DenmarkFurther description of the project, its work packages and the participating organisations can be found on the EUonQoL website: http://www.euonqol.eu/
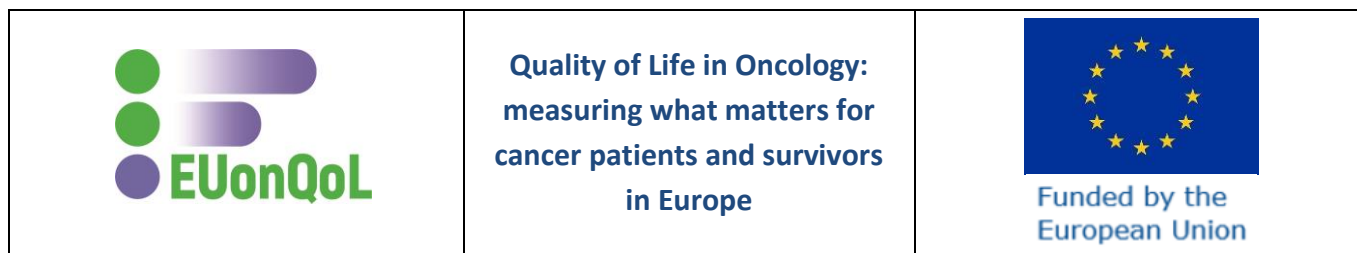
2. Introduction

Aim of the project is to create a set of questionnaires (EUonQoL-kits) to be submitted via digital tools to individual patients for obtaining information about disease impact on Quality of life for oncology patient at different time-points of their disease journey. WP6 will develop a set of digital tools for submitting, storing, retrieving and analyzing the answers of patients involved. Moreover, a part of the EUonQoL-kits, will be provided by the computerized adaptive test (CAT) engine. Computerized adaptive testing (CAT) is a form of computer-based test that adapts to the patient. CAT successively selects questions for the purpose of maximizing the precision of the exam based on what is known about the patient from previous questions. As a result of adaptive administration, different patients will carry out different tests, but their scores will be comparable to one another.

Taken together the digital tools will manage:

1) The templates of the EUonQoL-kits for the 3 groups of patients (i.e. In active treatment, Survivors, In need of Palliative Care), in all the languages used in the countries that join the project.

2) The bridge to CAT sections of the CAT version of the EUonQoL-kits in all the languages

3) The bridge to a mobile app that will submit questions to patients based on the group, the language, the questionnaire associated.

4) The pilot survey for validating the kits.

5) The storing of all the patients' answers for the pilot survey first and for auto-enrolled patients too.

6) The export of this data for statistical analysis.
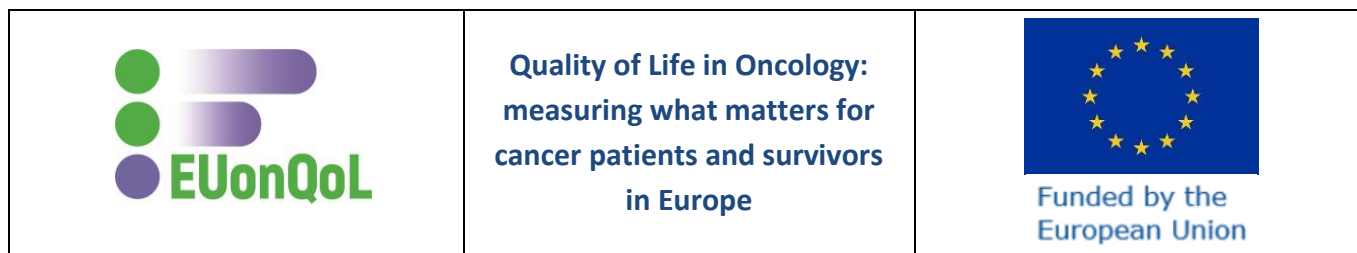
3. Technologies used for developing the digital tools

Developing the deliverables of the digital tools, will involve several technologies for different goals.

The pilot survey will be managed by a custom version of the CRF.net platform previously developed by Istituto Nazionale Tumori IRCCS Fondazione G. Pascale (Napoli, Italy) for managing clinical trials in oncology since 2007. This platform has managed by now more than:

- 110 clinical trials
- 831 Centers
- 3360 investigators
- 15420 patients
- 394520 CRFs

CRF.net platform and the EUonQoL custom platform are based on the following technologies:

1) ASP.net framework v. 4.6 by Microsoft

2) MySQL Community edition v. 5.7.29 by Oracle

3) Ruby language v. 2.7.2

4) Ruby on Rails framework v. 5.0.7.2

CRF.net platform and the EUonQoL custom platform are based on the following technologies:

1) ASP.net framework v. 4.6 by Microsoft. The .net framework by Microsoft is a set of libraries that manage Microsoft Operating Systems objects and interfaces. Can be used for both desktop and web applications and platforms and support various programming languages to do that. CRF.net needs a Windows server to run so it was developed by this Microsoft technology

2) MySQL Community edition v. 5.7.29 by Oracle. The CRF.net platform needs a to store templates and data. So it needs a Data Base Management System (DBMS). MySQL is one of the most popular DBMS, powerful, scalable, multiplatform relational database systems. It comes also in a community edition that is full open source and GPL 2.0 license released.

3) Ruby language v. 2.7.2. Ruby is an interpreted, high-level, general-purpose programming language which supports multiple programming paradigms. It was designed with an emphasis on programming productivity and simplicity. In Ruby, everything is an object, including primitive data types. Ruby is dynamically typed and uses garbage collection and just-in-time compilation. It supports multiple programming paradigms, including procedural, object-oriented, and functional programming. According to the creator, Ruby was influenced by Perl, Smalltalk, Eiffel, Ada, BASIC, Java, and Lisp

4) Ruby on Rails framework v. 5.0.7.2 Ruby on Rails (simplified as Rails) is a server-side web application framework written in Ruby under the MIT License. Rails is a model–view–controller (MVC) framework, providing default structures for a database, a web service, and web pages. It encourages and facilitates the use of web standards such as JSON or XML for data transfer and HTML, CSS and JavaScript for user
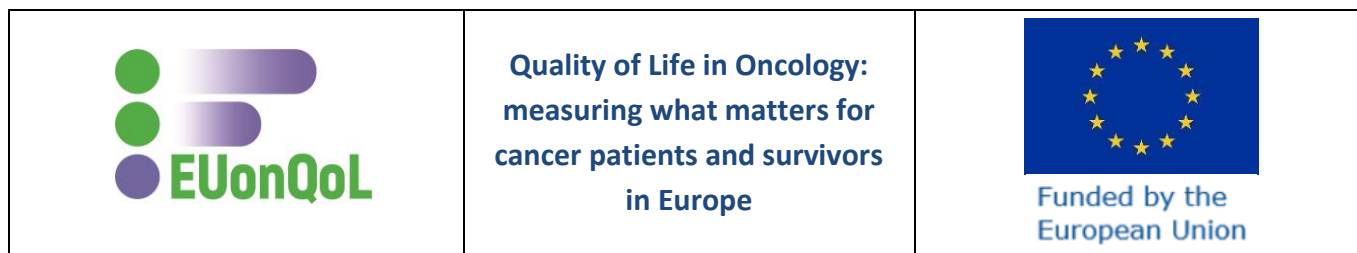
interfacing. In addition to MVC, Rails emphasizes the use of other well-known software engineering patterns and paradigms, including convention over configuration (CoC), don't repeat yourself (DRY), and the active record pattern. Ruby on Rails' influence on other web frameworks remains apparent today, with many frameworks in other languages borrowing its ideas, including Django in Python; Catalyst in Perl; Laravel, CakePHP and Yii in PHP; Grails in Groovy; Phoenix in Elixir; Play in Scala; and Sails.js in Node.js. Well-known sites that use Ruby on Rails include Airbnb, Crunchbase, Dribble, GitHub, Twitch and Shopify.

The customized platform will interface with a brand new web-app specifically developed for the EUonQoL project. This web-app will use the following technologies:

1) Ruby language v. 3.2.1
2) Ruby on Rails framework v. 7.0.4
3) MariaDB v. 10.6.

MariaDB is a community-developed, commercially supported fork of the MySQL relational database management system (RDBMS), intended to remain free and open-source software under the GNU General Public License. Development is led by some of the original developers of MySQL, who forked it due to concerns over its acquisition by Oracle Corporation in 2009.

MariaDB is intended to maintain high compatibility with MySQL, with exact matching with MySQL APIs and commands, allowing it in many cases to function as drop-in replacement for MySQL. However, new features are diverging It includes new storage engines like Aria, ColumnStore, and MyRocks.

The new EUonQoL dedicated web-app will interface with a mobile-app that is being developed by CR-Technologies and with the EORTC-CAT engine for the dynamic part of the EUonQoL-kits

4. The Web Platform and the Web App

The Web platform (CRF.net platform) will be customized to manage centers, investigators, CRFs and questionnaires for the EUonQoL project purposes. Questionnaires will be balanced with the minimization algorithm, distributing questionnaires to patients according to the EUonQoL study protocol. Users will be prompted directly to login in the Pilot Survey with their credentials. With few clicks clinical investigators will be able to enroll patients and to obtain the number and the set of questionnaires that they will have to submit to the patients.

Questionnaires will be submitted by a mobile-app that will be able to read a QRCode visualized on the web-platform patient main page and to begin a client-server session with the CRF.net platform.

The following image describes how the CRF.net platform will work to provide questions to patients, interfacing with the web app and the mobile app. The CRF.net platform will interface with the web app that extends the web platform to communicate with the mobile app providing questions of the assigned kits in the patient's language. CRF.net will store the answers. This will be done using an encrypted transport protocol.
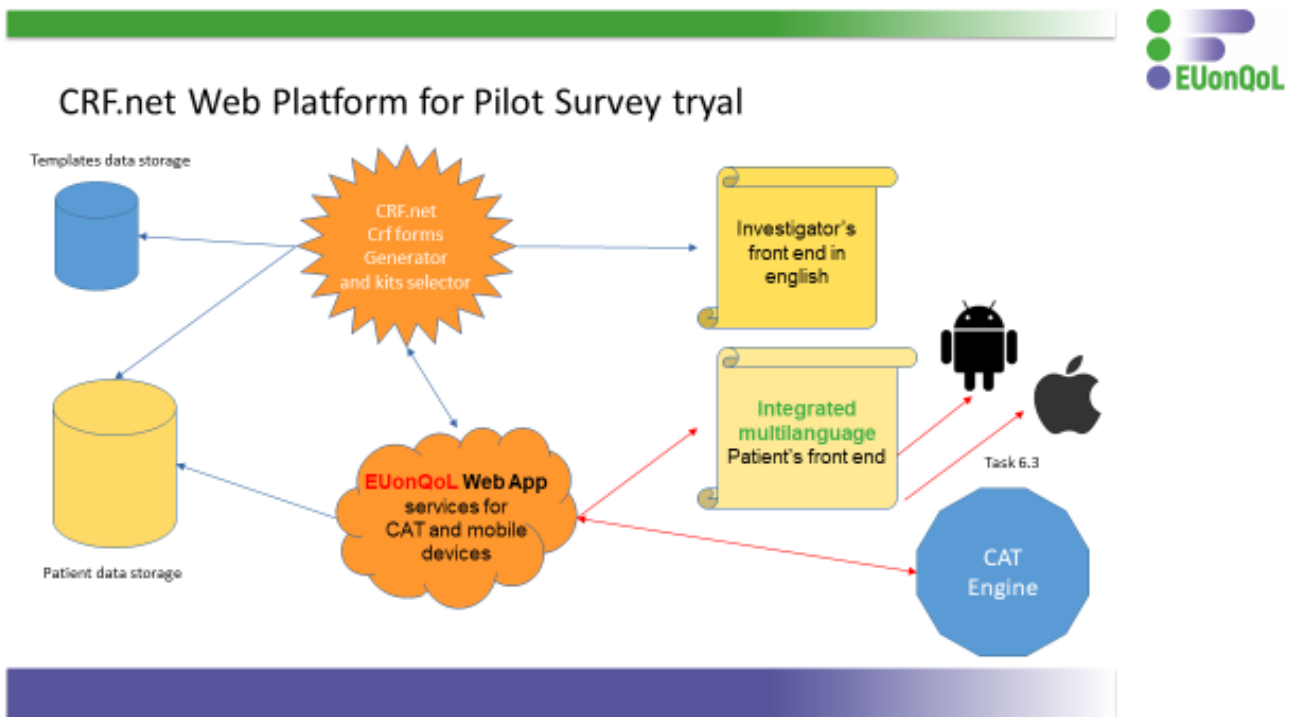
The Web app will exchange data between the Web platform and the mobile app. The Web platform will manage the questionnaires assignment to patients. The Webapp will read their assignment and will submit to the mobile app the questions one by one in the patient language. The Web app will store the patients' answers in a format readable by the Web platform.
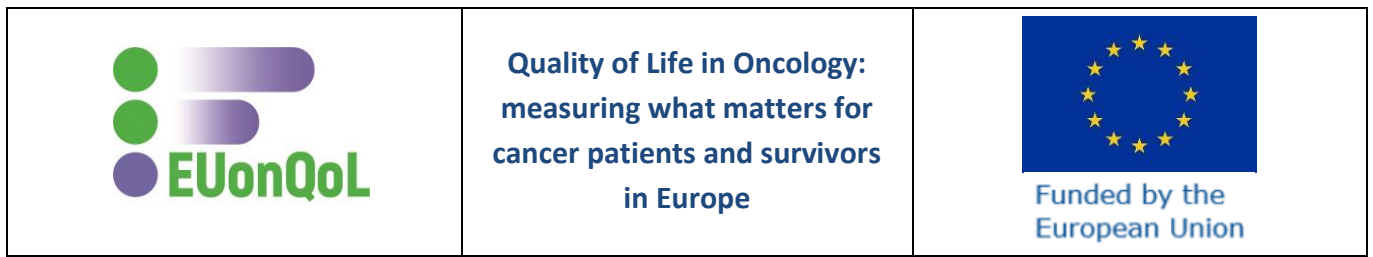
In the same way the mobile app will act as a client to the Web app, the Web app will act as a client to the CAT engine server to decide which question has to be submitted time by time to the patient during the dynamic part of the EUonQoL kit questionnaire. The CAT answers will be readable by the Web platform in a basic way and in advanced way by the Web app.

After a patient fills a questionnaire, all the data about the answers will be stored and managed back by the CRF.net platform. This will allow to associate answers to enrolled patients for further evaluations.

Clinical investigators will login in the platform with their credentials. From the EUonQoL Survey trial main page they will insert every new patient with his/her pathology status group, and the platform will provide an ID number to identify patient after the enrolment and assign a set of kits based on a minimization algorithm. The platform will show a QRCode that the mobile app can scan to start submitting questions to the patient. When kits are being completed by the patient, the investigator can print the results either in English or in the patient's original language.

5. The Web app for auto-enrolled patients

A subsequent goal of the EUonQoL project will be to submit the questionnaires to auto-enrolled patients all over Europe.

Therefore, a further evolution of the Web app will be to store and manage patient data by itself, without the intervention of the CRF.net platform and will have a web interface that the patient will be able to use for filling the questionnaires as an alternative to the mobile-app. The web-app will continue to interact with a template database for retrieving questions and answers in the right language for the EUonQoL-kit selected and act as a server for the mobile-app and a client to the CAT engine. The mobile-app will be released with the GPL V2 licenses and could be installed on various deploy environments like classic servers, virtual machines, cloud.

The following image describes how the web app will act as the main EUonQoL kits provider to multiple patient's front end either for static Kits and dynamic version provided by the CAT engine. The web app requests will use encrypted transport protocol.
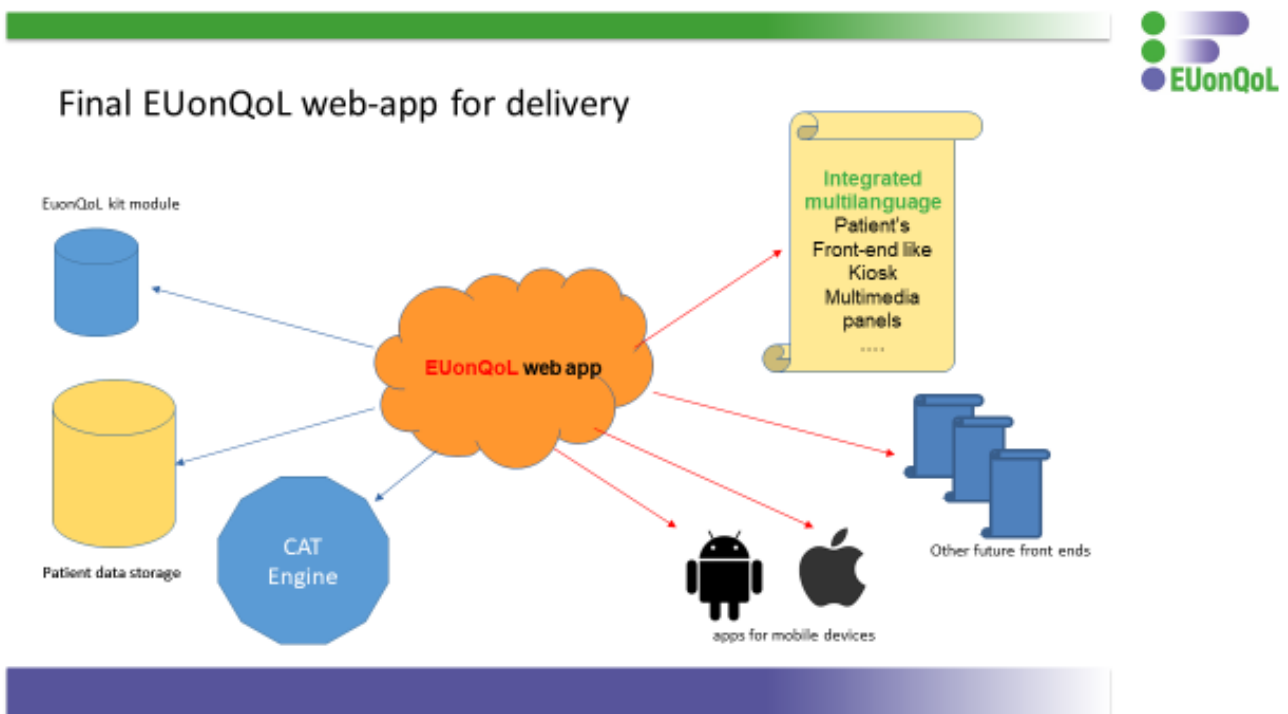
The web-app will integrate a front-end accessible via any internet browser and will interface with CAT engine for dynamic kits and mobile apps front end and any other front end that would use the web app service.

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6. Conclusions

In conclusion, the implementation of digital tools for the collection and assessment of the quality of life data among oncology patients within a European project represents a significant leap forward in personalized healthcare. By leveraging these innovative instruments, the project not only ensures a more nuanced understanding of the patient experience but also enables a holistic approach to cancer care that goes beyond traditional clinical metrics.

The utilization of digital platforms allows for the continuous monitoring and real-time analysis of patients' quality of life, providing healthcare professionals with valuable insights that can inform personalized interventions and support strategies. Furthermore, the collaborative nature of this European initiative fosters a collective effort to enhance patient-centric care practices and optimize overall well-being. As we embrace these digital advancements in the realm of oncology, the convergence of patient-reported outcomes and data-driven decision-making holds the potential to revolutionize the standard of care, ultimately improving the lives of oncology patients across the European continent.

7. References

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MariaDB DBMS: https://mariadb.org

Ruby language: https://www.ruby-lang.org

Ruby on Rail framework: https://rubyonrails.org